Hybrid L24 Study Update: Where Are They Now?
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Learning Objectives

1. After the completion of this course participants will be able to list the benefits of acoustic hearing.

2. After the completion of this course participants will be able to describe the expanded indications for the Nucleus® Hybrid™ system.

3. After the completion of this course participants will be able to outline the steps to programming a Nucleus Hybrid device.
Why Hybrid?

Audibility 125 → 8000Hz

High frequency electric hearing is critical for improved speech understanding

Benefits of Acoustic Hearing
- Enhanced sound quality
- Improved understanding in background noise
- Fundamental frequency cues for both pitch and vowel discrimination
- Interaural timing difference cues

Good frequency resolution
Restores HF Sensitivity

Pivotal Clinical Trial
Background

More than 15 years of research
- 8 year FDA trial of 50 adult subjects

FDA-approved March 2014
- 1st Hybrid implant system (U.S.) April 16, 2014
- 1st cochlear implant labeled for potential preservation of residual hearing
- 1st Indication using CNC words
- 1st Integrated Electric + Acoustic Sound Processor

Study Design

- Multicenter pivotal trial
- 14 surgeons at 10 US-based implant centers
- 50 adult subjects implanted
- Primary endpoint was 6 months postactivation
Pivotal IDE Study

Subject Demographics | N=50
---|---
Gender
Male | 25 (50%)
Female | 25 (50%)
Mean Age at Implantation (yrs) | 64.1 [37-86]
Mean Duration Hearing Loss (yrs) | 28.1 [3-74]
Mean Duration Sev/Prof Loss (yrs) | 13.1 [2-30]
Mean Preoperative CNC Score CI Ear | 28.4% [9-64%]
Mean Preoperative AzBio Sentence Score CI Ear | 16.3% [0-64%]

Hybrid L24: An Expanded Indication

Ear to be Implanted
- Aided CNC word score between 10% and 60% correct, inclusively

Contralateral Ear
- Aided CNC word score better than ear to be implanted but less than 80% correct

Audiometric
- Severe to profound HF SNHL bilaterally

Adults
- aged 18 years and older
Key Findings of Pivotal Study

United States Multicenter Clinical Trial of the Cochlear Nucleus Hybrid Implant System

J. Thomas Roland Jr, MD; Bruce J. Gantz, MD; Susan B. Waltzman, PhD; Aaron J. Parkinson, PhD; The Multicenter Clinical Trial Group

Published results demonstrate:

- Significant improvement in speech understanding in quiet and noise
- Expanded indications for individuals with severe high frequency hearing loss
- Increased satisfaction, consistent with speech perception results

Reimbursement

Since August 2016...

142,000,000
Covered Lives Now Have Access To Hybrid Coverage

- BlueCross BlueShield: 62 Million
- Anthem: 40 Million
- Aetna: 23 Million
- TRICARE: 9 Million
- FEHB: Federal Employees Health Benefits Program: 8 Million
Acoustic Component

Cochlear™ Hybrid Hearing™

- Amplify low frequency hearing and provide access to high frequencies via electrical stimulation
- The Acoustic Component is compatible with all N6 Sound Processors (CP910 and CP920)
- No processor exchange needed
- Available for use by all recipients, pediatric and adult, with all Nucleus implants

The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality. Not available for the Nucleus 22 series of implants.
Hybrid™ Hearing Availability Today:

Nucleus® Hybrid™ Hearing Now FDA Approved for **ALL** Nucleus Implants

- Cochlear™ Nucleus® Profile Slim Modiolar Electrode
- Cochlear™ Nucleus® Contour Advance®
- Cochlear™ Nucleus® Slim Straight
- Cochlear™ Nucleus® Full–Band Straight
- Cochlear™ Nucleus® Hybrid™ L24

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality.

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Hybrid L24 Clinical Trial Outcomes Update
Background:

- All Hybrid implant subjects upgraded to the N6 sound processor
  - 39/50 (78%) consented to long term follow-up and upgrade study

- Questions:
  1. What does long-term hearing preservation look like?
  2. What does Hybrid performance look like?
     > Electric Alone?
     > Electric + Acoustic?

Hearing Preservation

Established Definitions:

1. Preservation of measurable¹,² acoustic hearing
   - Definition used by industry and in most publications
   - Measure of detection/audibility but not usability

2. Preservation of functional¹,² acoustic hearing
   - A severe or better degree of hearing loss post-implantation that may provide a level of acoustic hearing to enhance electrical stimulation

Evolution of Sentence Materials

- CUNY Sentences were used in our earliest clinical trials (1999) with Hybrid implants but many recipients quickly topped out
- Members of AAA and AAO-HNS established use of HINT sentences in noise as part of the Minimum Speech Test Battery developed in 1996
- AzBio Sentences were developed by Spahr and Dorman in 2004
- Cochlear’s Hybrid L24 trial was implemented with use of AzBio Sentences in noise in an attempt to avoid ceiling effects
- The recommended MSTB protocol was updated in 2011 to replace HINT sentences with AzBio Sentences

Power of the Nucleus® 6:

**ACOUSTIC**
- ASC
- SCAN
- Wind Noise Reduction

**ELECTRIC**
- ADRO®
- ASC
- SCAN
- Wind Noise Reduction
- Background Noise Reduction
- Whisper™

TRUE WIRELESS
Speech Perception in Noise

AzBio Sentences in Noise (+5dB SNR)

Next Steps

- Long term follow up post approval study
  - Original pivotal Hybrid L24 subjects followed to 5 years postactivation
  - The majority of subjects have completed all requirements
  - Publication planned

- Newly implanted post approval study
  - Cochlear’s initiative to gather even more 5 year data
  - 19 implant centers currently enrolling subjects
  - Data collection and analysis ongoing
Programming Considerations

Smart Hearing Alliance

Industry’s only TRUE WIRELESS bimodal solution
Hybrid Mode: Cut-off Frequency

**What’s changed in Custom Sound® 4.4?**

Now each stimulation mode has its own cut-off frequency. We no longer have what we called a ‘cross-over frequency’.

- **Acoustic** cut-off at ≤90 dB HL up to 2 kHz remains unchanged
- **Electric** cut-off has been lowered to >70 dB HL up to 2 kHz

This results in more overlap for some audiograms between acoustic and electric stimulation, especially for shallow sloped audiograms.

**NOTE:** This change only applies when creating new MAPs (for existing or new recipients). The software uses the currently entered audiogram and applies the above calculations.
Acoustic Component Specifications

Hybrid Mode: Frequency Bands

Robust Custom Sound algorithm:
- Checks the Acoustic cut-off frequency at 90 dB HL, up to 2 kHz
- Checks the Electric cut-off frequency at 70 dB HL, up to 2 kHz
Electro-Acoustic Cross-over Ranges

Results in electro-acoustic overlap between 563 Hz and 685 Hz

Steps in Programming

1. Create a new recipient

2. Measure Impedances

3. Create a New MAP (will default to 37 PW) & check the box for Hybrid
Steps in Programming

4. Remove the coil from the head
   - Open the Acoustics screen
   - Select the fitting prescription, mold type, compression and vent size.

Steps in Programming

5. Go Live with acoustic stimulation only
   - Complete Real Ear measurements
   - Adjust gain and MPO if needed
   - Take into account the subjective feedback of the recipient.

If the desired gain cannot be met acoustically:
   - enable adjacent channel to obtain additional gain
   - disable acoustic channels not meeting target
   - the lower CI frequency boundary may need to be lowered further in the next step
Steps in Programming

6. Measure T levels using the streamlined programming method. Go live to obtain C levels so sound is comfortably loud.

7. Loudness Balance C levels

Acoustics Panel Options

What's new in the Acoustics panel in CS 4.4?
It is now possible to make very quick loudness comparisons between Hybrid mode and full electrical mode.
Hybrid MAP Checkbox

Uncheck ‘Hybrid MAP’ to revert to full electric MAP with 188-7938 Hz FAT default

Mute Acoustic Checkbox

Check ‘Mute Acoustic’ to stimulate only with electric frequency bands

Uncheck ‘Mute Acoustic’ to revert to default electro-acoustic stimulation
Summary of Quick Loudness Checks

CI only
(full frequency allocation)

Listen in CI mode

Finalize Programming

8. Check battery suitability and personalize MAPs by adding SmartSound® iQ
   - Program 1 primary MAP with SCAN
   - Program 2 default
   - Program 3 and 4 can be used to try other cut offs with SCAN.

9. Write MAPs to the processor and finalize

10. Verification of audibility
Summary

• Hybrid indication is continuing to gain momentum

• Programming of both the electric and acoustic portions can be completed with Custom Sound® Software
  – Overlap between acoustic and electric stimulation will vary by patient

• Hybrid L24 + Nucleus 6
  – 95% of subjects perform the same or better on AzBio +5 dB SNR


Summary

Electric-only patients continue to perform comparably to traditional CI patients

Hybrid Hearing™ continues to provide superior outcomes to traditional cochlear implants

Hybrid Hearing now FDA-approved for all Nucleus implants
References


The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality. The Hybrid L24 implant is approved in the US for adults aged 18 and older. SNR-WR, WNR and SCAN are approved for use with any recipient aged 6 years and older, who is able to: 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance; and 2) report a preference for different program settings.

Cochlear Americas is pleased to provide this guidance on insurance coverage about Cochlear’s products and technology, but please realize that this information is provided as guidance only. Cochlear Americas makes no representation, warranty or guarantee regarding the fitness for your particular situation of the guidance provided or that following these guidelines will result in any form of coverage or reimbursement. Please be sure to seek legal advice and consult with your own reimbursement advisors to confirm the applicability of our guidance to your particular needs. And remember that all services or products billed to an insurance company or payer must be medically necessary, actually performed or purchased, and appropriately documented.