Cochlear Implant Clinical Trials

Sarah Zlomke, Au.D., CCC-A
KSHA
October 1, 2016

Cochlear Implant Devices Currently Available in the U.S.

Advanced Bionics
- Internal device:
  • HiFocus Mid-Scala
- External device:
  • Naida Q90
  • Neptune

What is a Cochlear Implant?

Cochlear Implant Devices Currently Available in the U.S.

Med-El
- Internal Device:
  - Synchrony
- External Device:
  - Sonnet
  - Rondo

Cochlear Implant Devices Currently Available in the U.S.

Cochlear Americas
- Internal Device:
  • CI 512
  • CI 522
  • Hybrid L24
- External Device:
  • Nucleus 6

Current Candidacy Guidelines - Adults

- Moderate to profound SNHL
- <50% sentence score in ear to be implanted
- <60% sentence score in opposite ear
- Lack of benefit from hearing aids
Current Candidacy Guidelines - Children

- >12 months of age
- <30% speech scores
- Lack of auditory progress

Other Candidacy Considerations

- CT-scan or MRI showing no contraindications to electrode placement in the cochlea
- Medical exam showing no contraindications to surgery
- Appropriate expectations and high motivation

Predicting Performance

- Age at onset
  - Pre-lingual
  - Post-lingual
- Duration of deafness
- Hearing Aid Use
- Age at Implantation

Outcomes

- Open Set Sentences – AZ Bio, quiet >70%
- Open Set Words - CNC >50%
- Ability to use telephone
- Enhanced lip reading

Outcomes in Children

- Different expectations based on speech/language development
- Age at implantation makes a difference
- Auditory rehabilitation/education critical

Research directions

- Asymmetric
- Single sided deafness
- Hybrid
- Bimodal hearing
- Cognitive function
Current MEI Research

• Clinical Study of Cochlear Implants in Adults with Asymmetrical Hearing Loss
  – NIH study carried out with Washington University School of Medicine in St. Louis.
  – Purpose:
    • To investigate benefits of binaural hearing for non-traditional cochlear implant candidates (with Asymmetric Hearing Loss)

Clinical Study of Cochlear Implants in Adults with Asymmetrical Hearing Loss

• Designed for patients with asymmetric hearing loss who are effectively functioning with one ear, but may be missing benefits of binaural hearing (localization, hearing in noise, quality)
• Does crossover from the “good” ear help keep the poorer ear functioning for an implant?
• Subjects are a traditional implant candidate in one ear, but not in the “good” ear (i.e. speech recognition better than 60%)

Clinical Study of Cochlear Implants in Adults with Asymmetrical Hearing Loss

• Patient example
  – 77 year old male
  – Aided speech understanding left: CNC words 0%, HINT sentences 0% with masking

Clinical Study of Cochlear Implants in Adults with Asymmetrical Hearing Loss

• Patient example
  – Surgery – Complication
  – Post Op
    • After only 2 weeks, patient reported he could localize sound source
    • At 1 month, 85% on HINTs with CI only
    • Bimodal improvements on all tests
  – 3 months post

Current MEI Research

• Post Approval Study: Extended Duration Monitoring of Subjects with the Cochlear™ Nucleus® Hybrid™ L24 Cochlear Implant System
  – Sponsored by Cochlear Americas
  – Purpose: The purpose of this study is to evaluate the long term safety and effectiveness of the Nucleus Hybrid L24 Implant in implanted subjects out to 5 years post-activation.

How Hybrid Hearing Works

Cochlear™ Hybrid Sound Processor
Cochlear Nucleus Hybrid L24 Implant
How Hybrid Hearing works

1. Microphones on the sound processor pick up sounds and the processor converts them into digital information.
2. The acoustic component amplifies the sound you hear and sends them through the ear canal in the normal pathway.
3. Missing sound information is transferred through the coil to the implant just under the skin.
4. The implant sends electrical signals down the electrode into the cochlea.
5. The hearing nerve fibers in the cochlea pick up the signals and send them to the brain, giving the sensation of sound.

Why Acoustic-Electric Hearing?

**Electric**
- Restore high-frequency sensitivity
  - Better speech perception
  - Completes the spectrum

**Acoustic**
- Maintain low-frequency acoustic hearing
  - Easier to understand speech in noise
  - Better music appreciation
  - More natural sound quality

**Two Ears**
- Available in both ears
  - Better localization and improved hearing for speech in the presence of spatially separated noise

What is Hybrid Hearing?

- Two proven hearing technologies in one device
- Combination of acoustic amplification and cochlear implant technology to give you access to the full spectrum of sound*

*Hybrid hearing approved only for use with the Nucleus Hybrid Implant.

Cochlear Implant Candidacy

**Hybrid Implant:**
- Implanted Ear: Word score between 20% and 60%
  - Normal to moderate SNHL in the low frequencies
  - PTA of 2k, 3k, 4k > 75 dB HL
- Opposite Ear: No better than 80% word score
  - PTA of 2k, 3k, 4k > 60 dB

Hybrid Implant (422/Contour):
- Sentence Score no better than 50% in the ear to be implanted and no better than 60% in the best aided condition

Patient KC: 6 mos Post -Op

**Management:**
- Satisfaction: Counseling issues
- Patient KC: 6 mos Post -Op

**Case History:**
65 year old male. Hearing loss due to noise exposure. Onset at 40 yo, severe-profound HF SNHL by age 50.
Continuous noise exposure since then. Wore hearing aids pre-op. Otitis media with effusion and aural discharge post-op. No change in hearing at initial activation.

Patient BB: Pre-Op

**Case History:**
65 year old male. Hearing loss due to noise exposure. Onset at 40 yo, severe-profound HF SNHL by age 50.
Continuous noise exposure since then. Wore hearing aids pre-op. Otitis media with effusion and aural discharge post-op. No change in hearing at initial activation.

Pre-Op Post Op (6 mos)

R L AU Hybrid Combined CNC 16% 69% 83% 98% 
AZ-Bio 22% AZ-Bio in Noise (+5) 63% 79%

Management:

Satisfaction: Counseling issues

Patient KC: 6 mos Post -Op

AC AC CI CI CI CI CI

XXXXX

Aided R L AU CNC 33% 61% AZ-Bio AZ-Bio in Noise (+5) 9%

**Case History:**
65 year old male. Hearing loss due to noise exposure. Onset at 40 yo, severe-profound HF SNHL by age 50.
Continuous noise exposure since then. Wore hearing aids pre-op. Otitis media with effusion and aural discharge post-op. No change in hearing at initial activation.
Patient BB: Post -Op

Management:

Satisfaction: Counseling issues:

Patient BB: Post -Op

3 months post-op
- Hearing test revealed 40-60 dB drop in hearing thresholds
- Patient had no idea he’d lost any hearing
- Thresholds beyond range of acoustic component (AC)

Change programming:
- Reprogrammed implant with 3 options
  1. CI only full freq. range
  2. Hybrid with low gain on AC
  3. Bimodal (CI programmed for mids/highs, lows from contra hearing aid

Patient to use preferred program for 3 weeks then return for study testing

Patient BB: 3 month Post -Op

Management:

Current MEI Research

Nucleus® Hybrid™ L24 Implant System: New Enrollment Study
- Sponsored by Cochlear Americas
- Purpose:
  - To evaluate the long term safety and effectiveness of the Nucleus Hybrid L24 Implant in a group of newly implanted individuals.

2

Nucleus® Hybrid™ L24 Implant System: New Enrollment Study
- 100 new subjects will be enrolled and followed for 5 years
- Study visits:
  - 2 study visits before the implant surgery (candidacy and baseline)
  - 8 study visits after the surgery (activation, 3 months, 6 months, 1 yr, 2 yr, 3 yr, 4 yr, 5yr) each of which will take 2 to 5 hours

Current MEI Research

Safety and Efficacy of the Cochlear Nucleus CI422 Cochlear Implant in Adults
- Sponsored by Cochlear Americas
- Purpose:
  - To assess whether the CI422 cochlear implant is safe and effective in people who may have more hearing than current cochlear implant candidates
  - To revise the indication for cochlear implantation
Safety and Efficacy of the Cochlear Nucleus CI422 Cochlear Implant in Adults

- Nucleus CI422 with Slim Straight Electrode
  - The industry's thinnest full length electrode
  - A soft tip combined with thin diameter, apical flexibility, and smooth lateral wall surface facilitates an easy single stroke insertion designed to protect the delicate cochlear structures
  - Hearing can be preserved in lowest pitches and stimulated if above 90 dB after surgery

Safety and Efficacy of the Cochlear Nucleus CI422 Cochlear Implant in Adults

- Revised indication
  - A hearing test alone does not provide the complete picture of those with hearing loss, such as how they function in the real world.
  - Currently used sentence recognition tests do not represent real world performance.
  - This study uses a single syllable word test to identify patients with more residual hearing that would benefit from cochlear implant technology

Current MEI Research

- Implantation of the HiRes90K™ Advantage Cochlear Implant With HiFocus™ Mid-Scala and Development of a Combined Electric and Acoustic Stimulation Technology in Adults With Partial Deafness
  - Sponsor: Advanced Bionics
  - Purpose: The purpose of this feasibility study is to evaluate whether low-frequency acoustic hearing sensitivity can be preserved in newly implanted adults with partial deafness using the HiResolution™ 90K™ Advantage cochlear implant with the HiFocus™ Mid-Scala electrode to support the development of electro-acoustic stimulation technology (EAS)

Implantation of the HiRes90K™ Advantage Cochlear Implant With HiFocus™ Mid-Scala and Development of a Combined Electric and Acoustic Stimulation Technology in Adults With Partial Deafness

Inclusion criteria: Newly Implanted Group

- Ability to provide informed consent
- No previous cochlear implant experience in either ear
- English language proficiency
- Willingness to use an ear-level sound processor postoperatively for the duration of the study trial
- Willingness to participate in all scheduled procedures outlined in the protocol

Exclusion Criteria: Newly Implanted Group:

- Preoperative audiometric conductive overlay of 15 dB or greater at two frequencies or more in range of 500-1000 Hz in the ear to be implanted
- Congenital hearing loss (for purpose of this study, onset prior to age 2 years). *Based on critical period for speech and language development
- Duration greater than 30 years of severe-to-profound high-frequency hearing loss
- Cochlear malformation or obstruction that would preclude full insertion of electrode array in the ear to be implanted
- Medical or psychological conditions that contraindicate surgery or impact the ability to manage an implanted device or the study related procedures as determined by the investigator
Implantation of the HiRes90K™ Advantage Cochlear Implant With HiFocus™ Mid-Scala and Development of a Combined Electric and Acoustic Stimulation Technology in Adults With Partial Deafness

Exclusion Criteria: Newly Implanted Group:

- Deafness due to central auditory lesion or cochlear nerve deficiency, diagnosis of auditory neuropathy/dys-synchrony in either the ear to be implanted or the contralateral ear
- Active middle-ear disease/infection in the ear to be implanted
- Unrealistic expectations regarding potential benefits, risks and limitations inherent to implant surgical procedures as determined by the investigator
- Unwillingness or inability of subject to comply with all investigational requirements as determined by the investigator

Cochlear Implant Summary

- Cochlear Implants provide safe, effective auditory (re)habilitation to adult and pediatric patients with varying degrees of hearing loss
- Bilateral Implantation provides greater benefit than unilateral implantation
- Restoring bilateral hearing in asymmetric or SSD patients is very important
- Indications have increased along with performance

Upcoming studies

- Asymmetric IDE study
- REACH study – drug eluding electrode

Contact Information:

Sarah Zlomke, Au.D., CCC-A
sking@saint-lukes.org
816.932.1660