



Clinical Outcomes with an Instant-Fit DSP Hearing Aid

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ABSTRACT

The results of clinical evaluations with a DSP-based, instant-fit hearing aid are presented. Fittings were routinely verified. Objective performance and patient benefit (SIN and HINT), and subjective sound quality and satisfaction (APHAB), were evaluated on 24 subjects in one investigation and on a subset of five subjects in a second investigation. The relative value of features such as instant-fit, cost, digital signal processing, single-microphone noise reduction, and cosmetic appeal are discussed.

INTRODUCTION

CONFORMA 2 SE is an instant-fit, completely-in-the-canal hearing aid incorporating the digital signal processing (DSP) and Personalized Noise Reduction™ (PNR) features found in the NATURA 2 SE custom and BTE products¹. It is comprised of a core unit that houses the transducers and DSP chip, and a soft, non-custom, foam shell, available in five sizes, that covers the core and conforms to the ear canal of the wearer (Figure 1).



This report describes two investigations. The first was an evaluation of the performance and communicative benefit of the CONFORMA concept (non-custom, instant-fit, low-cost, DSP) relative to that of high-quality, analog, custom CICs. The second was a comparison of CONFORMA 2 SE to the benchmarks established by the NATURA 2 SE CIC, containing identical DSP and PNR features in a custom shell.

METHODS

First Investigation

Twenty-four wearers of analog CICs were fit with CONFORMA devices without Noise Reduction. The Speech-In-Noise (SIN)² test was administered and performance scores were obtained on the unaided, aided-analog, and aided-CONFORMA conditions. The Abbreviated Profile of Hearing Aid Benefit (APHAB)³ was administered for both the analog and CONFORMA hearing aids, and probe microphone measures were obtained on each subject to verify the fittings of each set of devices.

Second Investigation

A subset of five subjects from the first investigation were additionally fit with both NATURA 2 SE CICs and CONFORMA 2 SE devices, both with PNR. Subjects were tested with the Hearing In Noise Test (HINT)⁴ to compare the unaided condition with the aided-CONFORMA 2 SE and aided-NATURA 2 SE conditions. The APHAB was administered for the new aided conditions. Sound quality ratings were obtained in order to assess any performance differences that could be attributed to product features other than signal processing. Stimuli for the sound quality ratings consisted of the subjects' own voices, two samples of recorded music, and a male and female talker in quiet and noise.

RESULTS OF FIRST INVESTIGATION

SIN Test: Among several main effects and interactions reported by MANOVAs on the SIN test data (Figure 2) was a significant main effect for Aided Condition between the subjects' own analog hearing aids and the CONFORMA hearing aids [$F(1, 23) = 20.304, p < .001$]. There were no significant interactions involving the variable Aided Condition when the unaided scores were removed from the statistics. These results indicate significantly better performance with CONFORMA than with the analog hearing aids across all conditions of the SIN test.

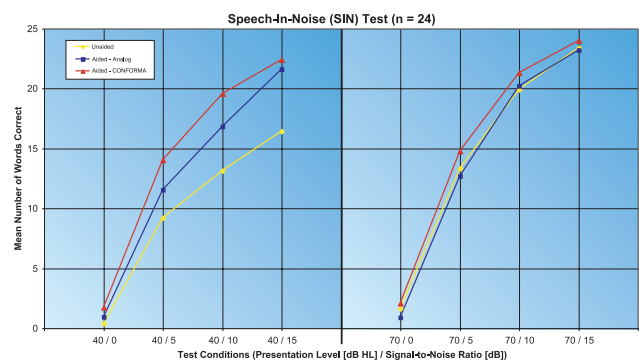


Figure 2. Speech In Noise Test Results

APHAB: The subjective benefit reported by the subjects favored CONFORMA over their own analog hearing aids on all subscales (Figure 3). An ANOVA showed significant main effects for both Aided Condition [$F(1, 23) = 22.357, p < .001$] and Subscale [$F(3, 69) = 44.448, p < .001$], with no significant interactions, indicating that the subjects perceived more benefit from CONFORMA than from their own analog hearing aids.

Probe Microphone Measures: Routine real-ear verification of the subjects' fittings was performed at input levels of 50, 65, and 80 dB SPL. Figure 4 compares the real-ear performance of the analog and CONFORMA hearing aids.

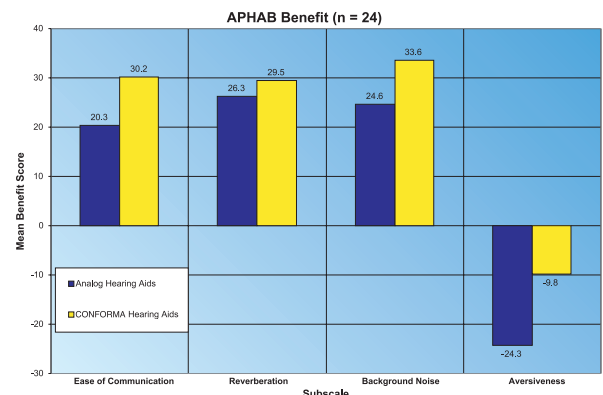


Figure 3. APHAB: Analog and CONFORMA

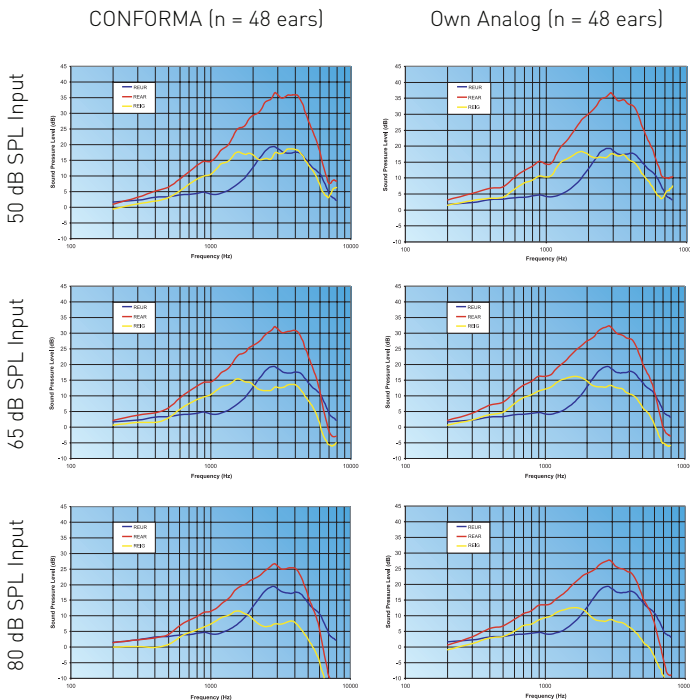


Figure 4. Probe Microphone Curves at 50, 65, & 80 dB SPL Inputs

RESULTS OF SECOND INVESTIGATION

A subset of five subjects from the original pool was fit with both NATURA 2 SE and CONFORMA 2 SE in order to evaluate the effectiveness of Personalized Noise Reduction technology and see if the different form factors (custom vs. non-custom) contributed to any noticeable differences in objective benefit or subjective performance.

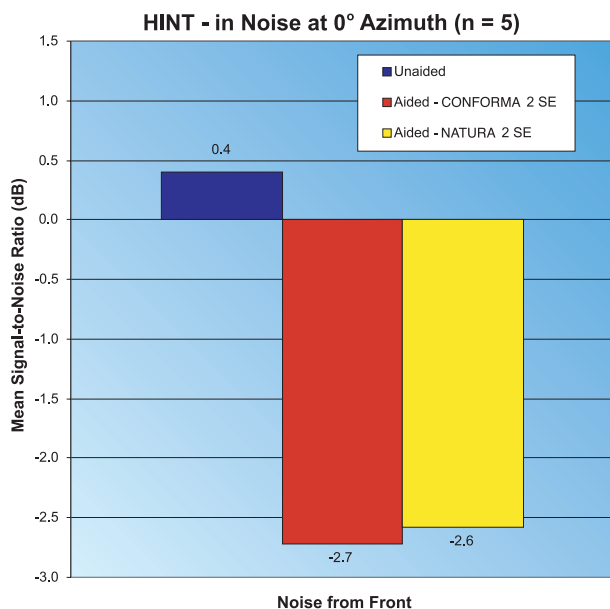


Figure 5. HINT Results, Noise Front

HINT: HINT thresholds in noise (Figure 5) were obtained with the target and masker presented from the same location (0° azimuth). The spectrally-matched masking noise was modified for a longer onset time than is available in the original HINT. This was done to allow the PNR sufficient time to engage prior to presentation of the target stimulus.

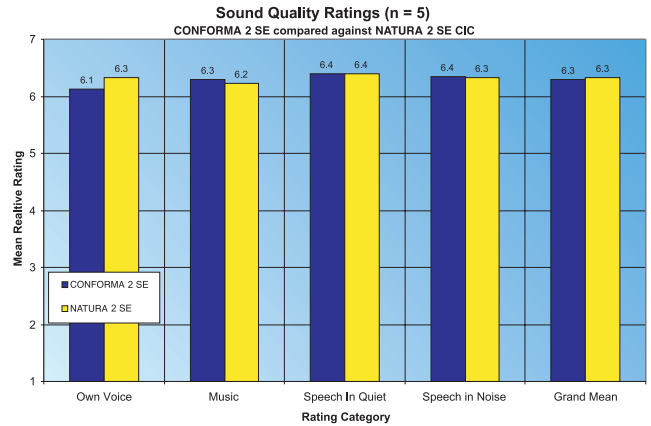


Figure 6. Sound Quality Ratings in Sound Field

Aided speech understanding in noise was significantly better with both CONFORMA 2 SE and NATURA 2 SE than with the unaided condition [$F(2, 8) = 4.687, p < .05$] and there was no difference between the two aided conditions.

Sound Quality: Each sound quality category was rated for Volume, Naturalness, Clarity, and Ease of Understanding. An Overall Sound Quality rating was included to assess the gestalt impression of each subject's listening experience. Figure 6 shows that there was no difference in sound quality ratings between CONFORMA 2 SE and NATURA 2 SE.

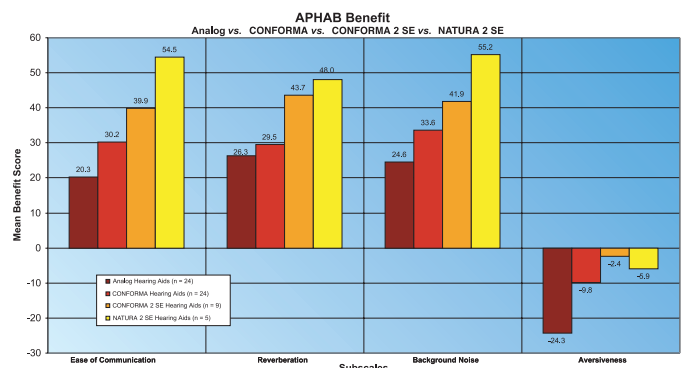


Figure 7. APHAB: Benefit Scores for All Devices

APHAB: The APHAB was again administered to those wearing CONFORMA 2 SE and NATURA 2 SE devices. These scores were combined with data from Figure 3 for comparison in Figure 7, showing an overall preference for NATURA 2 SE. No statistics were run due to unequal sample sizes.

CONCLUSIONS

The APHAB comparison in Figure 7 suggests some contradictions. In the first investigation, objective data support the finding that subjects preferred the non-custom, DSP-based CONFORMA over their own analog, custom CICs. Yet, given a choice between the custom NATURA 2 SE and the non-custom CONFORMA 2 SE, each with identical DSP, experienced hearing aid wearers preferred the custom hearing aids, even though the objective data demonstrated no measurable difference between them. Additional probing revealed two factors that contributed to this observation:

1) The ideal candidate for CONFORMA 2 SE has an ear canal morphology that allows the product to fit "CIC-like," well within the meatus of the canal (Figure 8). When CONFORMA 2 SE fits more like an ITC (Figure 9), there is greater occlusion effect, more opportunity for feedback, and the aesthetics are less acceptable. The ratings of two of the five subjects represented in Figure 7 were influenced by "ITC-like" fittings.



Figure 8. CIC-like fittings

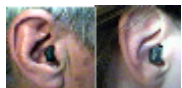


Figure 9. ITC-like fittings

2) Product cost was not considered on any of the subjective scales, but influenced the ratings of all five subjects. When data collection was completed, subjects were told that the cost of the non-custom CONFORMA 2 SE is approximately half that of the NATURA 2 SE CICs. With this knowledge, the subjects were equally divided as to their stated preferences.

This report shows that the non-custom, instant-fit, CONFORMA 2 SE delivers superior performance and communicative benefit as compared to conventional analog CICs, and provides the same performance and benefit as the NATURA 2 SE custom CIC. Among experienced hearing aid wearers, a custom fit is preferred over a non-custom fit when sound processing and price are equivalent. However, when the instant-fit product is priced significantly less than the cost of the custom device, there is equal preference for the two device styles.



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