

Blinded Comparison of Three Levels of Hearing Aid Technologies

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Introduction

With the advent of digital technology in the hearing aid industry, there has been a rapid introduction of new capabilities in amplification. These improvements have been based on intriguing design goals, with the expectations of increased user benefit. However, in many cases, these technical improvements have been introduced at such an accelerated rate that the corresponding confirmation of true clinical benefit has not kept pace. The introduction of programmable analogue circuitry in the early 1990s and then digital platforms in the late 1990s allowed for widespread use of multi-channel, wide dynamic range compression (WDRC) as a solution for sensorineural hearing loss. The use of programmable WDRC circuitry has been demonstrated as offering the patient more benefit than can be achieved via the use of high quality linear amplification (Goedegebure et al., 2001; Kam & Wong, 1999; Kochkin, 2002; Verschuure, Prinsen & Dreschler, 1994). However, over the past couple of years, advanced second generation digital technology has offered improved feature sets that have introduced new potential advantages beyond the core advantages of WDRC circuitry. Specifically, the Adapto product line has taken the core advantages of WDRC circuitry and added three important improvements: VoiceFinder™ speech processing, OpenEar Acoustics™, and Client-Focused Fitting (Schum & Pogash, 2001; 2002). The goal of the current study was to examine the patient benefit provided by these improvements compared to two well established alternatives: Linear and WDRC.

What should be expected? When comparing Linear to the two non-linear options, we would expect certain core benefits to be reflected in the results. For example, multi-channel nonlinear technology is designed to provide greater gain for soft inputs and better comfort, acceptability and/or sound quality in louder environments due to the decrease in gain for more intense inputs. In addition, the fully automatic nature of non-linear technology should provide more effortless use in the changing environments that many users experience throughout the day. When looking more closely at the expected differences between the two non-linear options (WDRC and Adapto), we would expect to see the unique features of Adapto show up in the patient responses. For example, the larger vents provided by OpenEar Acoustics would be expected to lead to higher levels of physical comfort and sound

quality. The gain changes used in the VoiceFinder when speech is not present should be reflected as a reported relief from annoyance. The personalized selection of the fitting rationale as part of Client-Focused Fitting should be reflected in improved generalized communication effectiveness.

In order to get a true estimate of the additional benefit provided by such advanced features, several important study design safeguards were used. For example, the study used a blinded design in order to minimize any bias based on expectations on the part of the subjects. New sets of in-the-canal hearing aids for all three technologies were built for all patients in order to guard against any "old" versus "new" comparison. The study was conducted at thirteen different audiological facilities, in order to gain experience from a variety of settings, yet the clinical staff at all sites were required to have met minimum numbers of fittings of all three technologies prior to the study in order to ensure fitting expertise. A variety of objective and subjective measures were used in order to guard against a one-dimensional view of hearing aid benefit.

Design

Test Facilities: Thirteen different audiological practices agreed to participate in the study. Each of the facilities were required to have had completed fittings on at least ten patients with each of the hearing aid models used in the study during the six months preceding the study. This requirement was instituted to ensure a minimal level of expertise with the particular hearing devices used. The practices were instructed to enroll patients from their normal patient population.

Subjects: Seventy-seven patients (36 males and 41 females) from across the thirteen practices were included. Both new (n = 21) and experienced (n = 56) patients were enrolled. Of the experienced users, 40 were binaural users and 16 were monaural users. The average number of years of use was 9.5. In terms of technology for the experienced users, 39% wore Digital Signal Processing (DSP) circuitry, 21% wore analogue programmable and 40% wore linear.

All patients were required to have sensorineural hearing loss within the fitting range of all three hearing aid models used (listed below). The average (+ 1 s.d.) hearing thresholds for the subject group are displayed in Figure 1. As can be seen, audiometrically, these patients represent a typical population of hearing aid users.

The mean age of the patients was 61.7 years, with a range of 20 to 89. All patients were judged by the clinical staff at the participating clinics to be capable of completing all required tasks as described in the study protocol.

Hearing Aids:

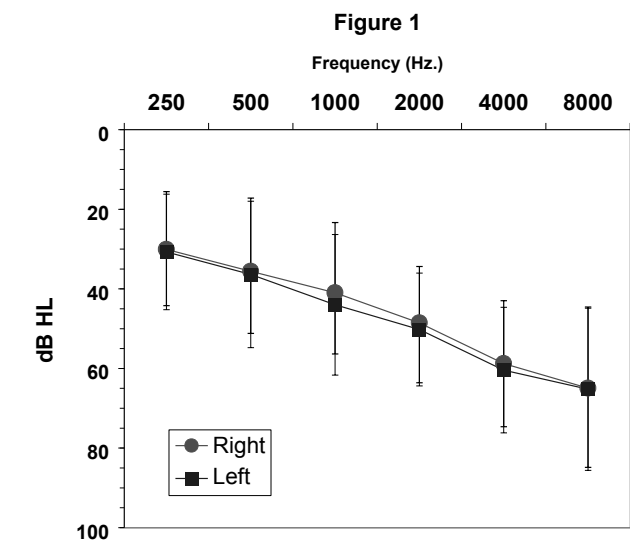


Figure 1: Mean audiogram (+ 1 s.d.) of the 77 patients.

The Linear technology class was represented by the Oticon Ergo hearing aid. This product is a single channel, analogue programmable circuit. The product was fit to the NAL-R prescribed targets via OtiSet fitting software. The WDRC class was represented by the Oticon DigiFocus II hearing aid. DigiFocus II is a seven band, two channel DSP device. The product was fit to the ASA² fitting rationale via OtiSet software. Adapto was fit via Genie fitting software to either the Linear (n = 4), Fast (n = 44), Slow (n = 25) or Ski (n = 4) fitting rationale, depending on patient audiometric and demographic variables. The selection of different fitting rationales is an integral part of the Client-Focused Fitting process.

Patients with previous binaural experience were fit binaurally. Patients with previous monaural experience were fit to the same ear as their previous hearing aid. All new users were fit binaurally.

New hearing instruments in all three technology categories were constructed for all patients. The same earmould impression was used to create the shell for all three devices for a given ear. The Oticon production staff was instructed to produce all three hearing aids for a given ear to the same approximate size. The same production technician made all of the hearing aids for any given patient. The final produced instruments were examined by a production supervisor and one of the authors (RRP) to insure similarity in overall size across the three devices for a given ear. All instruments were intended to be of the in-the-canal style, although for a small number of smaller sized ear canals, the devices were more accurately described as half-shells. No model names were used on the devices-only serial numbers.

Protocol: The patients wore each set of devices for at least three weeks before any performance measures were obtained. The order of technology was randomly varied across the patients. The patients were informed only that

there were three different types of hearing aids to be evaluated: one had a volume control (Linear), one was fully automatic with a smaller vent (WDRC) and one was fully automatic with a larger vent (Adapto). Neither product names nor technology class indicators were used when describing the devices to the patients. Rather, they were referred to as the first, second or third set. They were not informed of the presence or absence of DSP technology in any of the devices. All three technologies were programmed via the use of the PC and fitting software, so there was not an apparent difference to the patients as to technology level used in one product or another.

The patients were seen over a series of at least five scheduled sessions. In the first session, the purpose and design of the study was explained, an updated audiogram was measured and earmould impressions were obtained. In addition, the Client Oriented Scale of Improvement (COSI) (Dillon, James & Ginis, 1997) was used to elicit up to five different patient goals, in order of importance, for the new fitting. At the second session, the first set of devices was fit. The first time that one of the two fully automatic options was fit, the Adaptation Manager was set to Step 1 for new users and Step 2 for experienced users. The patient returned within the first week to have the Adaptation Manager moved to Step 3. Other than that specific process, the clinical staff was encouraged to fit the patients to the prescribed device settings, with fine tuning used only if acoustic feedback or loudness tolerance precluded use of the devices. If needed, the patients were seen within the first week of the fitting of any of the devices for patient-initiated fine tuning. However, this option was used infrequently.

At the third session, the performance with the first set of devices was measured and the second set of devices was fit.

At the fourth session, the performance with the second set of devices was measured and the final set of devices was fit.

At the fifth session, performance with the final set of devices was evaluated and then a subjective comparison across the three sets of devices was obtained.

Performance Measures: Two types of measures were obtained: performance indicators collected for each technology independently immediately after the patient had been using a given set of devices and subjective preference comparisons made across all three technologies after the final use period.

COSI Performance: After using each technology, the patient rated how successfully they performed with amplification on each of the stated fittings. The patient used a 1 to 5 scale, with 1 representing "Hardly Ever" and 5 representing "Almost Always".

Word Recognition Performance: Percent correct word recognition scores were obtained in the soundfield with speech presented at 40 dB HL in quiet, at 60 dB HL in cafeteria noise (+10 dB S/N) and at 70 dB HL in cafeteria noise (+5 dB S/N), designed to replicate, respectively, listening in Quiet, listening in Moderate Noise and listening in High Noise environments. The CD version of the W-22 50-word lists were used. Speech and noise signals were presented at 0 degrees azimuth.

Situational Ratings: A locally developed questionnaire was developed to assess perceived performance using each technology in a variety of listening environments. This scale is reproduced as Appendix A. Briefly, the patient was asked to use a five-point scale to rate perceived performance in the following environments (the scale was administered orally, as the patient did not see the document):

- Cosmetics
- Overall Sound Quality
- Understanding Speech in Quiet
- Understanding Speech in Café/Party Noise
- Understanding Speech in Traffic Noise
- Acceptance of Loud, Non-speech Signals
- Physical Comfort
- Reduction of Day-long Annoyance
- Transient Acoustic Feedback

A score of 1 represented "Very Satisfied" and 5 represented "Very Dissatisfied".

Situational Preferences: After using all three technologies, the patient was asked to express a preference in four different listening environments:

- Physical Comfort
- Easiest to Use All Day
- Overall Sound Quality
- Speech Understanding in Noise

Overall Preference: The questionnaire is reproduced as Appendix B. The patient was allowed to select "No Preference" in any of the environments.

The patient was asked to select one of the sets of hearing aids as the overall preference. In addition, in an open response format, they were asked to provide the three most important reasons attributing to this overall preference.

Dimension	Major Findings	Notes
COSI Performance	Higher technology = better rated performance across goals	Adapto > Linear (p<. 01) Adapto > WDRC (p<. 05) WDRC > Linear (p<. 05)
Word Recognition	Higher technology = higher speech understanding across test environments	
Situational Ratings	Higher technology = higher rated performance generally across environments	Adapto > Linear (p<. 01) Adapto > WDRC (p<. 01) WDRC > Linear (p<. 01)
Situational Preferences	Adapto preferred choice typically 3 to 4 times more often compared to either of the other options.	
Overall Preference	Adapto = 74% WDRC = 16% Linear = 10%	

Table 1: Summary of results.

Results

Table 1 summarizes the major findings of this study. As can be seen, there is (1) a general tendency for Adapto to clearly outperform Linear, (2) a tendency for WDRC to outperform Linear on many dimensions and (3) a tendency for Adapto to outperform WDRC on certain dimensions.

COSI Performance: All 77 patients expressed at least two COSI goals and 75 patients expressed a third goal. The ability to formulate a 4th and 5th goal was inconsistent (n = 55 for a 4th goal and n = 26 for a 5th goal). Therefore, mean results for only the first three goals were analyzed.

The COSI goals were categorized following the scheme presented by Dillon, Birtles & Lovegrove (1999). For the first goal, the two most common goal categories were "Conversation with 1 or 2 persons in Quiet" and "Conversation within a Group in Noise". For the second goal, the most common categorizations were "Conversation with 1 or 2 persons in Quiet", "Conversation within a Group in Quiet" and "Conversation within a Group in Noise". For the third goal, the most common categorizations were "Conversation with 1 or 2 persons in Quiet", "Conversation with 1 or 2 Persons in Noise" and "Familiar Speaker on the Phone".

As can be seen in Figure 2 (see next page), mean rated performance increased when moving from Linear to WDRC and then to Adapto for all three goals. A factorial ANOVA revealed a significant (p<. 01) effect of Technology and non-significant Goal and interaction effects.

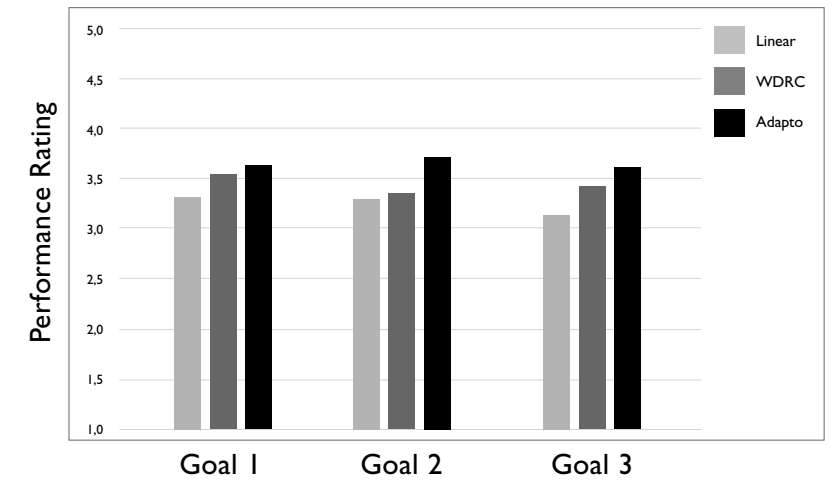


Figure 2: Mean rated COSI Performance on the three most important goals as nominated individually by the patients.

These results show that mean differences from one technology class to another were statistically significant on a consistent basis across all three goals.

Follow-up testing revealed a highly significant (p<. 01) improvement when comparing Linear to Adapto, and also significant (p<. 05) differences when comparing Linear to WDRC and WDRC to Adapto. Basically, as the technology class was increased, the perceived ability to meet the patient's personalized goals were improved.

Word Recognition Performance:

Figure 3 provides the mean word recognition results for the three listening environments for all three technologies. As can be seen, the differences between the technologies became more pronounced as the listening environment became more challenging.

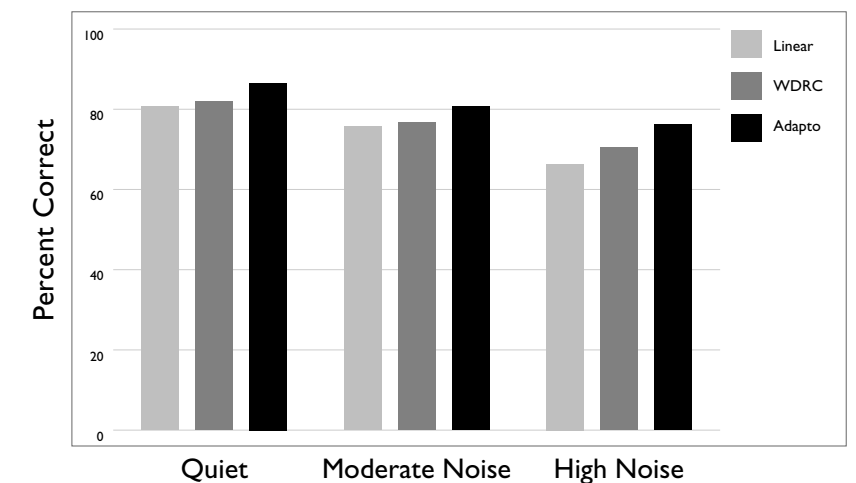


Figure 3: Mean Word Recognition in Quiet, Moderate Noise and High Noise for 50 word lists of the W22 test.

ning task became more difficult. A factorial ANOVA revealed significant ($p < .01$) effects of Level (as would be expected) and Technology, with a non-significant interaction effect. These results indicate, again, that the improvement afforded by higher technology classes was consistent across the test environments.

Situational Ratings:

Figure 4 provides the mean ratings of performance across the ten environments for each of the technologies. As can be seen, in all situations, the mean ratings typically improve when moving from Linear to WDRC and then to Adapto. The differences between Linear and the two non-linear options are most pronounced for the Non-speech, Annoyance and Changing Environments questions. Pronounced differences between WDRC and Adapto exist for the Speech in Quiet and Feedback questions.

A factorial ANOVA revealed significant ($p < .01$) effects of Environment and Technology, with a non-significant interaction effect. These results indicate that although the ratings generally varied from environment to environment, the differences between the technology classes tended to be consistent across the ten situations. Follow-up testing revealed significant ($p < .01$) overall improvements when comparing Linear to Adapto, Linear to WDRC and WDRC to Adapto.

To provide more detail, ANOVAs were conducted for each of the ten situations individually. In all cases, Adapto was rated significantly ($p < .01$) more positive than Linear. In the following conditions, Adapto was rated significantly ($p < .05$) more positive than WDRC: Sound Quality, Speech in Quiet, Speech in a Café or Party Environment, Speech in Traffic and Acoustic Feedback. In the following four conditions, WDRC was rated

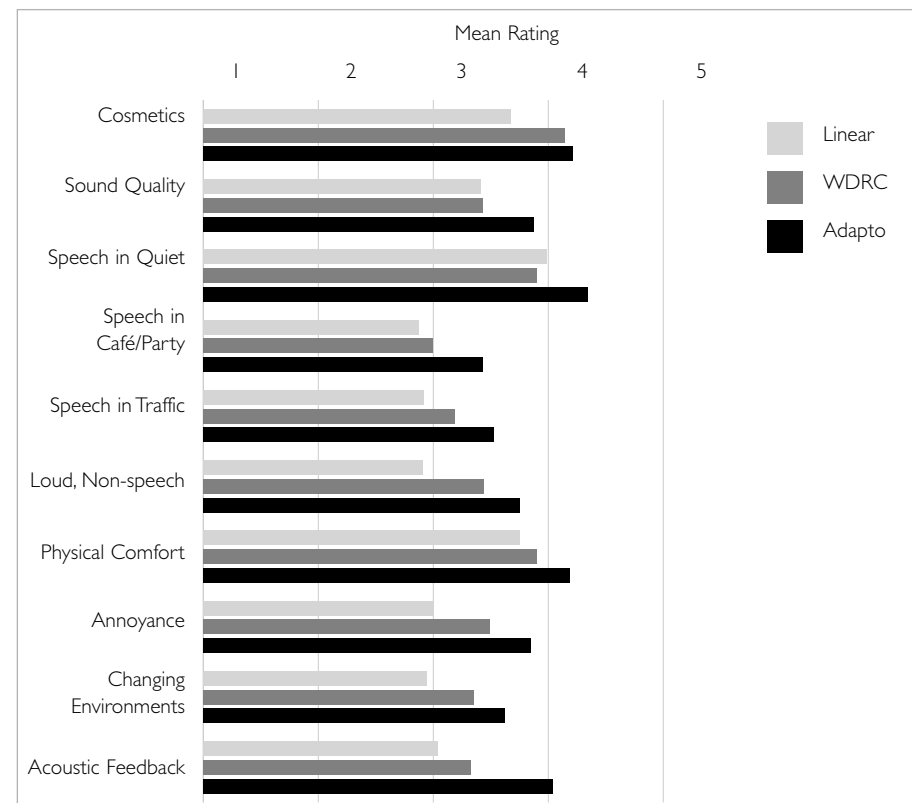


Figure 4: Mean Situational Ratings across ten environments for the three technologies. A rating of 1 indicated "Very Dissatisfied" and a rating of 5 indicated "Very Satisfied".

significantly ($p < .05$) more positive than Linear: Cosmetics, Loud Non-speech Sounds, Annoyance and Changing Acoustic Environments.

Situational Preferences:

The patient preferences across the four listening environments are presented in Figure 5. As can be seen, there is a clear preference for Adapto over the other two technologies in all four environments. The relatively high rate of "No Preference" on the "Physical Comfort" dimension likely reflects the effort to carefully produce all three sets of devices to the same overall size and fit, especially since they were made from the same earmould impression. The fact that Adapto still was selected much more often than either of the other two alternatives likely reflects the additional effect of the larger vent.

For those patients expressing a preference, the rate of selection of Adapto was statistically ($p < .01$) greater than chance in all four environments.

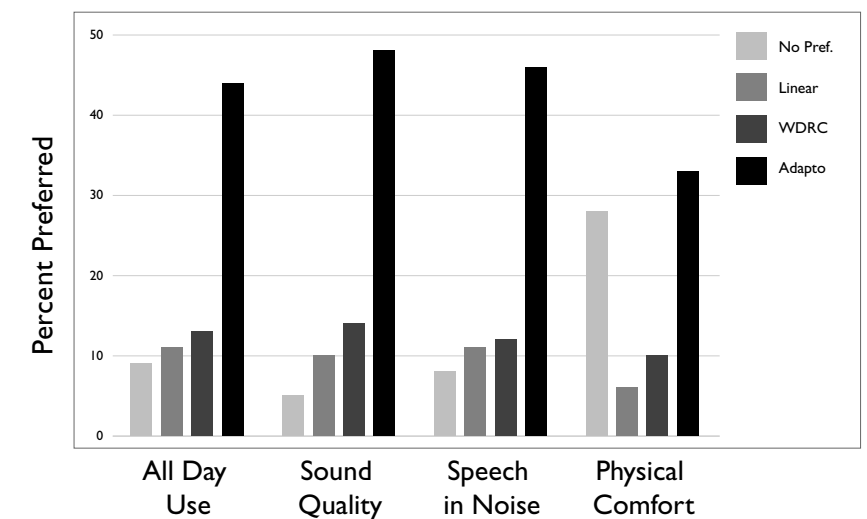


Figure 5: Preference rates for the three technologies across the four listening environments.

Overall Preference:

Figure 6 provides the rate of Overall Preference across the three technologies. ("No Preference" was not an option for this question.) Fifty-seven of the 77 patients (74%) selected Adapto, with 12 of the remaining patients choosing WDRC (16%) and 8 choosing Linear (10%).

The reasons for selection were tabulated. The most common primary reason for selecting Adapto was "Comfort", "Sound Quality" and "Speech Understanding". The reasons for selecting WDRC were not consistent, but the most commonly mentioned reason was "Sound Quality". For those patient selecting Linear, seven of the eight patients mentioned the presence of a volume control as either the first or second most important reason leading to an overall preference. No other reason was mentioned consistently across this small group of patients.

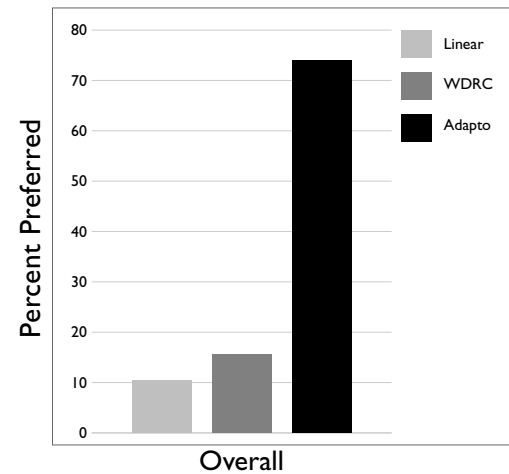


Figure 6:
Overall preference rate for the three technologies.

Volume Control Follow-up Study:

The desire for a volume control by a subset of patients who have had experience with fully automatic instruments has been documented (e.g., Kochkin, 2002). Although these patients represent a minority of the users with advanced technology, it is important to be able to meet such an important, personalized need.

Since the inception of the current study, an updated model of Adapto has been released that included the option of a volume control wheel. Seven of the eight patients who selected Linear as their overall preference have subsequently been refit with a newer model of Adapto with a volume control wheel. The patients were given a new 3-week use period with the volume control model of Adapto. Although this new model is larger than the ITCs used in the main study (typically produced as a half shell), all seven of those patients have changed their preference to Adapto as long as they had the availability of a volume control. Situational ratings and preferences have all consistently been in favor of Adapto compared to Linear despite the original preference for Linear.

New versus Experienced Users:

A variety of analyses were performed to see if the New users provided data that was significantly different than the Experienced users. In terms of Overall Preference, of the New users, 14 chose Adapto, 5 chose WDRC and 2 chose Linear. These proportions are not significantly different than the Experienced users.

On several other performance dimensions such as COSI Performance, Word Recognition, and Situational Ratings, the New users demonstrated, on average, better performance than the Experienced users. However, the New users also had between 5 and 10 dB better hearing in the mid and high frequencies compared to the Experienced users. There were significant correlations between hearing loss and performance on dimensions such as COSI, Word Recognition and Situational Ratings for the group as a whole. Such high correlations are common in studies such as this (e.g., Humes, 2002).

Therefore, the better performance demonstrated by the New users on the performance measures is likely related to their better hearing and not necessarily related to their hearing aid experience.

In general, these results indicate that Adapto appears to be an effective treatment option for those both with no experience and with extensive hearing aid experience. Previous work (Schum & Pogash, 2002) indicated that New users did not appreciate the beneficial effects of OpenEar Acoustics as much as Experienced users (although they still provided very positive ratings about the product overall). However, in the more comprehensive current study, ratings on dimensions such as Physical Comfort and Sound Quality (dimensions that are expected to be positively impacted by large vents) were as positive for New users as for Experienced users. In the previous study, New users were fit only with Adapto, and thus could only compare to the condition of using no hearing aid. In the current study, new users were fit with all three options, so they could compare closed versus open fittings.

Discussion

What conclusions can we draw from this study?

- Primarily, the fact that patients performed significantly better with Adapto compared to Linear on every dimension studied in a blinded design establishes without question the superiority of the advanced digital design of this product.
- Adapto outperformed WDRC on several key dimensions (i.e. overall preference, easiest to use all day, physical comfort, acoustic feedback, various measures of speech understanding in noise), indicating that **Adapto combines both the general benefits of non-linear sound processing with the unique advanced features of OpenEar Acoustics, VoiceFinder and Client-Focused Fitting.**
- Patients experienced specific advantages when using WDRC compared to Linear (i.e. Speech understanding, acceptability of loud, non-speech signals, acceptability in changing acoustic environments), re-affirming the well-known general advantages of multi-channel, non-linear processing.

Several other specific observations should be made. First of all, several design features were included to minimize the effects of bias. Basically, the patients were provided with three new sets of hearing aids. There was no indication of differences in technology. All three sets were programmable and they were all built to a similar size. All of the clinicians who performed the fittings were familiar with all three models used in the study. Importantly, not only were measures of side-by-side preference made (Situational Preferences, Overall Preference), but the COSI, Word Recognition and Situational Ratings were performed independently for each technology.

In other words, patients did not have access to their ratings from the first device used when providing ratings for the second or third set. Any mean differences between technologies are that much more robust. The ability to institute a blinded design in a clinical study using actual production units is infrequent in the literature. However, that level of control allows the reader to have confidence that the results obtained are a true reflection of the patient experiences with these different technologies.

There is no Gold Standard outcome measure for hearing aid investigations. Although our field has traditionally favored objective speech recognition testing, there is no evidence to suggest that this particular measure is more relevant or valid than any other. Due to this lack of an agreed upon standard, this study used a variety of outcome measures. The fact that the ranking of technologies was extremely consistent across this wide variety of measures is strong evidence that there are true advantages for patients of the more advanced options.

A unique feature of this study was the use of the COSI as an outcome measure. Although this tool has gained widespread acceptance as a clinical tool, its use as a research tool has been limited. However, use of this tool has allowed us to demonstrate, compared to traditional Linear technology, the effectiveness of WDRC and especially Adapto at meeting patients' **individually stated needs**. This result can be especially important in the mind of future hearing aid users who are considering obtaining advanced technology devices: patients in this large scale study felt that these advanced technology options were particularly beneficial from **their own point of view**.

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Appendix A: Situational Rating Questionnaire

Performance Questionnaire

Patient Name: _____

Hearing Aid - *please circle one*

Linear WDRC Adapto

Listed below are various performance measures. Please circle the number that best represents your answer for each question. Your answers are to be based on the hearing aid that you are currently wearing.

Question	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
1. Cosmetics	1	2	3	4	5
2. Overall Sound Quality	1	2	3	4	5
3. Understanding Speech in Quiet	1	2	3	4	5
4. Understanding Speech in Café/Party Environment	1	2	3	4	5
5. Understanding Speech in Traffic Noise	1	2	3	4	5
6. Acceptance of Loud Non-Speech Signals	1	2	3	4	5
7. Physical Comfort	1	2	3	4	5
8. Reduction in Day-Long Annoyance	1	2	3	4	5
9. Performance in Changing Sound Environments	1	2	3	4	5
10. Transient Feedback	1	2	3	4	5

Appendix B: Situational Preferences Questionnaire

Overall Assessment

Patient Name: _____

Please provide which hearing aids you prefer for the following situations. In other words, for that situation, which device(s) allowed for better performance.

1. Physical comfort

First set second set third set no preference

2. Easiest to use all day

First set second set third set no preference

3. Overall sound quality

First set second set third set no preference

4. Speech understanding in noise

First set second set third set no preference

5. Overall preference

First set second set third set

Please list the three most important factors, in order of importance, which led you to your overall preference decision:

1. _____

2. _____

3. _____

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