Clinical outcomes with a next generation sound processor

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Introduction

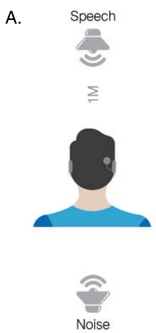
As cochlear implant recipients move throughout their day, they encounter a variety of acoustic environments, each of which present unique listening demands. AutoSense OS, featured in Advanced Bionics Naída and Sky CI M sound processors, is a system designed to address these demands through real-time environmental classification that automatically adapts cochlear implant sound processing to optimize hearing performance, listening comfort, and sound quality. This multi-center clinical trial evaluated outcomes with the Advanced Bionics Naida CI M90 sound processor with AutoSense OS in comparison to the prior generation Naída CI Q90 sound processor that featured the AutoSound classification system. Study objectives focused on measurement of speech recognition ability and the collection of subjectively reported outcomes based on experiences during daily life.

Methods

Qualifying participants were enrolled in this study that used a prospective, within-subjects, repeated-measures design. The primary objective was to compare sentence recognition in quiet between the Naida CI M90 and Naída CI Q90 sound processors, and secondary objectives were to evaluate speech recognition in noise between these systems. All participants completed a chronic wear period with the next generation system that ranged from 14 to 20 days, and they reported on their experiences during daily life. The primary safety objective was absence of unanticipated adverse device effects related to the use of this next generation sound processing platform. All participating centers received ethical approval and the study was conducted as part of an FDA-approved investigational device exemption.

A total of 22 subjects enrolled in the study. Based on the level of residual hearing, subjects were assigned to an electric only (EO) or aidable residual hearing (ARH) cohort, each with 10 and 12 subjects, respectively. Subjects in the aidable residual hearing cohort were fitted with an acoustic earhook for the duration of the study. Average subject ages were 67.2 years for the EO cohort and 61.1 years for the ARH cohort. Data from the intent to treat population are reported.

AzBio sentences were used for measurement of speech recognition[1]. Sound field testing was conducted in a sound booth with loudspeakers positioned at 0° and 180° one meter from the listener; speech was calibrated to 65 dBA and noise to 60 dBA. Testing was performed unilaterally and contralateral devices were removed from the non-test ear when necessary. Following the fitting of the study sound processors and testing of acute speech recognition, subjects completed the chronic wear period with the Naida CI M90 sound processor and answered a custom questionnaire that asked about their listening experiences in a variety of listening scenarios. Subjects were asked to compare their listening experience with the Naída CI M90 to listening in similar scenarios with their personal sound processor.



B.

1. Sound Quality Ratings

Based on your experience listening with cochlear implant systems, rate the **quality of sound** for each condition below on a scale from 1-5, with 1 being "Strongly disagree", 3 being "Neither agree nor disagree" and 5 being "Strongly agree". If you did not listen in the condition listed below please select "N/A".

	N/A	Strongly disagree 1	Slightly disagree 2	Neither agree nor disagree 3	Slightly agree 4	Strongly agree 5
a. Sound quality is acceptable when listening in quiet	☐	☐	☐	☐	☐	☐
b. Sound quality is acceptable when listening in noise	☐	☐	☐	☐	☐	☐
c. Sound quality is acceptable when listening in transportation (e.g., Car, Truck, Bus)	☐	☐	☐	☐	☐	☐
d. Sound quality is acceptable when listening in a large or reverberant room	☐	☐	☐	☐	☐	☐
e. Sound quality is acceptable when listening to music	☐	☐	☐	☐	☐	☐

Figure 1. *Panel A provides an illustration of the subject and loudspeaker positions during acute testing of speech recognition. Panel B provides a sample of one category (Sound Quality) from the custom subjective questionnaire.*

Results

Results of speech recognition measures are displayed in Figure 2. The pattern of results was consistent across the two cohorts. In quiet (Figure 2, left panel), performance with Naída CI M90 and AutoSense OS was non-inferior to performance with Naída CI Q90 and AutoSound (EO: p=0.0010; ARH: p=0.0018). In noise (Figure 2, right panel), performance with Naída CI M90 with AutoSense OS was significantly better than performance with Naída CI Q90 with AutoSound (EO: p=0.0088; ARH: p=0.0053). Additionally, in noise (Figure 2, right panel), performance with Naída CI M90 with AutoSense OS was significantly better than performance with the same processor with AutoSense OS off (omnidirectional; EO: p=0.0005; ARH: p=0.0001).

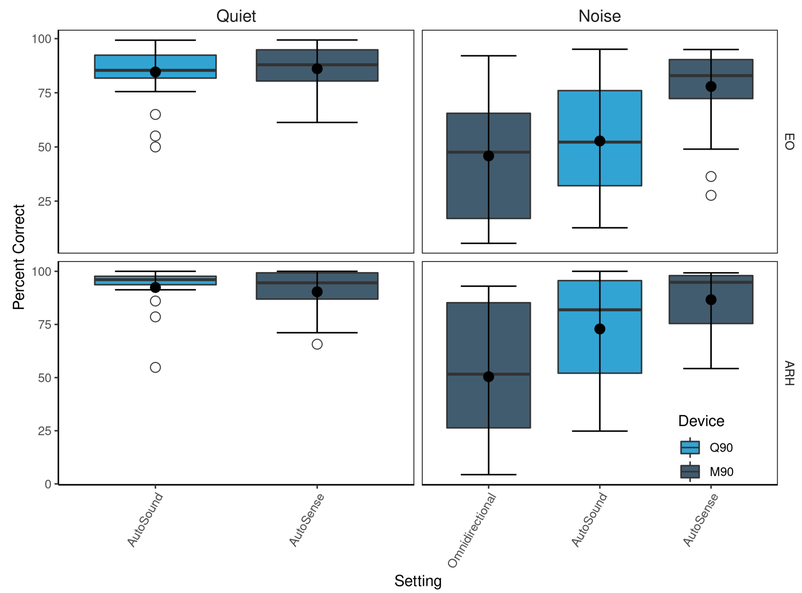


Figure 2. *Speech recognition is shown in percent correct as a function of listening condition, in quiet or noise, with AutoSense OS on the Naida CI M90 or AutoSound on the Naida CI Q90. Box plots illustrate data mean, median, quartiles and outliers.*

Responses to the custom questionnaire are shown in Figure 3. Within the EO cohort, the total response counts in favorable categories were higher for the Naida CI M90 when compared to subjective reports to the same questions for subjects' own processor. Ratings within the ARH cohort were more similar between the two processor types. Taken together, the subjective reports show clear agreement that the Naida M90 is satisfactory for daily use across a range of listening scenarios.

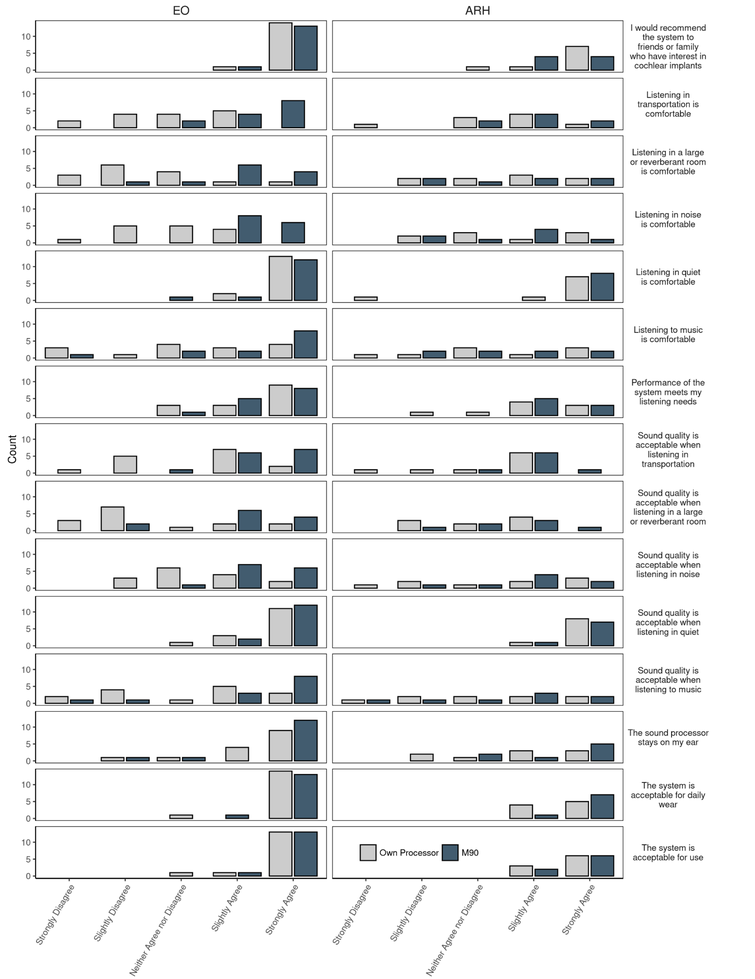


Figure 3. *Total response counts are shown for each question in the custom questionnaire. Subjective judgments for listening with the Naida CI M90 sound processor and subjects' own processor are displayed.*

Conclusions

Clinical outcomes with the Naída CI M90 sound processor showed speech recognition was similar or improved when compared to the prior generation Naida CI Q90. Specifically, AutoSense OS automatically classified challenging acoustic environments and steered signal processing in a manner that significantly improved speech recognition in noise. Subjectively reported outcomes clearly demonstrated that the next generation platform was satisfactory during daily life and across a wide range of listening environments.

References

1. Spahr, A. J., Dorman, M. F., Litvak, L. M., Van Wie, S., Gifford, R. H., Loizou, P. C., ... & Cook, S. (2012). Development and validation of the AzBio sentence lists. Ear and hearing, 33(1), 112.

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