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Does microphone location affect speech understanding? A comparison between Zerena BTE and ITE hearing instruments.

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With respect to the location of the microphone when worn in the ear, the in-the-ear (ITE) hearing aids should give as good as or better speech understanding than the behind-the-ear (BTE) hearing aids. A study was made with 17 hearing-impaired subjects using speech testing to compare the performance of the hearing aid styles. Speech was measured using the Oldenburg Speech Test and the Göttingen Speech Test in three conditions: unaided, aided with the BTE, and aided with the ITE. The ITEs were found to be not inferior to the BTEs, and there were no significant differences between the speech scores of the hearing aid styles.

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Introduction

In 2017 Bernafon released the Zerena hearing aid family onto the market with a new chip capable of more memory and faster processing. The new chip facilitated the addition of original technology and the introduction of features including Dynamic Environment Control System™ (DECS™), the Dynamic Range Extender, and wireless connectivity capabilities. DECS™ allows your clients to listen effortlessly in changing environments without waiting for the hearing aid to catch up to the situation and without hearing the artifacts caused by late automatic changes. Four features work together to comprise DECS™ and provide proactive, constant changes to the amplification system in response to the listening environment. Continuous Environment Detection monitors the listening environment in real-time by processing 32,000 data points per second. Dynamic Noise Management™ removes noise without adversely affecting speech using a combination of the highly sensitive Dynamic Directionality and ultra-fast Dynamic Noise Reduction. While Dynamic Amplification Control™ measures the long- and short-term signal-to-noise ratio (SNR) that tells the Dynamic Speech Processing™ the correct amount of amplification to accurately apply. The Dynamic Range Extender ensures that music and loud sounds are amplified more naturally without clipping or distortion, and wireless connectivity options set your clients free from interfaces worn around the neck to stream sound from their favorite devices. The Zerena release initially included only behind-the-ear (BTE) styles of hearing aids. But with the latest release of in-the-ear (ITE) styles, your clients can now enjoy this listening experience in the form of an ITE. With the success already experienced with the Zerena BTEs, it was necessary to ensure that Bernafon customers would encounter the same with the Zerena ITEs.

There are generally no differences in the overall benefit that each style provides. The decision between a BTE and an ITE is based on the preference of the client and advantages of one style over the other when considering the hearing loss and handling capabilities of the client. However, there is a difference in microphone location of each style which can potentially contribute to small differences in localization and directionality benefits. While many studies have investigated the directional benefits of BTEs with open and closed ear pieces, there are few articles comparing speech understanding between ITE and BTE hearing aids.

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Additionally, there is no agreement between the data that does exist to support an argument for one style over another. Leeuw and Dreschler (1987) found a significant difference in speech reception threshold (SRT) scores between ITEs and BTEs. They tested SRTs in three conditions (unaided, aided with ITEs, and aided with BTEs) and showed that the ITEs produced the lowest SRT scores. However, the authors credit the better SRTs to more functional gain achieved at 2 and 4 kHz with the ITEs rather than the placement of the microphones. A study by Pumford et al. (2000), found no statistically significant difference between the aided scores recorded as signal-to-noise ratio (SNR) when comparing speech scores between ITEs and BTEs. As there is no conclusive evidence to support ITEs or BTEs regarding speech understanding, the Bernafon research audiologists decided to compare speech scores using BTEs and ITEs from the Zerena family of hearing aids.

Bernafon carried out testing with volunteer participants who have hearing loss to compare the speech performance of the ITE and BTE hearing aid styles.

For this study, Bernafon carried out testing with volunteer participants who have hearing loss to compare the speech performance of the ITE and BTE hearing aid styles. All participants were compensated for their time. All procedures were approved by the Swiss Ethics Committee for research involving humans, specifically the Bern canton committee, and by the local authority for regulation of therapeutic products, Swissmedic.

Design

This was a controlled, randomized, open label, comparative clinical investigation conducted monocentrically at the premises of Bernafon AG, Headquarters in Bern, Switzerland. There was no blinding as the difference between the styles is obvious.

The exploratory study included 17 people that had a hearing loss appropriate for a BTE and an ITE hearing aid. The overall study involved field and lab tests. The field tests allowed the participants to wear the devices at home and in everyday situations while the lab tests used a simulated environment in the clinic to test speech understanding in noise. Two speech tests were measured: The Oldenburg Sentence Test (OLSA) and the Göttingen Sentence Test (GOESA). Scores were recorded as SRTs for both tests.

A single group assignment to the devices was used for the field tests. The participants were first fit with Zerena 9 miniRITE BTEs and then fit with the Zerena 9 ITEs (with directional microphones) upon return to the clinic after approximately 10 days. The lab test order was randomized by test condition and by the speech lists based on a randomization created by the statistician. The test conditions were unaided, aided with the BTE, and aided with the ITE. The participants were tested in the unaided condition as a control. Randomizing the speech lists and the condition order reduces bias by using a different starting and ending condition as the last condition has a greater chance of scoring higher due to a learning effect from the speech test. All subjects were given a Patient Information and Informed Consent form which was signed, dated, and returned before any testing activities began.

Standard audiometry was performed on each subject and the hearing aids were fit with the first fit as prescribed by the Oasis^{nxt} fitting software. Acoustics (domes for the BTEs and vents for the ITEs) were selected according to the recommendations made by the fitting software. Real ear measurements were made using the Audioscan Verifit 2 (Dorchester Ontario, Canada) to ensure that the output for each style of hearing aid was as close to each other as possible. All subjects were given training on the use of the hearing aids and an Instructions for Use booklet before leaving the clinic.

Determination of sample size

The results with the ITE and the BTE were collected on the same subject. SRTs are continuous and normally distributed data. We can therefore apply the sample size determination for mean difference on one sample.

The formula to compute the sample size is:

$$n = \left(\frac{\sigma(z_{1-\alpha} + z_{1-\beta})}{\delta}\right)^2$$

For this formula n represents the sample size, σ the standard deviation from the population, δ the non-inferiority margin, α the type I error, and 1-β the power of the test.

With the following input: σ = 1.6 dB SNR, δ = 1 dB SNR, α = 0.05, and 1-β = 0.8, we needed a sample size of 16 to satisfy the test hypothesis.

Statistical analysis

As stated in the sample size calculation, the analysis was based on a single group that had the same treatment. The included subjects were experienced hearing aid users (minimum 6 months) with the same hearing aid model across the population. As hearing loss does not normally fluctuate, we assumed that their hearing capabilities were stable over time, and that the performance with a hearing aid could be compared over a longer interval without any wash out period. Subjects' individual auditory capacities (hearing loss degree, noise tolerance, speech recognition) vary; however, the sample is considered as a homogenous population regarding their experience with hearing aids. The acceptance to generic amplification via hearing aids was not tested but an actual evaluation of the difference between the BTE and the ITE. A single assignment treatment was considered representative of clinical intervention, i.e., when an experienced hearing aid user tests the ITE device.

The acceptance to generic amplification via hearing aids was not tested but an actual evaluation of the difference between the BTE and the ITE.

Primary analysis

Speech Reception Threshold (SRT) from the OLSA test was measured under three test conditions: unaided, aided with the BTE, and aided with the ITE. Test condition order was randomized using a Latin square design to control for any potential order effect. The difference between the two aided conditions was compared to the non-inferiority margin to test for non-inferiority. The non-inferiority margin was calculated using previous OLSA test results collected with the Zerena BTE. The goal of the current test was to prove that the ITE was as good as or better than the BTE, meaning that the SRTs achieved with the ITE should be equivalent or better than those with the BTE. If the confidence interval falls to the left of the non-inferiority cut-off, it can be considered as equivalent. If it is greater than zero, it would signal the possibility to run a superiority test to show that the ITE was better than the BTE. The unaided condition was used as a control of the ITE benefit in the case that non-inferiority could not be shown. Under these circumstances, the control would at least show that the ITE was better than the unaided condition.

The results of the non-inferiority test showed significant non-inferiority.

Secondary analyses

OLSA test:
If the results of the primary analyses showed significant non inferiority, a superiority test would be completed. Sufficient non inferiority is based on the recommendation by the CPMP (2001):

"If the 95% confidence interval for the treatment effect not only lies entirely above the non-inferiority margin but also above zero then there is evidence of superiority in terms of statistical significance at the 5% level ($P < 0.05$). In this case it is acceptable to calculate the P value associated with a test of superiority and to evaluate whether this is sufficiently small to reject convincingly the hypothesis of no difference." (p. 225)

GOESA test:
Speech Reception Threshold (SRT) from the GOESA test was measured under three conditions: unaided, aided with the BTE, and aided with the ITE. Test condition order was randomized using a Latin square design to control for any potential order effect. The benefit of amplification was evaluated for both the ITE and the BTE with exploratory analysis. The hypothesis was that there is a significant improvement of SRTs in the aided (both BTE and ITE) over the unaided condition with the GOESA test.

Results

Demographic and other baseline characteristics
Table 1 shows the demographics of the trial participants. There was a total of 17 subjects included in the test, 16 of which were men and 1 woman. They had an average age of 68 with a minimum of 44 and a maximum of 81.

The average hearing loss was a mild to severe sloping sensorineural hearing loss for both ears. See Figure 1 for an illustration of the average audiogram including error bars for all included subjects.

		Subjects (N = 17)
Gender	Male	16
	Female	1
Age (years)	N	17
	Mean	68
	Min	44
	Max	81

Table 1. Demographics of the study subjects

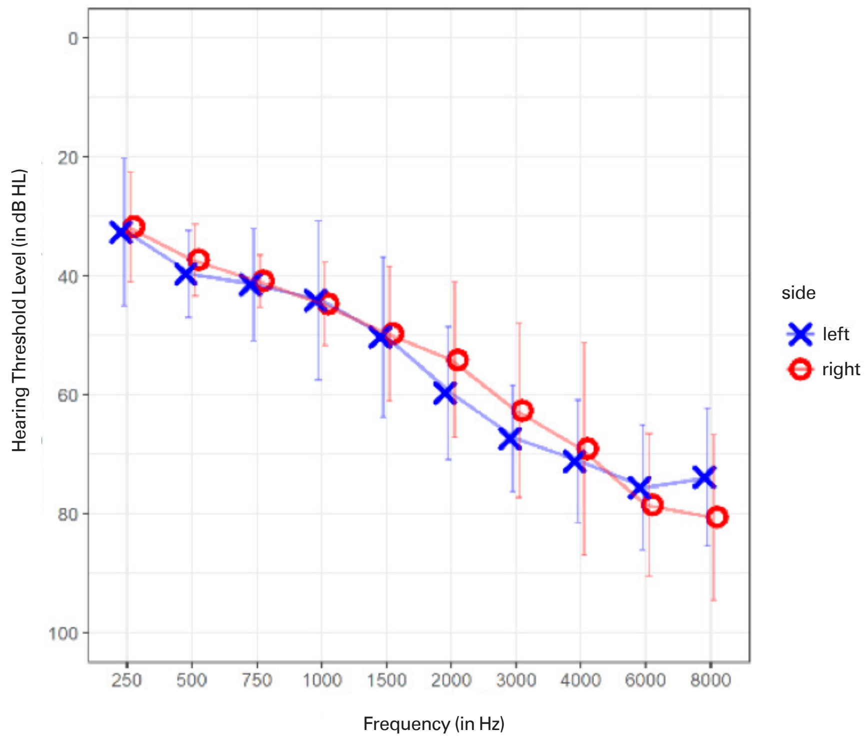

Figure 1: Average audiogram including error bars for all subjects.

Primary analysis: non-inferiority test, OLSA speech reception thresholds

The Oldenburg Sentence Test (OLSA), an adaptive speech-in-noise test, is comprised of 40 lists with 10 nonsense sentences per list. Each sentence contains 5 real words (name–verb–number–adjective–object). Test subjects were seated in the middle of a circle of 3 loudspeakers and were instructed to focus on the loudspeaker at 0° azimuth. Noise was presented through the 2 speakers located to the sides and back (at +/- 135°), the signal was presented only through the speaker at 0° azimuth. Figure 2 shows an illustration of the test setup used for both speech tests.

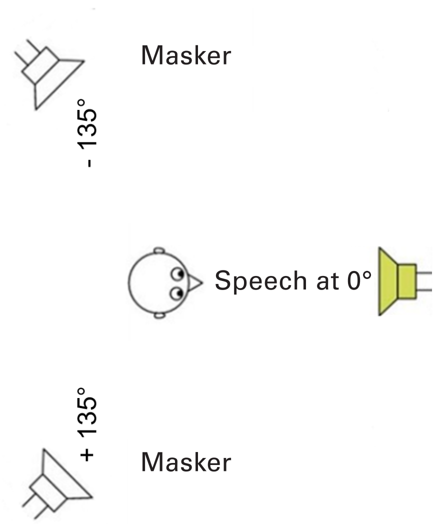

Figure 2: Spatial test configuration for speech reception threshold measures

Background noise for the OLSA consists of the same long-term spectrum as the speech material and was presented at a constant level of 65 dB SPL (as described by Bohnert et al., 2010). The speech signal was varied based on the standardized adaptive method described by Wagener et al. (1999). For each test condition, the 50% and 80% SRTs were calculated. Depending on the calculated percentage, the speech signal will increase or decrease with incorrect or correct answers, respectively, to maintain the specific targeted percentage. The graphs in Figure 3 show the results of the non-inferiority test from the OLSA.

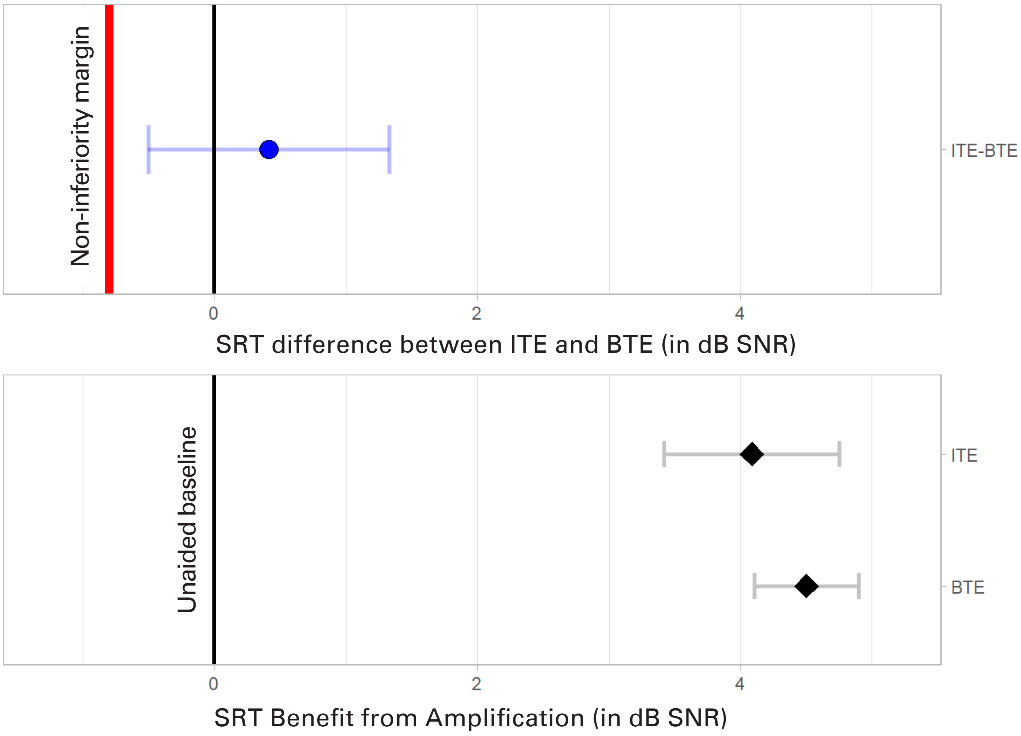

Figure 3: Graphs of the non-inferiority test between the ITE and the BTE (top) and the comparison of aided benefit with the BTE and with the ITE (bottom)

The ITE is significantly non-inferior to the BTE.

In the bottom of Figure 3, the average SRTs (reported in dB SNR) for BTEs and ITEs are shown. The graph on the top shows that the difference between those averages does not cross the non-inferiority margin meaning that the ITE scores were at least as good as the BTE scores. The ITE is significantly non-inferior ($t = 2.47$, $p = 0.01$) to the BTE with a non-inferiority margin of -1 dB SNR. The lowest boundary of the entire range of SRTs was not above zero, and therefore, did not indicate a difference great enough between the devices to warrant a superiority test.

Secondary analysis: aided benefit with GOESA speech reception thresholds

The Göttingen Sentence Test (GOESA) is an audiometric test for determining the speech reception threshold (SRT) in noise (Kollmeier et al., 2011). The material consists of 10 equivalent test lists each with 20 sentences, which reflect everyday linguistic situations. By adjusting the noise level to the speech material, the SRT can be determined within the range of ± 1 dB. Completing the GOESA via a loudspeaker configuration can simulate the spatial speech-noise situations from everyday life in order to investigate the benefits of hearing aids. Test subjects were seated with a loudspeaker at 0° azimuth from which the speech was played. Noise was presented through 2 speakers located at the back at -135 and 135 degrees azimuth. See Figure 2 for an illustration of the test set up.

Background noise consisted of the same long-term spectrum as the speech material and was presented at a constant level of 65 dB SPL. The speech signal varied based on the standardized adaptive method used in the OLSA test (described above).

The following graphs show the average scores and individual speech scores for all three test conditions (aided BTE, aided ITE, and unaided) for the SRTs at 50% and 80%.

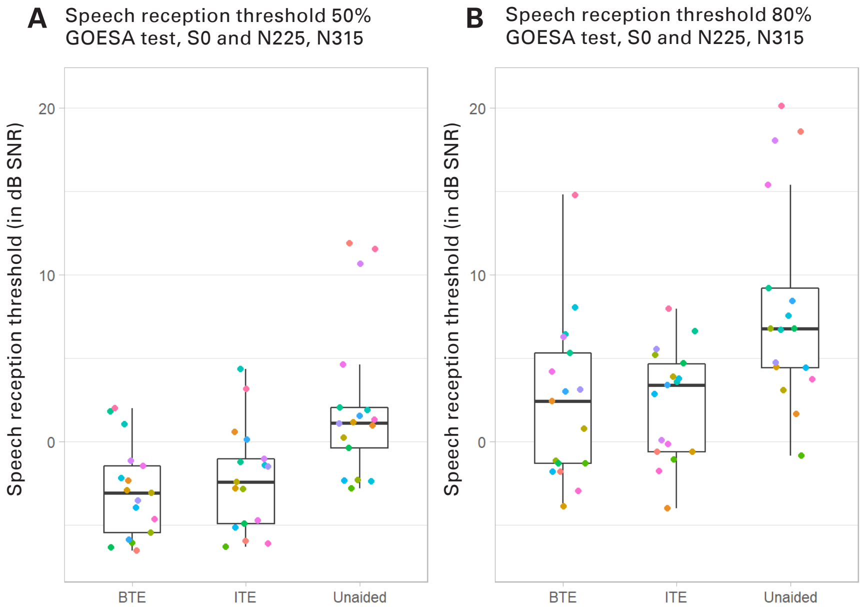

Figure 4: Average and individual GOESA SRTs at 50% (left) and 80% (right) reported in dB SNR for all three conditions (BTE, ITE, and unaided). Lower SRT scores indicate better performance.

Figure 4 shows that aided scores were better than unaided for both target performances. The differences between the aided conditions appear to be small and do not show any systematic trend. These observations are in line with the analysis, which includes age and hearing loss as covariates. The effect of amplification is significant ($t = -7.37$, $p < 0.001$) and the difference between BTE and ITE is not significant ($t = 1.02$, $p = 0.31$).

Discussion

As indicated in the introduction, the object of this study was to compare the speech performance of the Zerena 9 BTE and ITE. The OLSA speech test showed that the ITE does not provide inferior speech understanding compared to the BTE, but there was also not a difference great enough to prove that it was better than the BTE. In accordance with the OLSA results are the GOESA results which showed no significant differences between aided scores. Therefore, both speech tests showed that speech understanding is better than the unaided condition with either the Zerena 9 ITE or the BTE but not statistically different between styles. Choosing to fit a BTE or an ITE (as used for the testing) does not have to be a question of benefit. As long as the hearing loss is appropriate for the choice of hearing aid, the selection can be determined based on the client's wishes and dexterity levels. Bernafon offers a complete portfolio of hearing aids styles with the latest technology from which clients can benefit whichever style they choose to use.

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