The Journal of International Advanced Otology

J Int Adv Otol 2016; 12(2): 189-93 • DOI: 10.5152/iao.2016.1694

Original Article

The Effects of Silicone and Acrylic Ear Mold Materials on Outer Ear Canal Resonance Characteristics

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OBJECTIVES: The aim of this study is to investigate the effects of earmolds made of silicone and acrylic on outer ear canal resonance characteristics in terms of resonance frequency and amplitude measured in a hearing aid fitting.

MATERIALS and METHODS: Outer ear canal resonance frequencies and amplitudes in open ears and those measured with silicone and acrylic ear molds were obtained from 30 participants between the ages of 20 and 25 years (average age, 22.0 years; 18 females and 12 males) with a real ear gain measurement. To observe the changes depending on probe tube placement, test–retest variation was investigated in 10 participants before the study.

RESULTS: There was no statistically significant difference between open ear canal resonance frequencies and those measured with silicone and acrylic earmolds (p>0.05). the silicone earmold resonance amplitude values were statistically significantly lower than the open ear canal resonance amplitudes when compared to those of the acrylic earmolds (p<0.05).

CONCLUSION: Depending on the changes occurring in outer ear resonance features as a result of earmold materials used in hearing aid fittings, the application of earmolds should be done by experienced specialists.

KEYWORDS: Earmold, outer ear canal resonance, real ear gain measurement

INTRODUCTION

The use of earmolds for fitting hearing aids started approximately 80 years ago with the application of rubber [1]. With rapid advances in hearing aid technology, earmold materials and models have expanded to a great extent such that the design of earmold materials started aiming to prevent acoustic feedback as well as improve the cosmetic appearance. In the manufacturing of earmolds, a variety of soft and hard materials, such as ultraviolet resins, polyethylene, soft/hard acrylic, silicone, and polyvinyl chloride, can be used [2]. However, earmolds made of silicone and acrylic materials are mostly preferred particularly for behind the hearing aid fitting because of the advantages of application comfort, durability, and ease of cleaning considering the hearing loss configuration.

The outer ear canal acts as a resonator. In 1946, Wiener and Ross [3] inserted two probe tube microphones into the auditory canal: one was placed close to the tympanic membrane and the other was placed exactly in the middle of the tympanic membrane and concha. Sound pressure levels sent from a sound source were measured at these two different locations at 0°, 45°, and 90° in the horizontal direction in a sound-free booth. The authors indicated that the pressure distribution in the outer ear canal differs corresponding to the frequencies, that maximum gain is observed between 2.0 and 4.0 kHz, and that the peak at 3.0 kHz is 17–22 dB. Outer ear canal resonance features change depending on the canal length and diameter, which increase with age [4-5]. In adults, outer ear resonance provides an approximately 10 dB amplification to the auditory system between 2000-4000 Hz [6].

Another factor affecting outer canal resonance features is earmolds used for a hearing aid fitting. When an earmold is inserted in the ear, the resonance characteristics of the outer ear canal will change because of the deprivation of the acoustic signal, particularly in mid-frequencies, resulting in insertion loss. The amount of insertion loss changes depending on earmold features [7]. In addition, the characteristics of ear mold (i.e diameter and length of the tube, filters, and ventilation tube affect canal resonance features [8].

In real ear gain (REG) measurements to fit the hearing aid, first, the open ear canal resonance is measured, and then, by inserting a hearing aid into the ear with an earmold, outer ear canal gain features are calculated when the hearing aid is turned off. In the last measurement, the hearing aid amplification required for a given audiogram is determined by calculating the effects of earmold features on the outer ear canal resonance when the hearing aid is turned on. In this application, it is of vital importance to properly insert the earmold. In an REG measurement, it is the first rule to not smash the probe tube inserted into the ear. Earmold materials may affect the REG measurement features depending on whether they are soft or hard. In this study, the importance of earmolds (standard,

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Submitted: 14.10.2015 **Revision received:** 04.04.2016 **Accepted:** 05.04.2016

tubeless without a ventilation tube and filter) made of acrylic (hard) or silicone (soft) materials on the outer ear canal resonance frequency and amplitude in REG measurements is examined. As the hypothesis of this study, it was investigated that silicone earmolds affect external auditory canal resonance more than acrylic earmolds because of their low hardness and that they may result in more insertion loss.

MATERIALS and METHODS

Subjects

Thirty university students between the ages of 20 and 25 years (mean±SD: 22.29±1.82 years), of which 18 were males and 12 were females, were included. Inclusion criteria for participation were as follows: age between 18 and 25 years, no outer or middle ear surgery history, not experiencing outer or middle ear infection during the study period, and willing to participate in the study. Participants with normal otoscopic findings and diagnosed as having a normal type A tympanogram (with AZ 26 model acoustic immitancemeter; Interacoustics, Assens, Denmark) were included [9]. The hearing thresholds (with Equinox model audiometer; Interacoustics, Middelfart, Denmark) between 125 and 8000 Hz were measured as 20 dB and higher. Participants with earwax were excluded even after cleaning because the irritation of the outer ear canal skin may affect the measurements. Written informed consent was obtained from each participant.

Taking Earmold Impressions

Before taking ear impressions, all participants were thoroughly informed that they might experience a feeling of fullness in their ear. They were asked to sit on a comfortable chair, to hold their mouths in a regular closed position, to not talk, and to not move their chins. Three different size foam blocks (Otoblock; Surrey, Canada) were used to prevent the earmold material from flowing deeper inside the ear. While determining the earmold impression length, attention was paid to cover the second bend, which is the joint of the canal cartilage and bone tissue [10]. Hygienic conditions were preserved during this procedure. In all earmolds made of silicone and acrylic, a tube was not used because features such as the length and diameter of the tube may affect the outer ear canal resonance [8].

Outer Ear Canal Resonance Measurements

Real ear measurements (REMs) were taken in a silent room using Aurical Plus (Otometrics; Taastrup, Denmark) to record the outer ear canal resonance. For each participant, as the first measurement in the open ear, canal resonance characteristics were obtained as prescribed by the American Speech Language Hearing Association [11] in the "real ear unaided response" (REUR) section and earmold measurements were taken in the "occluded ear response" (OER). In the gain curve, resonance amplitude as the peak amplitude and resonance frequency as the peak frequency with the maximum amplitude of the outer ear were obtained in terms of dB sound pressure level (SPL) and Hz, respectively, in the open ear and with the silicone and acrylic earmold. Tube settings were completely turned off in the REM device to eliminate the effects of the variables depending on the tube features.

Participants were located 1 m away from loudspeakers with 45° angles. Before inserting the probe tube, room and probe tube calibrations were made. "Visually-assisted positioning" was employed in the probe tube placement as recommended in the literature [12]. In REM, for probe tube placement, the outer ear canal length was considered to be 25 mm in males. Therefore, assuming a 10 mm length from the outer ear opening to the intertragal cavity, it was stated [13] that probe tube was to be inserted at 30 mm from the tragus in males. In this case, the insertion of the probe tube was maintained 5 mm away from the tympanic membrane [13]. Further, in this study, the probe tube insertion was maintained approximately 25–30 mm and 25–28 mm away from the tragus for male and female participants, respectively. The input value of 65 dB SPL was used in the REUR and OER measurements.

In particular, considering conditions where the occlusion effect occurred because of the blockage of the probe tube when it contacted with the ear canal wall or bent during the insertion of the earmold, the measurements were repeated two or three times for each application. The measurements obtained with the silicone and acrylic earmolds were randomly taken. The test time was approximately 45 min for each participant. Ethics committee approval was received for this study from the ethics committee of Turgut Özal University/Reference No: 12122014399.

Statistical Analysis

It was investigated whether there was a statistical significance between the measurements of resonance frequencies in the open ear and those obtained with the silicone and acrylic earmolds. For standardization, resonance amplitude differences were obtained by subtracting the maximum amplitude in the resonance frequency from the standard input value (65 dB SPL) used in the REG measurement. The resonance amplitude differences were separately calculated for each measurement in the open ear and with the acrylic and silicone earmolds. Then, the results were statistically analyzed. In all analyses performed using Statistical Package for Social Sciences software 20.0 (IBM Corporation Inc.; NY, USA), the significance level was set at $p \leq 0.05$.

RESULTS

Analysis of Test–Retest Variability

The test–retest variability was investigated in a group of 10 participants to evaluate the differences between the two measurements in the open ear and with silicone and acrylic earmolds depending on probe tube placement. The second measurement was taken 1 h after the first measurement. The mean resonance frequencies±SD for the open ear and with the silicone and acrylic earmolds in the first measurement were 3714.6±593.65, 3648±803.08, 3562.8±32.45, respectively, and in the second measurement were 3716.50±565.88, 3629±809.62, 3539.8±527.14, respectively. The mean resonance amplitude differences±SD for the open ear and with the silicone and acrylic earmolds in the first measurement were 5.20±2.57, 7.40±3.97, and 2.50±1.78, respectively, and in the second measurement were 5.20±2.44, 7.50±3.40, and 2.70±1.63, respectively. In Table 1, the Mann–Whitney U test indicated that there was no statistically significant difference between both measurements made in the open ear and with silicone and acrylic earmolds with regard to resonance frequencies and resonance amplitude differences ($p>0.05$). Further, the intraclass correlation coefficient test exhibited higher reliability for the two measurements with the earmolds and in the open ear (Table 2). This shows the reliability of outer ear canal resonance measurements in REM. The individual resonance characteristics of a participant are given Figure 1 (with silicone earmold) and Figure 2 (with acrylic earmold).

Table 1. Statistical analysis of the test–retest reliability of the resonance frequency and resonance amplitude differences

	Resonance frequency			Resonance amplitude differences		
	Open ear	Silicone	Acrylic	Open ear	Silicone	Acrylic
Mann–Whitney U	47,000	49,500	48,000	48,500	49,500	49,000
Wilcoxon W	102,000	104,500	103,000	103,500	104,500	104,000
Z	−0.227	−0.038	−0.151	−0.115	−0.038	−0.076
P*	0.820	0.970	0.880	0.908	0.970	0.939

*not significant; p>0.05

Table 2. Analysis of the intraclass reliability

Intraclass correlation*	Resonance frequency	Resonance amplitude difference
Open ear	0.991 (0.963–0.998)	0.920 (0.709–0.980)
Silicone	0.996 (0.985–0.999)	0.967 (0.875–0.992)
Acrylic	0.991 (0.982–0.999)	0.784 (0.525–0.911)

*95% confidence interval

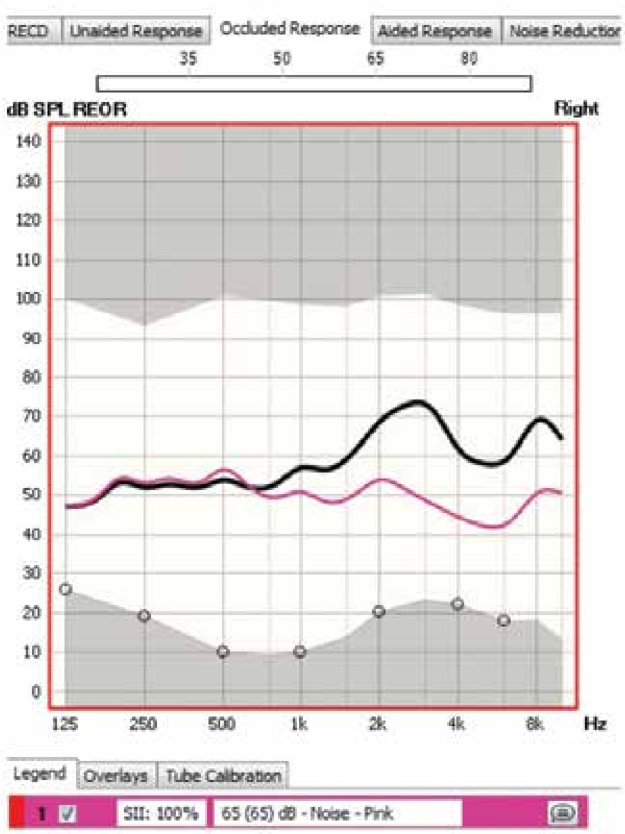

Figure 1. The individual open ear and silicone earmold resonance curves. This graphic shows the resonance curve of the open ear (top) and silicone earmold (bottom).

Analysis of Resonance Frequency

The mean resonance frequencies±SD in terms of Hz were 3610±630.20 in the open ear, 3649.03±633.62 with the silicone earmold, and 3539.03±606.54 with the acrylic earmold. When compared with the mean open ear resonance frequency, the mean resonance

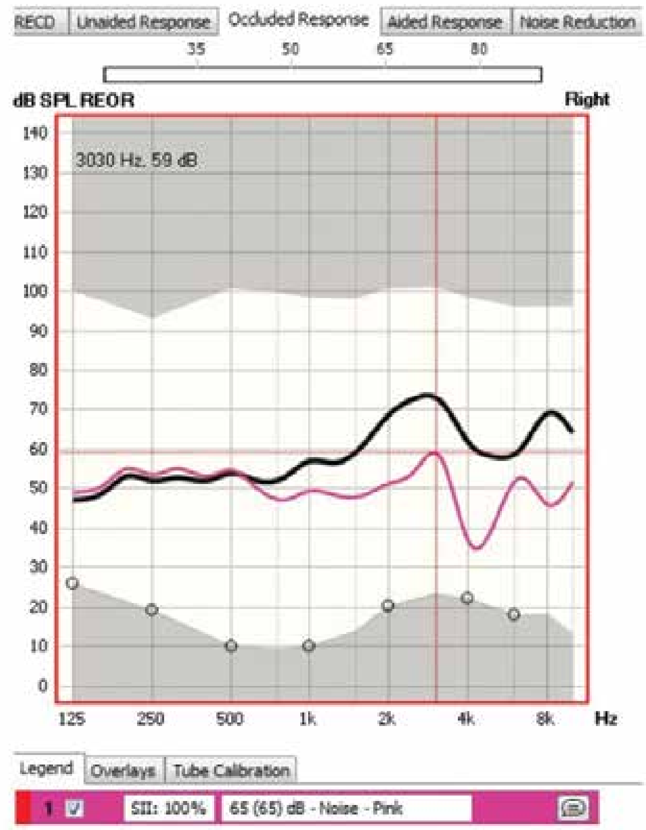

Figure 2. The individual open ear and acrylic earmold resonance curves. This graphic shows the resonance curve of the open ear (top) and acrylic earmold (bottom).

frequency of the silicone earmold was slightly higher and that of the acrylic earmold was slightly lower. The difference between these values was compared with paired sample t-test. It is indicated in Table 3 that both means of silicone and acrylic earmolds exhibited no statistically significant difference from the mean of open ear resonance frequency (p>0.05). As a result, although the silicone and acrylic earmolds led to a change in the outer ear canal resonance frequency, they did not significantly affect it.

Analysis of Resonance Amplitude Difference

The mean open ear amplitude difference±SD was 5.76±2.44. The mean silicone earmold amplitude difference±SD (6.66±2.85) and mean acrylic earmold amplitude difference±SD (2.22±1.71) were significantly lower than the mean open ear amplitude difference. Paired sample t-test results (Table 4) showed that both silicone and acrylic earmold resonance amplitude differences were statistically significantly lower than the open ear resonance amplitude difference (p<0.05). Obtaining significantly lower resonance amplitudes with both earmolds than those in the open ear shows that the earmold materials had a significant effect on outer ear canal resonance amplitudes.

Comparison of Resonance Frequency and Amplitude Difference between Silicone and Acrylic Earmolds

When compared to the open ear resonance frequency and amplitude difference, the mean resonance amplitude with the silicone earmold was lower than that with the acrylic earmold; the mean resonance frequency with the silicone earmold was higher than with the acrylic ear-

Table 3. Statistical analysis of the resonance frequency obtained in the open ear and with silicone and the acrylic earmold measurements

	Mean	SD	t	P*
**Open ear-silicone	−39.033	474.711	−0.450	0.656
***Open ear-acrylic	70.967	537.185	0.724	0.475

SD: standard deviation; t: paired sample t-test
*not significant; p>0.05
**Statistical analysis between mean values of open ear and silicone earmolds
***Statistical analysis between mean values of open ear and acrylic earmolds

Table 4. Statistical analysis of the resonance amplitude differences obtained in the open ear and with the silicone and acrylic earmold measurements

	Mean	SD	t	P
**Open ear-silicone	0.90000	4.49789	1.096	0.042*
***Open ear-acrylic	−3.56667	2.89689	−6.744	0.000**

SD: standard deviation; t: paired sample t-test
*p<0.05; **p<0.01
**Statistical analysis between mean values of open ear and silicone earmolds
***Statistical analysis between mean values of open ear and acrylic earmolds

Table 5. The comparison of the resonance frequencies and amplitudes in the silicone and acrylic earmold measurements

	Mean	SD	t	P
Frequency silicone-acrylic	110.0	439.605	1.371	0.181
Amplitude silicone-acrylic	4.46667	3.67408	6.659	0.000*

SD: standard deviation; t: paired sample t-test
*p<0.01

mold. T-test results showed that the resonance amplitude with the silicone earmold was significantly lower than that with the acrylic earmold, demonstrating that the silicone earmolds reduce the outer ear canal resonance amplitudes more than the acrylic earmolds (p<0.05). However, there was no statistically significant difference between the resonance frequencies of the silicone and acrylic earmolds (p>0.05) (Table 5).

DISCUSSION

Considering that most audiology clinics may still currently prefer silicone earmolds for all kinds of hearing aid applications due to their ease of use, this study was designed to show the effects of earmold materials on the fitting procedure in clinical settings. We examined the effects of silicone and acrylic earmolds on outer ear resonance characteristics in terms of frequencies and amplitudes obtained at REG measurements. The results, in relation to the application of the earmold materials and the effects of these materials on outer ear canal resonance characteristics in REMs, provided practical and useful information for daily routine clinical use.

The silicone and acrylic earmolds used in the measurements were prepared as a standard ear mold without tubeand with lengths that do not extend to the second bend of the outer ear. The results demonstrated that the mean resonance frequencies measured with the silicone and acrylic earmolds were similar to the mean open ear canal resonance frequency. However, regarding resonance amplitude, significant differences were observed in the silicone and acrylic earmold measurements when compared to the open ear resonance amplitude. In particular, the mean resonance amplitudes obtained with the silicone and acrylic earmolds were found to be statistically significantly lower than the mean open ear resonance amplitude. Further, it was found that the mean resonance amplitude obtained with the silicon earmold was lower than that obtained with the acrylic earmold. Therefore, earmold materials do not affect the outer ear canal resonance frequency but have a significant effect on canal resonance amplitude.

In our study, the resonance amplitudes obtained with the silicon and acrylic earmolds were found to be different compared to the open ear resonance amplitude. This difference may have resulted from the softness values of the earmold materials. The softness of a given material is described as the shore value; this differs depending on the material type. The shore value for soft acrylic and soft ultra-violet materials varies between 40 and 50; for PVC and silicon earmolds, it varies between 30 and 50 and between 25 and 55, respectively. The shore value is 90 for rigid materials [1]. The lower the shore value is, the more flexible the materials are. A silicone earmold, which is more flexible, completly fills the concha and supplies a better fit to the outer ear canal. However, an acrylic earmold, which has a low shore value, is thought to affect the outer ear canal resonance less because it would not completely covers the cocnha as much as its silicon counterpart.

One of the most important issues is deciding which earmold material should be preferred for better hearing instrument fitting; this is related to the degree and configuration of hearing loss. Regarding mild–to-moderate and moderate-to-severe hearing loss, high gain is not needed for hearing aid fitting. However, for severe hearing loss, the hearing instrument gain should be at the maximum setting. Professionals must decide to choose earmold materials considering the degree and configuration of hearing loss. For example, in a configuration with only high-frequency hearing loss where low frequencies are normal or nearly normal, a patient would feel an aural fullness once the ear is covered by an earmold. Our study that shows the resonance frequency with the acrylic earmolds was similar to that obtained in the open ear. Moreover, the acrylic earmolds had a less effect on the resonance amplitude when compared to the silicon earmolds. These results suggest that it would be more reasonable to prefer the acrylic earmold for hearing aid fitting that requires less or no gain in low frequencies to avoid fullness in the ear.

Once the earmold is inserted, an acoustic seal occurs between the ear canal opening and the second bend of the canal. If the seal is inadequate, external feedback occurs due to which the amplified signal escapes from the ear canal, reaches the microphone of the hearing aid, and causes the amplifier to oscillate. In the literature, preventing acoustic feedback using silicone and acrylic earmolds is an important issue [14, 15]. Pirzanski and Maye [14] investigated the usage of 1413 earmolds made of hard materials and 1318 earmolds made of soft materials. They stated that soft earmold materials are preferred for severe hearing loss (39%) to better eliminate the acoustic feedback better, while hard earmold materials are preferred for (24%) for the mild-to-moderate hearing loss. They also reported that soft earmolds particularly made of silicone are more difficult for the modification.

The viscosity of earmold impression materials, the earmold impression technique, and the thickness of the impression coating play an important role to eliminate the acoustic feedback in an earmold fitting. In 1990, Macrae conducted a series of experiment on a varying number of subjects to investigate the differences between earmolds made from waxed impressions with those made from non-waxed multilayer impressions regarding with the effectiveness of the seal [15]. He used silicone earmolds, and for each subject, he had been four earmold types, in which their wax thickness varied between A and D. The earmold A EM-A had the thinnest and the earmold D EM-D had the thickest impression coating. The earmold EM-O was not coated prior to making earmolds. He reported that when the wax thickness increased from A to D, the seal effectiveness measured also increased and that 65% of the thickest EM-D earmolds provided a better seal. Moreover, he pointed out that EM-O earmolds had the best seal quality (88%). This study showed us how to use earmold materials that affect the earmold's seal and fitting properties in the outer ear canal resonance. It is advisable to prefer a silicon earmold that fits in the ear tighter to eliminate the feedback. In our study, resonance frequencies of the silicon earmolds were similar to the open ear resonance frequencies, and this supports safely using silicone earmolds for hearing aid fitting considering the configuration of hearing loss. However, it should be noted that not only the earmold material but also modifications such as the length, diameter, and ventilation of the tube and reverse horn affect the resonance features of the external ear to a great extent. Therefore, hearing instrument applications should be applied by a specialist having knowledge of not only suitable earmold materials but also on the effect of the modifications. Further, modifications of the earmold might become more difficult depending on the hardness of the earmold material. In particular, acrylic earmolds may be reason for preference for up to mild-to-moderate hearing loss because it would be hard to apply the modifications on the silicon earmold. Likewise, in hearing loss where low-frequency gain is less desired, skeleton earmolds may be preferable. A skeleton earmold can be applied easier with a harder earmold material owing to its hardness. It is composed of "c"-shaped part covering the concha of the outer ear and a tube inserted in the outer ear canal [16, 17]. It is very difficult to obtain such a shape with a silicon earmold.

The other reason for preference of earmold materials may differ, i.e., durability, easy cleaning, and ear comfort [18]. Theoretically, softer earmolds are expected to be more comfortable than harder earmolds. However, this comfort may obtain with harder earmold materials. In 1977, Maye reported that with a suitable technique for taking impressions and a good manufacturing process, the modification in hearing aids might drop down to 0.7% [19]. In addition, both silicone and acrylic materials are hypoallergenic; this enables their usage on allergic or sensitive people. However, it is advised to perform allergy tests before using earmolds [1].

One of the most important problems is the placement of the probe tube that specialists face during REG measurements [20]. In particular, probe tube placement is really difficult during the fitting process in children and when the hearing aid is inserted with earmolds into the outer ear canal. The most common problem is that the probe tube is smashed under the earmold, resulting in an incorrect measurement due to the blockage. In this study, we statistically examined the effects of probe tube placement with test-retest. The results showed that there was no significant difference between the two measurements for each earmold material. This result supports the reliability of REG measurements. However, it should be noted that the measurements in our study were easily taken because the participants were young adults. In particular, the insertion of the probe tube in children should be carefully followed by audiologists.

In our study, while comparing the outer ear resonance characteristics of the silicon and acrylic earmolds, it was found that the silicon earmold affects the outer ear canal resonance amplitude more than the acrylic earmold; This suggests that earmold applications should carefully performed by a specialist. To conclude, earmold applications should be applied considering the earmold material in addition to factors such as the patient's age, the manual dexterity of the patient, the shape of the ear and earmold, and the degree and configuration of hearing loss.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Turgut Özal University/Reference No: 12122014399.

Informed Consent: Written informed consent was obtained from the parents of the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - A.E.; Design: A.E., Ş.A.; Supervision - A.E.; Resources - A.E., Ş.A.; Materials - A.E., Ş.A.; Data Collection and/or Processing - Ş.A., A.E.; Analysis and/or Interpretation - A.E., Ş.A.; Literature Search - A.E., Ş.A.; Writing Manuscript - A.E.; Critical Review - A.E., Ş.A.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

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