Evaluation of the Hybrid Cochlear Implant System: Clinical Trial Results

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Cochlear™ Nucleus® Hybrid™ Implant System Components

Nucleus Hybrid L24 Implant

Nucleus 6 Sound Processor

Remote Assistant Options

Acoustic Component

Electric Component

Custom Sound Fitting Software – Version 4.1

NYU Langone MEDICAL CENTER
Hybrid L24: Viable option for the “in-between” patient

Conventional, FLT, & implantable HAs

Hybrid L24

Cochlear Implantation
Why Hybrid 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**
- If available in both ears:
  - Better localization and improved hearing for speech in the presence of spatially-separated noise

*Diagram showing Low Frequencies and High Frequencies with Acoustic Hearing and Electric Hearing (CI).*
Cochlear® Nucleus™ Hybrid L24 Implant

Designed to restore hearing in higher frequencies through electrical stimulation.

- Soft Tip for Minimal insertion trauma
- Apical Diameter: .25mm
- 22 platinum electrode contacts
- Tapered basal stiffener designed for a smooth, single motion insertion
- Basal Diameter: .4mm
- White Stopper at 16mm to indicate a full insertion
- Surgical Handle located opposite of the electrode contacts to assist with electrode orientation and atraumatic insertion
- 15 mm of active length

Surgical Handle located opposite of the electrode contacts to assist with electrode orientation and atraumatic insertion
Candidacy criteria

Hybrid Aided word score between 10% and 60% in the ear to be implanted; 80% or less contralateral ear

Hybrid L Electrode Candidate
Cochlear Implant Electrode Candidate
HYBRID L24 PERFORMANCE OUTCOMES
Study Objectives

• Primary (Hybrid mode):
  – Mean scores for CNC (word and phoneme) measures, and AzBio (sentences-in-noise) measure, at 6 months postactivation will be significantly improved over the preoperative measures (unilateral acoustic-only condition).

• Secondary (Hybrid mode):
  – On both CNC words and phonemes, most (> 75%) of the subjects will score equal to or better than they did in the preoperative unilateral acoustic-only condition, and
  – On the AzBio sentences-in-noise, most (> 75%) of the subjects will score equal to or better than they did in the preoperative unilateral acoustic-only condition.
Study Sites: Nucleus Hybrid L24 Implant

10 Implanting Centers

- NYU (Lead Site)
- Center for Hearing & Balance
- Hearts for Hearing
- Mayo Clinic, Rochester
- Midwest Ear Institute
- Northwestern University
- The Ohio State University
- Rocky Mtn Ear Center
- University of Cincinnati
Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Average (S.D.)</th>
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<tbody>
<tr>
<td>Age at Implantation</td>
<td>64.1 years (±14.7)</td>
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<tr>
<td>Duration of Hearing Loss</td>
<td>28.1 years (±14.9)</td>
</tr>
<tr>
<td>Preoperative Aided CNC Score – Implant Ear</td>
<td>29.0% (±14.6%)</td>
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<tr>
<td>Preoperative Aided AzBio Sentence Score (+ 5dB SNR) – Implant Ear</td>
<td>16.3% (±14.4%)</td>
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Hearing sensitivity: RESTORED HIGH FREQUENCY AUDIBILITY

Pre to Post Hearing Thresholds Initial Activation

Frequency (Hz)

Hearing Level (dB)

Hearing Aid Preoperative
Hybrid Initial Activation

Soundfield Thresholds
Speech Understanding 6 Months Post-Activation

Speech perception significantly improved in both conditions.
CNC Word Recognition: Different listening conditions at 6 months

Preoperative
- Acoustic: 28%
- Bilateral: 43%

Postoperative
- Acoustic: 18%
- Electric: 52%
- Hybrid: 70%
- Combined: 80%

N=38
Two Definitions - Two very different outcomes

1. Preservation of measurable acoustic hearing
   - Definition used by industry and in most publications
   - Measure of detection/audibility
   - Indicator of atraumatic surgery

2. Preservation of functional acoustic hearing
   - A severe or better degree of hearing loss post-implantation may provide a level of acoustic hearing that enhances the electrical stimulation provided by the cochlear implant

Functional = 5 frequency LFPTA (125 – 1000Hz)

Why Hybrid Hearing?

CNC Word Recognition
6 Months Postactivation

- Freedom (N=53): Mean = 53.6, Medians F = 54, HE = 54.5, HE = 82
- Hybrid E Only (N=50): Mean = 50
- Hybrid Mode (N=33): Mean = 76

Percent Correct

0 10 20 30 40 50 60 70 80 90 100
Summary of Trial Results

- Audibility restored for the entire frequency range.

- Outcomes on speech discrimination and self-assessment measures demonstrate statistically significant improvements:
  - Over 30% improvement on average in both quiet and noise conditions for the implanted ear.

- At 6 months post-implant most individuals (90%) retain a level of measurable hearing and many (66%) utilize that hearing functionally in the implant ear.

Self assessment results corroborate speech perception results.
Thank you for listening
CLINICAL SIGNIFICANCE OF LOW FREQUENCY ACOUSTIC SENSITIVITY FOR THE IMPLANTED EAR
Improvement in Word Recognition and Sentence Recognition in Noise at 6 Months Hybrid (N=50)

Improvement in Word Recognition

Significant Decrement in Word Score

Improvement in Sentence Recognition

Significant Improvement in Word Score

Improvement in CNC Word Recognition (Percentage Points)

Improvement in AzBio Sentence Recognition at +5 dB SNR

Significant Decrement in AzBio

Significant Improvement in AzBio

Group 1 (N=33)

Group 2 (N=17)
Improvement in Word Recognition and Sentence Recognition in Noise at 6 Months Both Ears (N=50)

![Graph showing improvement in Word Recognition and Sentence Recognition in Noise at 6 Months Both Ears (N=50). The graph illustrates the improvement in CNC Word Recognition (Percentage Points) and AzBio Sentence Recognition at +5 dB SNR. Groups 1 (N=33) and 2 (N=17) are indicated with different markers, with significant decrements and improvements in Word Score and AzBio scores.]