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Cochlear Implants Before 12 Months of Age: How Much Younger Should We Consider?

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Cochlear Implants Before 12 Months of Age: How Much Younger Should We Consider?

Michael Scott, AuD
Audiology Online, 10/14/15
Learning Objectives

After this course, learners will be able to...

• describe current candidacy requirements as listed by the FDA.
• list three possible benefits to implantation prior to 12 months of age.
• describe the needs for patients and parents who are being considered for early implantation.

Schedule of Events

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>0-5 Minutes</td>
<td>Introduction</td>
</tr>
<tr>
<td>5-15 Minutes</td>
<td>Current CI candidacy</td>
</tr>
<tr>
<td>15-25 Minutes</td>
<td>Review of the literature</td>
</tr>
<tr>
<td>25-40 Minutes</td>
<td>Evaluation and Management</td>
</tr>
<tr>
<td>40-55 Minutes</td>
<td>Case Example Discussion</td>
</tr>
<tr>
<td>55-60 Minutes</td>
<td>Summary, Q &amp; A</td>
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</tbody>
</table>
Why?  (Simon Sinek)

Potential Benefits

• Provide access to sound sooner for those with the most profound losses
• Parents may be able to engage in auditory-verbal interaction at an earlier age
• Auditory skill development faster than if implanted later
• Rate of language development commensurate with hearing peers
• More “natural” progression of receptive skills due to earlier incidental hearing
• Four different age groups based on age of implantation:
  – Speech comprehension scores
  – Communication mode both pre and post-implantation
  – Proximity of language age to chronological age

• Youngest included in this study were 12-18 months

• Wide range of longitudinal data including: speech comprehension scores and proximity of language age to chronological age, relative to age at implantation.

Children implanted under 18 months demonstrated best outcomes for language acquisition, speech intelligibility, and spoken language.


- Evidence suggests a higher rate of receptive and language development in children implanted under the age of 1
- Outcomes data in auditory perception and linguistic development suggest that early-implanted children may be more likely to achieve their full potential and may reduce or eliminate the need for them to “catch up” or learn at a faster than normal rate to achieve age-appropriate norms

Current cochlear implant candidacy
Pediatric Candidacy

- Use of appropriately fit hearing aids
- Little or no benefit from appropriately fit amplification
- Lack of progress in development of auditory skills with HA or other amplification (3 – 6 months of HA use)
- Consistent speech and listening therapy
- High motivation and realistic expectations from family
- No medical/surgical contraindications

Pediatric Candidacy (12mo to 2 years)

- 12 months through 2 years of age
- Profound, bilateral sensorineural hearing loss (>90 dBHL)
- Use of appropriately fit hearing aids for at least 3 months in children 12- 23 months
- Failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale
Pediatric Candidacy (over 2 years)

- Severe-to-profound sensorineural hearing loss bilaterally
- Little or no benefit from hearing aids (3 – 6 months of HA use)
- Consistent speech/listening therapy

- <4 years of age, failure to reach developmentally appropriate auditory milestones measured using the Meaningful Auditory Integration Scale or <20% correct on a simple open-set word recognition test (Multisyllabic Lexical Neighborhood Test)

- >4 years of age, <12% on a difficult open-set word recognition test (such as the Phonetically Balanced – Kindergarten Test) or <30% on an open-set sentence test (Hearing in Noise Test for Children)

Trends in Cochlear Implant Candidacy
Age of Cochlear Implantation

Age Criteria – Pushing the envelope
- Initially, adults only
- Then 2-18 year old children
- Then 18 month old children
- Now 12 month old children
- Younger with special cases (such as meningitis and risk of cochlear ossification)

Historical notes on pediatric implants

1980: First child receives the Nucleus multi-channel implant.

1990: Gained FDA approval for use in peds over 2

1980s and 90s: Improved detection of environmental sounds and improved speech/language skills than without a CI

Currently: given ideal circumstances, children may develop auditory, speech and language skills commensurate with their normal hearing peers.
**Tech: A “culprit” behind the shift**

- Advancements in technique and technology
- Universal newborn hearing screening
  - Now, we know almost immediately after the baby is born
  - Baby can be fit with amplification quicker
  - Amplification is verified through objective means
  - Earlier determination of limited benefit
- Amplification and implant technologies are constantly improving

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**Bottom line questions:**

- When does patient performance with a cochlear implant exceed what they currently do with optimized hearing aids?
- CI technology is rapidly improving, but so are hearing aids- length of trial period?
- What are the key audiologic factors?
- How can we be certain that we have all of the (most accurate) information?
- Do the benefits exceed the risks?
Review of the literature


- Subjects: 96 children
- Ages 0-4 years of age
- Divided into 4 equal age groups
- Compared outcomes of children implanted in the various age groups
- Only 6 children in the “younger than 12 months” group

Results:
– in general earlier cochlear implantation led to better outcomes
– few differences in outcome between children implanted before 12 months of age and those implanted at 13 to 24 mos.
– oral language development progressed faster in children implanted earlier rather than later in life (up to age 4 years), whereas the rate of open-set speech recognition development was similar


- 69 children presumed to be deaf from birth
  - 27 implanted between 6 and 11 months of age
  - 42 implanted between 12 and 18 months of age
- All children were evaluated at 4.5 years of age for receptive and expressive vocabulary and receptive language
Nicholas, JG. And Geers, AE. (2013)

• Results:
  – Children implanted at 6–11 months (N=27) achieved higher scores on all measures as compared to those with surgery at 12–18 months (N=42).
  – Regression analysis revealed a linear relationship between age of implantation and language outcomes throughout the 6–18 month surgery-age range.

Nicholas, JG. And Geers, AE. (2013)

On average, children who received their CI earlier (age 6 to 12 months) demonstrated significant advantage with regard to vocabulary and receptive and expressive spoken language ability.

<table>
<thead>
<tr>
<th>Age of Implantation Group</th>
<th>6–11 months (N = 27)</th>
<th>12–18 months (N = 42)</th>
<th>p-value</th>
<th>t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receptive Vocabulary PPVT-III</td>
<td>103.07 (SD = 11.62)</td>
<td>94.17 (SD = 14.85)</td>
<td>.003</td>
<td></td>
</tr>
<tr>
<td>Receptive Language PLS-Aud Comp</td>
<td>103.96 (SD = 17.33)</td>
<td>90.45 (SD = 19.10)</td>
<td>.002</td>
<td></td>
</tr>
<tr>
<td>Expressive Language PLS-III</td>
<td>101.04 (SD = 19.92)</td>
<td>90.12 (SD = 20.57)</td>
<td>.016</td>
<td></td>
</tr>
</tbody>
</table>

* one-tailed

- Subjects: 26 patients (41 ears)
- At about 58 months post-implant:
  - 1 device failure (required re-implantation)
  - 2 electrode anomalies (programmed around)
- “surgical and anesthetic risk similar to that expected with older pediatric and adult patients”
- 73% of patients performed at or above normal hearing peers
- Children implanted below 12 months reached age appropriate speech and language skills by 24 months, whereas the later implanted group took 40 months


- Subjects:
  - 19 children implanted below 12 months
  - 87 implanted between 12 and 24 months of age
- Retrospective review
- Obtained language comprehension and expression scores through the Rosetti Language Scale

• Results:
  – Children implanted below 12 months of age achieved mean rates of receptive and expressive language growth comparable to their normally hearing peers
  – Growth rates were also significantly higher than those of children who underwent implantation between 12 and 24 months

• Conclusion: If normal rates of language acquisition can be maintained in this group, earlier cochlear implantation represents a cost benefit to the community due to improved employment opportunities and reduced reliance on specialized psychosocial and educational support


• Subjects: 66 children (94 implants)
• Retrospective case review
• Looked specifically at the incidence soft tissue complications at least 4 years post implant
• Found only one minor complication, where a child had a skin infection around the implant, treated with antibiotics

<table>
<thead>
<tr>
<th>Author and date</th>
<th>Study No.</th>
<th>Minor complication</th>
<th>Major complication</th>
<th>Total complication</th>
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</thead>
<tbody>
<tr>
<td>Bhatia et al., 2004 (20)</td>
<td>&lt;5 yr 300</td>
<td>16</td>
<td>2.3</td>
<td>18.3</td>
</tr>
<tr>
<td>Ovensen, 2008</td>
<td>All ages 313</td>
<td>11.2</td>
<td>4.5</td>
<td>15.7</td>
</tr>
<tr>
<td>Roland et al., 2009 (19)</td>
<td>&lt;1 yr 50</td>
<td>10</td>
<td>6</td>
<td>16</td>
</tr>
<tr>
<td>Current study</td>
<td>&lt;1 yr 94</td>
<td>1.1</td>
<td>0</td>
<td>1.1</td>
</tr>
</tbody>
</table>

- Subjects: 13 children
- Implanted between 4-11 months
- Results compared to children implanted at
  - 12-23 months
  - 24-36 months
- Retrospective chart review
- Results:
  - Receptive language growth trajectory was closest for normal hearing age-matched peers for the infants implanted between 4 and 11 months
  - the second and third group never reached the values of normal peers even after 9 years of CI use
  - No surgical or device complications were identified

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**Evaluation and Management**
Unpredictable Issues to Consider

- Some disabilities are not easily identifiable at the time of consideration for candidacy
- In more complex cases, hearing loss may not be the first priority
- Even in children without additional disabilities, outcomes depend on significant factors such as chosen mode of communication

“Despite the best efforts of many professionals, it is often difficult to diagnose learning disabilities, reduced cognitive function, and soft neurologic deficits in very young children...”

- Walzman, B. 2000

Determining Pediatric Candidacy

- Considerations:
  - Depending on the age, most children have not acquired speech and language skills.
  - Many professionals are involved in a “Cochlear Implant Team”
  - Lengthy evaluations and a strict trial with amplification are necessary.
  - Imaging
    - to confirm cause of hearing loss (such as EVA) and therefore, the appropriateness of a cochlear implant
    - to identify other structural anomalies that may further impact outcomes despite age of implantation
Pre-implant Concerns

- Etiology
- Parent/caregiver involvement
  - Understanding
  - Decision making
- Developmental age (prematurity) vs. chronological age
- Accuracy of audiometric testing
  - unaided
  - aided: fewer objective measures

Etiology

- Consider early
  - Meningitis
  - Genetic (where it is known that improvement should not be expected)
  - Cochlear abnormalities such as EVA
- Consider monitoring
  - Unknown
  - Auditory neuropathy
  - CMV
  - Multiple disabilities
Audiology Assessment

• Behavioral hearing measurements to reliably confirm limited access to sound
  • Speech and puretone thresholds
  • Air and bone conduction
  • Unaided *and* aided
• Objective measurements
  • Tympanometry
  • Acoustic reflexes
  • ABR/ASSR
  • OAE
  • Verifit
• Parent report (ASC, IT MAIS, Perceived Benefits Questionnaire)

Evaluation for Cochlear Implants

• Challenges:
  – Obtaining accurate audiometric information
  – Understanding family expectations
  – Time for provision of counseling and access to resources

• Tools:
  – Objective measures (ABR, ASSR, OAE, etc.)
  – Speech awareness- not always possible to obtain, but may be the only observable behavioral piece of information
  – Questionnaires and Profiles (IT-MAIS, ASC, etc.)
  – The implant team!
CI Team Participants

- Physicians
  - Surgeon
  - Radiology
  - Genetics
  - Developmental pediatrician
- Audiologists
  - Diagnostic
  - Aural (re)Habilitation
  - Cochlear Implant
- Speech-Language Pathologists
- Social Worker
- Research
- Psychologist
- School system/Early interventionist
- Parents and family

Surgical Risks

- Same risks involved with implanting children of any age, plus:
- Increased difficulty with anesthesia
- Increased impact of blood loss
- Anatomical differences- facial nerve and semicircular canals may be laterally or superficially displaced
- Skull and skin may be thinner
Surgical considerations

• For the device to lie flat, consider the smaller, more curved cranium in infants for best positioning of the receiver-stimulator.
• The coil of the stimulator should be placed above the apex of the pinna. This allows the infant to lie flat or sit in a car seat or stroller with less possibility of dislodging the device.
• The implant also must be positioned far posteriorly, ensuring that the processor does not rest on the device and risk undue pressure to the overlying skin.

Cosetti and Roland, 2010

After the Fact:
fitting and management

• OK, we chose to implant...now what?!?

• Similar issues with management of younger CI recipients
• Setting programming levels- two approaches:
  – Subjective: behavioral observation, visual reinforcement
  – Objective: eSRT, neural telemetry, eABR, ASSR?
Device Retention

– Pulling on device/falls off easily
– Chewing on the device
– Moisture
– Lack of head control
– Car seats
– Lack of mobility
– Learning to become mobile
– Etc.

Tools for keeping the devices on

• Employ the modularity manufacturers have built into their processor systems
• Toupee tape
• “Huggies”
• Headbands
• “Pilot Caps”
• Barrettes
• Tethers
After the Fact: Outcomes

• Similar issues with determining benefit from traditional amplification

• Will likely rely heavily on:
  – Parent/teacher/interventionist report
  – Observations of the child
  – Comparisons of the child to themselves over time

• May not be able to see “benefit” for several months
  – Difficult to make sure programming is appropriate
  – Even with ideal implant programming, the child’s performance ability is not immediately known

Verification after programming:

Can check through the use of:
  – Formal booth testing via VRA
  – Informal administration of Ling sounds
  – Eventually, formal aided speech perception testing as age appropriate

Speech Perception Tests
  • Ling thresholds
  • ESP
  • GASP
  • MLNT
  • LNT
  • PBK
  • WIPI
  • Etc.
Other Considerations

- Evaluate for communication ability, not just hearing sensitivity

- Does the child seem to be making use of the new stimuli?
  - Is there increased environmental awareness?
  - Do they change focus or turn to familiar voices?
  - Does the child seem to accept or reject this input?

- Changes in babbling (increased or varied) are signs of hearing

- Input from therapists, interventionist, parents, etc.

Beyond audiograms and speech perception measures...

Some thoughts and questions to ponder:
- Is there additional information that should be considered for closer analysis?
- Are we already getting the information without evaluating it’s value?
- Due to age, attention, etc., many children are not able to provide accurate feedback while the audiologist programs their cochlear implant, so there are several other tools...
Functional Outcome Measures

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<thead>
<tr>
<th>ASC: Auditory Skills Checklist</th>
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<tr>
<th>ELF (Early Listening Function)</th>
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<tr>
<th>IT-MAIS: Infant Toddler Meaningful Auditory Integration Scale</th>
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<tr>
<th>Little Ears:</th>
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<tr>
<th>PEACH: Parents’ Evaluation of Aural/oral performance of Children</th>
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<table>
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<tr>
<th>TEACH: Teachers’ Evaluation of Aural/oral performance of Children</th>
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<table>
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<tr>
<th>ABEL (Auditory Behaviors in Everyday Life)</th>
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Activation

- Video
  - https://www.youtube.com/watch?v=jaBWa6TsT-I
Summary

• Implantation prior to 12 months of age can be done safely
• Several pre-implant considerations need to be made; including etiology, degree of hearing loss, and motivation of the parents
• Follow-up may be more frequent initially, with limited feedback from the child
• Outcomes can be as good or better than those implanted after 12 months of age

Questions?
THANK YOU