

Bilateral Cochlear Implantation in Adults and Children

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Dallas Otolaryngology Cochlear Implant Program

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

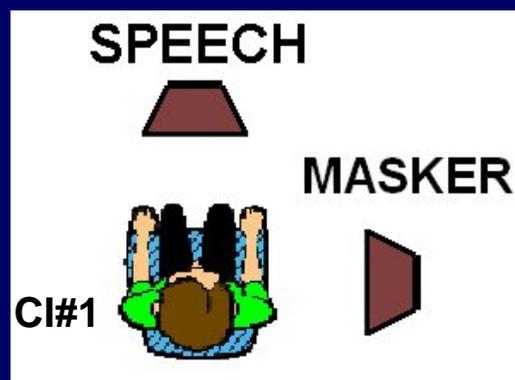


Binaural Hearing: Objective Benefits

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

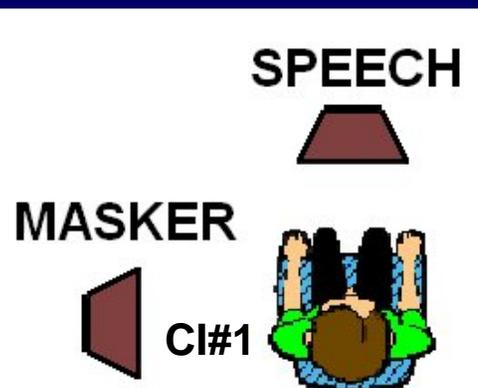


Binaural Hearing: Objective Benefits

Speech Understanding in Noise

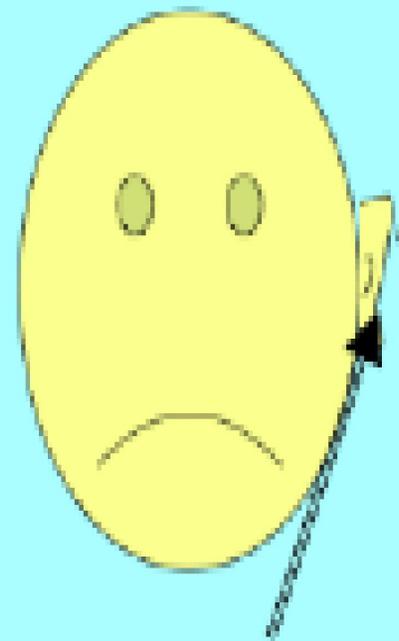
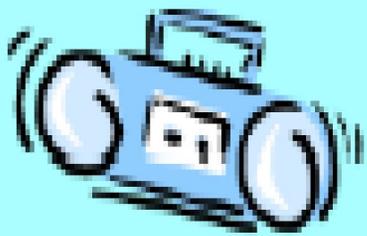
Binaural Squelch

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



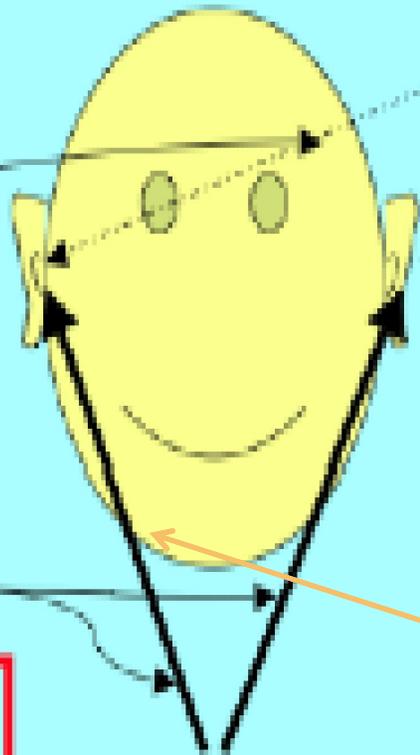
one ear

two ears



“hello”

head shadow



binaural summation

“hello”

squelch

Binaural Hearing Mechanisms

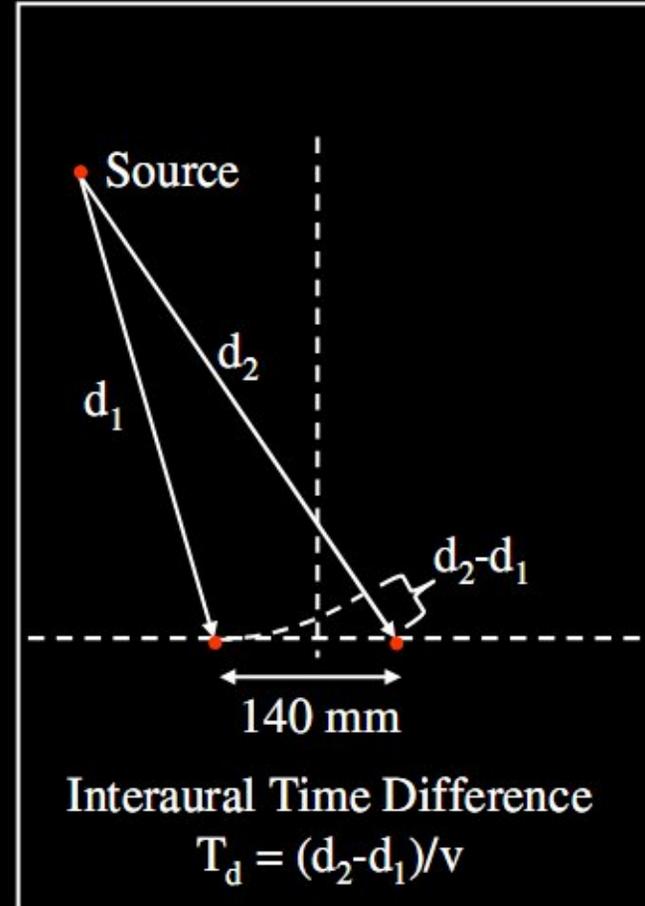
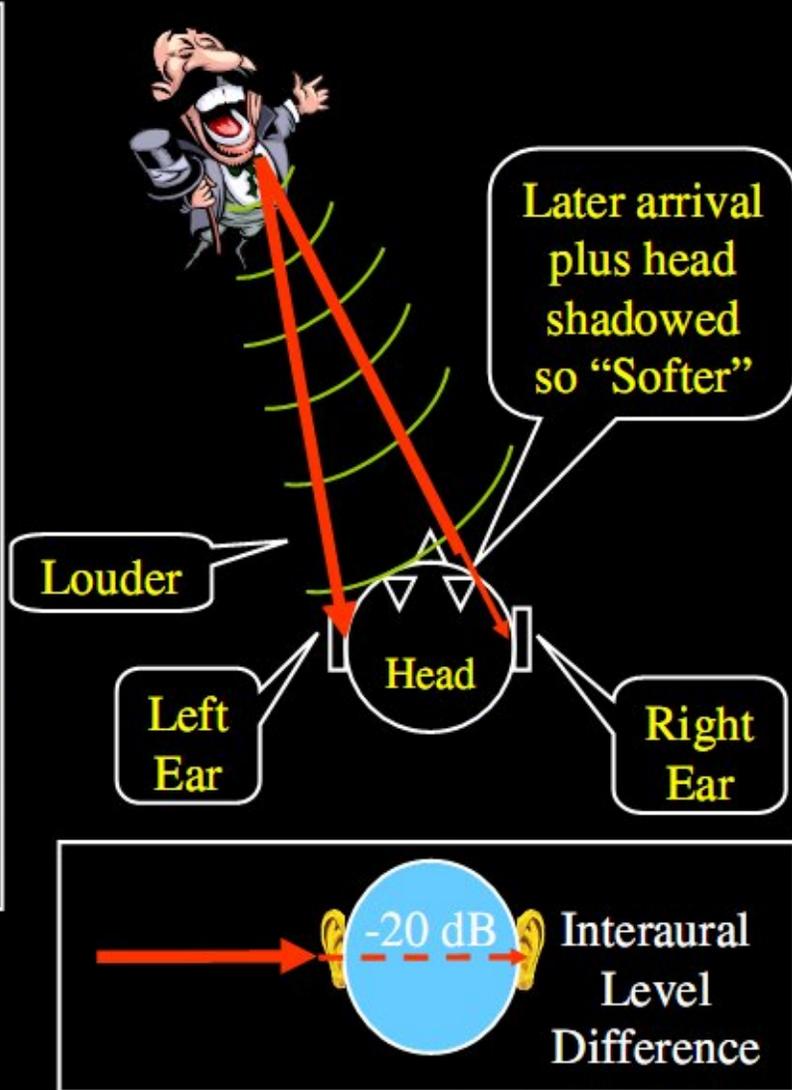
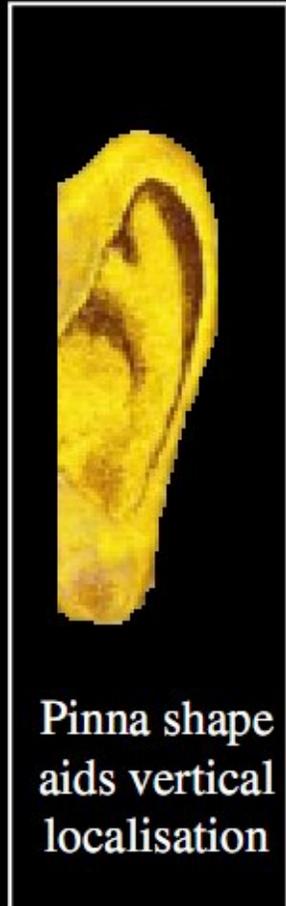
- Net effect is up to 60% increase (mean increase=34% at 10dB SNR) for speech discrimination in noise compared to unilateral condition (Welsh et al 2004)

Binaural Hearing: Objective Benefits

- **Sound localization**- central mechanism, detects subtle differences in a sounds
 - 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



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

- Bess et al (1986), Lieu 2004 - communicative, behavioral, psycho-educational problems
- “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**
Peters et al, “Vestibular Effects of Bilateral Cochlear
Implantation,” 2002
- **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.

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

* 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. I 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.

Worldwide Trends in BCI

Peters et al, Laryngoscope Suppl May 2010

- 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%)

Worldwide Trends in BCI

Peters et al, Laryngoscope Suppl May 2010

- 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

	Sequential	Simultaneous	Total
Children	80 (78%)	22 (22%)	102 (58%)
Adults	45 (63%)	27 (37%)	72 (42%)
Total	125	49	174

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

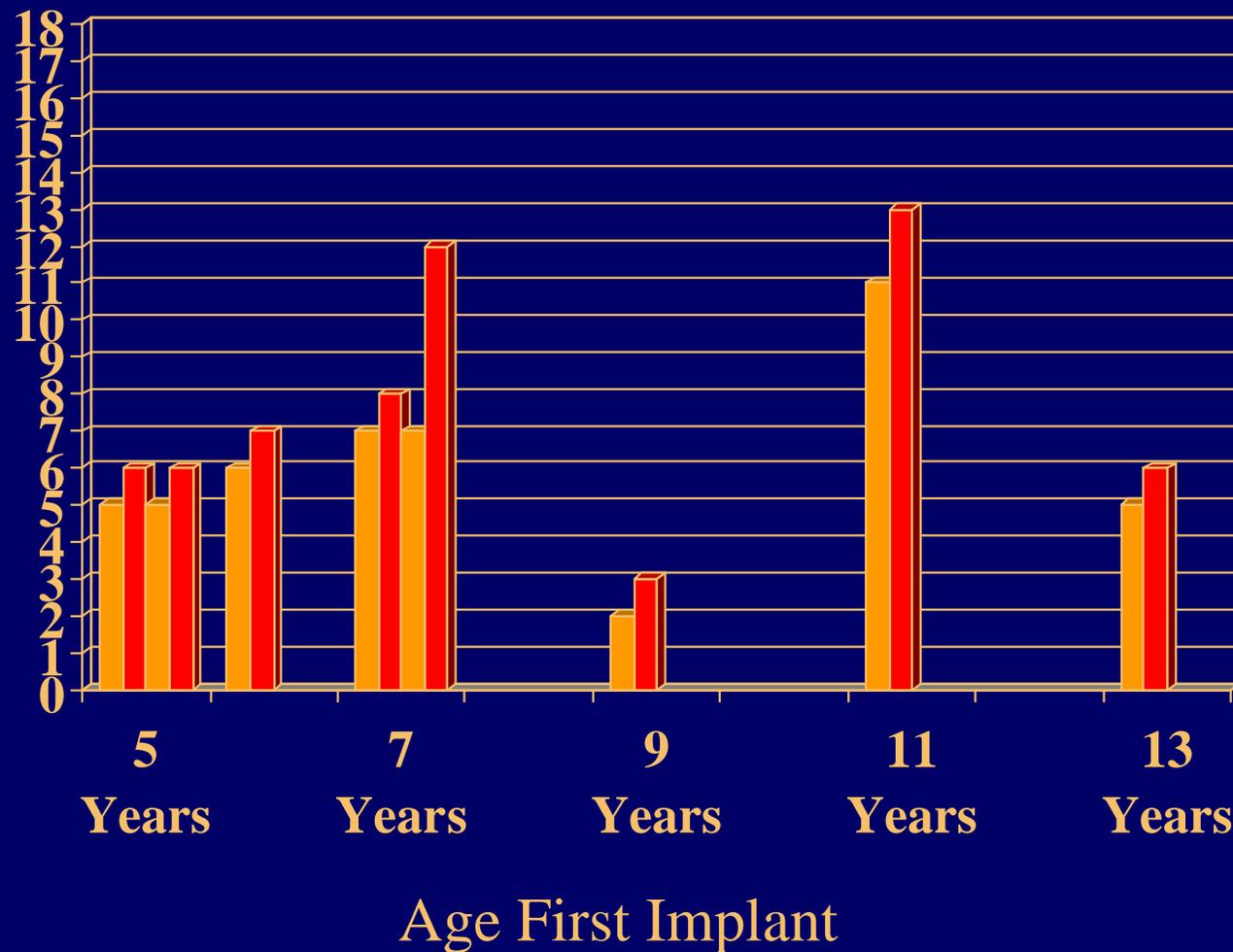
Clarion CII + Hi Res 90K

Clarion CII + Nucleus 24

Clarion→ Bilat Hi Res 90K

Bilateral CI Subjects- Children

Years
Duration of
Deafness



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

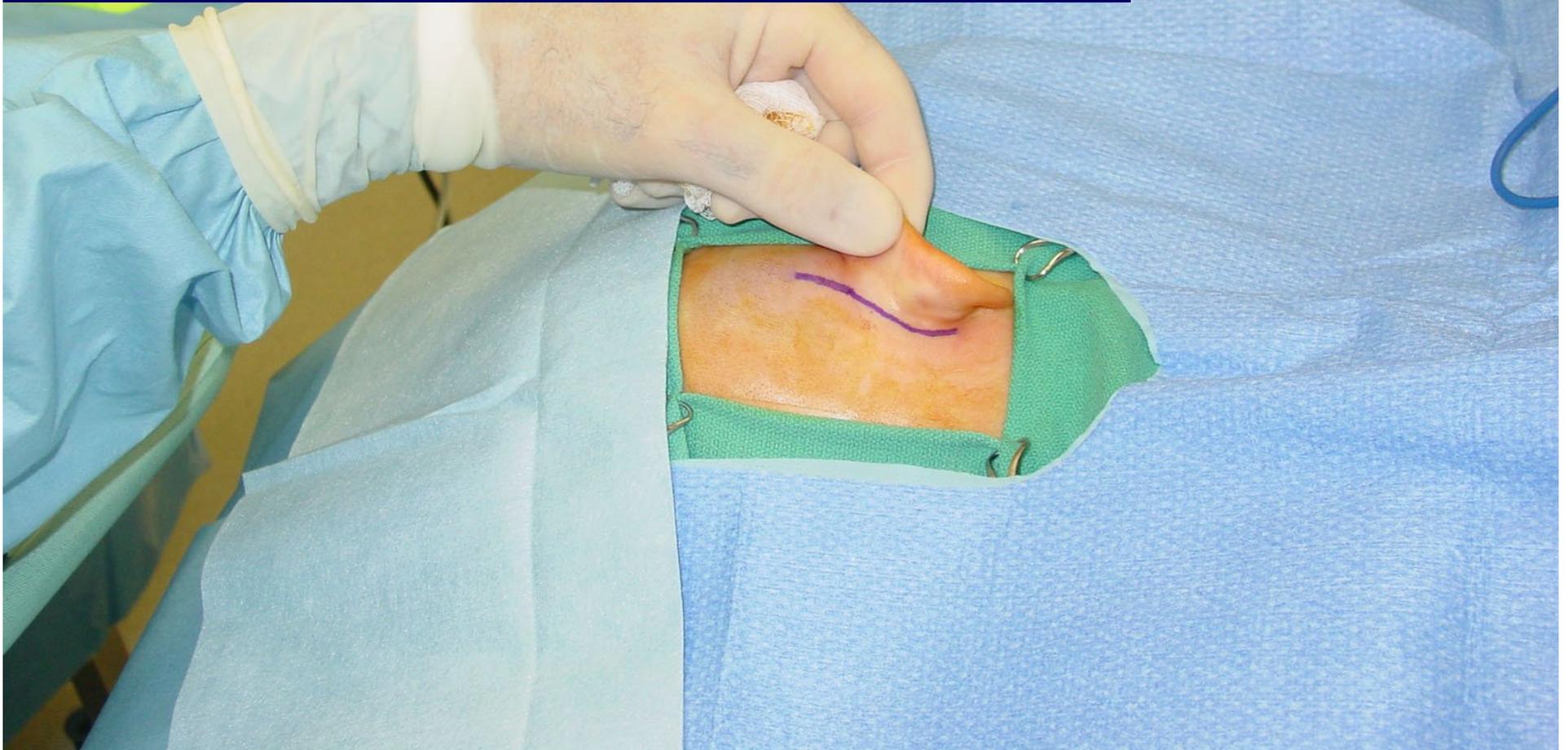


Anesthesia

- 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

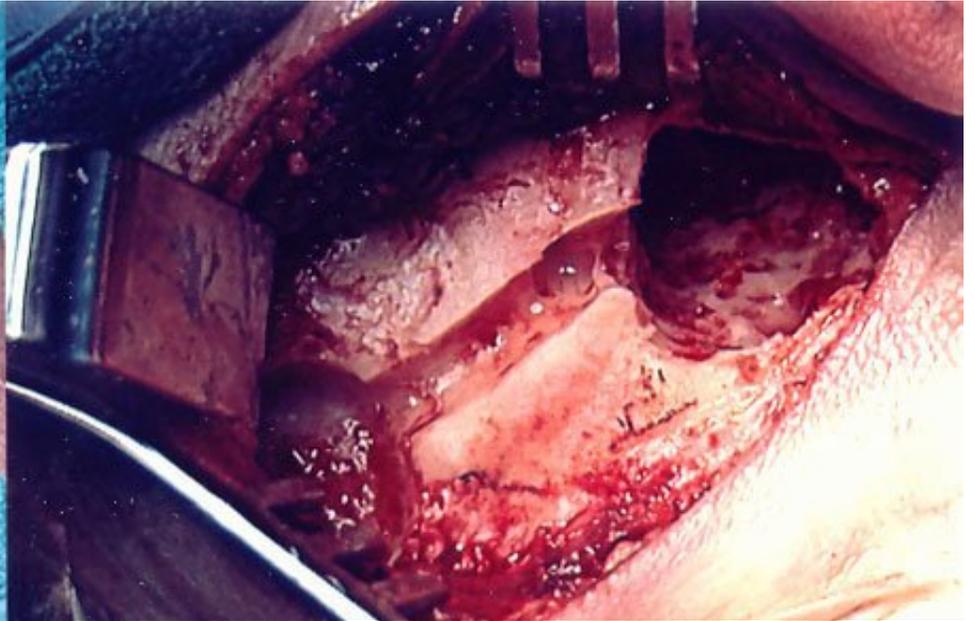
Prep and drape

- Separate (+ sterility; - ↑ time, drapes)
- Simultaneous (+ time, materials; - sterility, positioning, facial nerve monitor)

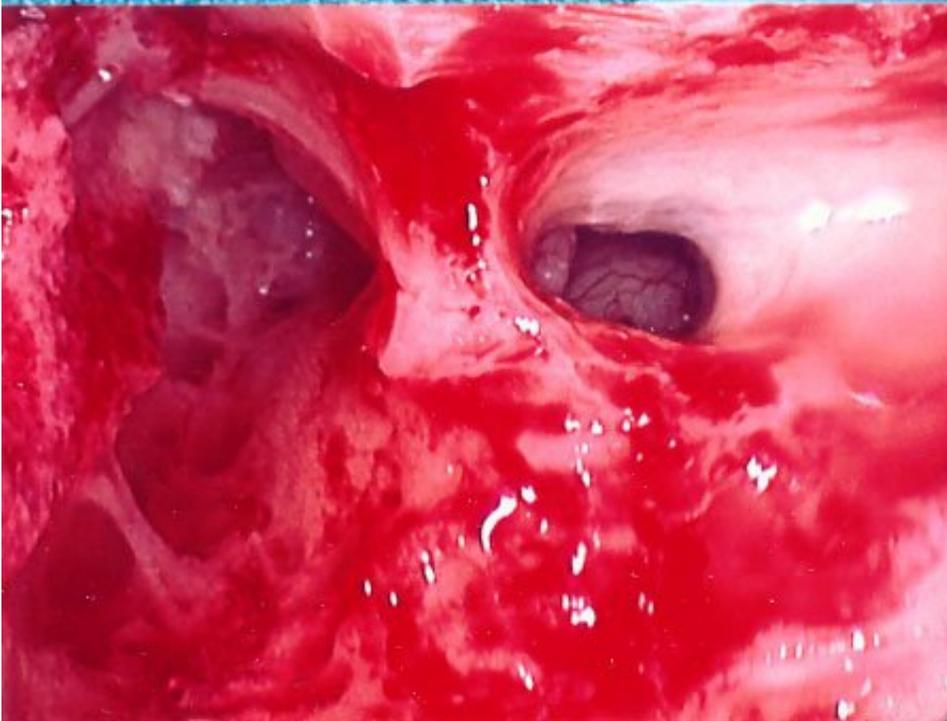


Second Side Caутery- Bipolar or Thermal Knife





**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.

(Arcaroli et al 2003, Nopp et al 2004, Schon et al 2002, Tyler et al 2002)

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)

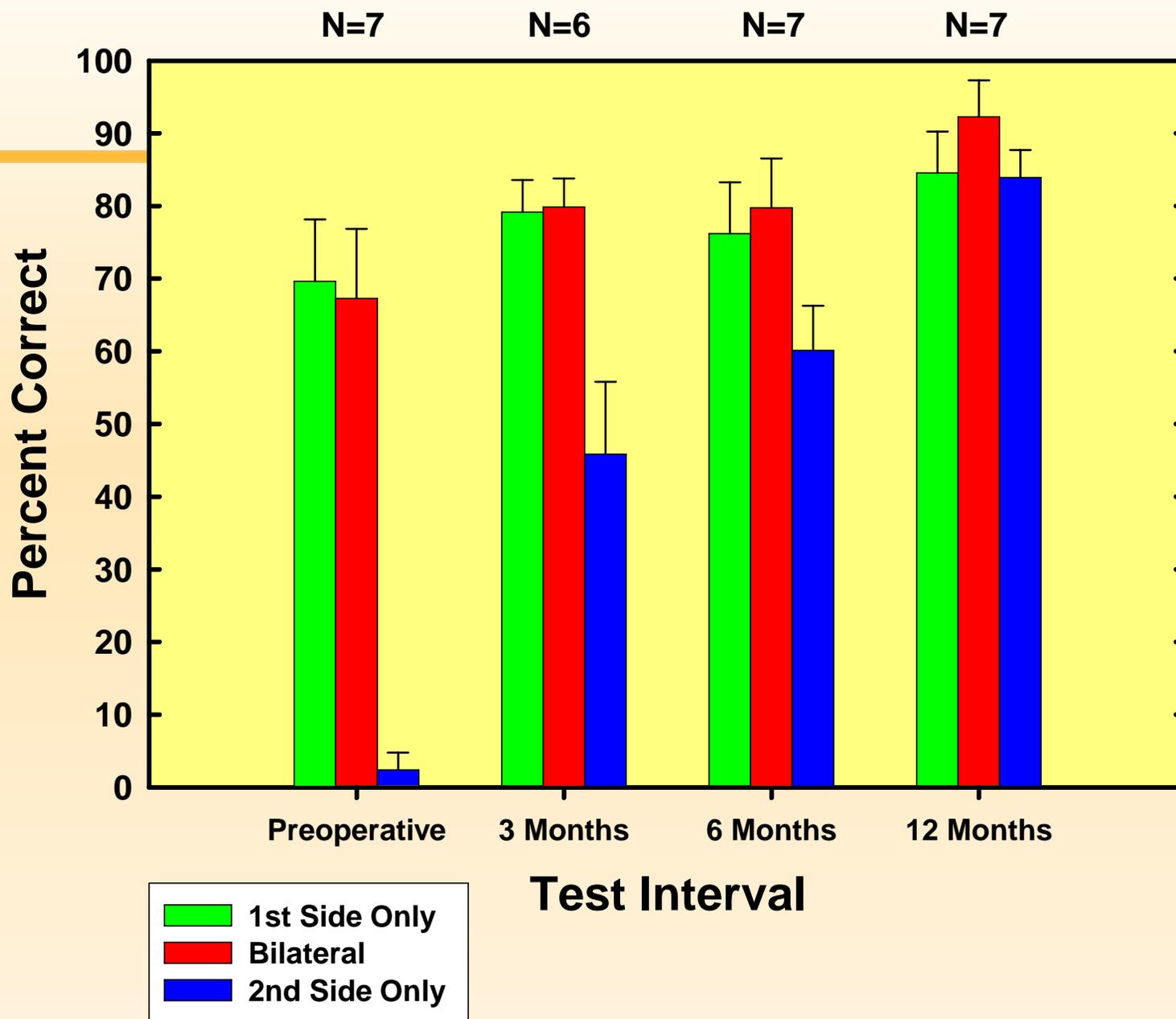
Bilateral CI Outcomes

- 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)

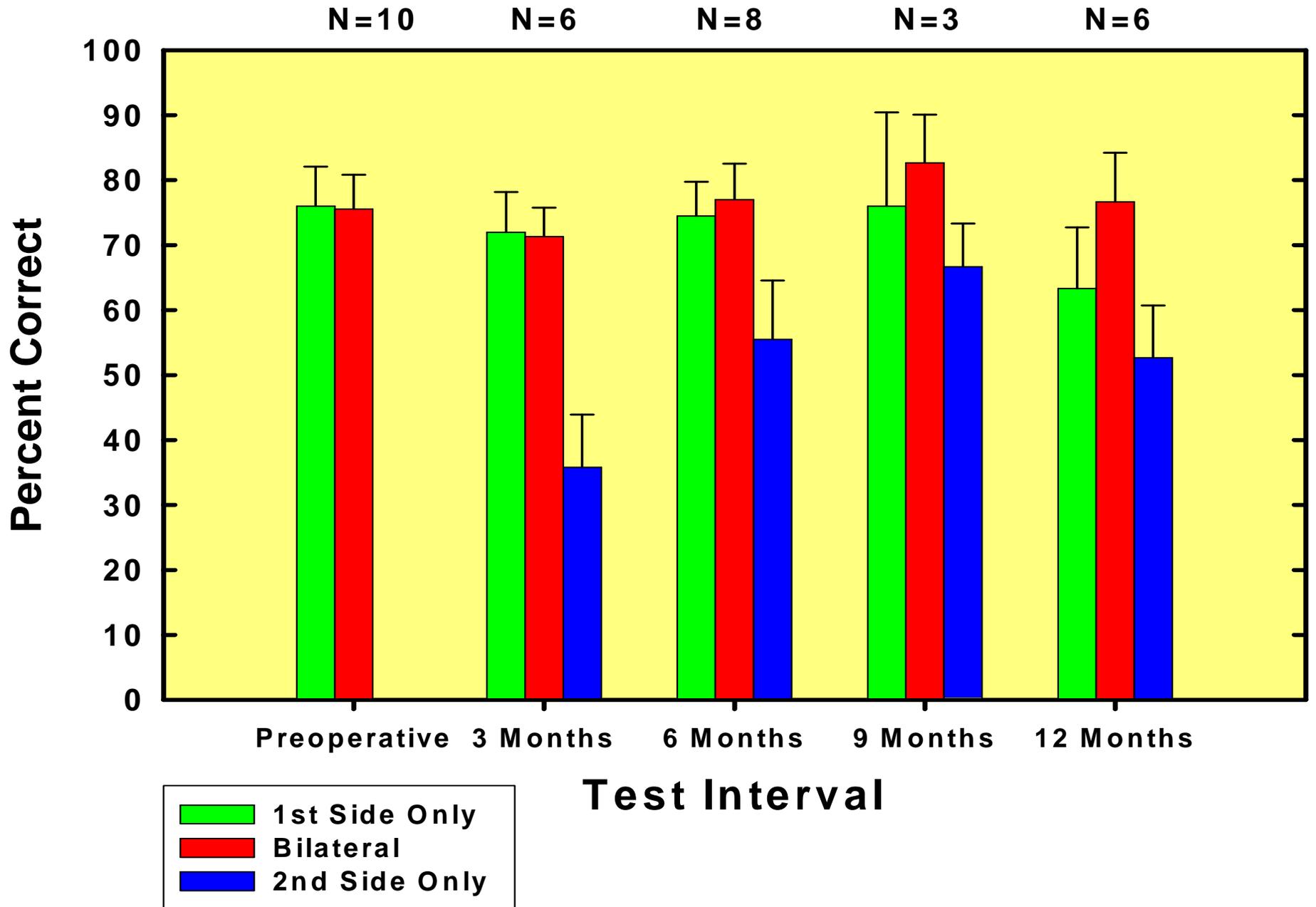
Bilateral CI Results/Conclusions

- 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)

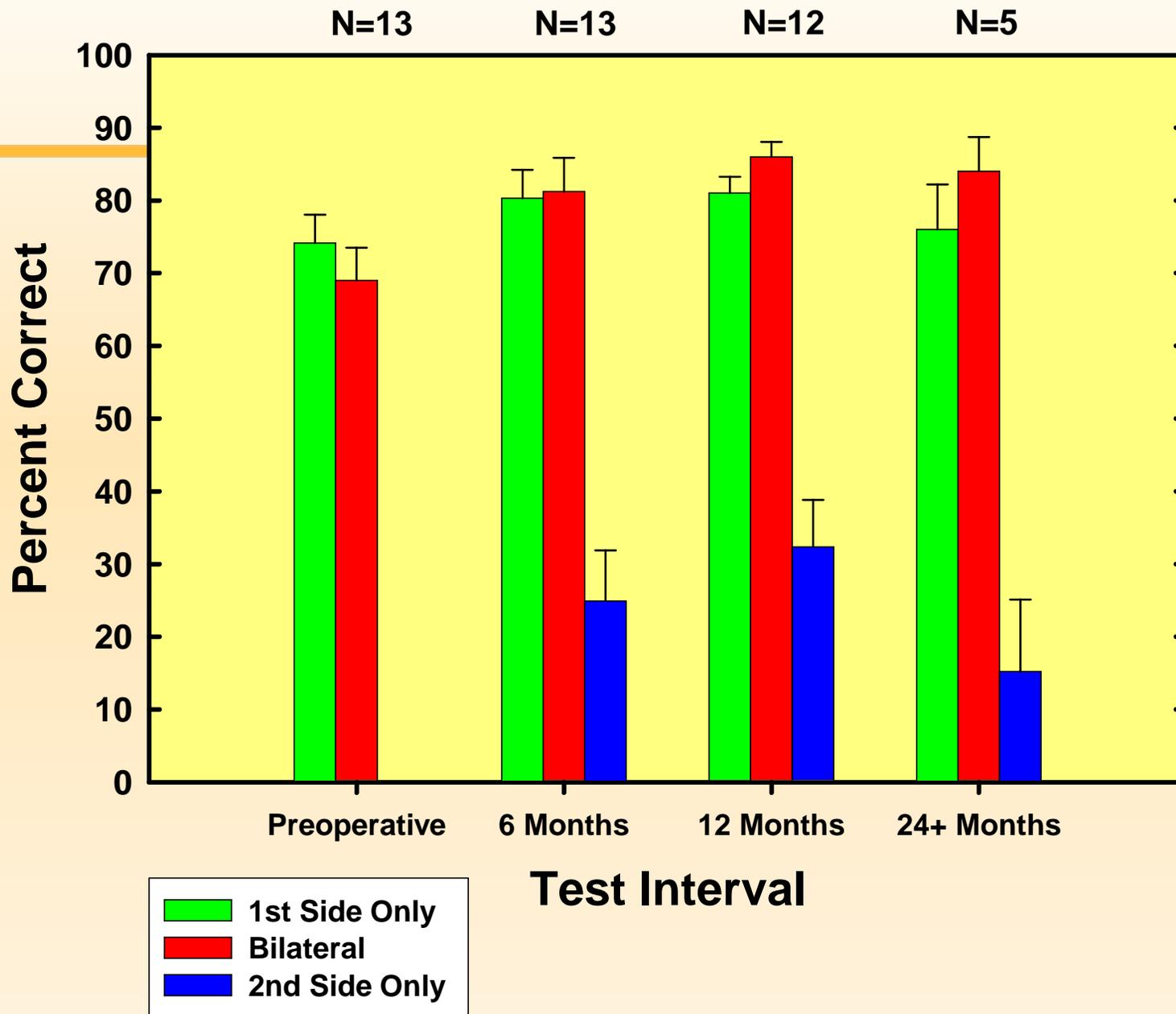
MLNT Words - 3 to 5 Years



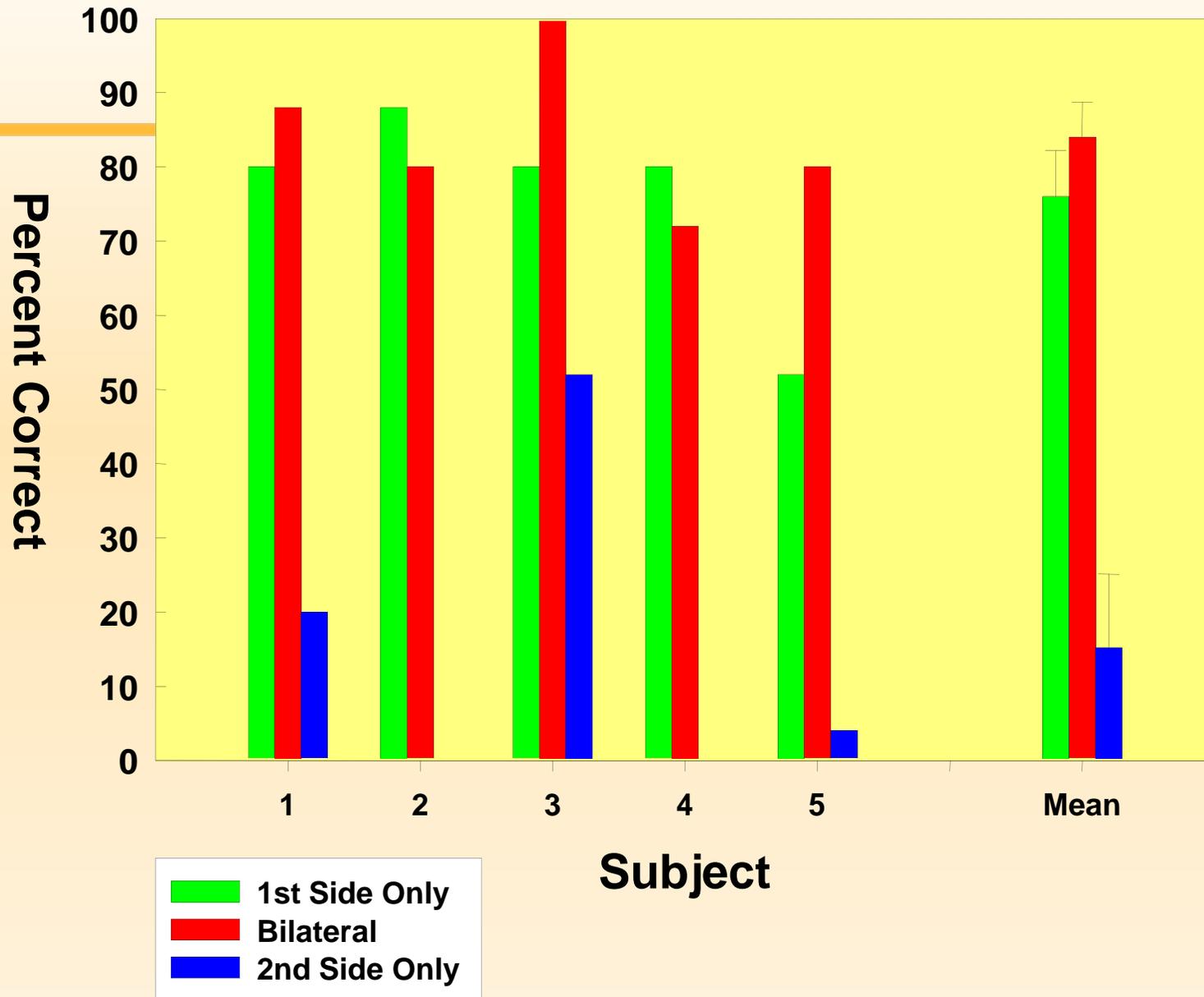
LNT Words - 5 to 8 Years



LNT Words - 8 to 13 Years

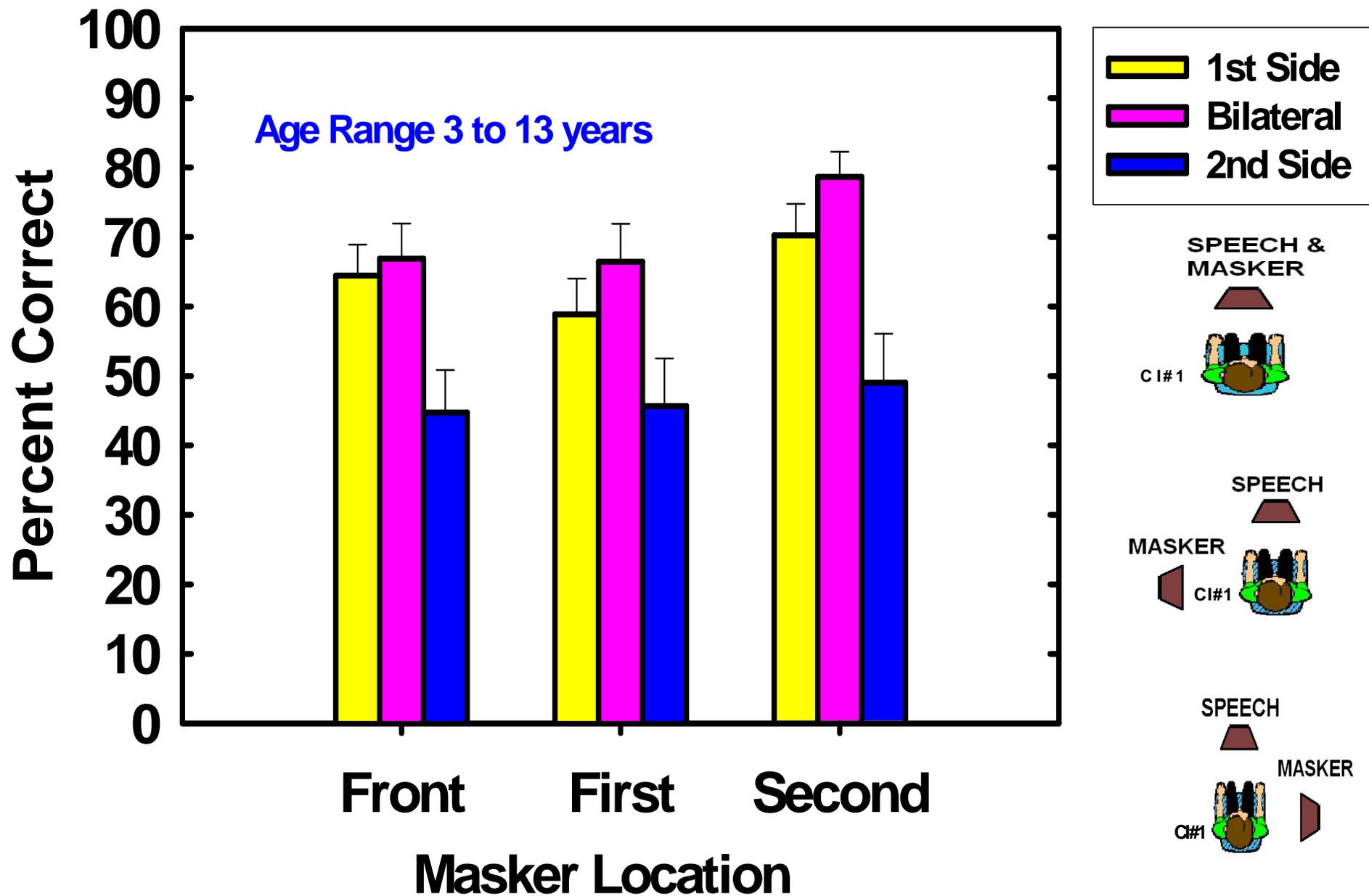


LNT Words - 8 to 13 Years 3 years of 2nd CI Experience



CRISP Test 9 Months

Mean Data N=18



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)

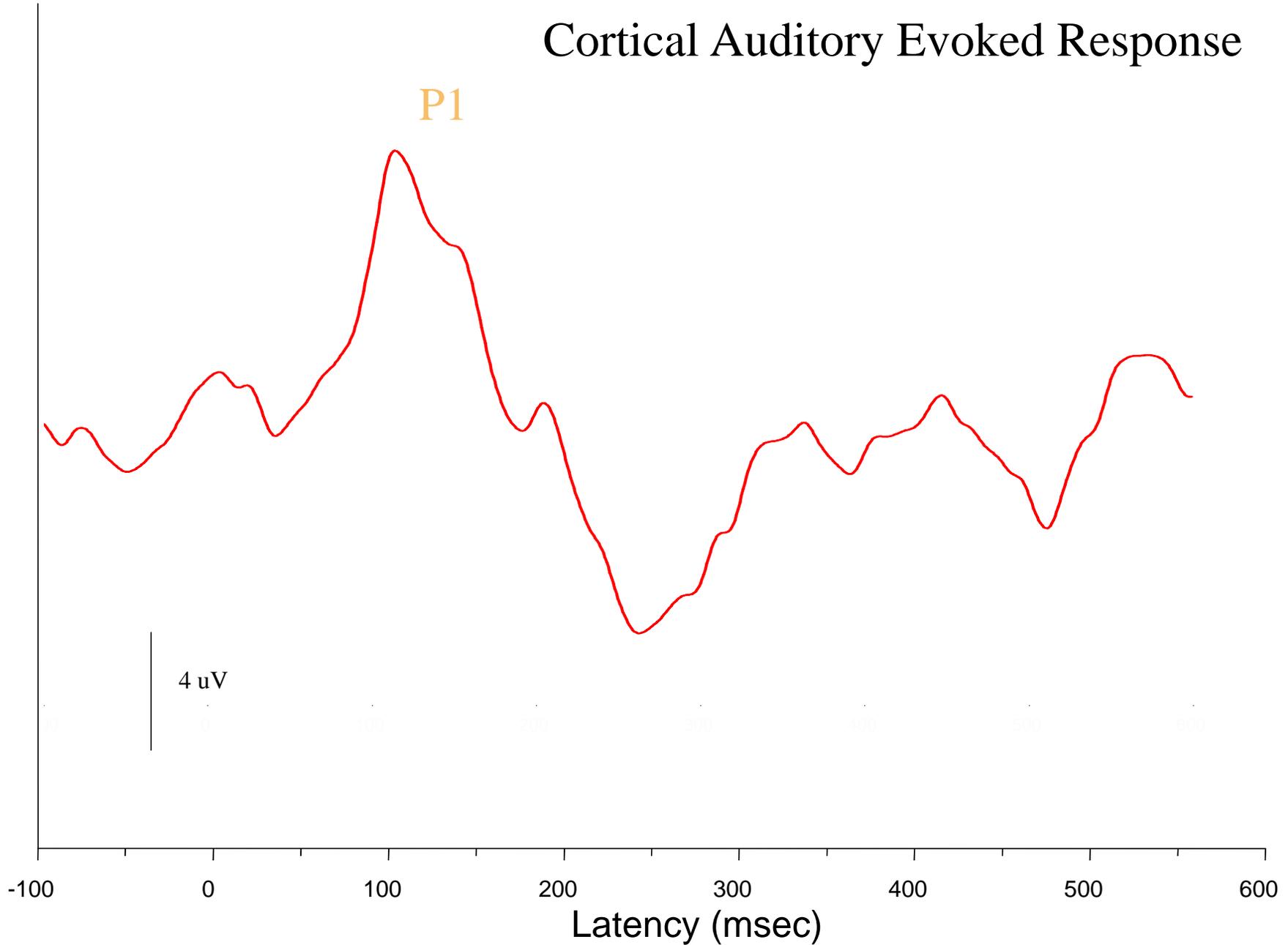
Cortical Auditory Evoked Potentials In Children- First Cochlear Implant

- 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 Response

P1



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).

Dallas Otolaryngology Associates
 7777 Forest Lane, Suite A-107 Dallas, Texas 75230
 Phone #972-566-7359 Fax #972-566-3883

Patient Name: Henry Z.

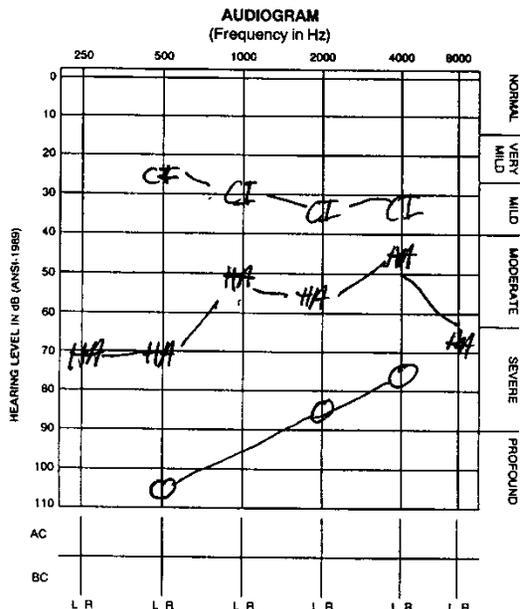
DOB: 2/9/03

Date of Test: 10/26/05

Behavioral Audiological Evaluation Summary of Results

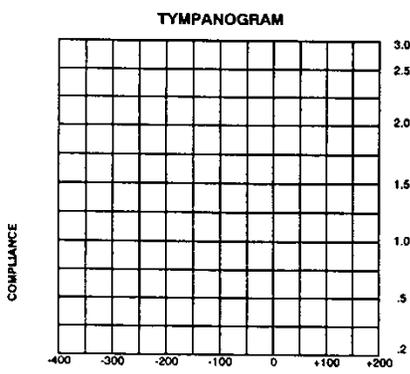
AUDIOLOGIST L.H. AUDIOMETER _____

TECHNIQUE _____ RELIABILITY _____ REASON FOR REFERRAL _____



SUMMARY				KEY		
	Right	Left	Sound Field	Aided Sound Field	Modality	Ear
AI: Peak Tone Average					Air Conduction-Earphones	Left Unspecified Right
					Unmasked	○ ○
					Masked	□ □
Speech Reception Threshold	0	25			Bone Conduction-Mastoid	○ ○
Speech Detection Threshold	50				Unmasked	△ △
					Masked	▽ ▽
					Bone Conduction-Forehead	○ ○
					Unmasked	▽ ▽
					Masked	▽ ▽
Discrimination @ 500 Hz					Air Conduction-Sound Field	○ ○
Discrimination 1/3w					Acoustic-Reflex Threshold	○ ○
					Contra	△ △
					Ipsi	▽ ▽

INTERPRETATION: _____



EUSTACHIAN TUBE FUNCTION: RE _____ LE _____

Recommendations: _____

COMPLIANCE	C ₁ CC@ +200 mm/H ₂ O				C ₂ CC@ Equivalent Middle Ear Pressure				Static Compliance
	Probe Right	Probe Left	Probe Right	Probe Left	Probe Right	Probe Left	Probe Right	Probe Left	
ACOUSTIC REFLEX	Contra (dBHL)				Ipsi (dB SPL)				Decay
Probe Right	Hz	500	1000	2000	4000	500	1000	2000	
Probe Left									
SUMMARY	Tymp (Type)				Static Compliance		Acoustic Reflex		
Probe Right							Contra Ipsi		
Probe Left									

Interpretation: _____

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Callier Advanced Hearing Research Center Electrophysiology Clinic
1966 Inwood Road, Dallas, Tx 75235 (Tel) 214-905-3186; (Fax) 214-905-3146

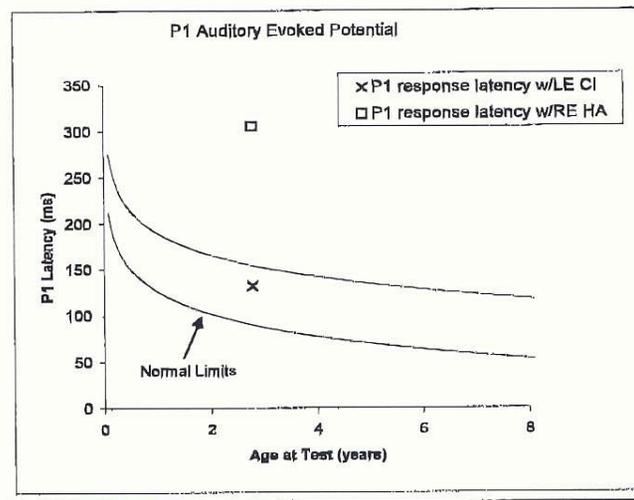
Name: Henry Z
Date of Birth: 2-9-03
Date of Test: 11-18-05
Implant Type: Nucleus
Test Age: 2 yrs, 9 mo
Fit Age / Approx. Implant Experience – LE CI: 1 yr, 6 mo / 1 yr, 3 mo
Fit Age / Approx. Hearing Aid Experience – RE HA: 4 mo / 2 yrs, 5 mo
Referral: Robert Peters, M.D.

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

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.

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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: Smith, 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/

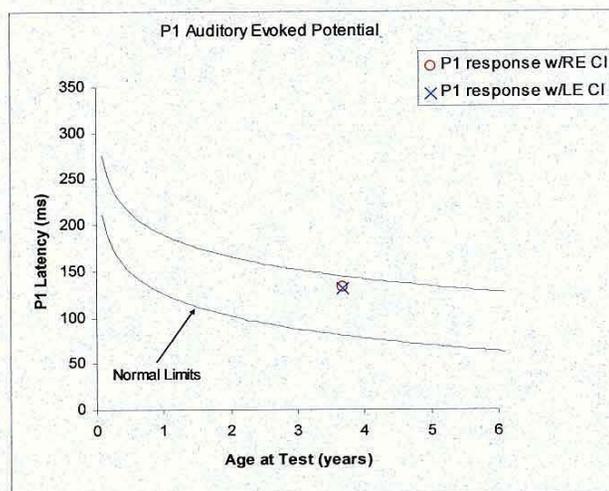
Condition(s): RE - CI; LE- CI

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.

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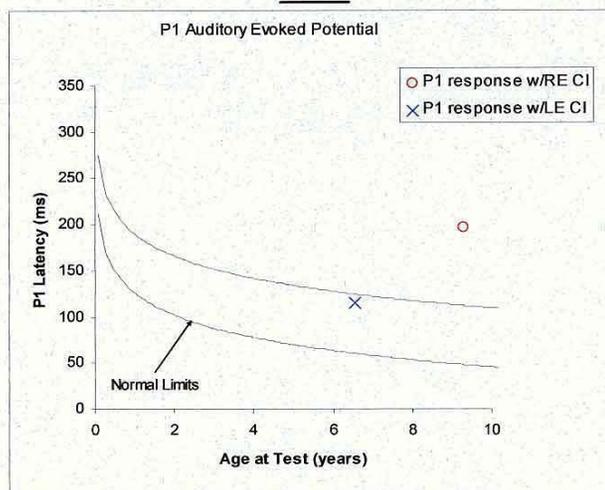
Name: G. _____, Justin
Date of Birth: 1-6-96
Date(s) of Test: 7-10-02, 4-20-05
Implant Type: Nucleus
Test Age: 6 yrs, 6 months (LE) / 9 yrs, 3 months (RE)
Fit Age / Approx. Implant Experience – LE CI: 2 yrs, 8 months / 3 yrs, 10 months
Fit Age / Approx. Implant Experience – RE CI: 7 yrs, 11 months /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



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.

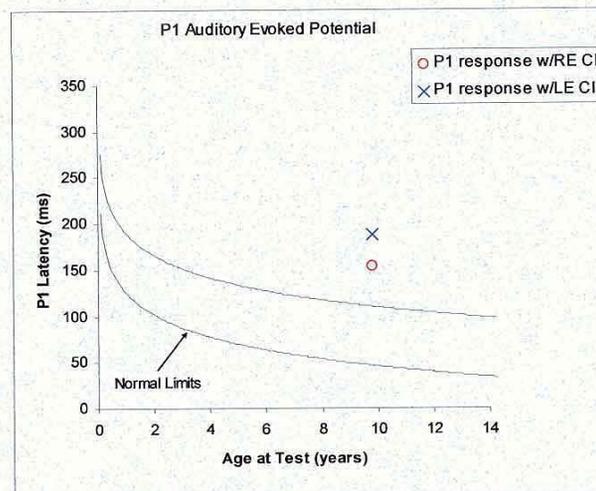
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Callier Center for Communication Disorders
Callier Advanced Hearing Research Center Electrophysiology Clinic
1966 Inwood Road, Dallas, Tx 75235 (Tel) 214-905-3186; (Fax) 214-905-3146

Name: Carr, Crockett	Test Protocol:
Date of Birth: 6-26-95	Stimulus Type: /ba/
Date of Test: 4-21-05	Condition(s): RE - CI; LE- CI
Implant Type: Clarion (RE) / Nucleus (LE)	Recording Electrode: Cz
Test Age: 9 yrs, 10 months	
Fit Age / Approx. Implant Experience – RE CI: 5 yrs, 11 months / 3 yrs, 11 months	
Fit Age / Approx. Implant Experience – LE CI: 8 yrs, 6 months / 1 yr, 4 months	
Referral: Robert Peters, M.D.	

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

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.

Bilateral CI Outcomes

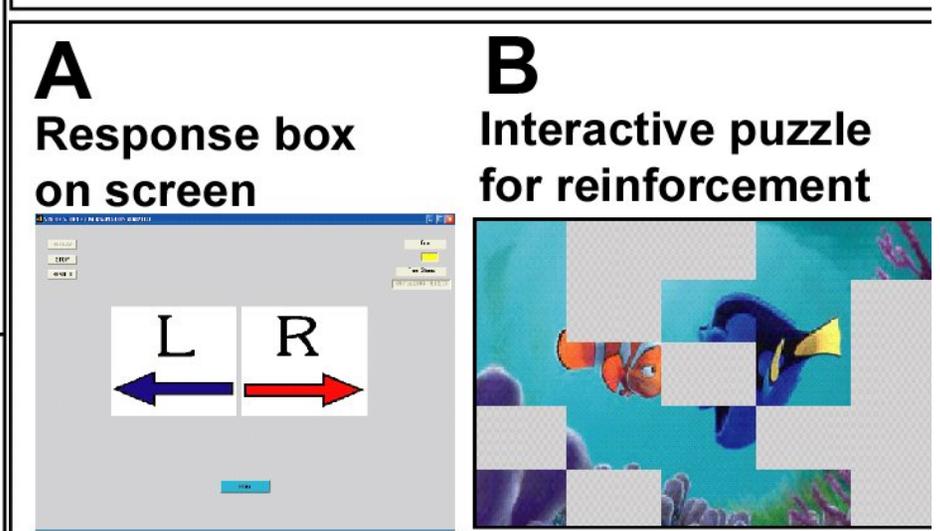
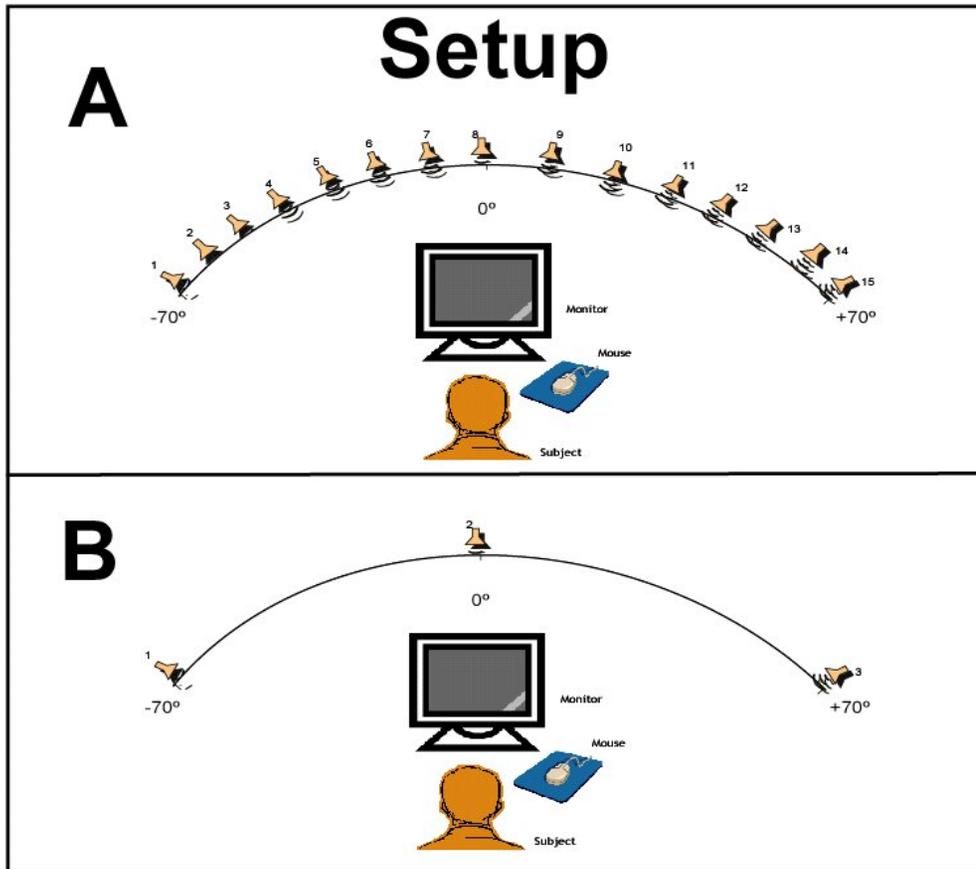
CAEP

- 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.

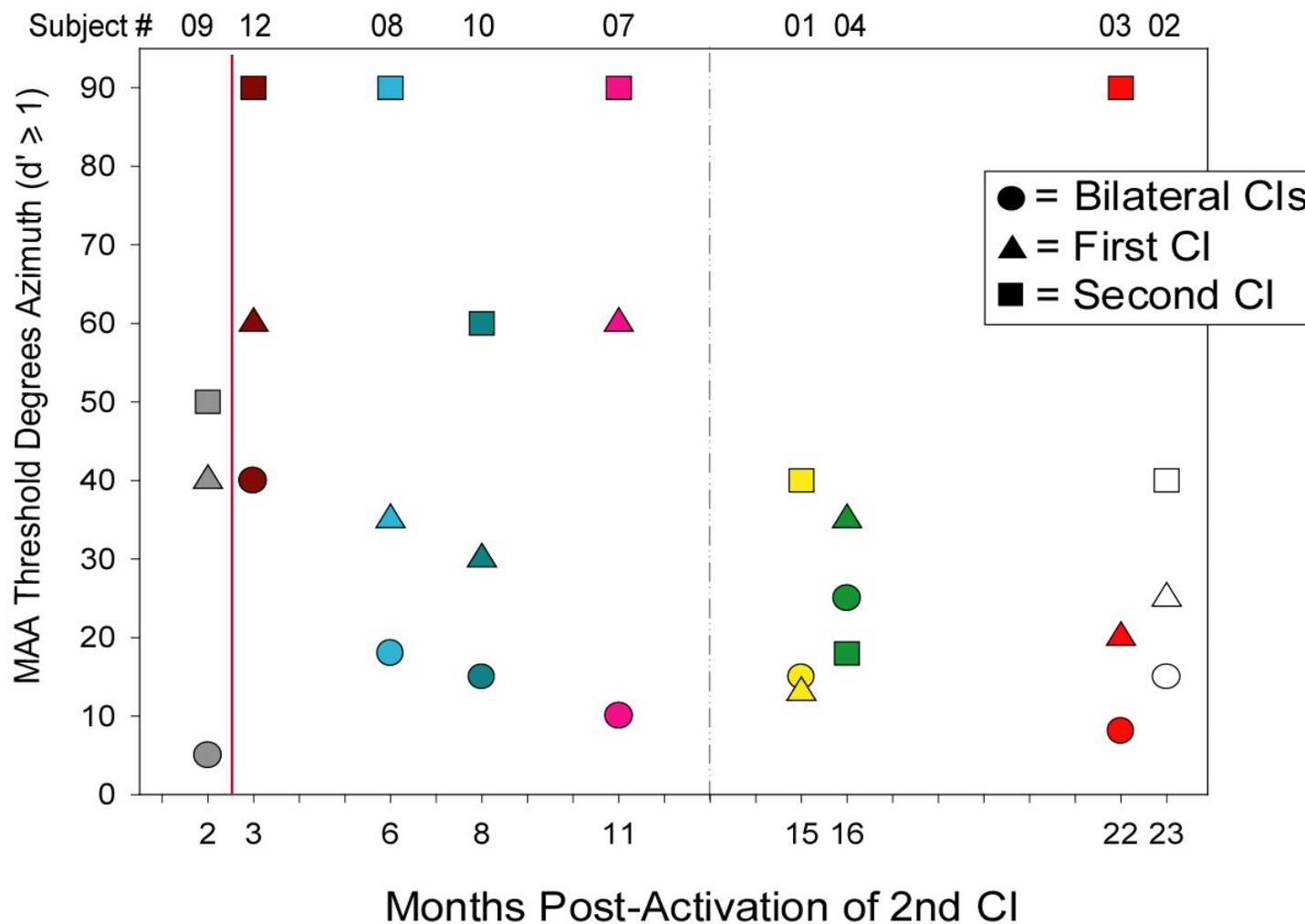
Bilateral CI Data-Implications

- 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



MAA Thresholds with Bilateral CIs: Effect of No. Months Post-Activation of Second CI Level Roved; Stimulus: Spondee "Baseball"



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

- International Consensus on Bilateral Cochlear Implants and Bimodal Simulation. Second Meeting Consensus on Auditory Implants. *Acta Oto-Laryngologica*, 2005;125;918-919.
- William House Cochlear Implant Study Group, 2007.
- American Academy of Otolaryngology-Head and Neck Surgery, 2007.

Future Issues

- Very early bilateral cochlear implantation (down to 6 months of age)- diagnostic and therapeutic requirements, simultaneous vs. sequential surgery
- Cost Effectiveness, Societal ROI (Return on Investment). Bichey et al 2008, Summerfield 2006
- Pharmacology and therapy techniques to open the “critical period”





Thank You