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Abstract

Objective. To evaluate and compare the efficacy of commercially available earplugs in preventing water intrusion in healthy individuals.

Study Design. Experimental study.

Setting. Tertiary care medical center.

Subjects and Methods. Ten subjects (20 ears) were assessed. After insertion of the earplugs, subjects underwent 3 standardized head-wetting protocols, including (1) surface swimming for 10 minutes, which entailed no head submersion and moderate splashing; (2) head submersion at a 90-cm depth for 20 seconds with their head upright; and (3) head submersion at a 90-cm depth with head tilted 90 degrees left and then tilted 90 degrees right for 10 seconds on each side to apply vertical pressure. Color change of a wetness indicator was used to determine water intrusion after each protocol. The same protocol was repeated for all 9 earplugs.

Results. Water intrusion was observed in 44%, 67%, and 88% of ears after surface swimming, horizontal submersion, and vertical submersion, respectively. The results revealed a significant difference in the waterproofing qualities of the various types of earplugs. The soft silicone type (Pillow Soft) earplug had the lowest rate of water penetration during all 3 protocols ($P < .001$). The difference between the most effective earplugs, Pillow Soft and Aquaseal, were only significant during the horizontal submersion protocol ($P = .008$).

Conclusion. Water intrusion occurred even with the use of earplugs. The intrusion was more significant with horizontal or vertical head submersion. The soft silicone Pillow Soft earplug was the most effective earplug for preventing water intrusion in surface swimming.

Keywords

ear-protective devices, tympanostomy tube, ear infection, earplug

M yringotomy with tympanostomy intubation is one of the most common surgical procedures performed on the pediatric population in the United States.^{1,2} One of its frequent associated complications is posttympanostomy tube otorrhea (PTTO),³ occurring at some point in time in 26% of the patients⁴ due to a variety of pathogens of internal (ie, nasopharynx) or external sources (ie, external auditory canal).^{5,6}

It remains controversial whether water intrusion during bathing or swimming increases the risk of PTTO. It is believed that water, carrying organisms of an external source, might enter the middle ear cavity through the patent tube⁷ and therefore needs to be prevented. The authenticity of this theory has been investigated in the past; however, the evidence is inconclusive. Although many studies, including 2 large meta-analyses,⁸⁻¹⁰ have disproved the theory, others have found water exposure prevention to be beneficial.^{11,12} The practice pattern of different physicians also varies when it comes to water exposure. A Southern and Eastern US survey in 1992 revealed that 13.1% of otolaryngologists recommended against swimming, whereas 68% only limited their patients' swimming, with 53.4% favoring the use of earplugs.¹³ Interestingly, the majority of the respondents were willing to revise their current practice based on new information generated from a clinical trial.¹³ A more recent survey in the Pacific Northwest also

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revealed that 47% of otolaryngologists and 73% of primary care physicians still recommend the use of barrier devices for swimming.¹⁴ This proves that earplugs have widely been recommended regardless of the role of water intrusion in PTTO. Despite this trend, the efficacy of modern earplugs in the prevention of water intrusion has not been well studied.

Parents and other clinicians often inquire, “Are earplugs effective in preventing water intrusion?” or “Which earplug would you recommend?” With the growing number of earplugs available in the market, an accurate evaluation is warranted. This would allow general practitioners and specialists to make an evidence-based recommendation and prescribe the appropriate earplug for patients. In an effort to answer these questions, the aims of the current study were (1) to evaluate the efficacy of modern-design earplugs in preventing water intrusion during swimming and (2) to determine the most effective ones.

Materials and Methods

Participants

Upon approval of the study protocol by the institutional review board at the University of California, Irvine, 10 healthy volunteers (20 ears, all with prior experience in either water polo or swimming; age range, 12-19 years; 8 males, 2 females) were recruited. The inclusion criteria were (1) no reported history of ear problems (ie, pain, itching, and infection), previous tympanostomy tube insertion, or any other relevant medical issues and (2) having an intact tympanic membrane and no sign of ear canal or tympanic membrane abnormalities under otoscopic examination.

Earplugs

Nine different types of the most commonly available earplug sets available over the counter were selected for evaluation. Three general types of earplugs were selected: (1) multi-flanged, (2) cylindrical moldable sponge, and (3) moldable silicone earplugs. These were chosen based on the 3 most common types of earplugs used by patients for the prevention of water intrusion. They included triple-flanged, premolded Aquaseal (Sperian Hearing Protection LLC, San Diego, California); cylindrical moldable Matrix (Sperian Hearing Protection LLC); quadruple-flanged, premolded Fusion (Sperian Hearing Protection LLC); cylindrical moldable Classic (E.A.R. Aearo Company, Indianapolis, Indiana); cylindrical moldable Safe Sound (Mack’s-McKeon Products, Inc, Warren, Michigan); triple-flanged, premolded UltraFit Plus (E.A.R. Aearo Company); bulbous, premolded Push-Ins (E.A.R. Aearo Company); triple-flanged, premolded Com-fit (North Safety Products, Cranston, Rhode Island); and the cylindrical moldable Pillow Soft Silicone Earplugs (Mack’s-McKeon Products, Inc) (**Figure 1**). Among all, Aquaseal and Pillow Soft were specifically advertised to be suitable for water protection according to the manufacturers’ instructions.

Water Exposure Procedure and Outcome Measurements

The mechanism for detecting water intrusion was an attached wetness indicator that changed color from yellow to blue in



Figure 1. Top row (left to right): Aquaseal (Sperian Hearing Protection LLC, San Diego, California), Matrix (Sperian Hearing Protection LLC), Fusion (Sperian Hearing Protection LLC), Classic (E.A.R. Aearo Company, Indianapolis, Indiana), and Safe Sound (Mack’s-McKeon Products, Inc, Warren, Michigan). Bottom row (left to right): UltraFit Plus (E.A.R. Aearo Company), Push-Ins (E.A.R. Aearo Company), Com-fit (North Safety Products, Cranston, Rhode Island), and Pillow Soft Silicone Earplugs (Mack’s-McKeon Products, Inc).



Figure 2. Wetness indicator attached to the inner surface of an earplug and color change observed from yellow (dry) to blue (wet) in the presence of water.

the presence of the slightest amount of water (Wetness indicator H9219; Bostik Corporation, Wauwatosa, Wisconsin). Water intrusion was defined as the presence of a color change in the indicator after swimming. To verify the ability of the indicator in detecting the slightest amount of water, a small drop of pool water (0.05 mL) was instilled on the indicator surface using an insulin syringe. The color change was observed and confirmed. Then, the indicator was cut into 3 × 3-mm pieces, and the pieces were attached to the inner surface of all earplugs using cyanoacrylate (**Figure 2**).

All subjects were instructed to clean their ears thoroughly until no signs of cerumen or sweat were noticed. None of them

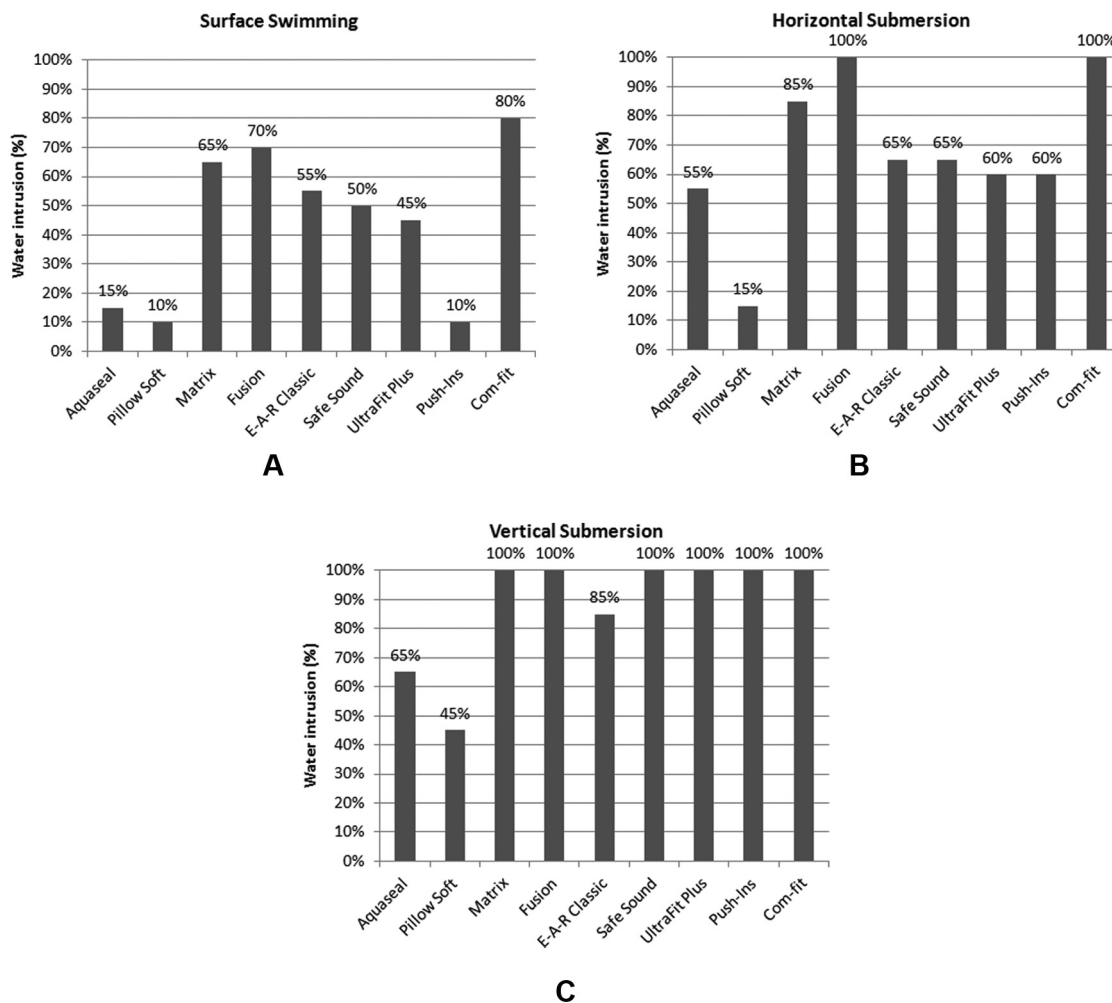


Figure 3. Rates of water intrusion with different tested earplugs in the (a) surface swimming protocol, (b) horizontal submersion protocol, and (c) vertical submersion protocol.

was permitted to wear swim caps. All participants returned to the swimming pool deck where they dried their ears, hair, and hands before putting an earplug in to prevent unwarranted aqueous exposure to the inner surface of the earplug. Before swimming, each earplug was removed after 30 seconds, checked for any color change, and then inserted again. The proper performance of all steps was supervised by the research team.

Three head-wetting protocols were defined to simulate the scenarios that might happen during water exposure: surface swimming, horizontal submersion, and vertical submersion. First, the participants were asked to surface swim for 10 minutes, which entailed moderate splashing with no head submersion. Afterward, they dried their hands, hair, and outer ears. The auricles were checked to be dry before removal of the earplug. Then, the earplugs were gently removed and checked for any color change in either ear. Second, the same preswimming precautions were repeated with the participants instructed to submerge themselves at a depth of 90 cm for 20 seconds with their head upright to apply horizontal water pressure. The indicator color change

was recorded. Finally, the subjects were instructed to submerge their head at 90 cm again, but for 10 seconds, and tilt their head 90 degrees left and then tilt their head 90 degrees right for the other 10 seconds to apply vertical pressure. The indicator color change was recorded. These protocols were repeated for all 9 earplugs. New earplugs were used for each protocol.

Results

A total of 60 data points were obtained per earplug type (180 experiments per head-wetting protocol). None of the earplugs was lost during the swimming tests. Across all types of earplugs, water intrusion occurred in 44%, 67%, and 88% of ears after surface swimming, horizontal submersion, and vertical submersion, respectively. **Figure 3a-c** shows the percentages of water intrusion in the 3 different water exposure protocols for each type of earplug. A moldable silicone plug (Pillow Soft in this case) had the lowest rates of water intrusion in all 3 head-wetting protocols (10%, 15%, and 45%, respectively). Six of the 9 earplug

Table 1. Incidence of Water Intrusion for Earplug Type

Earplug Type	Surface Swimming		Horizontal Submersion		Vertical Submersion	
	(n = 20 Ears), No. (%)	P Value	(n = 20 Ears), No. (%)	P Value	(n = 20 Ears), No. (%)	P Value
Waterproof	5 (13)	<.001	14 (35)	<.001	22 (55)	<.001
Nonwaterproof	75 (54)		107 (76)		137 (97)	
Total	80 (44)		121 (67)		159 (88)	

Water proof plugs included the Aquaseal (Sperian Hearing Protection LLC, San Diego, California) and Pillow Soft (Mack's-McKeon Products, Inc, Warren, Michigan).

types failed in all subjects during vertical submersion (100% water intrusion). There was no significant difference between the results of 2 waterproof earplugs (Pillow Soft and Aquaseal) during surface swimming and vertical submersion protocols. However, Pillow Soft proved to be significantly more effective compared with Aquaseal during horizontal submersion protocol ($P = .008$). **Table 1** shows the overall efficacy of the earplugs marketed as waterproof and nonwaterproof. The 2 waterproof earplugs were significantly more effective compared with the other 7 conventional earplugs in all protocols ($P < .001$).

Discussion

Swimming and water exposure after myringotomy with tube placement has been debated for decades.¹⁵ The primary question is whether children with tympanostomy tubes should be allowed to swim (or be exposed to water) and, if so, which type of earplug should be used. Many physicians still limit their patients or recommend the use of earplugs.¹⁴ The need for ear protection during swimming or other water exposure situations has been questioned in the past.^{7,16,17} The findings have varied from rejecting the occurrence of water intrusion, and eventually the need for earplugs,¹⁷ to acknowledging the intrusion.^{18,19}

In the current study, water intrusion was noted in 44%, 67%, and 88% of the ears after surface swimming, horizontal submersion, and vertical submersion, respectively. Furthermore, our results revealed that the 2 earplugs, specifically marketed as being waterproof, were significantly more effective compared with other available conventional earplugs, although they did not completely eliminate water intrusion. Among the waterproof earplugs, the soft silicone type (Pillow Soft in this case) had the lowest rate of water intrusion in all 3 protocols compared with the triple-flanged type (Aquaseal in this case), implying better efficacy. A similar study by Chisholm et al²⁰ in the United Kingdom discovered that water penetration occurred in the presence of earplugs. However, the amount of penetrated water was far less than the situation in which no earplug was used. They used a preweighed surgical pledget to record the weight gain after water exposure. In their study, cotton wool with petroleum jelly was the most effective way of protection.

Contemporary evaluation of earplugs enables physicians to advise their patients based on recent evidence. Efficacy

of different earplugs in preventing water intrusion has been studied before. However, these studies have been criticized either for the limitations of their methodologies or for providing untenable results on earplugs that are not as commercially relevant. One study tested earplugs in vitro using a nonstandard 0.8-cm diameter tube as opposed to the conventional 1-mm or larger diameter tubes more commonly used.²¹ Another study used a crystal violet dye as an indicator that was sensitive to the patient's sebum and other fluids.²² Others have created effective setups but limited their trial methodology to 15 seconds of bowl submersion, which does not accurately simulate the conditions of actual swimming.²⁰

In the current study, we attempted to simulate the actual conditions occurring during swimming and test 3 different scenarios of surface swimming, vertical head submersion, and horizontal head submersion. The wetness indicator used in this study is commonly incorporated into commercial infant diapers. It changed color from yellow to blue through an enzyme-substrate reaction only in the presence of water, which made it very sensitive and easy to read. In addition, we used extreme precaution to dry the external ear before inserting and removing the earplugs.

This study has a number of limitations. First, the currently tested method only detected the presence of water intrusion as a dichotomous outcome, whereas it would have been ideal to also measure the amount of penetrated water. The entry of water in the ear canal does not necessarily represent water entering the middle ear through the tube. Second, the number of evaluated earplugs was limited since it was not possible to evaluate every single earplug on the market. In addition, the use of custom-made earplugs, cotton wool with petroleum jelly, or secondary water barriers (ie, ear band) was not tested. Although these might improve the protection, water intrusion could still occur and should not be neglected. For example, cotton wool with petroleum jelly had better results in a similar previous study by Chisholm et al.²⁰ However, it did not eliminate water intrusion. We attempted to use at least 1 earplug per category of earplugs that are available. The number of tested earplugs in this study was greater than in the study by Chisholm et al.²⁰ Findings of the current study could assist physicians and parents in their decision-making process. Although the contribution of water exposure to PTTO remains uncertain, it should be noted that water intrusion occurs during swimming, even with the use of ear protection. We recommend the use of earplugs for water

activities to our patients, with the understanding that they will not prevent water intrusion in all cases. Although not tested in this study, the use of an additional ear/head band may help reduce the likelihood of water intrusion, and this remains to be explored in future studies. We recommend the use of an additional ear band when patients will be in ocean, lake, or river water

Conclusion

Commercially available earplugs do not eliminate the occurrence of water intrusion. Although increased risk of PTTO due to water exposure remains controversial, physicians should be aware of the shortcomings of the available earplugs while recommending them to their patients. Among the evaluated earplugs, the soft silicone type (in this case Pillow Soft) was found to be the most effective while swimming without head submersion. Both vertical and horizontal head submersion were associated with high rates of water intrusion and, therefore, should be avoided by patients even with earplugs.

Author Contributions

Hossein Mahboubi, designing, analysis and interpretation of data, drafting the article and final approval of the version to be published; **Austin Lee**, designing, acquisition of data, drafting the article, and final approval of the version to be published; **Saman Kiumehr**, analysis and interpretation of data, drafting the article, and final approval of the version to be published; **Shawn Zardouz**, analysis and interpretation of data, drafting the article, and final approval of the version to be published; **Shawhin Shahriari**, analysis and interpretation of data, drafting the article, and final approval of the version to be published; **Hamid R. Djalilian**, designing and interpretation of data, drafting the article, and final approval of the version to be published.

Disclosures

Competing interests: None.

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