

A Sound Decision At Every Level:

The Research Behind Starkey's Genesis AI Technology

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How to Ask a Question

Click Q & A, type your question, click Send

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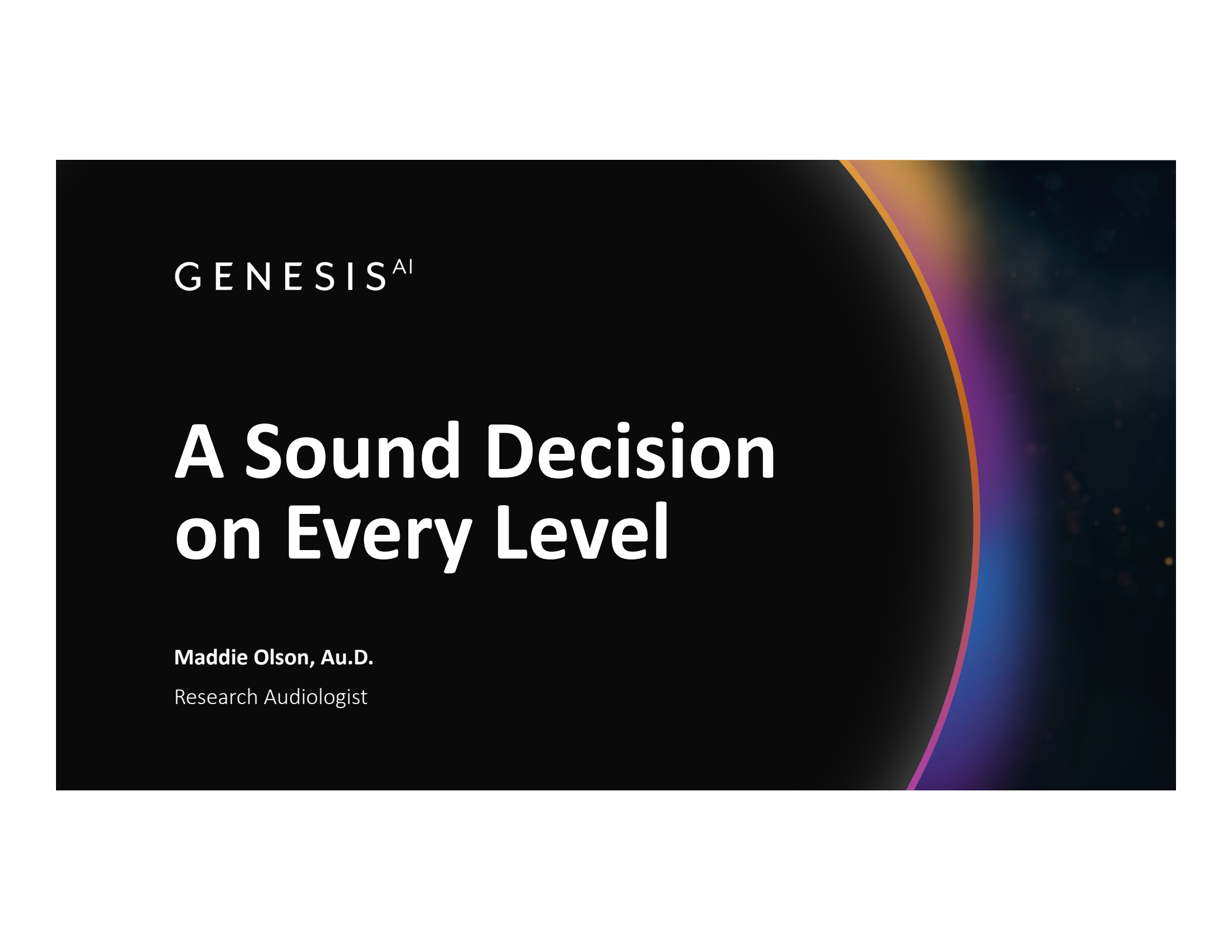
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GENESIS^{AI}

A Sound Decision on Every Level

Maddie Olson, Au.D.

Research Audiologist

Learning Outcomes

After this course, participants will be able to:

- 1** List the types of clinical studies employed by Starkey to validate Genesis AI benefits.
- 2** Describe the benefits of Additive Compression for the Genesis AI wearer identified during clinical trials.
- 3** Describe telecoil use and speech intelligibility features investigated during the clinical trials.

Caring Technology



Backed by Science

Clinical and Audiology Research Team



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Proven Clinical Performance

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Research Audiologists
Hearing Scientists
Research Coordinator
Clinical Audiologists

Clinical validation of new products and features to support **regulatory requirements** and **marketing claims**

Pre- and Post-market clinical research studies to assess benefit and performance of our products, often with **external collaborators**



Goals of Clinical Research

Does it work?

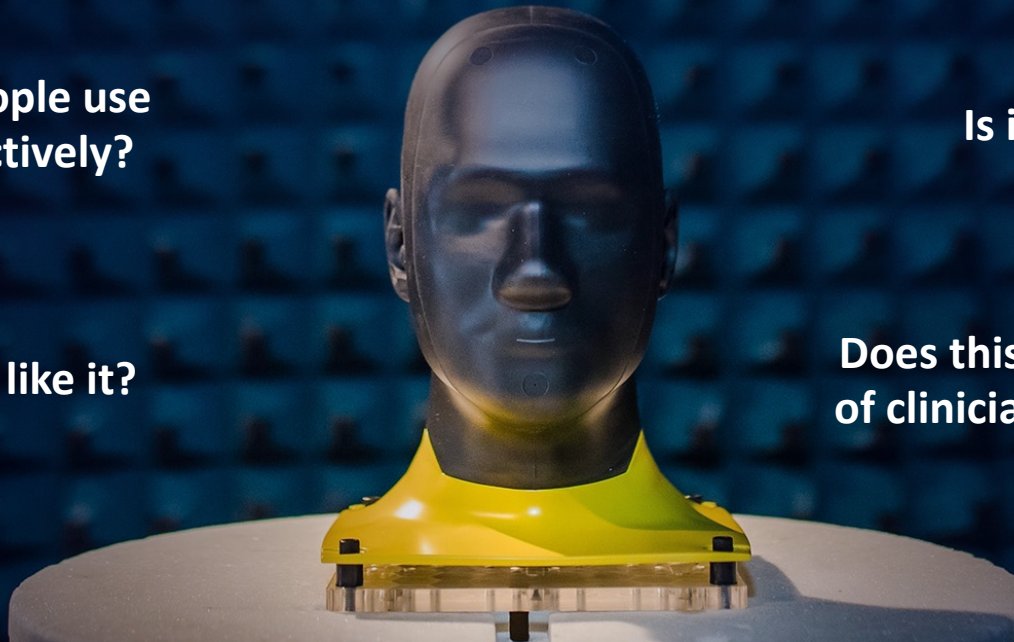
What benefit
does it provide?

Can people use
it effectively?

Is it safe?

Do people like it?

Does this meet the needs
of clinicians and patients?



Types of Clinical Studies

Laboratory and Field Studies with Normal-Hearing and Hearing-Impaired Participants

- Prototype Evaluations
- Feasibility Testing
- Human Factors or Usability Studies
- Fit and Comfort Studies
- Product and Feature Validation
- Competitive Evaluations
- Claims Substantiation
- Pivotal Studies on Clinical Performance, Safety or Effectiveness



Research and Good Clinical Practice

Medical Devices Directive 93/42/EU (MDD)/Medical Devices Regulation (MDR 2017/745/EU)

ISO 14155: Clinical Investigations of Medical Devices for Human Subjects: Good Clinical Practice

ISO 62366: Application of Usability Engineering to Medical Devices

HIA Guidelines for Hearing Aid Manufacturers for Substantiation of Benefit or Performance Claims



International
Organization for
Standardization



HIA Hearing Industries
Association



Medical Devices Regulation
EU MDR

How do we do it?

Volunteers! A lot of them...

- Recruit hearing-impaired individuals from the local community
- Database of over 1500 individuals
- Participants paid for their participation
- Study protocols approved through an external IRB (*Institutional Review Board*)

SoundNews

Seeking Hearing Aid Research Study Participants

We are recruiting participants for our [hearing research studies](#) at Starkey Hearing Technologies. As a research participant, you may test our hearing aids in your daily life and/or visit Starkey Hearing Technologies' global headquarters in Eden Prairie, Minnesota for testing at our research facility.

Although participants are required to return the research hearing aids at the end of the study, you will gain a better understanding of new technology, have the opportunity to share your opinions and experiences with us, and be paid a stipend plus mileage for your participation. Eligible participants must be within 30 miles of

GENESIS^{AI}



Studies over a **15-month period**



400+ hearing-impaired individuals



Over **550 hours** of lab testing



11,000 hours of field wear time

Design Validation

75 participants with a range of hearing losses, from mild to severe sensorineural hearing loss, bilaterally

- 5-6 Laboratory Sessions
- Over 6-8 weeks each
- 450 Pro Fit Sessions
- 200 Real-Ear Measurements
- 600 Questionnaires
- 850 Speech Test Conditions

Hearing Aid Fittings and Real-Ear Measurements

Optimize Vent Recommender

Hearing Aid, Charger, Mobile App Usability

My Starkey Mobile App features

Activity Tracking, Fall Detection, Edge Mode+

Speech Understanding in Quiet and Noise

TeleHear and In-situ Audiometry

CROS System

Accessories

Streaming Sound Quality Assessment

Loop and Telecoil Assessment

Performance for Phone calls

GENESIS^{AI}

Additive Compression

e-STAT 2.0

Speech Intelligibility and Sound Quality

Noise Management

Noise Reduction & Directionality

Speech Understanding in Noise

Telecoil & Phone Performance

Additive Compression and e-STAT 2.0

Additive Compression and e-STAT 2.0

e-STAT 2.0 is a proprietary new fitting formula that complements the Genesis AI compression architecture

**~4-6 dB more gain for
soft sounds***

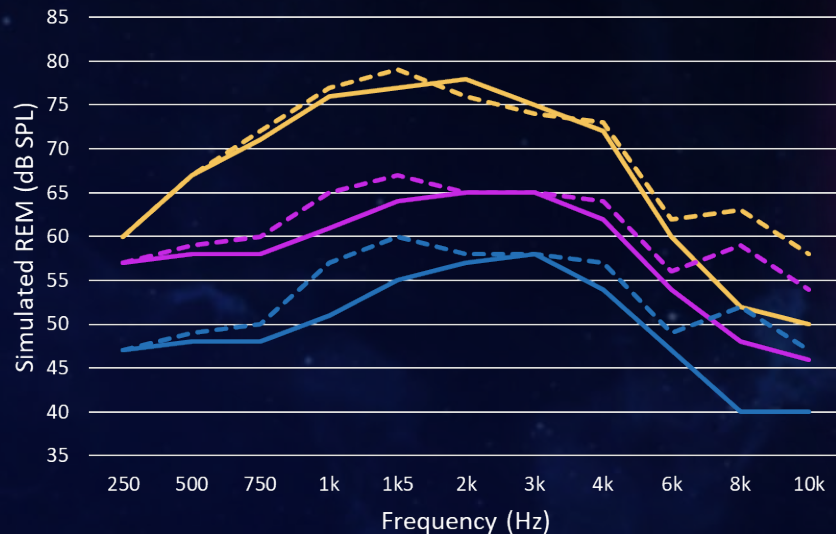
**10% higher speech intelligibility
scores for soft speech vs.
previous technology**

More gain at higher frequencies*
(> 3kHz)

Improved vent modeling

**Varies with the audiogram and with frequency*

e-STAT vs. e-STAT 2.0 Fitting Formula



**Example for Flat 40 dB HL Hearing Loss*

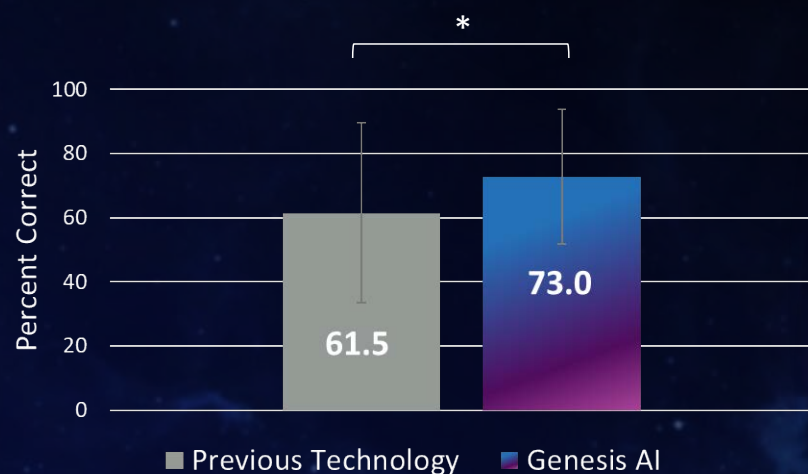
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(> 3kHz)

Improved vent modeling

CNC Word Recognition for Soft Speech in Quiet



Speech intelligibility for soft speech is significantly higher for Genesis AI than previous technology ($p < .001$)

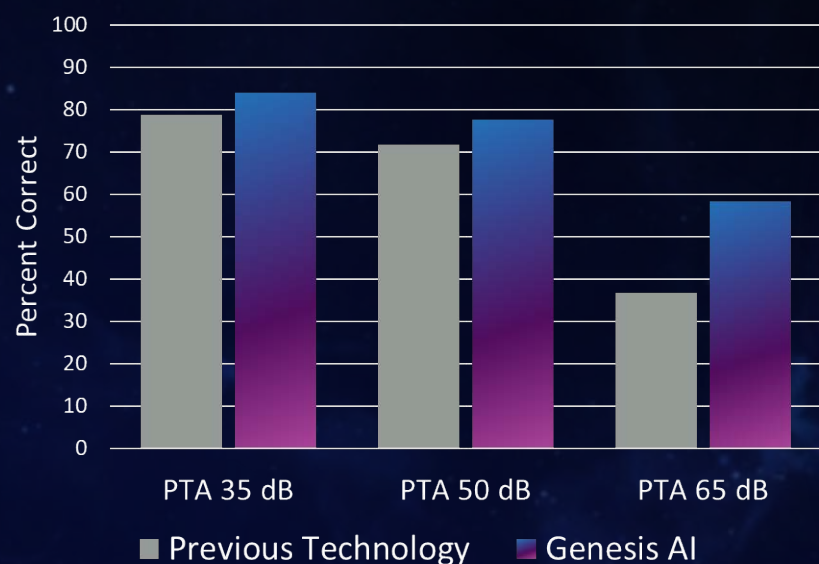
30 Participants wearing RIC devices

50 CNC word lists for 2 conditions

1. Previous Technology
2. Genesis AI

Presented at 50 dB A from 0 degrees azimuth

CNC Word Recognition by Hearing Loss



Improvement over previous technology appears to increase as hearing loss increases

30 Participants wearing RIC devices

50 CNC word lists for 2 conditions

1. Previous Technology
2. Genesis AI

Presented at 50 dB A from 0 degrees azimuth

Genesis AI features our best sound quality yet!

30 Normal-Hearing participants rated sound quality on a scale from 1-100

Devices set to “Best Fit” settings

Recordings based on 2 audiograms, 2 levels and 3 signal-to-noise levels

Self-paced listening test over headphones

Listeners rated Genesis AI sound quality higher than previous technology

93%

when listening to speech in quiet

84%

when listening to speech in noise

Noise Management



Speech Understanding in Noise

Conditions

Unaided
Omni + NR Off
Omni + NR On
Adaptive + NR On
(Pro Fit Personal Program)

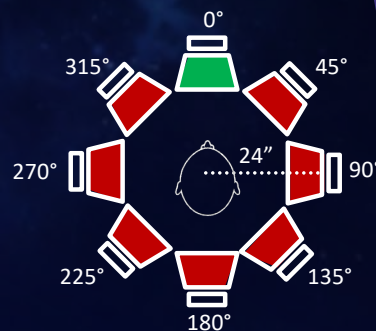
43 Participants

Speech

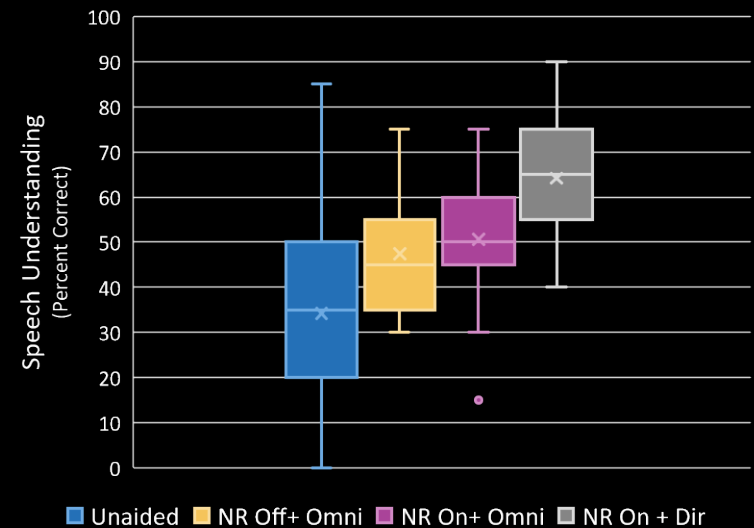
IEEE sentences presented at SNR 50
(est. with Omni + NR off)

Noise

Speech Babble at 67 dB A

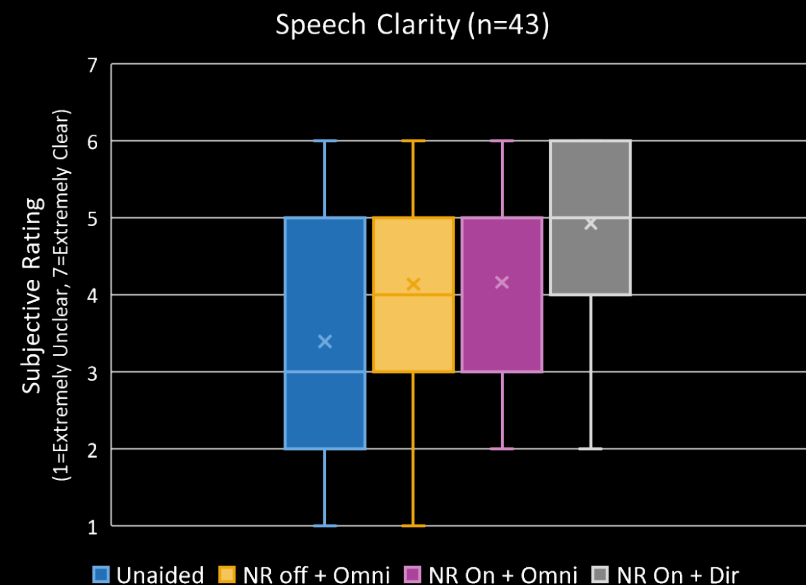
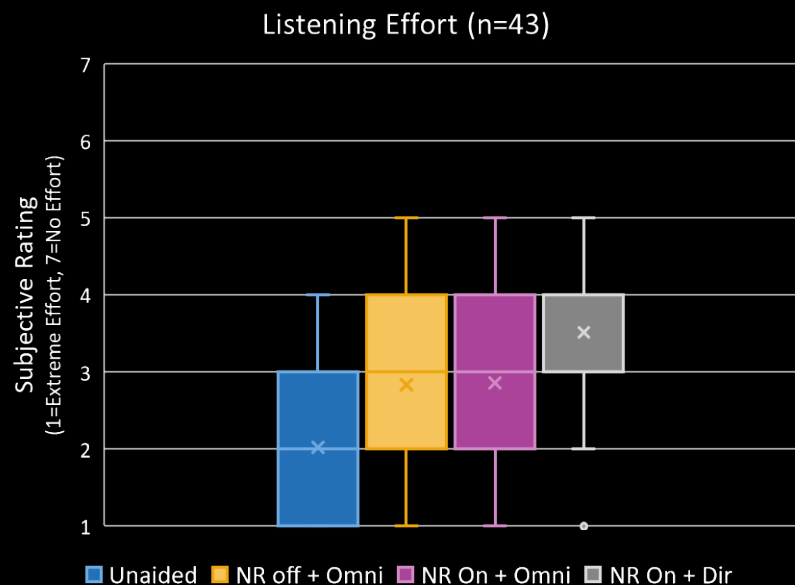


30% increase over unaided



All comparisons significant ($p < .001$)
EXCEPT Omni NR Off vs. Omni NR On

Subjective Ratings for Speech in Noise



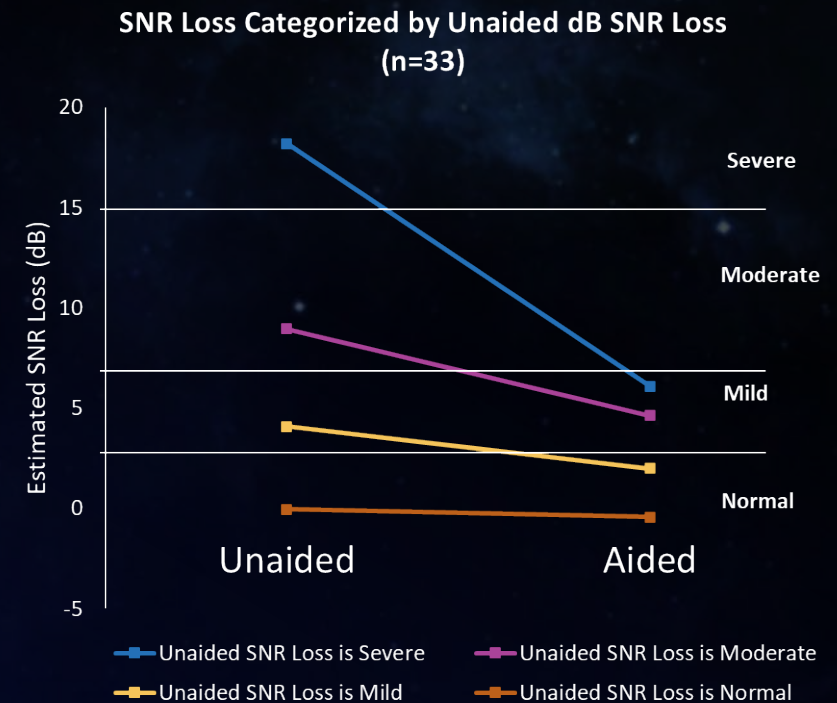
All comparisons significant ($p < .05$ or better)
EXCEPT Omni NR Off vs. Omni NR On

Genesis AI Improves SNR Loss

QuickSIN (Killion et al., 2004)

Six IEEE sentences, each with five target words, at SNRs decreasing from 25 to 0 SNR in 5-dB steps

Speech (front) and Noise (rear)

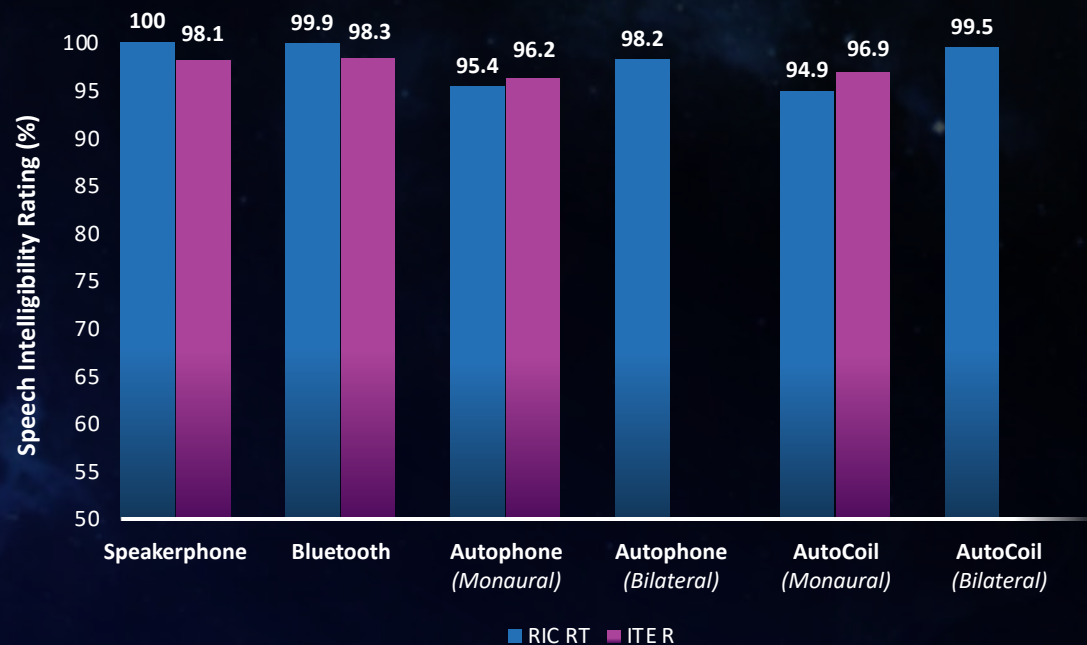


Telecoils and Phone Use

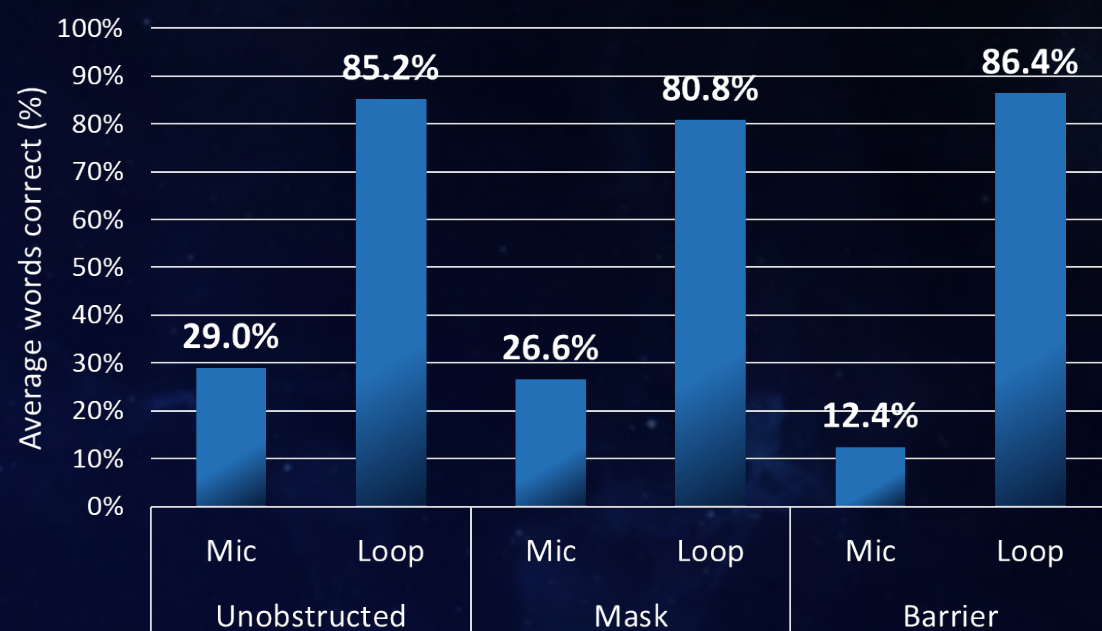
Telephone Options

Subjective Speech Intelligibility was estimated using the SIR for participants wearing Genesis AI RIC RT (n=13) and ITE R with telecoils (n=7)

Speech Intelligibility Rating (SIR) Test Scores



Telecoil/Loop Performance



RIC RT (n=13) & ITE R w/Telecoil (n=7)

Telecoils **significantly improve** speech understanding in degraded listening conditions

Genesis AI Telecoil Demo

Hearing Aids Only

Hearing Aid + Telecoil



“All aspects of the Bluetooth features were outstanding. Phone calls were super-easy and high-quality sound both for me and people I spoke to!”

“The new app gave me a lot of information and it was easy to use. I loved it.”

“The sound quality was amazing and being able to recharge was convenient.”



“The battery strength of the hearing aids was impressively long!”

“I liked the new My Starkey app. It was very helpful and useful in trying to maintain my health.”

“I liked the realistic sound and the comfortable design.”



A New Beginning