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Research Article

Clinical Significance or Statistical Significance: Which One Should Be Considered for Analyzing the Gain-Frequency Responses of Hearing Aids?

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Highlights

- Analyzing the gain-frequency response of the hearing aids
- Misinterpretation of statistical significance as clinical significance
- Considering both statistical and clinical analysis for interpretation of the result

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ABSTRACT

Background and Aim: When analyzing the gain-frequency response of a hearing aid, data can be analyzed both clinically and statistically. This study aimed to investigate and compare the gain-frequency responses using statistical and clinical analyses under active digital noise reduction (DNR-on) and inactive digital noise reduction (DNR-off) conditions.

Methods: The gain-frequency responses of a hearing aid for one of the most well-known commercial digital hearing aid manufacturers were measured using the FP35 hearing aid analyzer (Frye Electronics Inc., USA) by presenting two types of signals (digital speech and composite noise) at input levels of 65 and 80 dB SPL under the DNR-on and DNR-off conditions. Data analysis was performed both statistically (using Wilcoxon signed rank test) and clinically (using 3 dB difference criterion).

Results: A statistically significant difference was found in the gain-frequency responses for all speech and noise input levels between the two conditions; while a clinically significant difference was observed only at noise input levels of 65 and 80 dB SPL.

Conclusion: For analyzing the hearing aid performance, both clinical and statistical analyses should be considered.

Keywords: Digital noise reduction; gain-frequency response; clinical analysis

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Introduction

Hearing loss is one of the most common health problems in the world. According to the World Health Organization, 466 million people worldwide have disabling hearing loss. Sensorineural hearing loss (SNHL) is the most common type of hearing loss, and the use of hearing aids is the best treatment method for people with SNHL [1, 2]. Hearing aids provide audibility for soft sounds and comfort for loud sounds using compression and amplification so that a user can have a good speech intelligibility. Therefore, a good speech perception can be obtained with hearing aids in quiet condition [3]. However, hearing-impaired people still have difficulty understanding speech in noise even with hearing aids and usually need a higher signal-to-noise ratio (SNR) in comparison with normal-hearing people. In fact, the most common complaint of people with SNHL is reduced speech intelligibility in the presence of background noise or competing speech [4, 5]. Noise can interfere with speech and disrupt the communication process [6]. Different technologies such as directionality and digital noise reduction (DNR) algorithms are used in hearing aids to improve SNR and solve speech in noise problems [5]. The DNR technology is a processing that amplifies noise less than speech over a specified frequency range [7]. The DNR algorithms work by exploring the differences between speech and noise [8] and make a hearing aid user hear less competitive noise by reducing the hearing aid gain in the frequency bands with low SNRs. Although the DNR algorithms do not improve speech perception in noise, they provide improved listening comfort so that people have a tendency towards using hearing aids constantly in noisy situations [9, 10]. In most DNR algorithms, the input signal to the hearing aid is divided into different channels and the modulation is then examined in each channel. The acoustic principle for DNR algorithms is that speech has fewer modulations (Hz) with greater modulation depth (dB) than noise [11, 12].

The degree of hearing aid amplification is represented by the gain-frequency response. The gain-frequency response is shown by a graph of gain (dB) versus frequency (Hz) [13]. This graph is recorded by conducting coupler and probe microphone measurements in commercial hearing aid analyzers and can be used as an analogy for comparing the performance of different hearing aids in different adjustment modes. The effectiveness of various hearing aid technologies and acoustic modifications can be examined and investigated by measuring and examining the gain-frequency response of hearing aids. By measuring the gain-frequency response of hearing aids in two different adjustment modes or when an advanced hearing aid feature is active and inactive, the difference between the performance and amplification of hearing aids can be found [14].

One of the methods for evaluating the DNR is the measurement of the gain-frequency response of hearing aids in a 2 cc coupler and evaluating the difference in amplification over frequency ranges between the DNR-on and DNR-off conditions. In this regard, the gain-frequency response of hearing aids is measured and recorded under different conditions and then the significance of difference is statistically analyzed. One of the most common problems while reading clinical researches is that statistical significance is misinterpreted as clinical significance and results of statistical analysis provide no information on the clinically importance of an effect. Tests of statistical significance indicate the probability that the results may be due to chance, while clinical significance indicates the magnitude of the actual effect [15, 16]. Using statistics, the goal is to discover the difference in the gain-frequency responses of hearing aids based on probabilities and statistical models and it has nothing to do with clinical considerations for prescribing or fitting hearing aids. For example, in clinical setting, ±3 dB difference over the entire frequency range in the gain-frequency response is considered clinically insignificant [13, 17]. This makes the observed differences in the gain-frequency response of hearing aids to be statistically significant despite the fact that it is not considered clinically significant. Moreover, the difference in the gain-frequency response of hearing aids is sometimes clinically acceptable, but the difference may not be statistically significant and acceptable based on the effect size, sample size, statistical tests and hypotheses. Therefore, this study aimed to address this issue and investigate it from clinical and statistical perspectives by analyzing the gain-frequency responses for speech and noise signals. In this regard, data were analyzed statistically (using statistical tests considering a significance level of 0.05) and clinically (using 3 dB difference criterion). In overall, this study aimed to measure the gain-frequency responses under the DNR-on and DNR-off conditions when two stimuli (digital speech and composite noise) are presented during the 2 cc coupler measurement and examine the gain-frequency responses statistically and clinically and then compare statistical and clinical analyses.

Methods

A hearing aid made by one of the well-known hearing aid manufacturers was used in this study and its gain-frequency responses were measured (for more information about its technical specifications, see Appendix 1). The FP35 hearing aid analyzer (Frye Electronics Inc., USA) was used to measure the gain-frequency responses. The measurement microphone of the FP35 was levelled and calibrated before testing. For calibration, the microphone was placed in the center of the test box. A sample audiogram with a SNHL was given to NOAH software (Figure 1) and national acoustic laboratories-nonlinear 2 (NAL NL-2) formula was used to program the hearing aid by the software. The hearing aid was fitted linearly to prevent the interference of amplitude compression during the test, and the knee point and the maximum power output (MPO) of the hearing aid were set as default. The DNR algorithm was activated and other digital signal processing such as directionality, adaptive feedback cancellation and etc. were deactivated. All steps were performed in quiet to prevent the effect of noise on the gain-frequency response. Two types of complex signals were used for evaluating the effectiveness of DNR including digital speech and composite noise. Composite noise is a continuous broadband signal consists of 79 different frequencies which are presented simultaneously, and speech signal is an interrupted version of composite noise [12]. The gain-frequency responses were measured under the DNR-on and DNR-off conditions when the digital speech and composite noise with the input levels of 65 dB SPL (medium sound) and 80 dB SPL (loud sound), respectively, were presented during the 2 cc coupler measurement in the test box. Each measurement was repeated three times and the average of three measurements was recorded as the final result.

Data was analyzed statistically and clinically in IBM SPSS 17 (IBM Corp., Armonk, NY, USA). For statistical analysis, Since the distribution of differences between the paired measurements were not normally distributed, Wilcoxon signed-rank test was used. For clinical analysis, 3 dB difference criterion was used. A difference more than 3 dB SPL in the gain-frequency responses between the DNR-on and DNR-off conditions was considered clinically significant and a p-value less than 0.05 was considered statistically significant. Results of clinical and statistical analyses were then compared.

Results

Table 1 presents the descriptive statistics (mean and standard deviation) for the gain-frequency responses at a 200-8000 Hz range under the DNR-on and DNR-off conditions. There was a statistically significant difference between the two conditions for all speech and noise input levels ($p<0.05$).

In Figure 2 (A, B, C and D), the gain-frequency response curves are shown separately at a 200-8000 Hz range and in the frequency band of 100 Hz using two types of signals under the two conditions. As can be seen in Figures 2A and 2B for digital speech stimulus, the

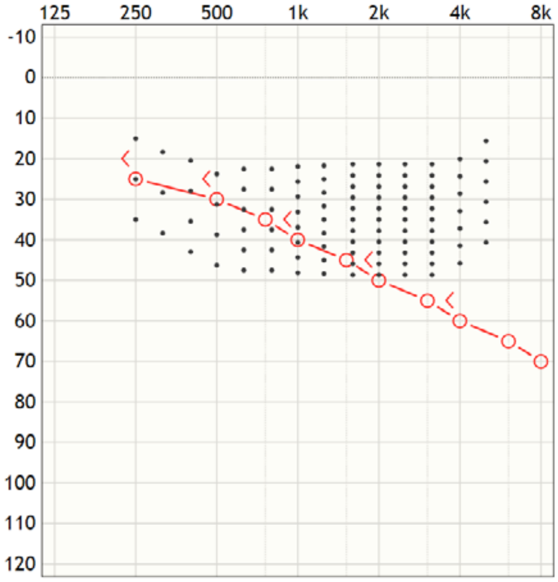

Figure 1. The audiogram configuration is in the form of falling sensorineural hearing loss. The hearing aid was fitted based on hearing thresholds shown on this audiogram and NAL-NL2 formula was used to program the hearing aid

Table 1. Mean and standard deviation of gain-frequency response in the 200 Hz to 8000 Hz range as measured by presenting digital speech and composite noise with levels of 65 and 80 dB SPL under the digital noise reduction-on and digital noise reduction-off conditions

Test condition	Mean±SD (dB)		p*
	DNR off	DNR on	DNR (on vs off)
Digital speech, 65 dB SPL	15.17±14.43	14.80±14.52	<0.001
Digital speech, 80 dB SPL	13.73±14.43	13.56±14.35	<0.001
Composite noise, 65 dB SPL	14.73±15.55	6.12±13.97	<0.001
Composite noise, 80 dB SPL	12.73±14.31	4.65±14.42	<0.001

DNR off; digital noise reduction off, DNR on; digital noise reduction on

* Wilcoxon signed ranks test

two gain-frequency response curves were overlapped. In other words, the difference in the gain-frequency responses of the hearing aid between the DNR-on and DNR-off conditions was less than 1 dB at most frequencies which is not considered clinically significant in terms of prescribing and fitting the hearing aids, if we consider 3 dB difference as a clinically acceptable level for significant performance of DNR technology; therefore, it can be said that this technology had no significant effect on the gain-frequency response under experimental conditions as shown in Figures 2A and 2B. However, according to Figures 2C and 2D, We can see a significant gap between the DNR-on and DNR-off gain-frequency response curves while presenting composite noise and the difference between the DNR-on and DNR-off conditions was more than 3 dB SPL at almost all frequencies which is clinically significant.

Discussion

In studies of DNR effectiveness, the degree of noise reduction at various frequencies is shown by the gain-frequency response curve or reporting the degree (mean) of gain reduction numerically under the DNR-on and DNR-off conditions [9, 12, 14]. In a study by Ahmadi et al. that the degree of gain reduction was reported numerically, the amount of gain reduction was reported 1-9 dB at low frequencies and 2.6-9.7 dB at all frequencies using composite noise in the omnidirectional-multichannel DNR and omnidirectional-broadband DNR

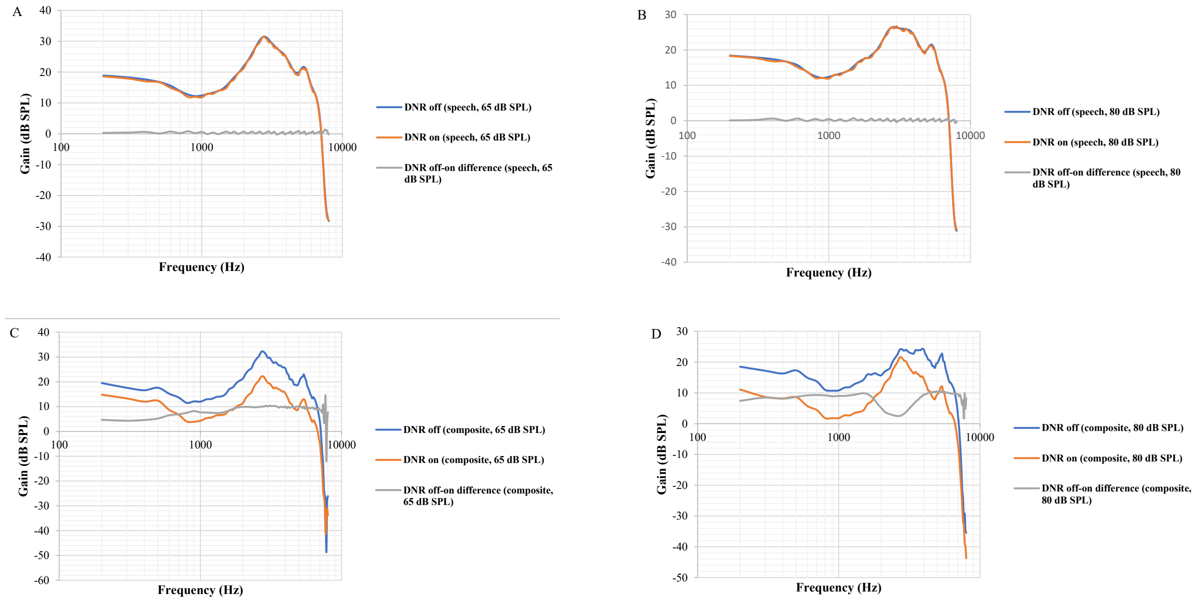

Figure 2. The gain-frequency response in the 200 Hz to 8000 Hz range in response to A) digital speech for input level of 65 dB SPL, B) digital speech for input level of 80 dB SPL, C) composite noise for input level of 65 dB SPL, and D) composite noise for input level of 80 dB SPL, under the digital noise reduction-on and digital noise reduction-off conditions. The difference between the gain-frequency responses for digital noise reduction-on and digital noise reduction-off conditions is shown graphically in dB in the 200 Hz to 8000 Hz range below the graph.

conditions [9]. In Brown's study, frequency response was measured using 80 dB SPL digital speech and composite input and the result showed that the gain of speech signal was not affected by noise reduction. Conversely, the DNR technology attenuated the amount of non-speech signal significantly [14]. In another study, When the signal type changed from modulated (digital speech) to unmodulated (composite noise), a significant gain reduction was found at all frequencies for all commercial digital hearing aids used in the study, and it was concluded that DNR helps to differentiate between modulated and unmodulated signals [12]. We found no study on comparing clinical and statistical results when analyzing the gain-frequency responses of hearing aids. As mentioned before, one of the most important issues in clinical setting is whether activating the hearing aid features (such as DNR) has significant effect on the gain-frequency response and consequently affects the individual's subjective feeling. In other words, whether the individual understands the difference made in sounds or not. Usually in the clinical setting, 3 dB is considered the minimum criterion which makes significant difference. Therefore, obvious difference is explained by this criterion. For example, hearing aid users cannot differentiate between similar gain-frequency responses and prefer one response over another response when the root-mean-square differences between different responses at various frequencies is more than 3 dB. Furthermore, over most of the frequency range, the standard deviation of the difference between a single measurement of the gain-frequency response and the average of several measurements is 3 dB; therefore, we can conclude that 95% of measurement results are within 6 dB of the actual value. At high frequencies, due to the impossibility of ensuring that the probe is placed in exactly the same place under the aided and unaided conditions as well as the effects of standing waves, the standard deviation rises to 5 dB [13].

Research with the developmental of NAL-NL2 revealed that ±3 dB of target is the preferred listening level of approximately 60% of patients. Due to the common use of correction factors, inaccuracy in measuring the patient's hearing threshold and the variability of applying average prescriptive targets to listeners, ±3 to ±5 dB deviation from real ear aided response is acceptable [17]. In the current study, we also considered more than 3 dB gap between the gain-frequency response curves under the DNR-on and DNR-off conditions at one or several frequency ranges as a clinically significant difference. This difference was made by DNR algorithm. Our results revealed a significant clinical difference between the gain-frequency responses under the DNR-on and DNR-off conditions when composite noise was presented at levels of 65 and 80 dB SPL. Moreover, there was a significant statistical difference when digital speech and composite noise were presented at levels of 65 and 80 dB SPL. Therefore, a similar result between statistical and clinical analyses were obtained when composite noise was presented at 65 and 80 dB SPL. Results can be significant based on statistical analysis although they are not clinically significant. Accordingly, while evaluating the hearing aid performance (gain-frequency response) using statistical tests and based on probabilities, we should cross-check the results with clinical analysis.

Conclusion

Although there is a statistically significant difference in gain-frequency responses of hearing aids between the digital noise reduction-on and digital noise reduction-off conditions, the difference is not considered clinically significant; therefore, for analyzing the performance of hearing aids, clinical analysis should be conducted in addition to statistical analysis.

Ethical Considerations

Compliance with ethical guidelines

This article has been extracted from ZS. Moossavi MSc thesis submitted to Shahid Beheshti University of Medical Sciences with Ethical Code No. IR.SBMU.RETECH.REC.1400.121.

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Authors' contributions

ZSM: Study design, acquisition of data, interpretation of the results, statistical analysis, drafting the manuscript; HJ: Study design, interpretation of the results, drafting the manuscript, revision of the manuscript; AN: Supervision, drafting the manuscript; SMT: Statistical analysis.

Conflict of interest

The authors declare that there is no conflict of interest.

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Appendix 1. Technical specification of the behind the ear hearing aid that was used in the study

Technical specifications		2 cc coupler[*]	Ear simulator[†]
OSPL 90, peak	dB SPL	121	127
OSPL 90, 1600 Hz	dB SPL	121	127
HFA OSPL 90	dB SPL	115	-
Full-on gain, peak	dB	50	55
Full-on gain, 1600 Hz	dB	50	55
HFA full-on gain	dB	43	-
Reference test gain	dB	38	48
Quiescent current	mA	1.2	1.2
Operating current	mA	1.2	1.2
Distortion 500/800/1600 Hz	Percent	2/2/1	2/2/1
Frequency range	Hz	100-6900	-
Equivalent input noise	dB SPL	11	10

OSPL 90; output sound pressure level 90, HFA; high frequency audiometry

[*] 2 cc refers to a coupler according to IEC 60318-5, [†] Ear simulator refers to a coupler according to IEC 60318-4

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