



Description, Rationale, and Efficacy of a Digital, Non-Custom, Instant-Fit CIC Hearing Aid

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ABSTRACT

A non-custom, instant-fit hearing aid has been developed with the goal of delivering improved speech recognition in quiet and in noise using advanced digital signal processing while providing economic advantages for the manufacturer, the dispensing channel, and hearing-impaired individuals. The product concept is an off-the-shelf, field-programmable, hearing aid that fits in the ear canal. Product design features are discussed along with the recommended instant-fit protocol. Data are presented that show benefit on objective measures (speech recognition performance on the Hearing In Noise Test [HINT] in quiet and in noise, and coupler target matching) and subjective measures including the Abbreviated Profile of Hearing Aid Benefit [APHAB]. Also included are data from an ear canal dimensional study that evaluated Adesso's physical fit with non-custom, foam shells.

INTRODUCTION

Instant-fit hearing aids hold the promise of many advantages compared to traditional, custom, ear-level instruments¹. By definition, an instant-fit hearing aid requires no factory customization, but is physically and electroacoustically flexible such that physically fitting it into an individual's ear canal, and programming accurate hearing loss compensation can be accomplished in a single visit to a dispensing office with minimal chair time. The elimination of factory customization reduces manufacturing costs and eliminates the costs associated with shell remakes. These savings are reflected in lower costs to the clinician and to the patient. AdessoTM is a non-custom, digital hearing aid designed to realize these goals.

Adesso is a two-part device. The core unit (Figure 1) contains the microphone, receiver, on/off switch, DSP chip, vent tube, and 10A battery compartment, and is available as a right or left device. The core fits inside a soft, pre-formed foam shell in one of four sizes (Figure 2). Each foam shell has an integrated removal cord. A custom shell is available as an optional after-market accessory.



Figure 1: Adesso Core



Figure 2: Assorted soft shell sizes.

The instant-fit procedure for Adesso typically takes about an hour, including the hearing evaluation and patient counseling. In practice, Adesso hearing aids are programmed immediately following the audiometric evaluation using a battery pill/flex wire connected to an EXPRESSfitTM fitting system running software that has been streamlined and simplified for clinical efficiency. The devices are then physically fit in the ear canals using the soft foam shells. Counseling takes place only after the patient has been aided and is receiving benefit from amplification. Since Adesso's digital signal processing is identical to the SONIC innovations NaturaTM 2 SE hearing aids, this fitting procedure allows the patient to experience the benefits of advanced digital signal processing without first having to make an otherwise uninformed purchase commitment.

An experiment was conducted to evaluate Adesso's performance on new and experienced hearing aid wearers using the instant-fit protocol. Fittings were verified with probe microphone measurements. Performance, benefit, and satisfaction were validated with the HINT², the APHAB³, and the 1997 MarkeTrak V Multiple Environment Listening Utility (MELU) survey⁴, respectively.

METHODS

Subjects. Twenty subjects, 12 male and 8 female, participated in the present study. Eight subjects were new users of amplification and 12 were experienced users of digital,

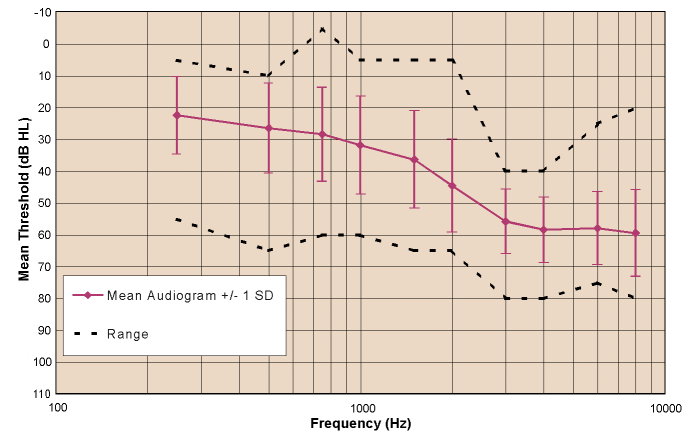


Figure 3: Mean audiogram +/- 1SD (n=40 ears)

custom hearing aids. The subjects ranged in age from 45 to 79 years with a mean age of 64 years. All had symmetrical, bilateral, sensorineural hearing loss of mild to moderately-severe degree and all were aided binaurally. Figure 3 shows the mean audiogram.

Test Battery. Coupler targets (2cm³) were generated for each subject by the proprietary EXPRESSfit fitting algorithm for 50 and 90 dB SPL inputs and compared to measured coupler responses obtained at these same input levels using pure tones. Results from the HINT were obtained in quiet and in noise. The noise condition used the standard HINT noise presented at 0° azimuth and modified to increase the onset time from 0.5 seconds to 5 seconds in order to allow Adesso's noise reduction algorithm to engage. The APHAB was administered before (unaided) and after (aided with Adesso) 30 days of wear by each subject. The MarkeTrak MELU provides satisfaction ratings on a five-point Likert scale in 13 different listening environments. Each subject completed a MELU survey at the end of every week. Weekly ratings were averaged together in each category for each subject, then averaged across the subject pool.

Sizing Study. Impressions of ear canals were measured at four locations. The anterior-posterior (X-dimension) and superior-inferior (Y-dimension) aspects were measured both medial and lateral to the first bend. Measurements were also made at corresponding locations on an Adesso core mandrel (Figure 4). The purpose of the measurements was to

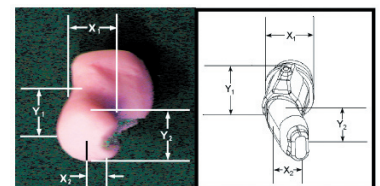


Figure 4: Sizing measurement locations

establish quantitatively a range of ear canal sizes that could be fit with the four sizes of soft foam shells and to determine candidacy for fitting with a custom shell. The bend angle of the core had been previously determined during product development by balancing engineering and manufacturing considerations against physiological parameters evaluated on hundreds of reference casts (investments) for CIC hearing aids.

RESULTS

Fitting System Performance. One of the design goals for this instant-fit device was to achieve excellent initial hearing loss compensation requiring little fine-tuning in order to minimize chair time. The simplified fitting system for Adesso was designed to generate coupler targets from the audiogram

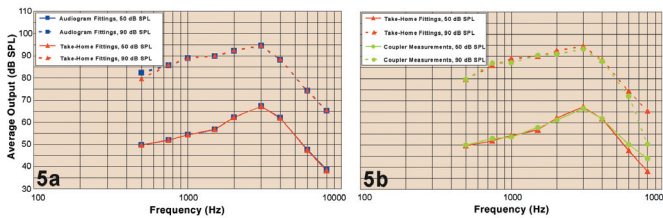


Figure 5a and 5b: 2cm³ coupler targets and measurements (n=40 ears)

without using the in situ dynamic range verification procedure used with other SONIC innovations products. Figure 5a indicates that very little fine-tuning was needed to derive ideal take-home fittings from the audiogram-generated initial fittings. The greatest change is in the 500-Hz channel where high-intensity inputs were reduced to minimize occlusion.

Speech Understanding in Quiet and Noise. Figure 6 shows the results of the HINT in the quiet condition. Adesso provided a significant 5-dB threshold improvement over the unaided thresholds [t(19) = 3.27, p = .004]. HINT results in the noise-front condition reveal a significant 1.3-dB signal-to-noise ratio (SNR) improvement for Adesso over unaided performance [t(19) = 3.30, p = .004] which translates to a 12-13% increase in speech understanding in noise (Figure 7).

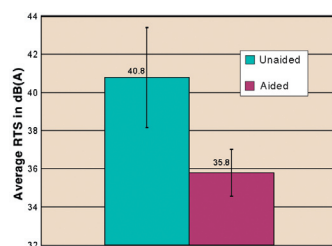


Figure 6: HINT, Quiet, +/- 1 SE (n=20)

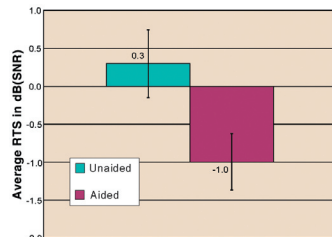


Figure 7: HINT, Noise-Front, +/- 1 SE (n=20)

Subjective Benefit and Satisfaction. The APHAB was completed by 19 of the 20 subjects (Figure 8). An ANOVA run

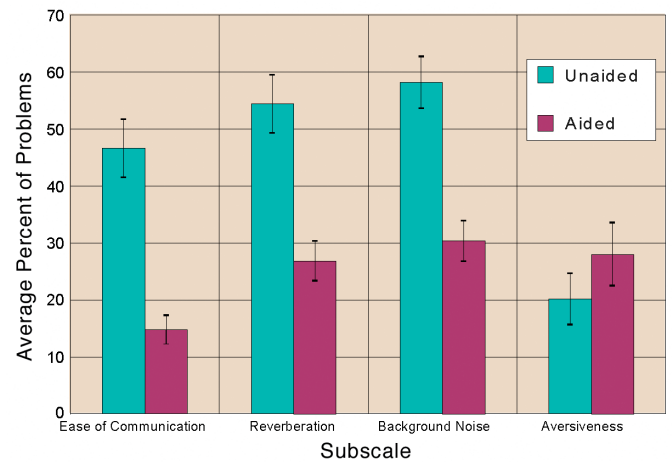


Figure 8 APHAB Results, +/- 1 SE (n=19)

on the three performance subscales (Ease of Communication, Reverberation, and Background Noise) revealed a significant main effect for Aided Condition [F(1,18) = 48.878, p < .001], whereby Adesso yielded a significantly lower percentage of problems reported than the Unaided condition on all three subscales. A paired t-test run on the Aversiveness subscale revealed no significant difference between Adesso and the Unaided condition [p = .182] suggesting that wearing Adesso hearing aids does not significantly increase aversion to amplified sounds.

The MarkeTrak MELU results in Figure 9 are graphed in comparison to the comparison to the national average ratings from the 1997 MarkeTrak V survey of 524 individuals⁴.

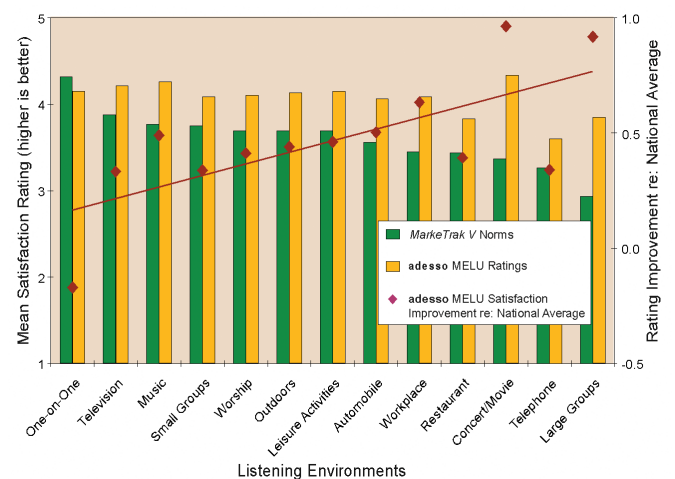


Figure 9: MarketTrak MELU Ratings re: National Average

The listening categories in Figure 9 are ranked in order of easiest to most difficult, per the 1997 survey norms. The red diamonds indicate the magnitude of the differences between the 1997 national averages and the Adesso results for the present study. The trend line shows the increased satisfaction with Adesso over the national averages as listening environments become more difficult.



Figure 10: CIC-like



Figure 11: MC-like



Figure 12: ITC-like

Sizing Study. In order to accommodate as many ear canals as possible, four sizes of disposable foam shell were created, as well as a custom shell. The results of the sizing study indicate that nearly 70% of ears can be fit with Adesso with one of the four foam shell sizes. About 25% of ears can be fit with a CIC-like microphone location (Figure 10) and the balance with a Mini Canal-like (MC-like) or ITC-like microphone location (Figures 11 and 12). Custom shells were successfully fit on all of the subjects in the present study.

CONCLUSIONS

An instant-fit hearing aid, Adesso, has been described. Results from performance, benefit, and satisfaction metrics show that Adesso's advanced digital signal processing and simplified fitting algorithm result in accurate fittings that are effective at improving speech understanding in quiet and in noise. Self-assessed ratings of benefit relative to no hearing aids are significant and overall satisfaction exceeds the national average among hearing aid wearers for difficult listening situations. The non-custom form-factor and fitting features keep Adesso cost effective for hearing-impaired patients and time-efficient for dispensing professionals.



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