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RESEARCH ARTICLE

The comparison of changes in hearing thresholds and insertion losses due to occlusion induced by ear impression in sound field assessment

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Abstract

Background and Aim: The methods of determining the amount of sound attenuation by ear mold, earplug or any other foreign body that placed in or out of the ear canal, is divided in subjective and objective. Due to the contradictory results in the studies in this field, this study aimed to use more audiometric frequencies considering the strengths and weaknesses of previous studies.

Methods: This study was conducted on 30 individuals with normal hearing in the age range of 21-26-year-old. First the impression mold was prepared from both ears. The evaluating real ear unaided response and the real ear occluded response. In the next step, hearing thresholds were assessed by sound field with a precision of 1 dB, once in both open ear and once in both closed ears. Finally, the insertion loss due to mold placement at each frequency was compared with the amount of behavioral threshold changes at the same frequency.

Results: By using paired t-test at frequencies of 400, 500, 800, 1000, 1500, 1600, 2000, 2500, 3000, 4000, 5000, 6000, 6300 and 8000 Hz, the difference in behavioral hearing thresholds with and without molding was greater than the amount of the insertion loss ($p < 0.001$).

Conclusion: The insertion loss due to impression for behavioral assessment at all of the tested frequencies were more than the attenuation in real ear evaluation ($p < 0.001$). In this regard, consequently the standard deviation of insertion loss due to impression in behavioral threshold condition was more than real ear measurement.

Keywords: Sound field assessment; insertion loss; real ear occluded response; ear impression; probe microphone measurement; real ear measurement

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Introduction

The methods for determining the extent of noise reduction via a mold, earplug, or any other external object placed inside the ear canal are categorized into subjective and objective groups [1-3]. The subjective assessments include the real-ear-attenuation-at-threshold (REAT) hearing threshold determination, while regarding objective assessment, the microphone-in-the-real-ear (MIRE) method can be mentioned [1,2,

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4-6]. Note that these two methods are mostly used in sound engineering and professional health areas. Thus, most research conducted so far through these methods have dealt with determining the reducing power of devices such as earplug, earmuff, and customized molds. In REAT method, using audiometer and through measuring the hearing threshold of a number of individuals with normal hearing using a reference sound, once with an open ear and another time with obstruction caused by headphone, mold, or earplug, the extent of its reduction power is determined in terms of dB [1,2,6,7]. REAT method is known as the gold standard for determining the reducing power of hearing protection devices [2,7]. Neitzel et al. stated that prediction of the extent of reduction obtained by mold or earplugs is dependent on the accuracy of the measurement system and variability of noise reduction over time (e.g. after refitting the device in the ear) [6]. In MIRE method, the reducing power of the headphone is obtained by subtracting the noise received by two microphones such that one microphone is placed inside the ear canal beneath the headphone, mold, or earplug, while the second microphone is embedded outside the ear and close to it [2,6]. Nelisse et al., citing the study by Berger, stated that in case of using only one microphone in the ear canal, the utilized method will be called MIRE [1,8]. This researcher also reported that in case of concurrent use of two microphones (one microphone inside the ear and the other outside the ear), the employed method will be called field-MIRE (F-MIRE) [1]. Kabe et al. reported that in case the REAT method is practiced by headphone, this method will be called headphone-based REAT. On the other hand, in case a speaker is used for presentation of the reference sound in MIRE method, it is called F-MIRE [5]. In any case, it is inferred that the MIRE method is similar to probe microphone measurement in audiology sciences.

Neitzel et al. [6] measured the extent of attenuation resulting from a spongy earplug and custom-molded model using REAT and MIRE measurement methods. The aim of this study was to compare the subjective values (REAT) and objective values (MIRE) of attenuation caused by the mentioned hearing protection devices. In this study, to conduct the REAT test, Supra-aural headphones were used; this means that the subjects were tested once with an open ear and another time through earplug (or mold) using Bekesy automatic audiometry by benefiting from the output sounds of a computer as sub-ear. The REAT test frequencies in this study were 250, 500, 1000, 2000, 4000, 6300, and 8000 Hz. Next, MIRE assessment was performed for the mentioned hearing protection devices using a broadband white noise for each of the subjects. Note that in REAT assessment, the difference of the hearing thresholds of each person was measured in the open and occluded ear states. However, in MIRE assessment, a microphone was placed inside the ear canal of the subject (under the hearing protection device), while the second microphone was installed on the person's shoulder. For this reason, in MIRE assessment, the effect of residence of the external ear was not applied to the input sound to the ear. In other words, REAT assessment measured insertion loss (IL) subjectively, while MIRE measured the noise attenuation (NR). Hence, to compare these two values, the extent resonance resulting from the external ear was added to the NR values. In the study by Neitzel, the term "transfer function of the open ear (TFOR)" has been used as equivalent to the term "ear resonance". Hence, the following relation can be inferred: IL = NR + TFOE [2,6].

Neitzel et al. added the norm, TFOE values to the NR values and then compared the results obtained from REAT and MIRE. The researchers in this study observed a greater measured attenuation for the REAT method as compared to MIRE at most tested frequencies. Further, these researchers reported that the extent of variability of standard deviation of this attenuation was greater in REAT (subjective) than in MIRE (objective). They attributed this to the subjective nature of REAT method and assessment of individuals with different hearing sensitivities in this study [6]. In other studies, greater standard deviation of REAT as compared to MIRE has also been noted [2,7,9].

Berger and Kerivan [9] in a review study on different methods for determining the attenuation power of hearing protection devices stated that the extent of noise attenuation was less in the REAT method at all frequencies except for low frequencies (e.g. 125 Hz) than the extent of attenuation calculated by MIRE method. Berger considered the effect of obstruction developed during ear blockage by headphones (or any other hearing protection devices) as the cause of more hearing of physiological noise of the body and thus masking the hearing thresholds at low frequencies. He viewed this as effective in the greater difference of thresholds in REAT method compared to the difference calculated in MIRE method at low frequencies. Also, Berger et al. stated that the shielding effect of the physiological notice of the body is evident at frequencies less than 500 Hz, whose value could be up to 6 dB. There are also some studies justifying this point [9,10]. Similar study suggest that the extent of noise attenuation at low frequencies is greater in REAT method as compared to MIRE [11]. Berger attributed the greater attenuation measured in MIRE method at other frequencies to the fact that normally, the bone conduction (BC) pathway also supports hearing noises through the air tract; in the REAT assessment method, this helps the person and their hearing thresholds improve. However, MIRE assessment is a kind of objective evaluation which does not benefit from the support of the BC pathway, and accordingly the extent of noise attenuation will be greater in MIRE method as compared to REAT [7].

In another similar study by Casali et al. on comparing the attenuating power of earmuff in REAT and MIRE methods in 1995, greater attenuation was observed for MIRE as compared to REAT at most frequencies tested [12]. Nevertheless, this difference was far less than the difference reported by Neitzel et al. between REAT and MIRE methods [6].

Nelisse et al. in a study on comparing objective and subjective methods for determining the attenuating power of hearing protection devices reported that quantitative studies have been conducted on the comparison and relationship between the extent of noise attenuation in subjective (e.g. REAT) and objective (MIRE/F-MIRE) methods. These researchers did not report any comparison or relationship between REAT and MIRE when presenting their initial results of their study [1].

So far, sparse studies have been conducted on comparing the attenuating power through hearing protection devices, precast molds, and customized molds in subjective and objective measurements. Considering the contradictory results in the above studies, this study was conducted while considering the strong and weak points of previous studies. In other words, the aim of comparing the values of attenuation resulting from the mold subjectively (assessment of hearing thresholds in the sound field state) and objectively (real ear assessment) in this study was the fact that through applying a larger number of audiometric frequencies for the comparison, in addition to confirming or rejecting previous studies, the difference between these two issues can be inspected more accurately.

Methods

The present study was of descriptive-analytical cross-sectional type. The study population included some students of School of Rehabilitation Sciences at Iran University of Medical Sciences. Following a call, they referred to an audiometry clinic located in the faculty, and based on the inclusion criteria (normal hearing sensitivity and tympanometry results, and lack of any structural pathology in pinna and/or outer ear canal), they were enrolled after receiving consent form. The age range of the studied individuals was 21−26 years old. In this study, 30 participants (16 male and 14 female) were chosen from the available population. The study was approved by Iran University of Medical Sciences Ethics Committee by Cod No. IR.IUMS.FMD.REC. 1396 9511301003.

For real ear assessments, FONIX FP35 (Frye Co.) device was used, while for sound field audiometric test, diagnostic audiometer device (Interacoustics, AC40) connected to two speakers of Pezhvak Ava Co. (AP12) was utilized.

At the beginning, a primary mold (impression) was prepared from both ears of the individuals using classic future molding paste made of silicon type c (Detax Co.). Then, real ear and audiometric assessments were performed. The stages were initiated by the real ear assessment. Since the geometric status of the external ear canal and the impedance of the middle ear play a significant role in determining the acoustic characteristics of the external ear canal, and since sound pressure distribution is not the same across the entire external ear canal [13], the manner (depth) of the probe microphone placement will influence the real ear assessment results. Accordingly, in order to achieve precise real ear measurements (REM), the probe microphone should be placed at a standard depth of the external ear canal. In this study, the probe microphone incorporation method at a depth of 5 mm beyond the end of the mold has been adopted [14]. Next, the speaker of the real ear assessment device was connected 30 cm away from one of the right ear of the subject with a 45° azimuth angle, followed by calibration of the reference microphone of the device-placed alongside the ear lobe. In the next step, the real-ear-unaided-response (REUR) of the same ear of this subject was assessed from a distance of 30 cm with an azimuth angle of 45° through a sweep of input sounds (stimulus) with an intensity of 70 dB SPL at 43 frequencies between 200 and 8000 Hz. Note that this measurement was replicated three times, and eventually a mean of the data in the ear canal at each frequency is chosen as the REUR for that frequency. Next, using the primary molds, the ear of the candidate is blocked, and this time the real-ear-occluded-response (REOR) of the same ear is evaluated from the same distance, with the same angle, at the same frequency points and using the same intensity of stimuli. This measurement is also replicated three times, and a mean of values in the occluded ear canal at each frequency was considered as the REOR for that frequency. The discrepancy between REUR and REOR values at each frequency was considered as insertion loss (IL) value.

In the next stage, the hearing thresholds of the subjects were evaluated at octave and half-octave frequencies of 400, 500, 800, 1000, 1500, 1600, 2000, 2500, 3000, 4000, 5000, 6000, 6300, and 8000 Hz with an accuracy of 1 dB, once in both-ears-open state and another time in both-ears-occluded state (with the primary mold) as sound field then, the subject was taken to the sound field audiometry room, whereby the threshold of 14 octave and half-octave frequencies was evaluated within the range of 400-8000 Hz through 1 dB thresholding method, once in the both-ears-open state and another time in both-ears-occluded state (with the primary mold) (among the producible frequencies by the real ear assessment device of Frye Co. Model FONIX FP35 (USA) and the diagnostic audiometer device of Interacoustics Co., AC40 model (Denmark), 14 frequencies are common). Note that in the sound field audiometric test, the sound was presented at an azimuth degree of 45° from the same side of the subject's ear which had been tested for REUR and REOR. Next, the difference of the behavioral hearing thresholds was applied in the open ear and occluded-ear states as the extent of attenuation caused by mold placement at each frequency. Eventually, the obtained statistical data were analyzed by IBM SPSS 25, where the IL value was compared against the extent of sound attenuation resulting from mold incorporation. The obtained data were first analyzed descriptively. Given the normal distribution, data were analyzed by paired t-test.

Results

The results of descriptive statistics (mean of three assessments) of REUR and REOR at different frequencies are presented in Table 1.

The results of descriptive statistics (mean of three assessments) resulting from behavioral assessment of hearing thresholds of the subjects in the open ear and occluded ear conditions, at 14 different frequencies tested with an accuracy of 1 dB are shown in Table 2. The results of descriptive statistics of insertion losses and threshold shifts at 14 different frequencies tested are reported in Table 3.

In order to compare the extent of attenuation resulting from the mold embedment between the

Table 1. Descriptive measures of real ear unaided and real ear occluded response at different frequencies (n = 30)

	Real ear unaided response				Real ear occluded response			
Frequency (Hz)	**Mean (SD)**	**Min**	**Max**	**Range**	**Mean (SD)**	**Min**	**Max**	**Range**
400	70.85 (0.68)	69.03	72.13	3.10	68.72 (2.29)	64.97	72.33	7.37
500	71.47 (0.66)	70.03	73.00	2.97	68.15 (2.94)	63.57	72.50	8.93
800	72.27 (0.61)	71.10	73.63	2.53	65.31 (4.35)	58.70	74.43	15.73
1000	73.05 (0.70)	71.67	74.37	2.70	64.36 (4.38)	57.07	74.67	17.60
1500	75.16 (1.30)	72.60	77.60	5.00	62.09 (3.71)	56.10	69.17	13.07
1600	75.89 (1.32)	73.80	78.23	4.43	61.83 (3.62)	56.57	68.40	11.83
2000	80.46 (1.94)	77.83	86.30	8.47	61.96 (3.35)	57.10	68.63	11.53
2500	84.74 (2.73)	79.83	91.67	11.83	61.13 (3.55)	53.73	67.17	13.43
3000	85.13 (2.85)	78.73	89.23	10.50	61.47 (3.26)	53.90	69.67	15.77
4000	81.75 (7.65)	59.10	89.73	30.63	59.77 (3.94)	52.67	68.03	15.37
5000	79.76 (3.21)	71.60	85.70	14.10	55.01 (5.04)	43.53	66.83	23.30
6000	76.67 (5.09)	63.77	83.50	19.73	53.97 (4.23)	45.27	63.13	7.37
6300	75.76 (5.10)	63.40	82.87	19.47	54.98 (4.15)	47.13	64.43	8.93
8000	72.66 (5.50)	59.77	81.43	21.67	57.23 (4.57)	47.03	63.80	15.73

subjective and objective state, paired t-test was used. The results obtained from this comparison are shown in Table 4.

According to the data of Tables 3 and 4, at all frequencies tested, the extent of attenuation measured in the subjective state (behavioral) was greater than the extent of attenuation measured in the objective state (real ear assessment). Note that given the p value in the Table 4, there is a significant difference between all pairs compared ($p < 0.001$).

Discussion

In this study, the extent of variability of hearing threshold resulting from occlusion of the primary mold with the extent of attenuation measured in real ear assessment (IL) of the subjects was evaluated at 14 different frequencies as single decibel and then compared as paired comparisons. At all of the tested frequencies here, the extent of attenuation was greater in the subjective state (changes in the behavioral threshold) than extent of attenuation in the objective state (IL). Note that considering the p value in Table 4, there was a significant difference between all of the pairs compared ($p < 0.001$). Also, in the present study, considering the standard deviation values obtained in Tables 1 and 2, variability of the real ear assessment was far less than that of the behavioral assessment.

Neitzel et al. measured the extent of attenuation resulting from a spongy and custom-molded earplug through REAT (subjective) and MIRE (objective) methods. They found that when using the spongy earplug, the extent of attenuation was greater in the subjective state (REAT method) than in the objective method (MIRE method) except at frequencies 4000 and 6000 Hz. Also, when using the custom-molded plug, the extent of attenuation in the subjective state

Table 2. Results of descriptive statistics from behavioral assessment of auditory thresholds in both-ear-open and both-ear-occluded conditions (n = 30)

	Both-ear-open condition				Both-ear-occluded condition			
Frequency (Hz)	**Mean (SD)**	**Min**	**Max**	**Range**	**Mean (SD)**	**Min**	**Max**	**Range**
400	17.86 (5.84)	7.00	24.00	17.00	40.26 (8.91)	26.00	59.00	33.00
500	13.03 (5.17)	6.00	20.00	18.00	35.30 (8.23)	22.00	55.00	33.00
800	11.23 (5.29)	5.00	19.00	14.00	34.76 (9.25)	19.00	58.00	39.00
1000	7.23 (5.23)	1.00	15.00	14.00	30.83 (9.04)	16.00	53.00	37.00
1500	6.56 (8.23)	−2.00	16.00	18.00	33.76 (11.31)	15.00	64.00	49.00
1600	8.53 (10.36)	−1.00	17.00	18.00	32.53 (8.70)	20.00	60.00	40.00
2000	7.70 (7.98)	−2.00	14.00	16.00	40.93 (9.83)	26.00	70.00	44.00
2500	8.20 (7.96)	−4.00	15.00	19.00	48.76 (9.76)	30.00	76.00	46.00
3000	4.50 (7.43)	−5.00	14.00	19.00	43.66 (8.79)	30.00	71.00	41.00
4000	5.56 (7.97)	−7.00	13.00	20.00	45.46 (7.14)	29.00	64.00	35.00
5000	9.53 (7.05)	0.00	19.00	19.00	49.00 (8.99)	31.00	68.00	37.00
6000	5.60 (8.34)	−7.00	18.00	25.00	42.30 (9.10)	24.00	63.00	39.00
6300	7.23 (7.78)	−5.00	17.00	22.00	43.60 (8.20)	24.00	59.00	35.00
8000	2.53 (5.39)	−8.00	12.00	20.00	34.40 (10.13)	14.00	54.00	40.00

was greater than that of the objective state except that 6300 Hz. Further, the extent of variability of objective assessment was far less than that of the subjective assessment; the mentioned researchers attributed this to the subjective nature of REAT method and evaluation of individuals with different hearing sensitivities in this study [6]. In other studies conducted by Biabani et al., Berger and Berger and Kerivan, greater standard deviation of REAT compared to MIRE has been noted [2,7,9].

One of the weaknesses of Neitzel et al. study was applying REAT method as under-ear, the low number of audiometric frequencies tested (seven frequencies), usage of Békésy audiometric method through the sound generated by the computer sound card, insufficient control of background noise in REAT assessment, placement of the second microphone on the shoulder of the subjects and comparison of the intra- and extra-ear sound in MIRE assessment, not measuring the extent of external ear resonance and addition of normalized values of the external ear resonance to NR values to compare NR and IL values. In the present study, in addition to considering and controlling all of the mentioned issues, 14 audiometric frequencies have been used for the research.

Berger in a review study on different methods of determining the attenuating power of hearing protection devices reported that the extent of noise attenuation is lower in REAT method at all frequencies except for low frequencies (e.g. 125 Hz) as compared to the attenuation level calculated in MIRE method [7]. Thus, the results of this study are in line with the following study at low frequencies, while being incongruent at all frequencies.

The justification of Berger for the larger difference of thresholds in the REAT method as

Table 3. Descriptive measures of insertion losses and threshold shifts at different frequencies

Frequency (Hz)	Insertion loss (dB)	Threshold shift (dB)
400	2.13	22.40
500	3.32	22.27
800	6.96	23.53
1000	8.69	23.60
1500	13.07	27.20
1600	14.06	24.00
2000	18.50	33.23
2500	23.61	40.56
3000	23.66	39.16
4000	21.98	39.90
5000	24.75	39.47
6000	22.70	36.70
6300	20.78	36.37
8000	15.43	31.87

compared to the difference calculated by MIRE method at low frequencies is the shielding effect of the physiological noises of the body during occlusion of the ear by the earplug and the influence of these noises on the behavioral thresholds. Berger considered this shielding effect as evident at frequencies less than 500 Hz. Also, Berger attributed the lower extent of attenuation in REAT as compared to MIRE at high frequencies to the supportive role of bone conduction in transmitting sound to the inner ear and thus improved behavioral thresholds. In this study, by keeping the physical conditions governing the measurements constant and comparing the behavioral thresholds of the subjects with and without mold, the bone conduction has absolutely no confounding role in the course of measurement and comparison [7].

In another similar study by Zera and Mlynski it was found that the extent of sound attenuation at low frequencies was greater in REAT method as compared to MIRE [11].

Based on the above studies, it is found that in most of them there is consensus over the extent of attenuation in the subjective measurement method as compared to the objective measurement method at low frequencies. However, there is controversy over comparison of the attenuating power of these two methods at high frequencies.

In all of the above studies, the extent of standard deviation of the results obtained from subjective method has been larger than that of the objective method. This can be attributed to issues such as the subjective nature of the first method, differences between the test-retest accuracy of the subjects in the mentioned studies, and differences in the hearing sensitivity of the subjects in those studies.

Note that in this study, the greater attenuating power in the subjective method compared to the objective counterpart can be attributed to factors such as the effect of physiological noises of the body on behavioral assessments (during placement of the primary mold in the ear canal) as well as better sealing of the ear canal by the mold in the behavioral assessment. This is because during the real ear assessments, the probe tube is placed between the mold canal and ear canal of the person, and can potentially cause diminished extent of occlusion resulting from mold placement especially at low frequencies. Further, behavioral assessments of the subjects have been performed as single decibel.

Since in the present study first the primary mold was prepared from the ear of the subjects and then the probe tube of the real ear assessment was placed inside the ear of the subjects, deploying the probe tube between the wall of the external ear canal and the primary mold may cause underestimation of IL (especially at lower frequencies). This can be considered a confounding factor in measuring the induced attenuation at the mentioned frequencies. On the other hand, in the behavioral assessment, the primary mold caused ear occlusion completely and without any seals between the body of the mold and the ear canal wall. This can potentially be effective

Table 4. Comparison between subjective and objective assessment of the extent of sound attenuation due to occlusion induced by ear impression placement

Type of comparison		Difference of the pairs		
		Mean (dB)	**SD**	**p**
Pair 1	**dif REM 400Hz - dif mold 400Hz**	-20.270	10.011	< 0.001
Pair 2	**dif REM 500Hz - dif mold 500Hz**	-18.940	7.994	< 0.001
Pair 3	**dif REM 800Hz - dif mold 800Hz**	-16.574	8.468	< 0.001
Pair 4	**dif REM 1000Hz - dif mold 1000Hz**	-14.914	8.289	< 0.001
Pair 5	**dif REM 1500Hz - dif mold 1500Hz**	-14.125	10.528	< 0.001
Pair 6	**dif REM 1600Hz - dif mold 1600Hz**	-9.943	11.193	< 0.001
Pair 7	**dif REM 2000Hz - dif mold 2000Hz**	-14.731	7.764	< 0.001
Pair 8	**dif REM 2500Hz - dif mold 2500Hz**	-16.960	9.987	< 0.001
Pair 9	**dif REM 3000Hz - dif mold 3000Hz**	-15.501	9.169	< 0.001
Pair 10	**dif REM 4000Hz - dif mold 4000Hz**	-17.918	11.055	< 0.001
Pair 11	**dif REM 5000Hz - dif mold 5000Hz**	-14.717	11.674	< 0.001
Pair 12	**dif REM 6000Hz - dif mold 6000Hz**	-14.002	13.201	< 0.001
Pair 13	**dif REM 6300Hz - dif mold 6300Hz**	-15.590	11.988	< 0.001
Pair 14	**dif REM 8000Hz - dif mold 8000Hz**	-16.444	14.473	< 0.001

dif; difference, REM; real ear measurement

in the larger values of behavioral official differences as compared to the induced drop. Hence, this point has been one of the limitations of this study, and if one could mold the ear after placement and deployment of the probe tube in the external ear canal (without withdrawing the probe tube from the external ear canal), the measured IL value may increase.

With regards to future research areas and in order to increase the knowledge in this regard, it is suggested that other studies are conducted with a larger sample size. Also, preparation of the primary mold after placement and fixation of the probe tube in the external ear canal (without extracting the probe tube from the external ear canal) is suggested.

Conclusion

The present study, comparing the changes in the hearing thresholds with and without primary mold occlusion in sound field with its resulting insertion loss (IL), indicated the extent of attenuation arising from the primary mold in the case of behavioral assessment (the difference of hearing thresholds with and without mold) was greater than the extent of attenuation in the real ear assessment (IL) at all tested frequencies. Further, the extent of attenuation caused by the primary mold was far greater in the behavioral assessment case as compared to the real ear assessment.

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Conflict of interest

The authors declared no conflicts of interest.

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