Research Paper

Conformity of the Real-Ear Aided Response With the Target Response From the Desired Sensation Level V5 Formula

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Citation Pirasteh E, Hamzehpour F, Sharafi Z, Absalan A, Arbabsarjoo H. Conformity of the Real-Ear Aided Response With the Target Response From the Desired Sensation Level V5 Formula. Iranian Rehabilitation Journal. 2022; 20(1):89-98. http://dx.doi.org/10.32598/irj.20.1.1554.1

doi http://dx.doi.org/10.32598/irj.20.1.1554.1

Article info:
Received: 06 Aug 2021
Accepted: 08 Dec 2021
Available Online: 01 Jun 2022

Keywords:
Hearing loss, Real-Ear measurements, Degrees of hearing loss, Gender, Ethnicity

ABSTRACT

Objectives: Real-ear measurements are critical in children for hearing aid fitting. This study aimed to evaluate the conformity of measured and predicted real-ear aided response of prescribed formula of Desired Sensation Level (DSL) version 5, (Pediatric form) in children aged 4 to 7 years. Since there is limited information about the effect of degrees of hearing loss, ethnicity, gender, and ear on this conformity, the present study investigated the influence of the mentioned factors, too.

Methods: This study was conducted on 92 children aged 4-7 years (37 girls and 55 boys) with moderate to profound hearing loss. After auditory evaluations, the children's hearing aids were fitted based on the DSL formula. Then, the hearing aid output was measured with a real-ear measurement system, and the difference between predicted and measured curves were compared.

Results: This study showed a significant difference between the predicted values and the measured ones at three intensity level inputs (50, 65, and 80 dB SPL) and a frequency range of 0.5 to 6 kHz for both ears ($P<0.05$). However, there was no significant difference between predicted and measured values curves (predicted-measured) regarding the effects of the hearing loss degrees, gender, ethnicity, and ear (right or left) ($P>0.05$).

Discussion: According to the difference observed between the predicted and measured curves, especially at the frequencies of 6 and 4 kHz, it is essential to conduct real-ear measurements in children.

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Highlights

- It is essential to fit children's hearing aids based on the results of the real-ear measurements, especially at high frequencies.

- The degrees of hearing loss do not affect the difference between the predicted and measured curves.

- Gender, ethnicity, and ear (left or right) do not affect the difference between the predicted and measured curves.

Plain Language Summary

Childhood hearing loss is a common chronic disorder that may adversely impact children's life and damage their speech, language, and cognitive development. Today, hearing aids are the preferred option for helping individuals with hearing loss. The hearing aids fitting aims to guarantee that users will desirably hear sounds, especially people talking. Real-ear measurements are used to confirm the proper performance of hearing aids. The current study investigates the conformity of the measured real-ear aided response with the predicted response based on the prescribed formula of desired sensation level (v5, Pediatric form) in children aged 4 to 7 years. We examined the influence of ethnicity, gender, and ear (right and left) on this conformity, as little information exists about their effects on hearing loss. The results suggest that real-ear measurement is essential to fit children's hearing aids, especially at high frequencies.

1. Introduction

Childhood hearing loss is a common chronic disorder that may adversely impact a child's life [1]. The most significant effect of hearing loss is the auditory deprivation of all or some sound and speech cues provided to humans [2]. Hearing loss may damage speech, language, and cognitive development, resulting in speech disorders [3]. Today, hearing aids are the preferred option for helping individuals with hearing loss establish more effective communication with others [4]. The goal of hearing aids is to guarantee that individuals will hear sounds, especially speech sounds, in a desirable way [5]. Although the required intensity of hearing aids could be adjusted based on the prescribed formula used by hearing aid fitting software programs, this intensity depends on numerous factors, including the size of the ear, the remaining volume in the ear canal, the insertion depth of the earmold in the ear, as well as the resonance of the pinna and the ear canal [6]. Thus, when hearing aids are fitted in individuals with sensorineural hearing loss, the frequency response of hearing aids must be fitted correctly and appropriately [7]. Verifying hearing aids could guarantee proper hearing ability and an appropriate output for different inputs. Real-ear measurements are a method used for confirming the performance of hearing aids [8].

Aarts and Caffee investigated the clinical accuracy of measured and manufacturer-predicted real-ear aided response (REAR) in adults and reported that these values differed significantly from the predicted response values [9]. Aazh et al. (2012) [10] and Campos et al. (2011) [11] investigated the fitting accuracy of Real-Ear Insertion Gain (REIG) with the initial fitting of hearing aids in 30 and 62 adults, respectively. They reported that the target insertion gain could rarely be achieved through the first fit. In another study, Bretz (2006) examined a child with hearing loss and reported that the output measured by the hearing aid was generally lower than the target curve of the national acoustic laboratory, non-linear 1 (NAL-NL1) and Desired Sensation Level (DSL) [12]. Sanders et al. (2015) examined the differences between the NAL-NL2 target and measured REAR. All hearing aids were mini Behind-The-Ear (BTE) and receiver-in-canal, prescribed as a close-fitting. The results showed a significant difference between target and measured responses at some frequencies; the difference was as much as 10 dB or more [13]. It is noteworthy that most of the mentioned studies have investigated the differences between the predicted and measured frequency response in adults. Therefore, like the current study, they did not apply the prescribed desired sensation level (DSL v5 Pediatric formula). The population in the current study included children aged 4 to 7 years who were different from adults in terms of ear anatomy. Moreover, the present study investigated the degree of hearing loss, gender, ethnicity, and the ear on the conformity between measured and predicted frequency response.

The anatomical features of the body, head, and ears significantly affect the results of real-ear measurement [14]. In terms of anatomical features of the ear, the outer ear of girls and women is smaller than boys and men [15, 16]. Regarding head and face, there is a difference between the two Iranian populations of Fars and Baluch [17, 18]. In addition, the asymmetry between the dimensions of the two ears has been reported in some studies [19, 20]. Anatomical differences in the ear canal can lead to functional differences [16], and this is likely to affect the frequency response of the hearing aid at the level of the tympanic membrane.

Hence, the current study attempts to investigate the conformity of the measured REAR to the predicted response from the prescribed formula of DSL v5 Pediatric in children aged 4 to 7 years. Moreover, the current study examined the effect of degrees of hearing loss, gender, ethnicity, and ear on this conformity.

2. Materials and Methods

The current cross-sectional study was conducted on 92 children aged 4 to 7 years (37 girls and 55 boys) with moderate to profound hearing loss referred to Razmju Moghadam Clinic in Zahedan City, Iran. Regarding ethnicity, 27 out of 92 children were Fars, and 65 were Baluch. Sistani (Fars) and Baluch refer to those born from residents in Sistan and Baluchistan Province and whose parents had intragroup marriages for three generations [21]. In this study, 79 participants were fitted bilaterally. The remaining 13 participants had a unilateral fitting. Among all participants, 88 used hearing aids on the right ear and 83 on their left ears. In total, 171 Unitron BTE hearing aids were evaluated. The models included Stride 700 P and Max 6 SP. The Mean±SD age of the participants was 5.96 (1.93) years. A non-random sampling method was employed in the current study. Based on hearing tests and case histories, the inclusion criteria were obtaining written informed consent from the children's parents, the presence of moderate to profound hearing loss; the absence of an outer ear anomaly, ear surgeries, recurrent middle ear infections; and the normal function of the middle ear (type of tympanogram). Also, children with a high level of ear cerumen were referred to a specialist, who entered the current study after removing cerumen from their ears. The children with inappropriate earmolds (in terms of size or ruptured on the tube) were included in the current study after solving the problem of their earmolds. Auditory evaluations were carried out with an AC33 interacoustic two-channel audiometer and a MADSEN Zodiac 901 tympanometer. For children who did not participate in the routine audiometry test, we conducted Labat play audiometry. To conduct the test, the performance accuracy of the hearing aids was tested using a Primus hearing aid analyzer. Upon confirming performance accuracy, every child's hearing aid was fitted using the software program of the related company based on DSL v5 Pediatric. In these fittings, expansion, noise reduction, and feedback circuits were switched off.

Moreover, microphone directionality was set on the omnidirectional mode. The automatic adaptation manager was defined at 100%. To conduct the test, we placed the children at a 0.5-m distance from the speaker with an azimuth of 0° to the speaker. This position reduces the measurement errors created by an individual's movements. Before the test, probe microphone calibration was conducted for all participants using a pink noise stimulus at the intensity level of 65 dB SPL. Next, the probe tube was inserted in the ear canal by 20 mm for children aged 5 years and younger and 25 mm for children over 5 years, with the tube probe placed at the intertragic notch. Under such conditions, the real-ear unaided response was measured with a pink noise stimulus at the intensity level of 65 dB SPL, and its curved shape was analyzed. The correct placement of the probe tube was ensured when the response curve was not very peaky and when the absolute gain at 6 kHz was not below -5 dB. Afterward, the hearing aids were placed behind the children's ears, and their outputs were measured by the real-ear measurements system for the International Speech Test Signal (ISTS) stimulus at three intensity levels (50, 65, and 80 dB SPL) and 0.5, 1, 2, 4, and 6 kHz frequencies. To minimize measurement errors, the children's placement position was accurately monitored by a second examiner so that head and body movements were avoided. The difference between the target curves and the measured curve was determined for all individuals based on the degrees of hearing loss, ethnicity, gender, and ears at the mentioned frequencies and intensities. For statistical data analysis, SPSS software v. 19 was used at the significance level of $P<0.05$. A paired sample t test was conducted to compare the conformity between measured and predicted REAR values. Moreover, another paired sample t test was applied to compare this conformity between the two ears. To determine the effects of gender and ethnicity on the conformity between the measured frequency response and the predicted frequency response, we used the independent samples t test. Finally, we employed the 1-way ANOVA to determine the influence of hearing loss on the conformity between the measured and the predicted frequency response.

3. Results

Of 92 children who participated in the current study, 17 children had a moderate hearing loss; 26 children had moderate to severe hearing loss; 29 children had severe hearing loss, and 16 children had profound hearing loss in the right ear. Concerning the left ear, 16 children had a moderate hearing loss; 23 children had a moderate to severe hearing loss; 30 children had a severe hearing loss, and 14 children had a profound hearing loss. Table 1 presents the results for the mean predicted and measured REAR values.

To better understand the effects of the hearing loss on the difference between the predicted and measured curves, the predicted values were subtracted from the measured values, and the difference was expressed based on the degrees of hearing loss (Figures 1, 2 and 3) and gender (Figure 4). The percentages of acceptable initial fitting (considering the criterion of ±10 dB) at 50, 65, and 80 dB SPL from 0.5 to 6 kHz frequency range in two ears are presented in Table 2.

The current study showed a significant difference between the predicted and measured responses at 50, 65, and 80 dB SPL inputs and 0.5, 1, 2, 4, and 6 kHz frequencies (Table 3).

The degrees of hearing loss, gender, ethnicity, and ear do not affect the difference between the predicted and measured curves (P>0.05).

4. Discussion

Based on the finding of the current study, there was a significant difference between predicted and measured REAR curves for the international speech test signal stimulus at the frequencies of 0.5 to 6 kHz at the 50, 65, and 80 dB SPL (the mean measured REAR curve had lower values than those of the predicted REAR). Moreover, the lowest conformity between the measured and predicted REAR curves was related to the frequencies of 6 and 4 kHz, respectively. Thus, it is essential to fit children's hearing aids based on the results of the real-ear measurements, especially at high frequencies, for two reasons. First, the lowest conformity between the measured and predicted REAR curves was observed at high frequencies. Second, the initial fitting of the hearing aids was acceptable in fewer cases at high frequencies compared to other frequencies.

In this regard, the results of the current study are similar to Afshar et al. [21] results. They reported a significant difference between the mean SPL of the predicted and measured curves for wideband digital speech stimuli at 50, 65, and 80 dB SPL inputs in 17 children with hearing aids with moderate to profound sensorineural hearing loss. The largest difference between the predicted and measured curves (over 10 dB SPL) was recorded for 6 and 4 kHz. Moreover, the mean of the measured curve had lower values than the predicted curve at all frequencies except for 0.5 kHz [21]. In some samples investigated in the current study, the measured values were higher than the target ones. Based on the minimum values of the difference between the predicted and measured values, the mean of the measured values was, however, less than that of the target ones. This finding indicates that in most studied samples, the measured amounts were less than the predicted ones.

Aarts and Caffee (2005) [9] investigated 41 individuals aged 19 to 55 years and reported a difference between

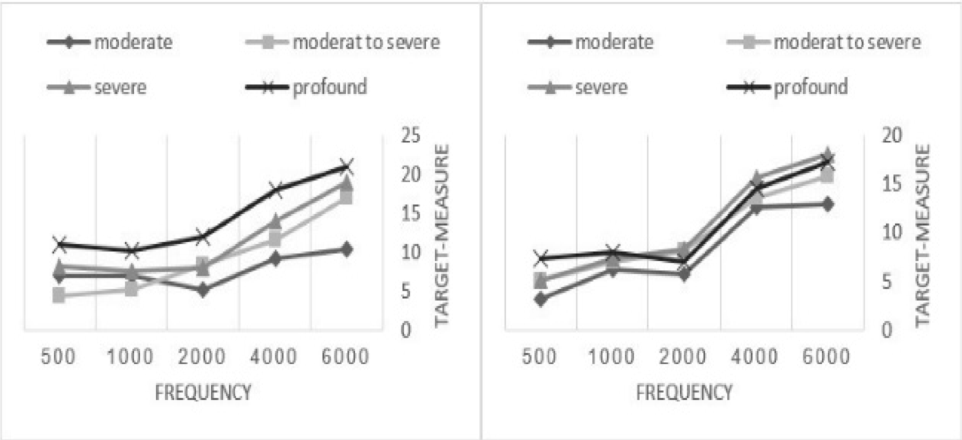

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Figure 1. Comparing the differences between predicted and measured based on degrees of hearing loss in 50 db spl input, right ear in the left side and left ear in the right side

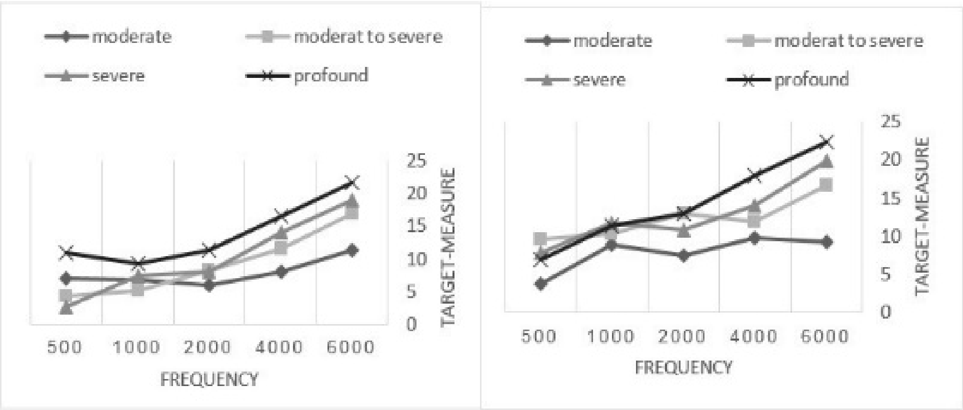

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Figure 2. Comparing the differences between predicted and measured based on degrees of hearing loss in 65 dB SPL input, right ear in the left side and left ear in the right side

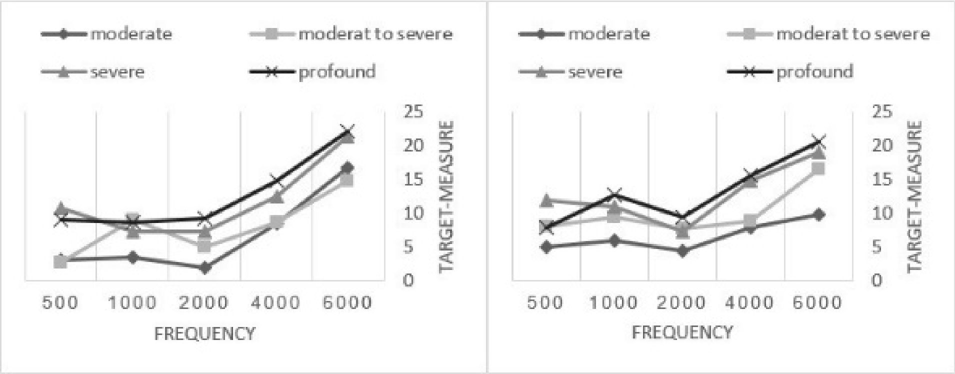

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Figure 3. Comparing the differences between predicted and measured based on degrees of hearing loss in 80 dB SPL input, right ear in the left side and left ear in the right side

Table 1. Mean predicted and measured real-ear aided response values (dB SPL) at three intensity levels in two ears within 0.5 to 6 kHz frequency range

Ear		Frequency				
		0.5	1	2	4	6
Right	Predicted/50	62.89	70.44	76.08	74.05	70.97
	Measured/50	57.37	63.26	67.96	60.51	53.36
	Predicted/65	73.21	82.36	89.37	87.87	84.09
	Measured/65	66.99	74.68	79.68	72.67	62.80
	Predicted/80	81.85	87.75	93.23	91.72	89.86
	Measured/80	76.34	80.93	87.30	80.75	71.19
Left	Predicted/50	62.23	70.63	76.47	74.54	71.09
	Measured/50	57.26	63.40	69.46	61.12	55.06
	Predicted/65	73.70	83.20	90.34	86.24	84.00
	Measured/65	66.86	73.23	79.77	72.93	64.98
	Predicted/80	83.32	88.54	94.35	92.52	90.85
	Measured/80	75.48	79.30	87.56	80.66	74.05

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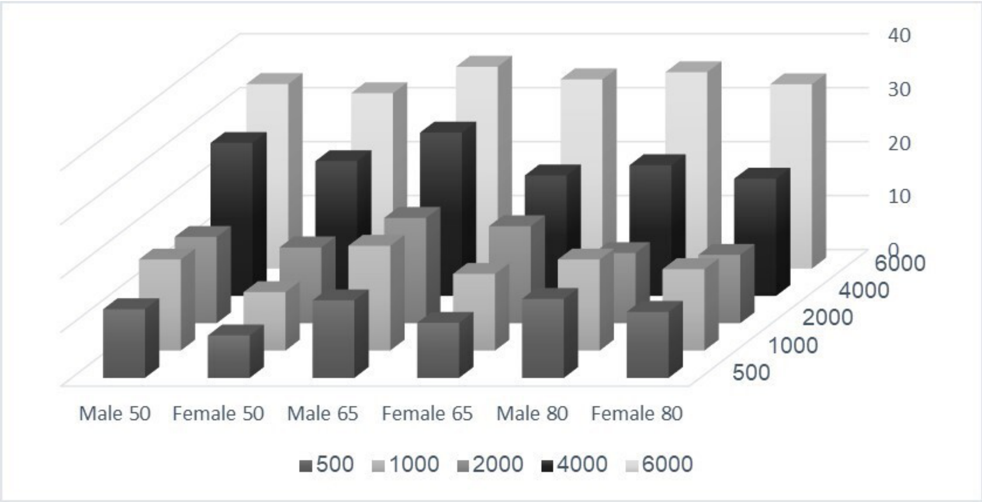

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Figure 4. Comparing the differences between predicted and measured based on gender in 50, 65, and 80 dB SPL inputs

predicted and measured REAR curves. At some frequencies (e.g., 0.5 and 6 kHz), the mean measured values were larger than the predicted ones. Moreover, there was a less significant difference between the predicted and measured curves at some frequencies and intensities compared to the current study. It is of note that the individuals investigated in the study mentioned above suffered from flat mild hearing loss and sloping mild to moderately severe hearing loss, while the current study investigated individuals with moderate to profound hearing loss. Moreover, the population investigated in the current study included children aged 4 to 7 years who were different from adults in terms of ear anatomy.

According to the results of the present study, 81.13% of the first fittings would not reach the ±10 dB of the DSL (v5 Pediatric) predicted REAR at one or more frequencies for 0.5, 1, 2, 4, and 6 kHz. Moreover, if the frequency of 6 kHz were ignored, the first fittings would not reach the ±10 dB in 68.48% of the cases. If a stricter criterion (a ±3 dB distance) were taken into account, the first fitting would not reach the ±3 dB of the predicted curve in 93.26% of the cases. In other words, the first fitting of hearing aids reached the ±3 dB of the predicted curve only in 6.74% of the cases. The study conducted by Aarts and Caffee (2005) shows that in the presence of flat mild hearing loss and an input of 50 dB SPL, the first fitting of the hearing aid, in 2% and 5% of cases, reached within ±3 dB of the predicted curve in males and females, respectively.

In Aazh and Moore's (2007) [22] study on 24 individuals with a pure tone average of 53 dB in 0.5, 1, 2, and 4 kHz frequencies, in 64% of the cases, the first fitting failed to reach within ±10 dB of the predicted curve within the of 0.25 to 4 kHz frequency range. Moreover,

Table 2. Percentage of acceptable first fitting (considering the criterion of ±10 dB) at three intensity level inputs in two ears and within 0.5 to 6 kHz frequency range

Ear		Frequency,%				
		0.5	1	2	4	6
Right	50	70.70	65.20	66.30	33.50	22.80
	65	68.51	64.20	65.70	31.50	18.30
	80	71.70	67.40	68.50	40.20	9.80
Left	50	66.30	57.60	70.70	39.60	30.40
	65	67.40	53.30	44.65	31.50	22.80
	80	50.70	53.30	75.00	29.30	16.30

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Table 3. Results of paired sample t test comparing predicted and measured real-ear aided response in two ears within 0.5 to 6 kHz frequency range

Frequency	P				
	0.5	1	2	4	6
Input 50	0.001*	0.040*	0.009*	0.001*	0.001*
Input 65	0.024*	0.047*	0.001*	0.001*	0.001*
Input 80	0.015*	0.031*	0.001*	0.001*	0.001*

*P<0.05.

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the proportion of failures for the first fitting was higher at high frequencies compared to low frequencies. This result is similar to the findings of the current study. In another study, Aazh et al. (2012) [10] investigated 30 adults with mild hearing loss at 0.25 kHz and moderate to severe hearing loss at 4 kHz. According to the study's findings mentioned above, in 71% of the cases, the first fitting would not reach the ±10 dB of the NAL-NL1 REIG at one or more frequencies within the frequency range of 0.25 and 4 kHz. However, in the study mentioned above, hearing aids were prescribed as open fittings, and noise management and feedback cancellation systems were also active.

In comparison, in the current study, the hearing aids were prescribed as occluded, and the mentioned systems were not active either. Moreover, in this research, the initial fittings of hearing aids at 6 and 4 kHz were unacceptable in most cases. However, in Aazh et al. (2012) study, the initial fittings of the hearing aids at the frequencies of 1 and 4 kHz were unacceptable in most cases. This outcome was possibly due to their open prescription. It is noteworthy that the population investigated in the mentioned studies consisted of adults, while the current study population consisted of children with different degrees of hearing loss.

Given the results of the current study, no significant differences were found between predicted and measured curves (predicted-measured) of REAR in the degrees of hearing loss, gender, ethnicity, and ears. This finding indicates that the mentioned factors do not affect the difference between target and measured curves. Heidari and Sagheb (2006) showed that Fars and Baluch children are different regarding head and face type indicators, phenotypes [17], and the effectiveness of the factors mentioned above in the results of real-ear measurements [14]. Nevertheless, the results of the current study indicated no significant difference between Fars and Baluch children in terms of predicted and measured curves.

Although the difference between predicted and measured curves was greater in boys than in girls (Figure 4), it was not statistically significant. The greater difference observed in boys is likely due to the differences in the middle ear impedance and ear canal volume. In the current study, the boys' mean ear canal volume and compliance were higher than those of girls. As the difference was not statistically significant, the values related to tympanometry were not reported. The effects of the middle ear impedance and ear canal volume on predicted real ear values have already been confirmed [23, 24]. In this regard, the findings of the present study are different from those of the study conducted by Aarts and Caffee (2005) [9]. In their study, 17 men and 24 women aged 15 to 55 years were investigated. According to the findings of their study, the difference between predicted and measured REAR was more in men than in women and statistically significant. It is worth noting that the current study investigated the effects of gender in children, while the mentioned study examined the effects of gender in adults. Moreover, in the mentioned study, there was a significant difference between men and women in the ear canal volume, while there was no significant difference in compliance and middle ear impedance.

According to the results of the present study on the effects of degrees of hearing loss, there was no significant difference between the predicted and measured curves. However, as the degree of hearing loss increases, discrepancies between the predicted and measured curves also increase. As seen in figures 1, 2, and 3, discrepancies between the predicted and measured curves in individuals with profound hearing loss were larger than in those with moderate and moderate to severe hearing loss. However, these differences were not significant in some cases. To the best of the authors' knowledge, no study has been conducted on the difference between predicted and measured curves with regard to the effects of the degrees of hearing loss. Hence, there was no possibility of conducting a comparison in this respect.

5. Conclusion

Given the results of the present study and the difference observed between predicted and measured curves, especially at the frequencies of 6 and 4 kHz, it is essential to conduct real-ear measurements in children. Given the results of the current study, no significant differences were found in the effects of the degrees of hearing loss, gender, ethnicity, and ears between predicted and measured (predicted-measured) REAR.

Ethical Considerations

Compliance with ethical guidelines

The current study was approved by the Ethics Committee of Zahedan University of Medical Sciences. Children's parents provided informed consent forms before engagement, per the standards of the Declaration of Helsinki (Code: IR.ZAUMS.REC.1400.144).

Funding

This study did not receive any grant from funding agencies in the public, commercial, or non-profit sections.

Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

We are very thankful to the children and parents who engaged in this study.

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