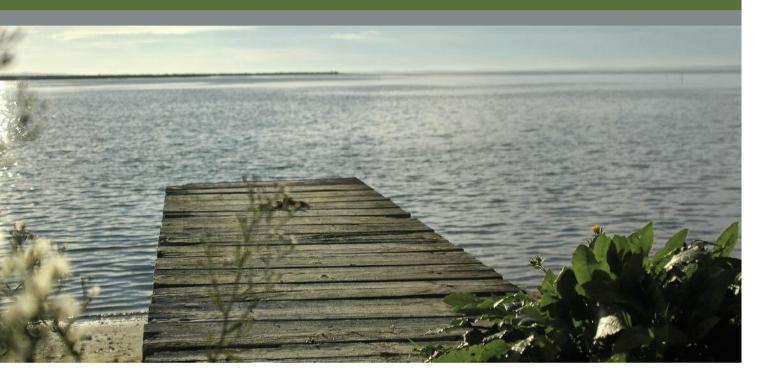
Open Fit - Custom CIC as a valid alternative to a microStyle BTE



The increase in popularity of "mini" and "micro" behind-the-ear (BTE) devices has been due, in part, to the effective combination of style and substance that appeals to a new generation of hearing aid users. A recent survey by Kochkin (2006) for the Better Hearing Institute indicates that slim tube, "open" fit devices have increased the number of first-time hearing aid users by 29%, lowering the average age of new users by nearly a decade in the process. In the US market in particular, which for several decades has been dominated by custom instruments, these devices have fueled large gains in BTE sales overall, which now comprise roughly one-half of the total number of instruments dispensed in the US. Of this amount, about 20% are "mini" or "micro" BTE devices.

This dramatic growth has come largely at the expense of larger in-theear (ITE) devices. However, completely-in-the-canal (CIC) devices have remained relatively stable at 10% of the total instruments sold. Although BTEs dominate most European markets, a German study by

the Akadamie für Hörgeräte-Akustik reports that 80% of customers entering a hearing instrument clinic actually would like to get an invisible CIC hearing instrument even though most leave with a BTE. Clearly, many consumers prefer the cosmetic advantages and ease-ofuse of small custom devices. Furthermore, although directional microphones are not practical for use with CICs, preservation of pinna and concha resonances provides directional benefits comparable to those with the unaided ear (Roberts and Schulein, 1997). Historically, CICs have enjoyed limited success with high-frequency losses due to feedback, occlusion, and gain restrictions. Recent technical innovations, however, have addressed these shortcomings, providing hearing aid users with a choice of CIC or BTE solutions for "open" hearing aid fittings. Exélia CIC Petite introduces a new Acoustically Optimized Venting (AOV) system which, combined with WhistleBlock Technology, provides reduced occlusion and feedback along with superior sound quality when compared to other commerciallyavailable devices, offering a viable alternative to open fit micro BTEs.

Open fittings

"Open" hearing aid fitting strategies have existed for decades, using large vents to minimize occlusion in patients with normal low-frequency hearing sensitivity. However, difficulty providing high-frequency audibility without feedback compromised the success of early systems. The development of real-time feedback phase inversion systems for use with digital hearing aids has dramatically improved this situation, particularly for the current generation of "mini" and "micro" BTE devices, which permit larger vent sizes and separate the hearing aid microphone and receiver more than in-the-ear (ITE) devices. This factor, in combination with aging "baby boomers", who are beginning to feel the impact of their "rock and roll" lifestyles with noise-induced and presbyacusic hearing losses, has led

to considerable increases in BTE sales. This growth is largely thanks to micro BTE devices. A survey by the Better Hearing Institute (BHI) explored the reasons for the increased popularity of micro BTE devices, in particular. Consumers and clinicians alike listed minimal occlusion and reduced feedback as primary reasons for improved outcomes in comparison with other devices (Figure 1).

Optimization of venting parameters, continued improvements in feedback cancellation algorithms and further miniaturization of hearing aid components now provide the potential for open fittings in small custom devices, which are favored by many patients for cosmetic, ease-of-use, and performance reasons.

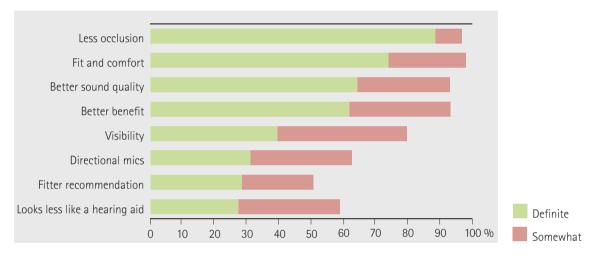


Figure 1:
Top reasons for fitting open-fit BTE hearing aids (Kochkin, 2006).

Individualized venting

With the new Exélia CIC Petite, Phonak introduces Acoustically Optimized Venting (AOV). AOV uses vent mass information as it applies to the total acoustic sound performance of the hearing instrument. An acoustic mass describes the effect of the vent on the acoustical response of the hearing instrument. The amount of sound that escapes through the vent depends not only on the vent diameter but also the length and shape. The same acoustic mass can be achieved with very different dimensions; a small vent area with a long tube can be equivalent to a large vent area with a short tube. Acoustically Optimized Vents can only be achieved through a combination of highly integrated 3D digital instrument modeling, production and fitting systems. A variety of data is used to calculate a "target" vent mass value including the patient's audiometric data, needed gain in the high and low frequencies, potential for occlusion, potential for feedback, etc. This information is used by Phonak's 3D shell modeling software in a multi dimensional calculation to produce a weighted target mass value. This target value is then used to model the AOV. The vent style (e.g. circular, D-shape, IROS, inverse IROS, discontinuous D-Shape), the diameter and the overall length can each be manipulated

independently by the modeler in order to achieve the calculated target mass value. Several new advanced venting designs have been developed such as the "discontinuous D shaped inverse IROS vent" which maximizes the total size of the vent using a varying cross sectional area while simultaneously optimizing the space available within the shell for component placement. This process, exclusive to Phonak, helps guarantee the smallest possible instrument size with the largest possible vent needed for the patient's specific hearing loss.

The resulting actual acoustic mass value can then be stored and electronically transferred to the instrument in the final stages of the production process. The AOV value is used by the fitting software to optimize vent compensation in the fitting calculation, which will affect the frequency shaping, feedback canceller setup and other fine tuning parameters to deliver an ideal insertion gain and natural sound quality. The ultimate result of all this technological advancement: Truly customized venting offering the smallest possible instrument with the best possible vent.

Laboratory and real world investigation

A study was conducted to investigate a series of laboratory and realworld conditions that compare the effectiveness of micro BTE and CIC styles for open fittings, specifically investigating 4 key issues:

Occlusion management

through the use of acoustically optimized venting. Typically, this means use of as large a vent as possible, but it also reflects the interplay between vent acoustic mass, representing vent diameter, length, volume and rated occlusion. Kiessling et al. (2005) reported that acoustic mass is directly related to reported occlusion by hearing aid wearers. Vent mass is an essential factor relating to occlusion, but it is not possible to optimize vent size without small components, optimal placement and reliable digital shell manufacturing techniques. This is made possible in modern hearing aids largely via digital circuitry and digital shell production.

Feedback prevention

Modern feedback phase inversion systems provide added stable gain (ASG) beyond what is available when the algorithm is not active. As stated above, however, the interplay between audibility and ASG should be evaluated in-situ to ensure speech audibility for different vocal efforts.

Audibility

Early open fit instruments reduced the potential for feedback by reducing high-frequency gain, which in turn impacted speech intelligibility for high-frequency fricative and sibilant consonant sounds. Effective open fit systems must not sacrifice audibility – particularly in the high frequencies – in order to prevent feedback when large vents are used.

Smooth frequency response

via appropriate "acoustic matching" between the in-situ hearing aid response and the residual ear canal volume, reflecting the impact of tubing resonances, vent volume, length, and diameter, and the impedance of the ear and hearing aid receiver. Hearing aids that minimize resonant peaks will provide higher sound quality and speech intelligibility than systems that do not take these factors into account (Davis and Davidson, 1996; van Buuren, Festen and Houtgast, 1996). In open fit devices, lack of proper acoustic optimization can also lead to increased feedback.

The study asked several important questions:

- Can occlusion and feedback be reduced in CIC instruments to comparable levels for micro BTE devices for typical open fit candidates?
- Will state-of-the-art feedback management provide effective performance in combination with speech audibility for varying speech input levels?
- Will acoustic optimization of hearing aid parameters combined with improved feedback cancellation provide user benefits, in terms of occlusion, in-situ frequency response, sound quality and speech intelligibility?

Laboratory assessment of a new feedback cancellation algorithm

The primary difference between present and past open fit devices relates to prevention of feedback under real-world conditions. As such, the technical performance of any system should be compared to benchmark data to determine the potential for success. Freed and Soli (2006) and Merks et al. (2006) have suggested an approach that uses

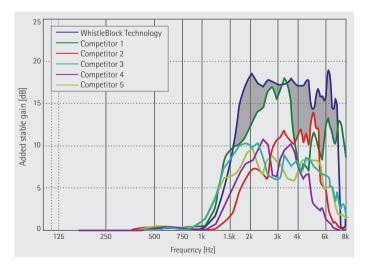


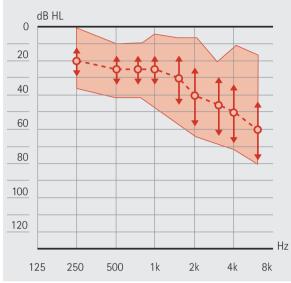
Figure 2: Added Stable Gain (ASG) measures as a function of frequency for six different commercially available open fit hearing aid systems.

"added stable gain" (ASG) as a measure of technical performance, using an artificial head placed in a sound treated box with a linear motor to move an object reproducibly close to the ear and the hearing instrument. This allows for a realistic simulation of different feedback conditions. Using this type of test set-up, the performance of a new feedback cancellation system (WhistleBlock Technology by Phonak) also used in a new open-fit CIC device (Exélia CIC Petite) was compared to existing commercial products in terms of ASG. ASG calculates how much more gain may be applied with the feedback canceller turned on versus feedback canceller turned off. Figure 2 illustrates ASG measured for six different hearing instruments. All instruments were equalized to produce the same amount of gain. Figure 2 illustrates that Phonak's WhistleBlock Technology provides significantly more added stable gain than benchmark systems used for open fit hearing aids, particularly for the important range of frequencies between 1500 and 3000 Hz (e.g. 16.7 dB versus 13.8 dB for Competitor 1).

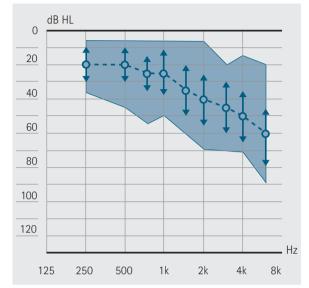
Clinical assessment of Phonak's new open Exélia CIC Petite

Subjects

Twenty-six (16 male, 10 female) hard-of-hearing patients served as subjects. Average age was 65 years, and the majority were previous hearing aid users. All were typical candidates for open fitting; average audiometric thresholds are presented in Figure 3.







Hearing Instruments

Each subject was fitted binaurally with three sets of hearing instruments:

- 1. Exélia CIC Petite with Acoustically Optimized Venting (AOV)
- 2. Savia Art CIC with IROS venting
- 3. microSavia Art CRT with Open Dome Tip

The hearing aids were programmed using each subject's audiometric thresholds input into iPFG V2.0 software to meet NAL-NL1 prescriptive targets. Subsequently, real-ear measurements were made to evaluate speech audibility for soft (50 dB SPL) and moderate (65 dB SPL) recorded speech for a male talker (carrot passage), and to ensure that loud sounds (85 dB SPL MPO sweep) did not produce loudness discomfort. Speech Intelligibility Index (SII) measurements were computed for each instrument for the 50 and 65 dB SPL conditions, to evaluate the degree to which each system provided speech audibility for real-world stimuli. The SII is an updated metric derived from Articulation Theory that uses one-third octave band-weighted calculations of speech audibility, taking into consideration the speech and noise levels in a listening environment, degree of hearing loss and the degree to which sounds have been amplified by hearing aids in the test condition. SII includes level distortion effects that may occur with amplified sound, so it is ideal for predicting benefit with hearing aids. The SII has proven to be a very robust measure for predicting

performance for both normal-hearing and hearing-impaired persons in a variety of listening environments. In addition to real-ear measurements, subjects evaluated the effectiveness of the feedback cancellation system for each device under three conditions:

- 1) When the feedback test was not performed
- 2) When the feedback test was run with the instrument in a 2-cc coupler
- 3) When the feedback test was run in-situ using the iPFG fitting software

For each condition, both ears were tested for the presence of feedback under "dynamic" listening conditions by slowly moving the subject's left or right hand in a parallel plane from the pinna, beginning at 12 inches (30 cm) and moving until feedback occurred. The hand-to-ear distance (in inches) when feedback occurred was recorded binaurally for all three hearing aids. In addition, for each condition, subjects listened to two music passages and subjectively rated them for sound quality and the presence of entrainment. Finally, each subject wore the Exélia CIC Petite devices with AOV for a period of two weeks, after which they completed a subjective questionnaire regarding the benefits in terms of sound quality, speech intelligibility, occlusion and feedback.

Results

Occlusion

Results indicate that subjects wore the hearing instruments an average of 9.5 hours daily, for a total of 155 hours use. Subjects responded to an initial fit questionnaire after being fit with each of the three devices. Average subjective occlusion ratings for Exélia indicated superior sound quality and loudness of their own voice, in comparison to Savia Art CIC and microSavia Art CRT. 20 out of 26 subjects rated Exélia as comparable to or better than Savia Art CRT. In addition, questionnaire data were obtained from the subjects after a two-week trial period with the Exélia CIC Petite AOV devices. Excellent subjective performance was reported for speech intelligibility in quiet and in noise, for the loudness and sound quality of their own voice, and for overall satisfaction.

Feedback

For all three hearing devices, optimization of the feedback cancellation system via in-situ feedback measurement resulted in NO feedback for static listening conditions. The results of the "dynamic" feedback test revealed a statistically significant improvement for Exélia CIC Petite AOV versus the Savia Art CIC and CRT devices, as shown in Figure 4. Feedback occurred with the subject's hand moving towards his/her ear at an average distance of 0.21 inches with Exélia, while both Savia Art models produced feedback at an average distance in excess of 0.5 inches.

Audibility calculations

All three devices evaluated in this study feature multiple-channel compression and wide-band output transducers. As a result, it is not surprising that calculated SII were similar. As with all wide dynamic range compression (WDRC) systems, feedback is most likely to occur for soft inputs, so the fact that average calculated SII were greater for Exélia CIC Petite AOV (0.55) than for Savia Art CRT (0.48) suggests that the improved feedback canceler provided increased audibility for soft sounds (Figure 5). In fact, for 22 of 26 subjects, calculated SII were greater for the Exélia CIC Petite AOV than for the Savia Art CRT for the 50 dB SPL aided speech condition. The combination of improved audibility for soft speech and comparable subjective occlusion values suggests that acoustically optimized venting in combination with effective feedback cancellation provides a favorable outcome for Exélia CIC Petite with open fittings.

Smoothness of Real-ear Aided response (REAR)

A modification Frequency Response Smoothness Quantification Index (FReSQI) developed by Schultz et al. (1992) was used which determines the irregularity of hearing aid frequency responses by computing the "error" between the REAR and a second order polynomial computed between the selected low- and high-frequency cutoff. Using this measure, the computed FReSQI values were lower, indicating a smoother response for Exélia CIC Petite AOV (15.1) than for either the Savia Art CIC (26.1) or Savia Art CRT (25.2).

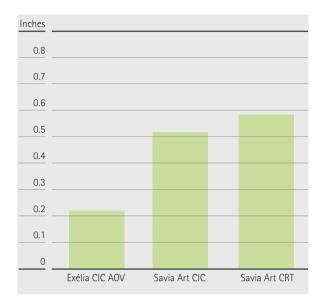


Figure 4:
Average distance at which feedback occurred for the "dynamic" feedback measure, when subjects moved their hand in a parallel plane towards the ear, beginning from a distance of 12 inches until feedback occurred or they touched the ear.

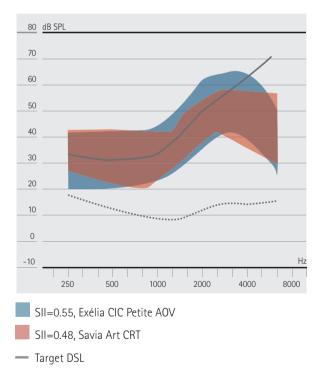


Figure 5: Average amplified speech values and SII calculations for Exélia CIC Petite with AOV (blue) and Savia Art CRT (red).

Conclusions

In response to the experimental questions, the findings of the present study indicate that acoustic optimization of venting and hearing aid parameters provide smoother in-situ responses that relate positively to user benefits in terms of occlusion, sound quality and speech intelligibility. In addition, occlusion and measured feedback with the Exélia CIC Petite with AOV were reduced relative to that observed with the Savia Art CRT micro BTE device for typical "open fit" hearing aid candidates. Finally, Exélia's improved feedback management system resulted in improved feedback cancellation for "dynamic" listening conditions while also assuring improved audibility for soft input speech levels.

In summary, effective performance with open fit devices depends on:

- 1. Occlusion management
- 2. Prevention of feedback for static and dynamic listening conditions
- 3. Audibility for soft speech and other sounds
- 4. Smooth in-situ frequency response

Exélia CIC Petite with Acoustically Optimized Venting, digital shell manufacturing techniques and WhistleBlock Technology achieves these objectives offering a prescription for success and providing patients with a valid open fit alternative to micro BTE devices.

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