FIELD TEST OF AN OCCLUSION-FREE HEARING INSTRUMENT

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It is well-known that freedom from occlusion is a high priority issue for many hearing aid users. A primary complaint of those fit with conventional hearing aids is that their own voice sounds boomy, hollow or muffled due to the effect of occluding the ear canal. This is particularly problematic for patients with hearing losses in the high frequency range, and can in fact be so annoying for the wearer that it may outweigh the benefits of amplification. It is common practice in hearing aid fitting to alleviate the occlusion effect by increasing the openness of the hearing aid fitting through venting of the earmould or hearing aid shell. However, this increases the likelihood of acoustic feedback, which severely limits the amount of high frequency gain available for the fitting. Consequently, one of the main challenges in the acoustic design of hearing instruments is to achieve the highest degree of openness even for high frequency losses where significant amplification is needed in the high-frequency range.

There is clearly a high market potential for products that combine an occlusion-free solution with the ability to provide sufficient high frequency gain, which is reflected in the current hearing aid market. Various manufacturers offer hearing aids or signal-processing strategies specially designed for high-frequency hearing losses while attempting to provide the maximum possible degree of openness. However, no product has yet been introduced which does not involve some trade-off in either high frequency gain or degree of occlusion. Thus, patient needs in this area remain unfulfilled. A novel entry to this product group is the ReSoundAIR hearing system from GN ReSound, which we have had the opportunity to test in the laboratory and in daily use in an extensive field study. A report of this practical test follows.

Test hearing instruments

The test device in this study was an occlusion-free hearing instrument. This system *(Figure 1)* is characterized by an innovative acoustic coupling to the ear canal and a particularly small, light and easy-to-wear case.

Figure 1.
The tested occlusion-free hearing instrument with the complete acoustic tubing and coupling system.

The novel acoustic tubing and coupling system *(Figure 2)*, which consists of an extremely thin sound tube and a special silicone ear plug, is snapped onto the BTE housing as a single unit and can therefore be easily replaced. As *Figure 2* shows, the silicone dome of the ear plug has multiple vents like a sieve *(cf. Figure 2)*. This makes it acoustically transparent and ensures great comfort when the device is worn. The acoustic tube is available in three different lengths from where it attaches to the case to where it bends into the ear canal. Moreover, 2 insertion depths for the ear canal portion are available. Combined with the 2 diameter options for the silicone dome, hearing aid dispensers have a total of 12 options per ear at their disposal.

Figure 2.
The innovative acoustic tubing and coupling system, consisting of a connector to the hearing instrument (left), extremely thin tubing (centre) and open silicone ear plug with flexible supporting strip (right).

In addition, the coupling system has a flexible plastic strip attached, which is placed in the concha to give better retention of the acoustic tube in the ear canal. This novel form of acoustic coupling allows an occlusion-free, open fitting, which has the added bonus of being virtually invisible on the ear.

The acoustic effect thus achieved is supplemented and supported by the instrument's signal-processing algorithms, which have been specially optimized in terms of high-frequency gain and reduction of feedback. The signal processing is characterized by the following elements:

- fast signal processing to avoid interfering phase effects due to combination of the processed sound and the direct incoming sound
- frequency-specific fine-tuning of the frequency response with frequency resolution equivalent to the 14-band compressor utilized in the manufacturer's other digital products
- fast-acting, low distortion WDRC in three bands, to provide suitable input level dependent gain
- expansion for suppression of noise at low input levels, as candidates for this device have normal or near-normal hearing in some regions
- adaptive digital feedback suppression through the addition of a reverse phase signal to the input signal, providing more feedback-free real ear gain that is needed for fitting high frequency hearing losses with a non-occluding device
- fast-acting modulation-based noise reduction in 3 bands

Test subjects

Seventeen experienced hearing aid users with sensorineural high-frequency hearing loss took part in the trial. The pure-tone audiometric selection criterion (highlighted grey in Figure 3) included a maximum hearing loss of 30 dB up to 0.5 kHz and 40 to 80 dB in the high frequency range (3 to 8 kHz). *Figure 3* shows the mean air and bone conduction hearing losses pooled for all left and right ears from 0.25 to 8 kHz, as well as the mean Ucomfortable Loudness Levels (UCL) in the frequency range from 0.5 to 4 kHz. The pattern of the mean hearing and UCL's show recruitment consistent with cochlear hearing loss.

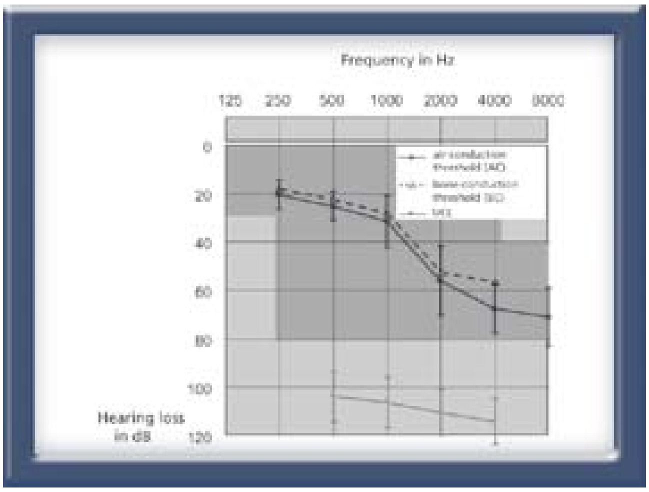

Figure 3.
Air and bone conduction hearing threshold levels together with UCL's pooled for both ears of the 17 test subjects (average ± standard deviation). Inclusion range shaded grey.

At the start of the test, 9 of the 17 subjects were using BTE instruments fit binaurally with open earmoulds while the remaining subjects were using ITE or ITC hearing aids on both ears.

Test procedures

Subjects participated in 5 separate sessions over the course of 10 weeks. In the first session the case history was taken, otoscopy was performed, audiograms were measured and ear impressions were taken. The ear impressions served to document the shape of the ear canal, so that this could be included in later analyses. As described in the introduction, custom made earmoulds are not needed for this product. A questionnaire based closely on the "Glasgow Hearing Aid Benefit Profile (GHABP)" by Gatehouse (1999) was also given to the test subjects to fill out at home in relation to their own hearing aids.

In the second session, the completed questionnaires were collected and reviewed with the subject for completeness. Then the test hearing aids were fitted on both ears according to the manufacturer's fitting rule ("Audiogram+"), fine-tuned if needed using systematic paired comparisons, and then the gain setting was documented by means of probe microphone measurements. During the fitting session, the digital feedback suppression system was individually calibrated and activated. The test subjects were then given the opportunity to use the test hearing instruments with this setting over a test period of approximately two weeks. The test subjects were instructed to wear the test instruments as regularly as possible and during the whole day.

If required, further fine-tuning was carried out at the beginning of the third session; however, this was only necessary in a few cases. Then the Oldenburg sentence test (Wagener et al., 1999 a-c) was administered in continuous 60 dB SPL speech-shaped noise both for the subjects' own and the test hearing instruments, and the SNR for 50% speech recognition (SRT: Speech Recognition Threshold) was determined. In addition, the modified GHABP questionnaire was again handed out, with instructions to fill it in for the test hearing instrument over the following four-week test phase.

At the fourth session, the GHABP questionnaire with the assessment of the test hearing instruments was collected and completed as necessary. If required, fine-tuning following acclimatization was carried out and documented. Finally, subjects were given a questionnaire designed to assess practical handling of the test instruments in everyday use.

After a further four-week period of wear time, the final evaluation took place. This included the following items:

- collection of the every day use questionnaire and completion when necessary
- probe microphone measurement of the final insertion gain curves for input levels of 50 and 80 dB.
- subjective assessment of the hearing aid performance in terms of speech compehension, sound quality, own-voice perception and loudness of the test instruments. For this purpose the test subjects assessed well-defined real life listening situations, known in our laboratory as the "Giessen Walk".
- measurement of the maximum stable gain without feedback. To do this the overall gain of the test instruments was increased in the linear mode in 1 dB steps until shortly before the onset of feedback.

Results of the study

Speech audiometry

The results of the Oldenburg sentence test are shown in *Figure 4* for both the subjects' own and the test hearing instruments. The subjects performed significantly better on this task with the test hearing aids than with their own hearing aids. The mean signal-to-noise ratio at the subjects' individual SRT was -2.5 dB with their own devices and -5.1 dB with the test devices, which represents a mean improvement of 2.6 dB with the test devices. What does this improvement mean for the hearing aid wearer? For normal hearing individuals, an improvement in the signal-to-noise ratio of only 2.6 dB would result in an improvement in speech recognition of nearly 45%. Taking hearing loss into account, a more realistic estimate would be an approximately 20% increase in speech recognition with the test devices, which can still be considered a notable benefit.

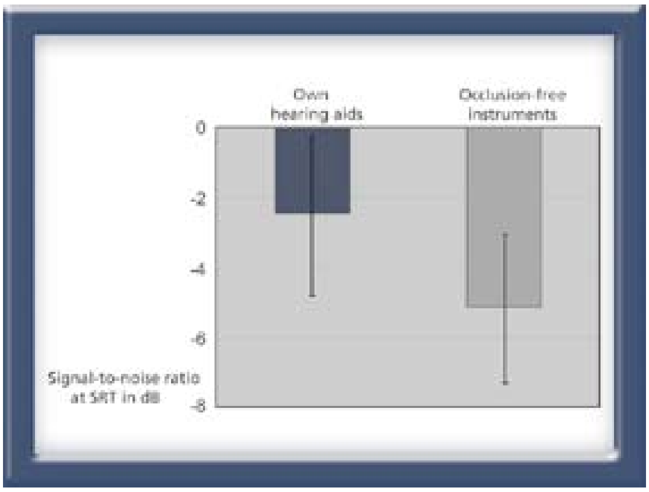

Figure 4.
Results of the Oldenburg sentence test for the test hearing instruments compared with the subjects' own hearing aids. The plot shows the signal-to-noise ratio for 50% speech recognition (average ± standard deviation).

Maximum stable gain and occurrence of feedback
Measurement of the maximum stable gain without feedback confirms that the digital feedback suppression system that has been implemented enables on average some 10 dB higher gain than without this algorithm. We also observed that about 1/3 of the ears in this study exhibited feedback at the target gain settings without the feedback suppression active, while there were very few instances of feedback with the feedback suppression active. The clinical implication of this observation is that the feedback suppression processing is not just nice-to-have, but absolutely critical for this device. Without it, the limitations in usable gain could be expected to severely limit the application area. Note that in the commercial version of the test instrument, the feedback suppression is always active.

Subjective assessment
In the subjective assessment, the test hearing instruments scored especially well. The results of the modified GHABP questionnaire show lower perceived hearing disability in critical listening situations and considerably higher benefit and satisfaction compared to the subjects' own devices.

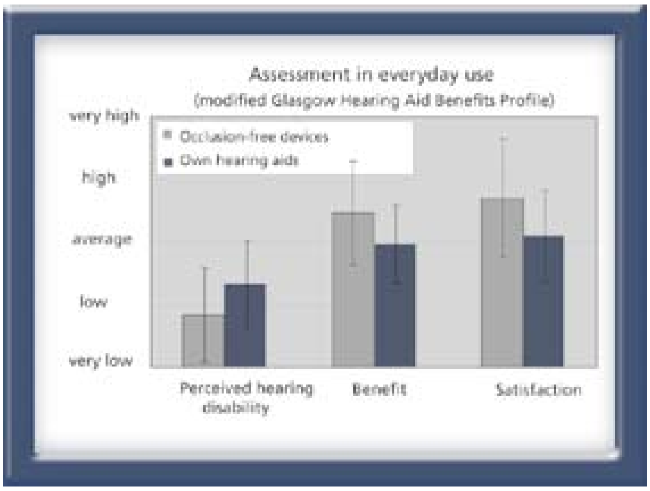

Figure 5.
Results from the modified Glasgow Hearing Aid Benefit Profile (GHABP) for the test hearing instruments compared with the subjects' own devices. The plot shows average results (± standard deviation) for all 17 test subjects and all listening situations (pre-defined and individual).

The product-specific advantages of the non-occluding hearing aid are particularly evident in the responses to the questionnaire on practical handling in daily use *(Figure 6)*. Overall, insertion of the test hearing instruments, battery replacement and handling were judged to be similar to the subjects' own devices, whereas the absence of occlusion is rated as extremely high for the test hearing instruments. Comfort and design of the test devices are also rated distinctly higher than the subjects' own hearing aids; ultimately, this is reflected in a clearly better overall assessment. The absence of occlusion and the high level of comfort are not only expressed formally in the questionnaires, but were repeatedly mentioned by subjects as positive attributes during informal conversations.

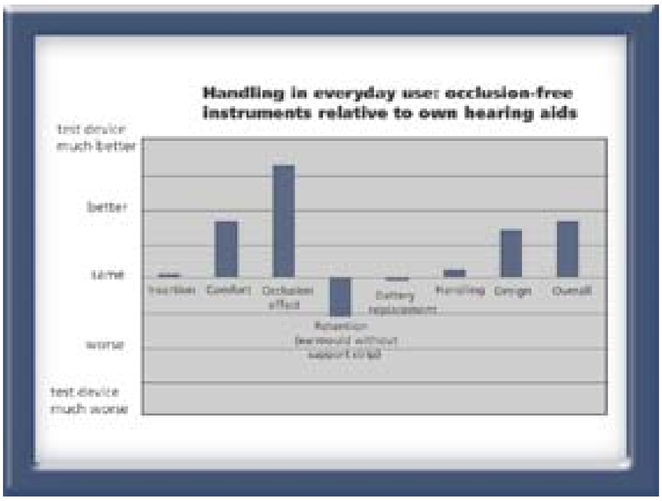

Figure 6.
Averaged results for the assessment of performance characteristics in routine use for the test hearing instruments relative to subjects' own devices.

As can be seen in *Figure 6* the one item on which the subjects' own hearing aids are rated slightly better than the test devices is in terms of retention in the ear canal. In response to this, the acoustic coupling system of the test hearing instrument was equipped with the supporting plastic strip shown in *Figure 2*. Two of our subjects who had experienced significant difficulties with retention of the test devices in the ear canal were given sound tubes with this additional supporting strip to try for several weeks. Following this modification, these subjects stated that the initially reported retention problems had been resolved.

The "Giessen Walk" was carried out with each subject at the final session, at which time the subject had been wearing the test devices for about 10 weeks. During the "Giessen Walk", test subjects were accompanied by the experimenter as they visited real listening situations (sound-treated test booth, room with normal acoustics, room with a high degree of reverberation, and a busy street) and assessed the performance of the hearing instruments in terms of the following aspects: loudness, speech comprehension, sound quality and perception of own voice. Subjects were asked to assign an absolute quality judgment for each of these aspects in each listening situation. As *figure 7* shows, the test hearing instruments were ranked on average as "good" in all of the listening situations and all of the aspects queried. The spread of ratings was very small. In fact, no negative ratings ("poor" or "very poor") were ever assigned by any of the subjects in any of the listening situations. This is a particularly surprising finding, considering the unfavourable listening conditions under which the device was judged. It is rare for listeners to assign equally positive judgements of sound quality and speech intelligibility for both noisy listening situations as well as quiet ones. This positive result also applies to the loudness of the test hearing instruments, which have no volume control. The loudness was judged on average to be "just right". These results are not shown in *Figure 7* because different assessment categories had to be used for judging loudness.

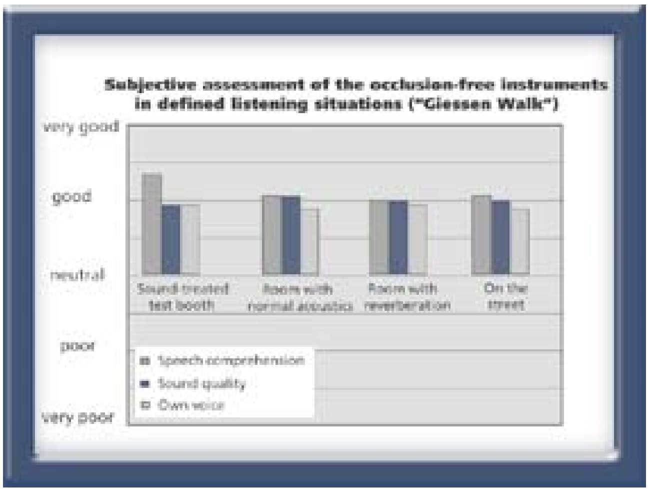

Figure 7.
Averaged results of the subjective assessment (speech comprehension, sound quality, perception of own voice) for the test hearing instruments in defined listening situations included in the "Giessen Walk".

Summary

The 10-week field trial of the occlusion-free hearing aid on 17 test subjects with severe high-frequency hearing losses showed that this new type of hearing aid is exceptionally well received by users. This is supported not only by the objective data (speech audiometry, insertion gain measurements and maximum stable gain measurements) and the subjective evaluation (various questionnaires) but also by the informal comments of the test subjects. Features rated especially positively by the test subjects were the open nature of the hearing instrument, the transparent acoustics associated with this, the high degree of comfort when wearing the instrument, and the innovative design. Some subjects indicated problems with retention of the test device in the ear canal. These were satisfactorily resolved with the addition of the supporting plastic strip to the sound tube.

The assessment of new hearing aids by test subjects is inevitably biased by a "novelty bonus" when the trial cannot be conducted as a blind study. Even so, the results reported here may still be regarded as extremely favourable for the test device. It is therefore not surprising that most of the test subjects preferred the test hearing instruments over their own devices. Several of them reported that they would have purchased the test hearing instruments if they had been on the market at the time of the study. In one case there was such great interest in the new device that the test subject explored all information sources available (Internet, his hearing aid dispensers, the manufacturer) in an attempt to obtain the occlusion-free device at the earliest opportunity.

The majority of the test subjects found that the test hearing instrument afforded sufficient gain for their personal amplification needs without feedback provided the digital feedback suppression feature was active. Approximately 1/3 of the ears in this study could only be fit with this open device because of the digital feedback suppression processing. In cases with an excessively high amplification requirement, the gain in the high-frequency range had to be somewhat reduced compared to the manufacturer's proposal to keep away from the feedback threshold and achieve sufficient acoustic stability. In light of this fact, it may be advisable to limit the fitting range to about 70 dB HL (cf. *Figure 3*) for the frequencies above 2 kHz, and fit subjects with more severe high-frequency hearing losses with systems that are less vented, but also less prone to feedback.

In sum, this occlusion-free instrument allows patients with high frequency hearing loss to enjoy the benefits of amplification without the occlusion-related drawbacks. In comparison with the options which have been available until now, this solution gives dispensers a unique and effective alternative for open-ear fittings of patients with high-frequency losses.

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