Bilateral Cochlear Implantation in Adults and Children

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Dallas Hearing Foundation
www.dallascochlear.com
Bilateral Cochlear Implantation

- Rationale for Bilateral Implantation
- Worldwide Bilateral CI Trends
- Dallas Otolaryngology CI Program Experience
- Surgical Issues
- Programming Issues
- Outcomes in Adults and Children
- Candidacy
Rationale for Bilateral Cochlear Implantation

• **Monaural Hearing Objective Deficits** - head shadow effect, reduced hearing in noise, lack of sound localization, absence of binaural summation

• **Subjective Impressions** - adults with unilateral hearing loss
Binaural Hearing: Objective Benefits

Binaural Mechanisms

- Head Shadow Effect
- Binaural Summation
- Binaural Squelch
- Sound Localization
**Binaural Hearing: Objective Benefits**

**Speech Understanding in Quiet**

**Binaural Summation**

- Enhanced brainstem and midbrain neural response due to sound input from both ears compared to one ear only
- Perception of 10dB increase or near doubling of perceived sound intensity
Binaural Hearing: Objective Benefits
Speech Understanding in Noise

Head Shadow Effect

- Physical phenomenon, head acting as an acoustic barrier to sound
- Results in 3 to 20 dB of noise attenuation (frequency specific)
- Can result in up to 50% increase in speech understanding in certain noise situations
Binaural Hearing: Objective Benefits
Speech Understanding in Noise

- Binaural Redundancy - difference between bilateral and better ear performance in spatially coincident speech and noise
Binaural Hearing: Objective Benefits
Speech Understanding in Noise

Binaural Squelch

- Central auditory filtering phenomena when speech and interfering noise originate from different locations
- Compares the signal from each ear, accentuates speech signal 3-6dB
one ear

head shadow

binaural summation

squelch
Binaural Hearing Mechanisms

- Net effect is up to 60% increase (mean increase=34% at 10dB SNR) for speech discrimination in noise compared to unilateral condition (Welsh et al 2004)
Binaural Hearing: Objective Benefits

- **Sound localization** - central mechanism, detects subtle **differences** in a sound's intensity (1dB detectable difference)
  - **intensity** (1dB detectable difference)
  - interaural arrival **time** (<0.65 msec)
  - **frequency spectrum**
  - **phase** (frequency specific)

Minimum Audible Angle (MAA) 1-4°
Localisation of a Sound Source

Pinna shape aids vertical localisation

Later arrival plus head shadowed so "Softer"

Louder

Left Ear

Right Ear

Source

d

Interaural Time Difference

\[ T_d = \frac{(d_2 - d_1)}{v} \]

140 mm

-20 dB

Interaural Level Difference

D.R. Campbell

School of Computing

University of Paisley

3
Binaural Hearing: Subjective Impressions

• Adults with sudden onset unilateral hearing loss:
  - report marked reduction of hearing in presence of background noise
  - inability to localize sounds
  - increased attention, effort of listening
  - avoid challenging acoustic environments
  - troubling disorientation to surroundings
Rationale for Bilateral Cochlear Implantation

- Bilateral hearing aids is the standard of care. (Colburn et al 1987, Palmer 2002, Dillon 2001)

- Bimodal (CI + HA)- significant gains if residual hearing in HA ear. (Morera 2005, Armstrong 1997)
Rationale for Pediatric Implantation - Unilateral Hearing Loss in Children


- “Window” of opportunity for binaural integration in children

- Reduced duration of post implant therapy?
Rationale for Bilateral Cochlear Implantation - Potential Risks

• Surgical and Anesthetic
  Minimal additional risk

• Vestibular Effects

• Exclusion from Future Technology:
  Cochlear implants are replaceable
  Hair Cell Regeneration – D. Cotanche, 2007, 10-20 years away

• Cost Effectiveness - ?
Worldwide Trends in Bilateral Cochlear Implantation

Peters, Wyss, Manrique.
Laryngoscope Supplement
May 2010
Table 1: CI and BCI population statistics as of January 2008 from the data bases of Advanced Bionics Corp., Cochlear Corp., and Med El Corp. Percentages are for proportion of adults vs. children for each region.

<table>
<thead>
<tr>
<th>January 2008-3 Manufacturers*</th>
<th>Total Worldwide</th>
<th>US</th>
<th>Non-US</th>
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<tbody>
<tr>
<td>Total CI</td>
<td>153,000</td>
<td>59,670</td>
<td>93,330</td>
</tr>
<tr>
<td>Adults</td>
<td>81,090 (54%)</td>
<td>36,398 (61%)</td>
<td>48,516 (52%)</td>
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<tr>
<td>Children</td>
<td>71,910 (46%)</td>
<td>23,272 (39%)</td>
<td>44,814 (48%)</td>
</tr>
<tr>
<td>Total BCI</td>
<td>8042</td>
<td>4182</td>
<td>3860</td>
</tr>
<tr>
<td>Adults</td>
<td>3056 (38%)</td>
<td>1882 (45%)</td>
<td>1174 (30%)</td>
</tr>
<tr>
<td>Children</td>
<td>2686 (62%)</td>
<td>2300 (55%)</td>
<td>2686 (70%)</td>
</tr>
</tbody>
</table>

* Figures for Med El Corp were obtained from the manufacturer up to October 2005. The company subsequently declined to provide updated figures to January 2008. Therefore an extrapolation was made to estimate final numbers by keeping the percentage of Med El in the total CIs and BCIs the same for the 2 time periods.
• Although there is a predominance of adults (54%) in the worldwide CI population, there is a predominance of children (62%) in the BCI population.

• US clinics have a higher percentage of adults in their BCI population than do non-US clinics (45% vs. 30%)
Sequential surgeries outnumber simultaneous in all age groups except children < 3 years of age.

Prior to 2007 children age 3-10 years received the majority of BCIs in children.

Since 2007 children < 3 years predominate.

The trend is for younger application of BCI, often at less than 12 months of age.
Dallas Otolaryngology CI Program
Experience- Research Participation

- Clinical Study of Bilateral Cochlear Implantation in Adults- Cochlear Corporation

- Sequential Bilateral Cochlear Implantation in Children- Cochlear Corporation
Dallas Otolaryngology CI Program Experience- Research Participation

- Bilateral Cochlear Implantation in Adults with the MED-EL COMBI 40+/Pulsar Multichannel Cochlear Implant System

- Bilateral Cochlear Implantation in Children with the MED-EL COMBI 40+/Pulsar Multichannel Cochlear Implant (Between-Subjects design)
Dallas Otolaryngology CI Program Experience- Research Participation

- Bilateral Benefit in Adults Users of the HiRes® 90K Bionic Ear System

- Development of Auditory Skills in Young Deaf Children with Bilateral Cochlear Implants (Advanced Bionics Corp, Non-Randomized, Within-Subjects design)
# Dallas Otolaryngology CI Program Experience

<table>
<thead>
<tr>
<th></th>
<th>Sequential</th>
<th>Simultaneous</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>80 (78%)</td>
<td>22 (22%)</td>
<td>102 (58%)</td>
</tr>
<tr>
<td>Adults</td>
<td>45 (63%)</td>
<td>27 (37%)</td>
<td>72 (42%)</td>
</tr>
<tr>
<td>Total</td>
<td>125</td>
<td>49</td>
<td>174</td>
</tr>
</tbody>
</table>
Dallas Otolaryngology CI Program
Experience

• Adults Total                      N= 72 (41%)

  Nucleus 24/ Freedom Simultaneous
  Nucleus 24 Sequential
  Nucleus 24+ Nucleus Free
  Nucleus 22 + Nucleus 24
  Nucleus 22 + Nucleus Freedom
  Nucleus 22→Bilat N24
  Nucleus CI512
  Medel Combi 40/Pulsar Simultaneous
  Medel Combi 40 Sequential
  Medel Combi 40 + Pulsar
  Medel Sonata Simultaneous
  Hi Res 90K Simultaneous
Dallas Otolaryngology CI Program Experience- Devices

- Children Total N= 102 (59%)
  - Nucleus 24 Sequential
  - Nucleus Freedom Sequential
  - Nucleus 22 + Nucleus 24
  - Nucleus 22 → Bilat N 24
  - Nucleus 24 + Nucleus Freedom
  - Nucleus Freedom Simultaneous
  - Nucleus CI 512 Simultaneous
  - Medel Combi 40+ Simultaneous
  - Medel Pulsar Simultaneous
  - Medel Sonata Simultaneous
  - Medel Combi 40 + Pulsar
  - Clarion CII + Hi Res 90K
  - Clarion CII + Nucleus 24
  - Clarion → Bilat Hi Res 90K
Bilateral CI Subjects- Children

Months
Duration of deafness

Age First Implant

1st CI
2nd CI

12mos 18mos 24mos 36mos 48mos
Bilateral CI Subjects - Children

Years
Duration of Deafness

Age First Implant

1st CI
2nd CI
Pre and Postoperative Measures
Children

- MLNT, LNT, HINT-C (Speech perception in quiet)
- CRISP (Speech perception in noise)
- Sound Localization Testing
- VNG (older children only)
- CAEP (Cortical Auditory Evoked Potentials)
- Patient/Parent/Teacher Satisfaction and Benefit Questionnaires
Pre and Postoperative Measures

Adults

- NU-6 Words, CNC Words, HINT sentences in quiet (Speech perception in quiet) @ 60dB SPL
- HINT Sentences in noise (Speech perception in noise); if ceiling affect demonstrated do CNC Words in noise, @ 60dB SPL with 10 dB SNR; BKB-Sin.
- Sound Localization Testing- research protocols
- VNG
Surgical Issues
Issues in Simultaneous Surgery

- Combined or separate prep and drape
- Cautery instruments for second side
- Symmetry of Placement
- Drain (inconvenience) or no drain (potential swelling, hematoma)
- Length of stay in bilateral surgery vs. unilateral
• **Laryngeal mask anesthesia**
  - ideal for ear surgery, especially in infants and young children
  - decreased airway stimulation
  - less anesthetic agents needed
  - more rapid emergence
  - requires anesthesiologist experienced in their use
Prep and drape

- Separate ( + sterility; - ↑ time, drapes)
- Simultaneous ( + time, materials; - sterility, positioning, facial nerve monitor)
Second Side Cautery- Bipolar or Thermal Knife
Symmetry - approximate 45-60° to sinodural angle
Length of Hospital Stay

- Simultaneous pediatric bilateral surgeries 12 to 24 months old 10/11 (90%) overnight stay (compared to 11/50-22% unilateral surgeries < 24 months old)
Programming Issues
Programming with BCI

- Program each CI separately to start- do not feel that each ear must have the same pulse width, rate, or stimulation mode.
- When both implants are turned on together will likely need to decrease loudness growth 10% due to summation effect.
- Bilateral balancing is important to sound localization. May take several appointments.
Bilateral CI Outcomes

• Adults with adult onset deafness or a history of effective hearing aid use in both ears into adulthood achieve significant binaural benefit- improved hearing in noise (binaural summation, head shadow, squelch), sound localization ability, capture of better performing ear.

Bilateral CI Outcomes

- **Adults** with perilingual onset of hearing loss or long term deafness in one or both ears achieve more limited **objective** binaural benefits, primarily head shadow. Hearing in noise benefit is mild and sound localization ability is poor after 1 year of bilateral CI use. Capture of the better performing ear is a strong plus of bilateral CI in these patients. **Subjective** ratings are high and strongly prefer bilateral use.

(Arcaroli et al. 2003)
Bilateral CI Outcomes

• **Children**- simultaneous bilateral implantation of children 12 to 36 months of age can be done safely and can result in seamless use of both implants.

(Mueller et al 2003, Peters et al 2007)
Bilateral CI Outcomes

- Children who receive their first implant < 3 years of age adjust to a second implant and obtain binaural benefit in inverse relationship to their age at the time of second implantation - the younger the better. (Peters et al 2007, Litovsky et al 2005)
Bilateral CI Results/Conclusions

- Children who are successful unilateral CI users but > 8 years of age at the time of 2nd CI have increasing difficulty with age adjusting to second CI and take much longer to show even modest gains. Hearing aid use in the second ear prior to implantation may have a positive effect. (Peters et al 2007)
MLNT Words - 3 to 5 Years

Test Interval

Preoperative 3 Months 6 Months 12 Months

Percent Correct

0 10 20 30 40 50 60 70 80 90 100

N=7 N=6 N=7 N=7

1st Side Only
Bilateral
2nd Side Only

Test Interval
LNT Words - 5 to 8 Years

Percent Correct

0 10 20 30 40 50 60 70 80 90 100

N = 10 N = 6 N = 8 N = 3 N = 6

Test Interval

Preoperative 3 Months 6 Months 9 Months 12 Months

1st Side Only  Bilateral  2nd Side Only
LNT Words - 8 to 13 Years

Test Interval

- Preoperative
- 6 Months
- 12 Months
- 24+ Months

Percent Correct
0
10
20
30
40
50
60
70
80
90
100

N=13 N=13 N=12 N=5

1st Side Only
Bilateral
2nd Side Only

Test Interval

1st Side Only
Bilateral
2nd Side Only
LNT Words - 8 to 13 Years
3 years of 2nd CI Experience

Percent Correct

Subject

1st Side Only
Bilateral
2nd Side Only

Mean
CRISP Test 9 Months
Mean Data N=18

Age Range 3 to 13 years

Percent Correct

Front  First  Second

Masker Location

1st Side  Bilateral  2nd Side
Central (Cortical) Auditory Development

- Lessons from the ophthalmologic literature-
  Childhood amblyopia- 18 month critical period

  Binocular Fusion
  Monocular Dominance
  Visual Acuity
  Stereopsis
  Complex Feature Recognition
  Cortical Retinotopic Maps
  Direction Sensitivity
Central (Cortical) Auditory Development and Speech Perception

• Speech perception ability correlates with the density of central auditory higher cortical neural projections (Ponton 2001)

• Development of higher projections requires peripheral sensory input in infancy and early childhood during a “sensitive period” (Sharma 2001)
Cortical Auditory Evoked Potentials In Children- **First** Cochlear Implant

- P1 latency- thalamo-cortical in origin, an index of maturation of central auditory pathways.
- Cochlear implantation of an ear prior to age 3.5 years brings P1 latency into normal range within months. (Sharma et al 2002)
- With increasing age of implantation a delay in P1 is more likely to persist and correlates with poorer speech perception performance (critical/ sensitive period). (Ponton et al 2001, Sharma et al 2002)
Cortical Auditory Evoked Potentials in **Bilaterally** Implanted Children

- The older a child at the time of second ear implantation the more likely a persistent delay in P1 of that ear regardless of normalized P1 in the opposite first implanted ear. (Sharma, Dorman, et al 2005, 2007)

- This finding correlates with increasing difficulty of adjustment and poorer speech perception performance with the second implant with increasing age despite high performance with the first implant (Sharma et al, 2007).
P1 Auditory Evoked Potential Testing

Auditory evoked potentials reflect EEG activity in response to sound stimulation. The latency of the P1 cortical auditory evoked potential reflects synaptic propagation through the thalamo-cortical portions of the central auditory pathways. P1 latencies are considered to be an index of the maturation of the central auditory pathways.

Results

Impressions

Henry’s left ear P1 auditory evoked response latency is within the expected latency range for a normal hearing individual of a similar age. An age-appropriate P1 response latency suggests intact development of auditory thalamo-cortical areas in response to left ear stimulation.

Right ear P1 responses are outside the expected latency range for a normal hearing child of a similar age. A delayed P1 latency suggests slower than typical development of auditory thalamo-cortical areas in response to right ear input.
University of Texas at Dallas
Callier Center for Communication Disorders
Callier Advanced Hearing Research Center Electrophysiology Clinic
1966 Inwood Road, Dallas, TX 75235 (Tel) 214-905-3186; (Fax) 214-905-3146

Name: S. Hailey
Date of Birth: 8-29-01
Date of Test: 5-3-05
Implant Type: Nucleus
Test Age: 3 yrs, 9 months
Fit Age / Approx. Implant Experience — LE CI: 12 months / 2 yrs, 9 months
Fit Age / Approx. Implant Experience — RE CI: 2 yrs, 10 months / 11 months
Referral: Robert Peters, M.D.

Test Protocol:
Stimulus Type: /ba/
Condition(s): RE - CI; LE- CI
Recording Electrode: Cz

P1 Auditory Evoked Potential Testing

Auditory evoked potentials reflect EEG activity in response to sound stimulation. The latency of the P1 cortical auditory evoked potential reflects synaptic propagation through the thalamo-cortical portions of the central auditory pathways. P1 latencies are considered to be an index of the maturation of the central auditory pathways.

Results

Impressions

Hailey's P1 auditory evoked response latencies are within the expected latency range for a normal hearing individual of a similar age. An age-appropriate P1 response latency suggests intact development of auditory thalamo-cortical areas.

Recommendations

Hailey should continue to be monitored electrophysiologically and behaviorally to assess acquisition of auditory and speech skills.
University of Texas at Dallas  
Callier Center for Communication Disorders  
Callier Advanced Hearing Research Center Electrophysiology Clinic  
1966 Inwood Road, Dallas, TX 75235 (Tel) 214-905-3186; (Fax) 214-905-3146

Name: Justin  
Date of Birth: 1/6/96  
Date(s) of Test: 7-10-02, 4-20-05  
Implant Type: Nucleus  
Test Age: 6 yrs, 6 months (LE) / 9 yrs, 3 months (RE)  
Fit Age / Approx. Implant Experience – LE CI: 2 yrs, 8 months / 3 yrs, 10 months  
Fit Age / Approx. Implant Experience – RE CI: 7 yrs, 11 months / 1 yr, 4 months  
Referral: Robert Peters, M.D.

Test Protocol: 
Stimulus Type: /ba/  
Condition(s): RE - CI; LE - CI  
Recording Electrode: Cz

P1 Auditory Evoked Potential Testing

Auditory evoked potentials reflect EEG activity in response to sound stimulation. The latency of the P1 cortical auditory evoked potential reflects synaptic propagation through the thalamo-cortical portions of the central auditory pathways. P1 latencies are considered to be an index of the maturation of the central auditory pathways.

Results

![P1 Auditory Evoked Potential](image)

Impressions

Justin’s left ear P1 auditory evoked response latency is within the expected range for a normal hearing individual of a similar age. An age-appropriate P1 response latency suggests intact development of auditory thalamo-cortical areas.

Right ear P1 response latency is outside the expected latency range, suggesting slower than typical development of auditory thalamo-cortical areas.

Recommendations

Justin should continue to be monitored electrophysiologically and behaviorally to assess acquisition of auditory and speech skills.
P1 Auditory Evoked Potential Testing

Auditory evoked potentials reflect EEG activity in response to sound stimulation. The latency of the P1 cortical auditory evoked potential reflects synaptic propagation through the thalamo-cortical portions of the central auditory pathways. P1 latencies are considered to be an index of the maturation of the central auditory pathways.

Results

![P1 Auditory Evoked Potential Diagram]

**Impressions**

Crockett’s P1 auditory evoked response latencies are not within the expected latency range for a normal hearing child of a similar age. Delayed P1 latency suggests slower than typical development of auditory thalamo-cortical areas.

**Recommendations**

Crockett should continue to be monitored electrophysiologically and behaviorally to assess acquisition of auditory and speech skills.
Data indicates that a sensitive period or “window” of opportunity exists for children to acquire effective binaural integration from their second ear despite being high performing unilateral CI users.

Central auditory development is a bilateral process requiring bilateral peripheral input in order to develop effective central binaural mechanisms.
Bilateral CI Data-Implications

- Hearing aid use should be strongly recommended for all patients with any residual hearing in the opposite ear after unilateral cochlear implantation.

- We must seriously question the wisdom of “saving” one ear in children for future technology- they may not have a cortex capable of receiving it.
Localization measures in children with Bilateral CI’s

Litovsky lab, 2003-2005
MAA Thresholds with Bilateral CIs: Effect of No. Months Post-Activation of Second CI

Level Roved; Stimulus: Spondee "Baseball"

Litovsky lab, 2003-2005
Surgery- Simultaneous or Sequential?

- 26 adult, 18 pediatric (youngest 9 months of age) simultaneous surgeries- no complications, well tolerated in all age groups.

- An issue primarily of **candidacy** and **reimbursement**, not safety.
Surgery- Simultaneous or Sequential?

- EABR- rate of change of eV latencies, measure of brainstem binaural pathway development (Gordon et al, 2007)

- Dependency of length of interimplant interval and age at first implant upon the rate of change of the eV latencies
EABR eV Latencies

- Suggests a change in developmental plasticity in children with long-term unilateral implant use at the level of the auditory brainstem

- Simultaneous or short interval sequential may be advantageous for the development of binaural brainstem mechanisms in children
Bilateral CI Candidacy

- **Simultaneous:**
  - **Adult** - postlingually deafened bilaterally, profound < 10-15 years bilaterally, no history of vestibular disorders, “excellent” CI criteria.
  
  - **Child** - 6-36 months of age, bilateral profound, neurologically normal, “excellent” CI criteria.
Bilateral CI Candidacy

- Sequential

**Adult**- fair to excellent unilateral CI user, no significant binaural advantage (< 10% ↑ word scores or < 20% ↑ sentence scores in quiet and noise) with HA in opposite ear, good prognostic hearing history in 2nd ear.
Bilateral CI Candidacy

• Sequential

**Child**- good to excellent unilateral CI user, poor aided thresholds in opposite ear or no demonstrable binaural advantage with hearing aid on age appropriate speech measures. Age at time of second implant < 8 years preferred, 8-12 years difficult, > 12 years very difficult unless hearing aid use continued in second ear.
Bilateral CI Conclusions

- For patients who fit these defined candidacy criteria the benefits of bilateral cochlear implantation significantly outweigh the risks and should not be considered “experimental”.
- The provision of binaural hearing is the “standard of care” for patients with hearing loss of all levels of severity.
Professional Societies Supporting Bilateral CI in Children


Future Issues

- Very early bilateral cochlear implantation (down to 6 months of age)- diagnostic and therapeutic requirements, simultaneous vs. sequential surgery
- Pharmacology and therapy techniques to open the “critical period”
Thank You