Cochlear Implantation in the Very Young: Session Introduction

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Disclosure

• Member of the Audiology Advisory Board for Cochlear Americas and MedEl
Prior to cochlear implants...

- The only treatment options available for profoundly deaf individuals included visual communication (sign language and lipreading), tactile devices, and reliance on amplification that provided limited auditory information.
- This resulted in a strong tendency for low median education achievement levels, low median annual incomes, low employment, and poor self-rated general health for individuals who were profoundly deaf.
Historical Timeline

• 1972: first commercially available single channel system in U.S.
• 1980: 3M/House device available for children as young as 2 years of age
• 1982: first multi-channel system commercially available in Australia
• 1984: FDA approved the 3M/House device
• 1984: Multi-channel devices introduced in the U.S.
• 1985: FDA approves the Nucleus device for adults
• 1987: Clinical trials with multichannel device begins in children
• 1990: FDA approves Nucleus multichannel device for children ages 2-17 years
• 1998: FDA approves lowering the age to 18 months
• 2000: FDA approves lowering the approved age to 12 months
Introduction

• It was quickly evident that provision of a cochlear implant leads to improvements in speech perception, speech/language and academic performance of profoundly deaf children.

• CIs are now recognized as the standard of care in the treatment of children with severe to profound sensorineural hearing loss and numerous investigators have demonstrated that children do best if they receive a CI at a young age.

• There is strong evidence that supports a critical period for developing language and that a CI will work best if provided during this sensitive period.

• This naturally led to professionals considering expansion to even younger children.
Introduction

• Numerous authors report on the provision of cochlear implants to children younger than 12 months.
• Some authors report advantages of this earlier intervention, while a few others report little/no advantage.
• In some centers, implanting children prior to 12 months has become the standard of care, while others will only implant early for medical reasons such as ossification, or will not implant until the child is one year of age. In some cases, insurances will not cover the procedure if provided prior to one year.
• It is important to dialogue about this issue so CI centers can make informed choices regarding the optimal time to provide CIs to very young children.
FDA Approval: can we go younger?

- The FDA provides guidelines for candidacy. Guidelines for contemporary devices were written following completion of extensive clinical trials that demonstrated safety and efficacy. Many guidelines are outdated as new technologies with improved outcomes have been introduced since their initial approval.

- New technologies often appear as Supplements to the original approved device but they do not typically involve a clinical trial or rewording of the original guidelines.

- Many teams are comfortable providing implants outside the recommended guidelines (“Off-Label” use).
“Off-Label” use of devices

- The FDA states “Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.”
Technological Advances have fostered younger ages at implantation

- Reduced size of internal devices
- Improvements in surgical safety
- Increased likelihood of hearing preservation
- Infant-friendly options, such as smaller processors, pediatric alerts, and safety options
- Objective measures available for programming
Increased awareness of the benefits of CIs

- Increased data available to support this decision
- Improved hearing, speech, quality of life, academic outcomes, increased earning potential, and improved quality of life.
- More parents are asking us to go younger.
Universal Newborn Hearing Screening

• 1993: the National Institutes of Health (NIH) Consensus Development Conference on Early Identification of Hearing loss concluded that ALL infants should be screened for hearing impairment, preferably prior to hospital discharge.

• Today, more than 97% of newborns are screened for hearing loss, increasing the likelihood that children with profound losses will be identified sooner and will receive intervention at younger ages.

• Gives additional time to evaluate performance with aids, but with some children, we know they will not receive benefit.
Clinical questions for today

Is it safe to go younger?
If yes, how young should we go?
Why go younger?
When should we not implant younger?
What is expected when we do go younger?
What are the advantages and challenges of implanting at very young ages?
Should we go younger?

- This is a decision that clinics will likely make on a case by case basis
- Requires excellent, experienced care by surgeons, audiologists, and speech-language pathologists
- Information provided today will help you in that decision process
Today’s speakers

- Surgical Management of Cochlear Implants in the Very Young
- J. Thomas Roland, Jr., M.D.
- Audiological Management of Cochlear Implants in the Very Young
- Holly Teagle, AuD
- Role of the SLP in Management of Very Young Children Who Receive Cochlear Implants
- Teresa Caraway, Ph.D.
Today’s speakers

• Effects of Cochlear Implants on Young Deaf Children’s Language, Behavioral, and Social Development
  • Ivette Cejas, Ph.D.

• The Role of Early Auditory Experience on the Development of Word-Learning Skills after Cochlear Implantation
  • Derek Houston, Ph.D.

• Panel Discussion of current issues