Evidence for the expansion of pediatric cochlear implant candidacy

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Disclosures

- Audiology Advisory Board
  - Advanced Bionics
  - Cochlear Americas

- Scientific Advisory Board
  - Frequency Therapeutics

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Evolution of pediatric implant candidacy indications

- FDA approval
  - 6/27/1990: Nucleus 22 (n = 142)
  - F0/F1/F2-WSP III & Multipeak-MSP
- Profound SNHL bilaterally
- 2 to 17 years of age
- no open set speech recognition
- auditory oral education program

Pediatric Cochlear Implant Criteria

- based primarily on the audiogram and auditory progress (or lack thereof…)
  - varies with age
  - each manufacturer outlines slightly different criteria
- Many clinicians are uncomfortable recommending CI for children who do not meet all criteria.

Current CI criteria for children
Degree of hearing loss < 2 years

**AB, Cochlear, & MED-EL:** profound bilateral SNHL

Degree of hearing loss > 2 years

**Cochlear:** severe-to-profound bilateral SNHL

**AB & MED-EL:** profound bilateral SNHL

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**Auditory progress with HAs:**

**Younger children**

**Cochlear, AB & MED-EL:** little to no progress with appropriately fitted HAs

*e.g., IT-MAIS, MAIS, LittleEARS*

**Older children**

**Cochlear:** ≤ 30% word recognition (MLNT or LNT)

**AB:** < 12% word recognition (PBK) or < 30% HINT-C sentence recognition

**MED-EL:** < 20% word recognition (MLNT or LNT)

Children must miss 70 to 88% of the signal to qualify.

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**Evidence for the expansion of pediatric cochlear implant candidacy**

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**HYPOTHESIS:** Children who are non-traditional CI candidates, but are not making progress with appropriately fitted HAs and intervention will demonstrate significant benefit from cochlear implantation as defined by improvement in:

1) Speech perception and/or
2) Auditory skill development
Study inclusion criteria

CI recipients < 18 years of age with SNHL and one or both of the following:

- < 70 dB HL PTA for children between 2 and 17 years of age or < 90 dB HL PTA for those under 24 months
- Age appropriate word and/or sentence recognition scores > 30% in the best-aided condition

Primary outcome measures

Pre- & post-CI results for age appropriate materials:

- Speech recognition tests in the CI ear, contralateral ear and best-aided conditions
  - NUCHIPs, MLNT, LNT, CNC
  - HINT-C, BabyBio, AzBio
- Parental questionnaires gauging auditory skills development
  - IT-MAIS/MAIS, LittleARS, PEACH

Participants

- 51 patients (across 2 centers)
  - 39 unilateral, 12 bilateral
- Mean age of implantation: 8.3 years
  - Range: 7.0 months to 17.6 years
- Mean duration of CI experience at reported follow-up: 17.1 months
  - Range: 2.5 to 46.5 months
- All were implanted with the most recent technology
  - AB: 13, Cochlear: 44, MED-EL: 6
Carlson et al. (2015).

No decline in performance

Carlson et al. (2015).

Mean improvement in total language: 9.9 points (p = 0.024)

Carlson et al. (2015) Follow-up

- Expansion of Carlson et al. (2015)
- Excluded children with ANSD, CND, and SSD
- n = 65
- At least 3 months of CI experience (average follow-up = 12.78 months; range = 3 - 24 months)
- Compared pre- and post-operative speech recognition scores
  - Participants were tested post-operatively with the same or more difficult speech materials than they were tested with pre-operatively

Word Recognition

CI ear only

F(1,23) = 70.6, p < 0.001

Mean benefit: 41 percentage points
Word Recognition

CI ear + best aided

$F_{(1,15)} = 3.596, p = 0.077$

Mean benefit: 14-percentage points

CI ear only

Mean benefit: 46-percentage points

Sentence Recognition

CI ear + best aided

$F_{(1,17)} = 30.49, p < 0.001$

Mean benefit: 20-percentage points

CI ear only

Mean benefit: 46-percentage points

Carlson et al. (2015) & follow-up study

SUMMARY

- Children w/ less severe hearing losses than specified by FDA labeling, gain significant benefit from CI.
- All but 2 demonstrated equivocal or significantly better outcomes
  - 2 children showed a decrement in best-aided condition (words)
  - These 2 children demonstrated benefit for sentences.
- We have not seen a definitive point of diminishing returns.
- A large-scale reassessment of peds CI candidacy is warranted to allow more children access to the benefits of CI.

STUDY OVERVIEW:

- retrospective study
- n = 140 children
- sensory hearing loss, no additional disabilities
- 78 CI recipients—all implanted < 3 years
- 62 hearing aid (HA) users

RESEARCH QUESTIONS:

1) Which children are truly CI candidates?
2) What is the optimal age for implantation?
EXPERIMENT 1: audiometric criteria for implantation

- CI group: CI < 2.5 years
- HA group: HA fitting < 2.5 years of age
- Monosyllabic word recognition at 5 years of age


EXPERIMENT 2: optimal age at implantation

- 32 CI recipients
- All implanted < 2.5 years
- Language assessed postoperatively at 1, 2, 3, and 5 years post-activation
  - Rossetti Infant-Toddler Language Scale (RITLS)
  - Peabody Picture Vocabulary Test (PPVT)


SUMMARY

- Children with PTA ≥ 65 dB HL will have a higher likelihood of exhibiting improvement with CI vs. HA
  - Equivalent to adult indications
  - Moderate to profound SNHL
- Children tend to be exhibit language delay appx equivalent to the duration of auditory deprivation (prior to CI)
  - Earlier is better → minimize or eliminate delay!

**Other studies**

**Implanting children under 12 months of age**

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**Cosetti and Roland (2010). Trends Amplif, 14: 46-57**

A major concern is the issue of **specificity**: the risk of implanting a child without SNHL.

**Anesthesia concerns and complications**: incidence of morbidity, mortality, and life-threatening adverse events in children < 12 months was significantly higher than children older than 1 year of age.

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**Cosetti and Roland (2010). Trends Amplif, 14: 46-57**

Recall that audiometric criteria for pediatric CI…
- most stringent for youngest children
- our youngest language learners

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**Cosetti and Roland (2010). Trends Amplif, 14: 46-57**

Multiple studies demonstrate no greater anesthetic risk for children < 12 months for CI surgery.

Bertram and Lenarz, 2004; James and Papsin, 2004; Coletti et al., 2005; Miyamoto et al., 2005; Waltzman and Roland, 2005; Dettman et al., 2007; Valencia et al., 2008; Miyamoto et al., 2008
Age at implantation matters

• Infants can link sound patterns with meaning by 6 months (mommy, daddy, no, bye bye, etc.)

• Word segmentation abilities develop rapidly between 7.5 and 10.5 months (Jusczyk, 2002).

• 8 months of age: 60+ words/concepts

Pediatric Cochlear Implant Criteria

Age at implantation matters

• 8-month olds: long-term storage of words (up to 2 weeks)

• Important prerequisite for learning language!

• Houston et al., 2009, 2012; Bergeson et al., 2010: children implanted < 12 months → significantly better word learning abilities

• Tomblin et al. (2005): children implanted b/tw 10-15 months had significantly better expressive language

• Hearing and/or language learning opportunities likely begin BEFORE birth (DeCasper et al., 1980, 1986; Kisilevsky et al., 2003; Moon et al., 2013; Partanen et al., 2013)

Age matters! But current CI criteria are strictest for the youngest children.


• 3 Australian CI centers, n = 125

• Prospective assessment: speech perception, language, & speech production

• Assessment time points: school entry & late primary/early secondary
Outcomes for children implanted < 12 months


Case study
Case 1

- 4.5-year old male
- Term birth, no complications
- No family history of hearing loss
- Failed NBHS
- Bilateral moderate-to-severe SNHL identified at 2 months
- Fitted with HAs at 3 months of age
- 2 younger siblings
Case 1

- CI in RIGHT ear 3 months after CI workup
- 1 month before 5th birthday
- CI512

BabyBio

- current CI criteria for children are set too low
  - re: audiogram, function, and age
- pediatric criteria are much more stringent than labeled adult criteria (even more so than Medicare!)
- requiring children with the best, appropriately fitted HAs to miss 70 to 88% of the signal!
- and that’s in the quiet sound booth

### CONCLUSIONS

- CIs provide auditory access to HF information that HAs just cannot provide for those with severe-to-profound SNHL.
  - …this is critical because children are learning language!
- Pay attention to auditory and language progress with appropriately fitted HAs.
  - more valuable than audiogram

Questions? Comments?

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