



# Clinical Validation of the Omega AI Family

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## INTRODUCTION

Prior to releasing a new product family, several types of clinical studies are conducted in the laboratory and in the field with normal-hearing and hearing-impaired participants including prototype evaluations, usability studies, and fit and comfort studies. When a product family has met all acceptance criteria of the preliminary studies and is confirmed to perform as expected, it is ready for product and feature validation studies. The purpose of the validation study is to ensure the hearing aids provide clinical benefit, provide adequate amplification, perform as expected for the hearing aid user, and are safe and effective.

The Omega AI validation study covered a variety of clinical outcomes, including an investigation of the accuracy of e-STAT 2.0 fittings using real-ear measures, an evaluation of sound quality and listening effort in a variety of environments, and an assessment of new features, such as the DNN-powered directionality system (DNN 360), the LED lights on RIC products, TeleHear AI, and Balance Builder. This poster aims to summarize the primary outcomes measures, including the overall usability of the product family, speech intelligibility, and perceived benefit and satisfaction.

## METHODS

### Participants (N = 60)

- Mean age = 70 years (27-87 years; 31 female and 29 male)
- Average loss: mild sloping to severe sensorineural hearing loss
- Devices:
  - 36 fitted with Omega AI RIC products (RIC RT or mRIC R)
  - 12 fitted with Omega AI ITE/ITC R
  - 12 fitted with Omega AI CIC 312
- Average wear time = 41 days or approximately 6 weeks
- Results shown for n = 19-60 due to differing sample sizes and individuals not completing every study session

### Design

- Participants were fitted with Omega AI hearing aids and had three follow-up appointments, each two weeks apart.

#### Fitting

- Hearing aid fitting & orientation
- Real-ear measures
- Hearing aid usability

#### 1<sup>st</sup> Follow-Up

- Fine-tuning (as needed)
- Accessory fitting
- Accessory usability
- TeleHear AI

#### 2<sup>nd</sup> Follow-Up

- DNN 360
- Aided speech intelligibility w/ accessories
- Balance Builder

#### 3<sup>rd</sup> Follow-Up

- Subjective questionnaires
- Aided speech intelligibility w/ hearing aids

## RESULTS

### Speech Intelligibility

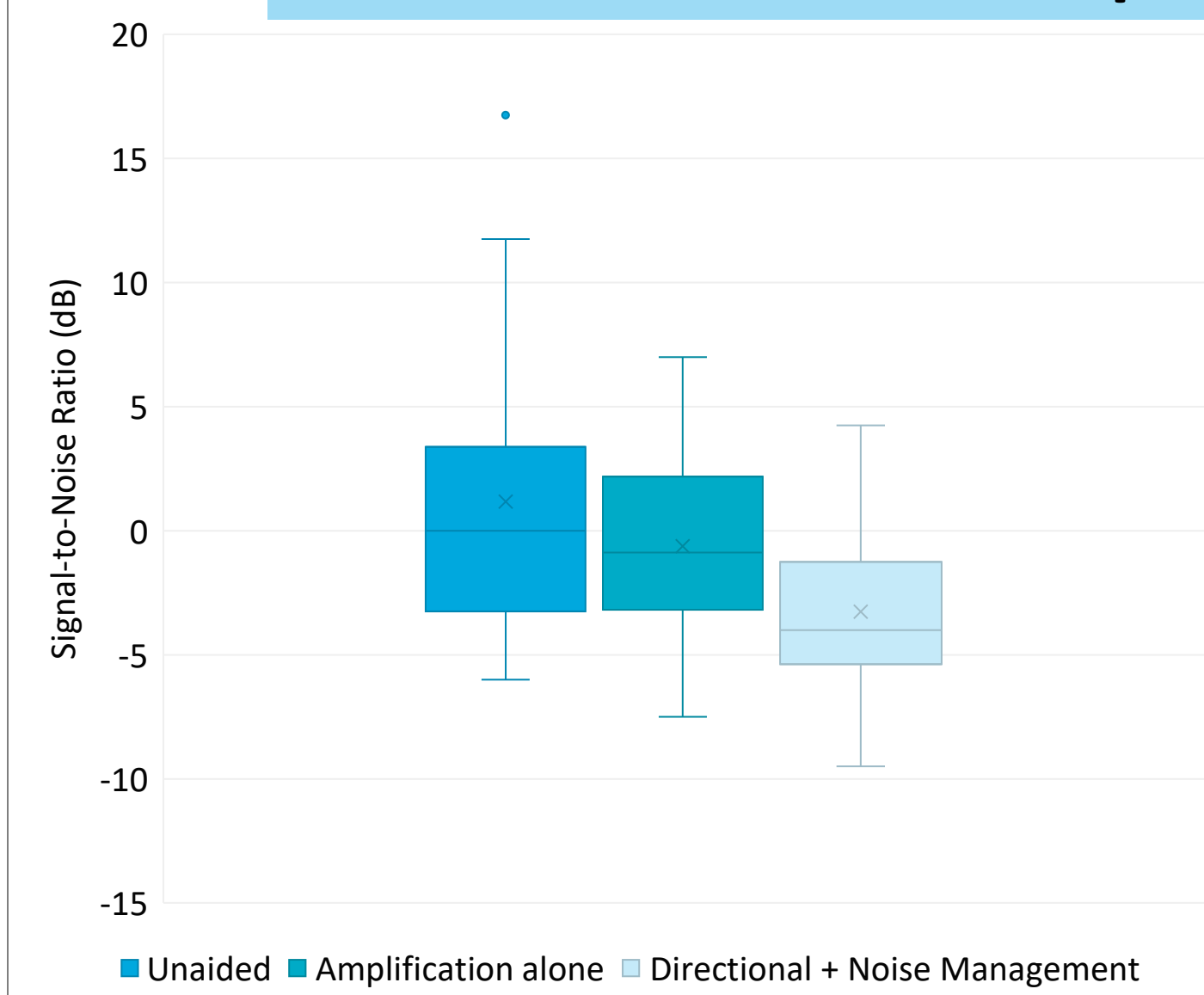


Figure 1. Boxplot of the HINT performance for all directional products (n = 45). Results are reported as SNR needed to repeat 50% of the sentences correctly, therefore lower values indicate better performance. The "x" symbols represent the mean values.

- HINT sentences<sup>1</sup> presented in an 8-speaker array with speech presented from 0° azimuth and uncorrelated speech-shaped HINT noise presented from all 8 speakers at a summated level of 65 dBA.
- Conditions: 1) Unaided, 2) Amplification alone (omni microphones + noise reduction disabled), and 3) Directional + Noise Management (directional microphones + noise reduction enabled).
- Aided benefit was achieved for both aided conditions (Paired t-test, Unaided:Omni t=4.09, p<0.001, Unaided:Dir+NM t=7.15, p<0.001).
- **The Directional + Noise Management condition performed significantly better than the Amplification alone condition, demonstrating the utility of directional microphones and noise reduction features** (Paired t-test, Aided:Aided+NM t=8.54, p<0.001).

- HINT sentences presented from 0° azimuth with uncorrelated speech-shaped HINT noise presented from the 4 corner speakers. (Fig. 3)
- **The StarLink Edge Remote Microphone provided an average of 12.57 dB SNR over the hearing aids alone** (Paired t-test, t=16.08, p<0.001) and **the StarLink Edge Table Microphone provided an average of 6.82 dB SNR over the hearing aids alone** (Paired t-test, t=8.27, p-value<0.001).

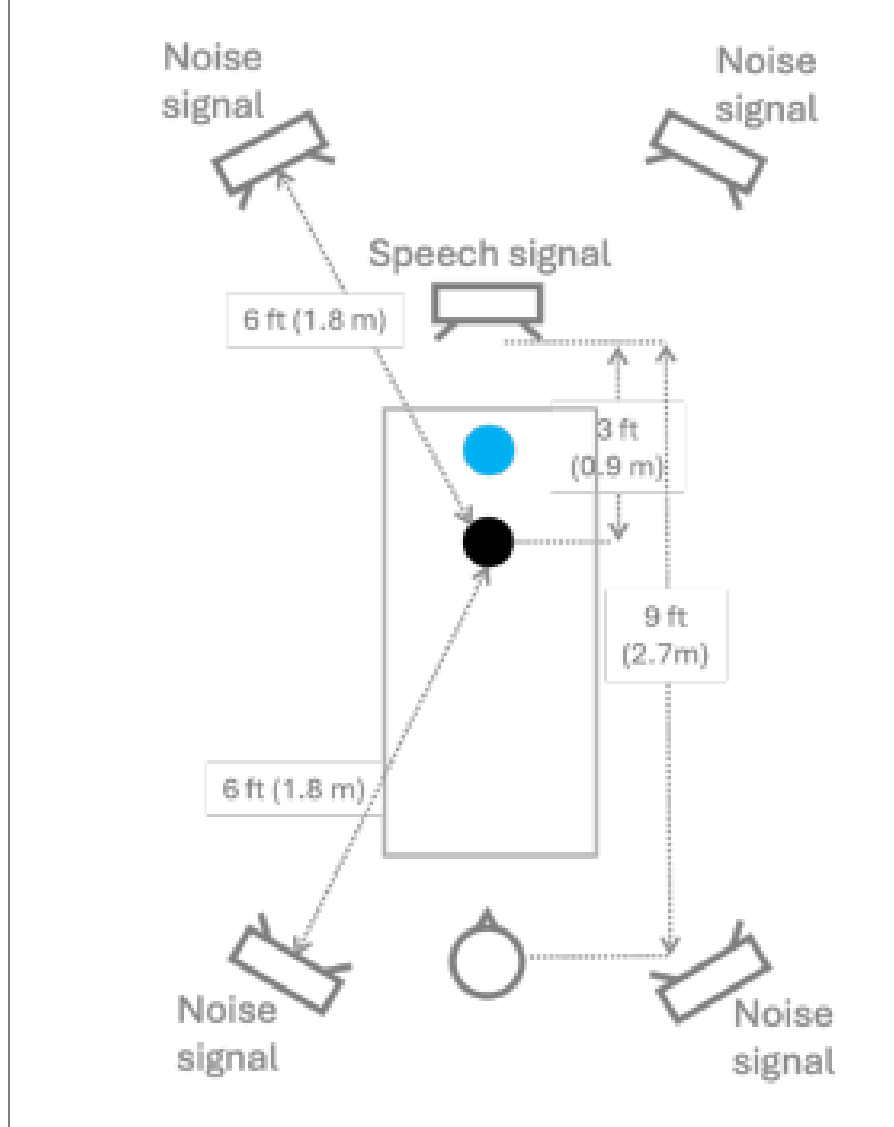


Figure 3. Participant seated at one end of a long table, 9 feet away from front (target) speaker placed at 0° azimuth. The black circle represents the StarLink Edge Table Microphone, positioned 3 feet away from the target speaker, and the blue circle represents the StarLink Edge Remote Microphone, positioned to simulate a neck-worn setup directly in front of the target speaker. The four noise speakers in the corners were each positioned 6 feet away from the table microphone.

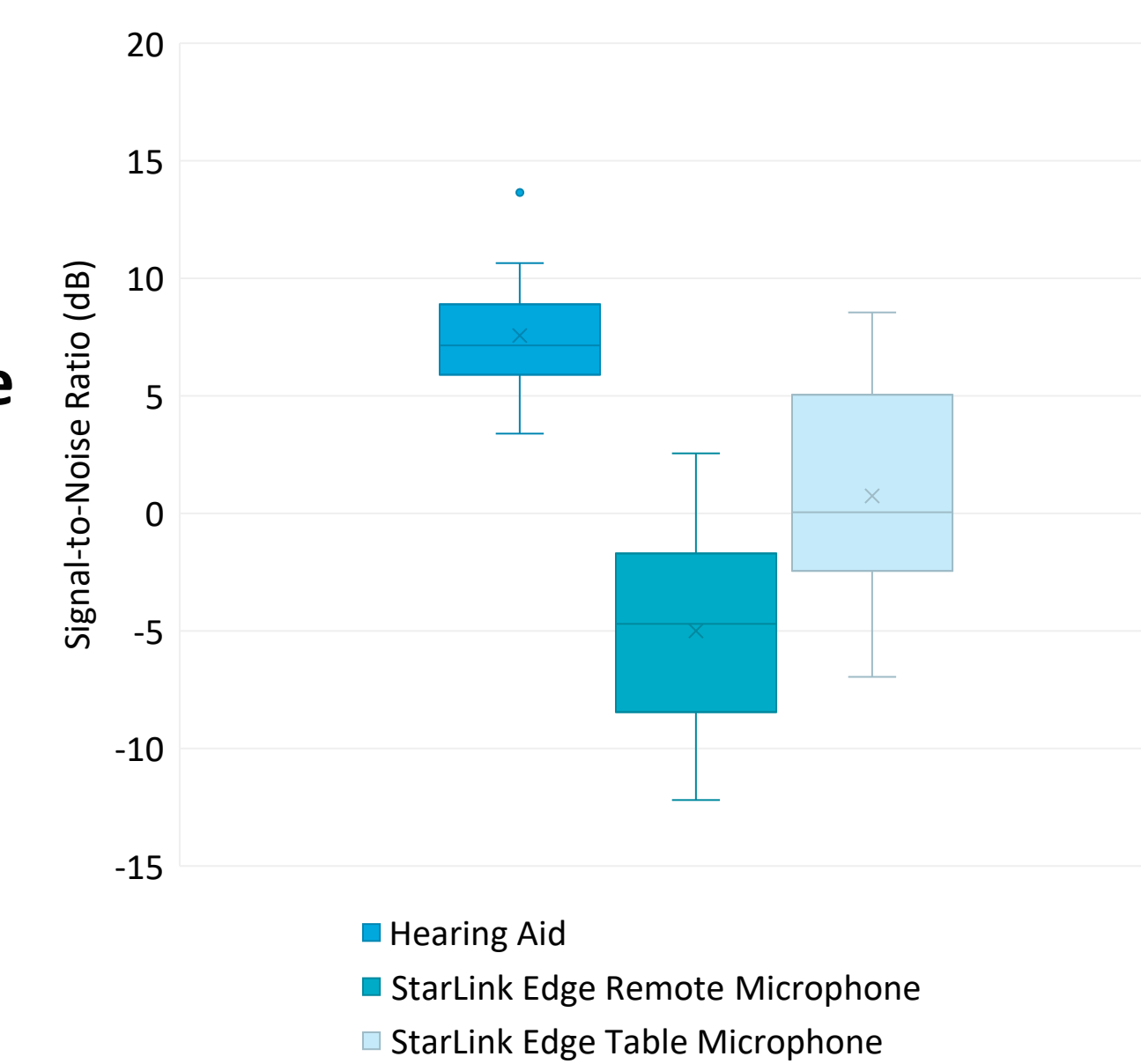


Figure 2. Boxplot of the HINT performance with hearing aids alone compared to streaming through the accessories (n = 19).

### Overall Usability

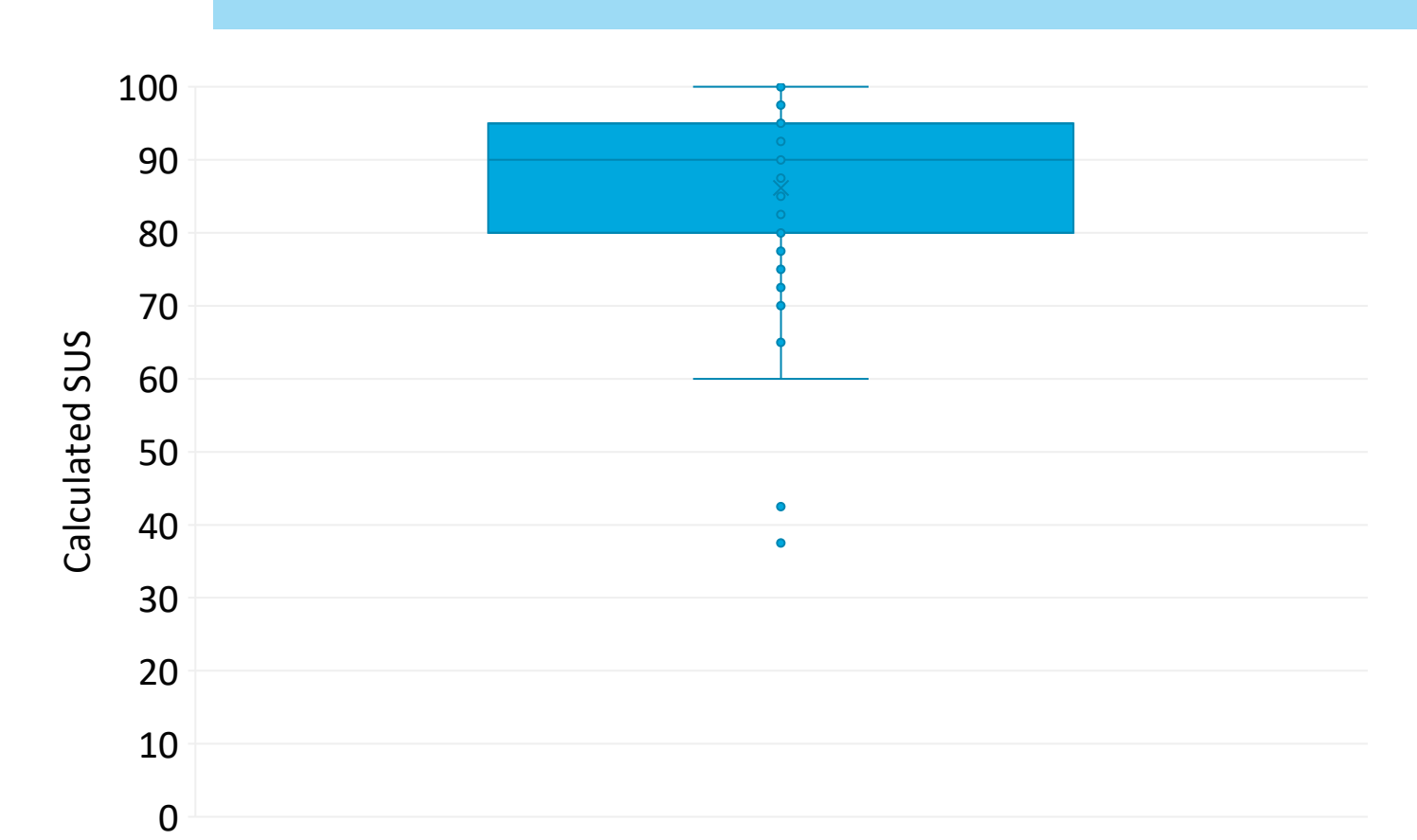
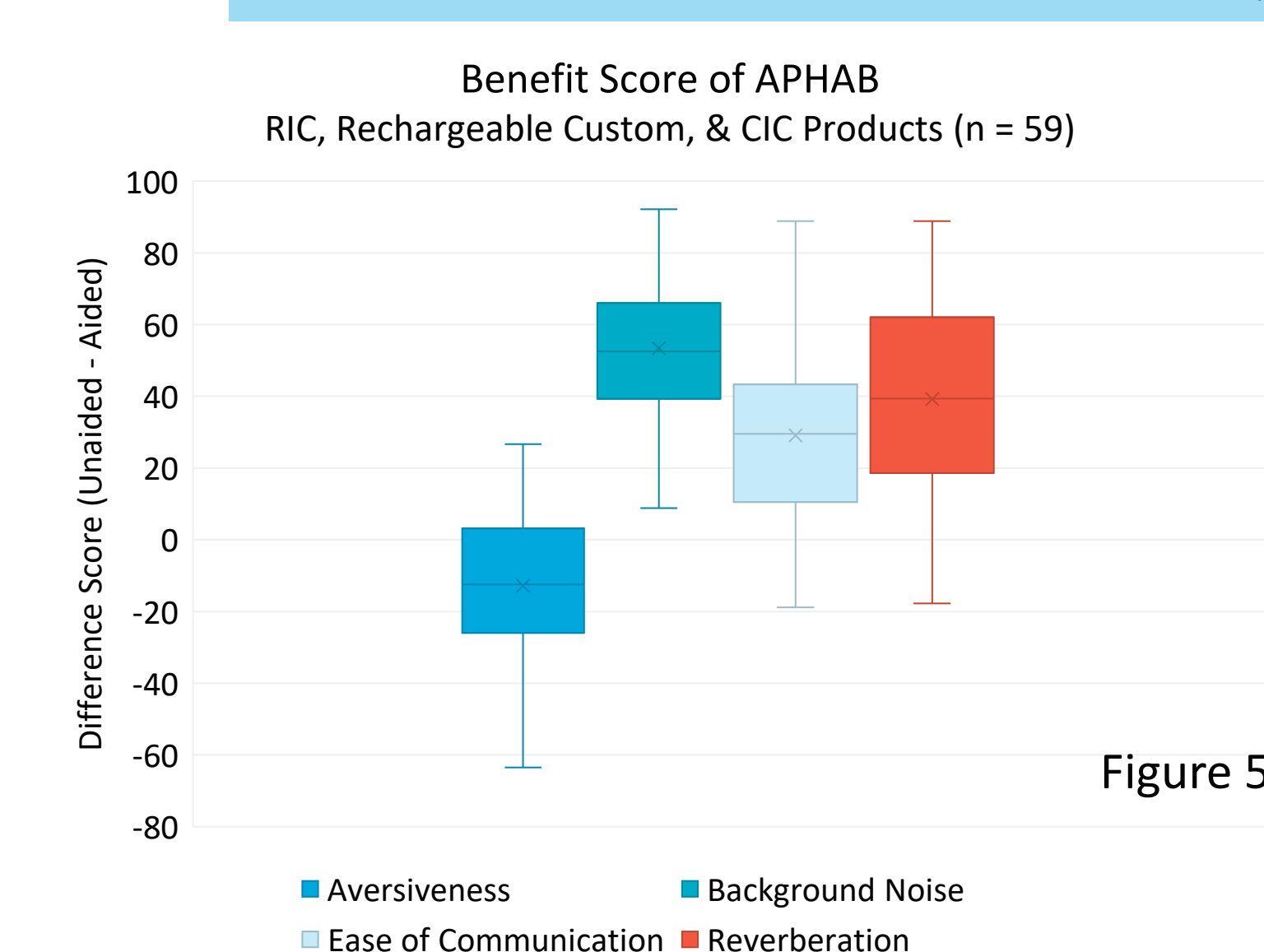


Figure 4. Box plot of the System Usability Scale (SUS). Participants (n = 59) rated the usability of the Omega AI hearing aids, charger, and mobile application.

- Participants evaluated all aspects of the hearing aids and charger. They were encouraged to use Edge Mode+, and fine-tune acoustic and streamed inputs via My Starkey.
- After approximately 6 weeks, the System Usability Scale (SUS) questionnaire was administered.
- **The average SUS score was 86, which exceeds the recommended "average" benchmark score of 68<sup>2</sup>.**

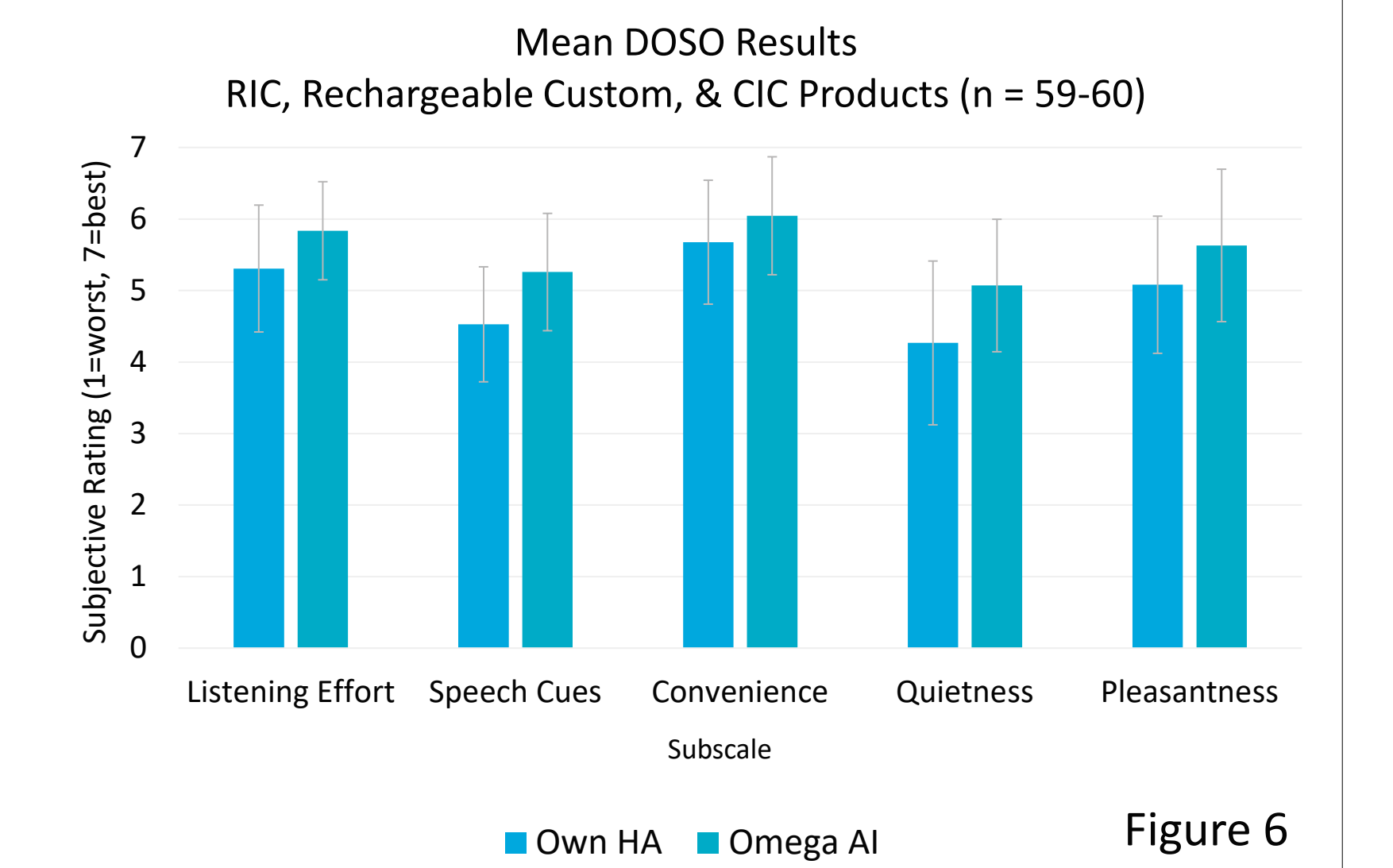
## RESULTS (CONT.)

### Benefit Questionnaires



- A benefit score for the Abbreviated Profile of Hearing Aid Benefit<sup>3</sup> (APHAB) was calculated (Unaided – Aided). A higher score indicates greater perceived aided benefit. (Fig. 5)
- **The minimal clinically important difference (MCID)<sup>5</sup> (≥ 5 pt. improvement on BN, EC & RV, or ≥ 22 pt. improvement on BN, EC, or RV) was met for 98% of participants, indicating meaningful aided benefit was achieved.**

- The Device Oriented Subjective Outcome<sup>4</sup> (DOSO) questionnaire was administered for the participant's own hearing aids and after trialing Omega AI hearing aids. (Fig. 6)
- **Average results were significantly higher across all five subscales when using Omega AI hearing aids** (Wilcoxon Signed-Rank Test, LE: z=-3.26, p=0.001; SC: z=4.28, p<0.001; Con: z=-2.59, p=0.01; Q: z=-3.74, p<0.001; P: z=-2.98, p=0.003).



## CONCLUSIONS

When validating a new hearing aid prior to launch, it is crucial to investigate the patient experience with the product. The validation study for the Omega AI hearing aid family indicates:

- Significant aided benefit in noise with directional microphones and noise management features compared to when noise management features are disabled.
  - Significant aided benefit in noise with StarLink Edge Remote Microphone and StarLink Edge Table Microphone accessories compared to hearing aids alone, in addition to the SNR improvement provided by the hearing aids using directional microphones and noise management features.
  - Above average usability scores for Omega AI hearing aids.
  - 98% of participants meet the MCID for APHAB, and 5/5 subscales on the DOSO are significantly higher when compared to their own hearing aids, indicating significant perceived aided benefit and satisfaction.
- Omega AI hearing aids were found to be easy to use and improve patient's listening experiences in clinically meaningful ways.

## REFERENCES

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