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Original Article

Identifying the Optimal Water–Occluding Earplugs: A Scientific Simulation Study

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OBJECTIVE: Numerous types of water-occluding earplugs are available as a means of preventing infection in patients with external and middle ear disease. However, little is known about the comparative efficacies of these earplugs with prolonged water exposure. In this study, we assessed the water impermeability of various earplug materials to prolonged water exposure.

MATERIALS and METHODS: Nine earplugs were tested: cotton wool mixed with petroleum jelly, cotton wool externally coated with petroleum jelly, Blu-Tack, foam earplugs, silicone putty, silicone earplugs, flanged earplugs, and hard and soft silicone custom-moulds. Precision-engineered cups were filled with 30 mL water and sealed with lids that contained a 10 mm diameter hole to simulate the ear canal. The aperture was occluded with different earplugs, and the cup was inverted. Computer software was used to record the water loss to the nearest 10 milligrams 720 times over a three-hour period. The test was repeated five times for each material.

RESULTS: The water permeability onset, rate, and total amount of water loss varied markedly between the materials; cotton wool mixed with petroleum jelly demonstrated the fastest onset of leak and the highest rate of water loss ($p < 0.00001$), as well as the largest amount of cumulative water loss ($p = 0.00213$). The soft silicone custom-mould plugs, hard silicone custom-mould plugs, foam plugs, and silicone putty demonstrated no leaks.

CONCLUSION: This study demonstrates a wide range of water permeabilities of commonly used ear-occluding materials during prolonged water exposure. We found that the generally suggested regimen of cotton wool mixed with petroleum jelly may be inefficacious for substantial periods of water exposure.

KEYWORDS: Earplugs, ear protective devices, water

INTRODUCTION

Maintaining dry ears is a fundamental aspect of aural care that is of paramount importance for patients with perforated tympanic membranes, mastoid cavities, or chronic otitis externa. This is because the middle ear cavity and the external auditory canal are susceptible to water; thus, water-borne pathogens from the external environment may pose a risk of infection. Furthermore, water ingress into the middle ear creates a humid environment that is favorable for microbial growth. Thus, water precautions are also relevant to patients with tympanostomy tubes; this is one of the most common surgical procedures for the treatment of otitis media with effusion, particularly in children [1].

Otolaryngologists often prescribe earplugs following tympanostomy tube insertion despite variation in professional opinion regarding the efficacy of this intervention [2, 3]. However, more recent literature evidence suggests that the use of earplugs may indeed prevent ear infections and subsequent otorrhoea in patients with tympanostomy tubes [4]. Furthermore, there is evidence to suggest that chlorine, found in many swimming pools, is a mucosal irritant; [5] when combined with urea or sweat, it forms nitrogen trichloride, an intense mucosal irritant [6]. Moreover, bathwater has been attributed to a higher incidence and increased severity of middle ear inflammation in experimental models due to high bacterial load [7]. Thus, on the basis of the abovementioned factors, earplugs are recommended for patients with at-risk ears when swimming, bathing, or participating in water sports.

Broadly speaking, there are three categories of ear occlusion devices in the UK that are commonly used to prevent water from entering otologically at-risk ears: commercially available earplugs, National Health Service (NHS)-funded silicone custom-made moulds, and "home-made" contraptions. The provision of custom-mould earplugs may be an unnecessary financial burden on the health service if other, more economical solutions provide a similar or greater level of protection. Furthermore, home-made solutions may be equally suitable or more effective than more expensive commercial earplugs.

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Previous studies have attempted to describe differences between earplug materials tested on healthy volunteers [8-10]. However, the evidence base for a controlled, specific comparison of the permeability properties of these devices is narrow. Furthermore, previous studies were conducted without access to some currently available earplugs and produced inconsistent recommendations regarding the optimal earplugs for preventing ingress of water [10, 11]. In addition, the existing evaluations of rates and amounts of leakage are limited in value, relying on eyesight measurements that preclude any quantifiable statistical analysis [10] or involving infrequent recordings over relatively short periods of immersion (maximum of three minutes) [8, 9]; this may not be relevant for patients with at-risk ears experiencing prolonged water exposure. Thus, this study aimed to collect data for several earplug materials and identify the optimal earplugs over a much longer period of water exposure, while quantifying the rates and amounts of leakage with precision and accuracy.

MATERIALS and METHODS

Nine earplug materials were selected for testing (Figure 1):

1. Cotton wool (0.3 g) (Boots, UK) mixed with petroleum jelly (1.0 g) (Vaseline®, Unilever UK Ltd., Surrey, UK) [A]
2. Cotton wool (0.3 g) (Boots, UK) externally coated with petroleum jelly (1.0 g) (Vaseline®, Unilever UK Ltd., Surrey, UK) [B]
3. Blu-Tack® (2.0 g) (Bostik, UK)
4. 3M™ E-A-R™ Classic PVC Roll Down foam earplugs (3M United Kingdom Plc., Bracknell, UK) coated with petroleum jelly (1.0 g) (Vaseline®, Unilever UK Ltd., Surrey, UK)
5. Mack's (silicone) ear-putty (McKeon Products, Inc., Michigan, USA)
6. "Soggy Froggy" Putty Buddies® silicone earplugs (Jaco Enterprises, Inc., Arizona, USA)
7. Mack's AquaBlock® (silicone) flanged earplugs (McKeon Products, Inc., Michigan, USA)
8. Hard (silicone) custom mould earplugs (Surgical Material Testing Laboratory, Wales, UK)
9. Soft (silicone) custom mould earplugs (Surgical Material Testing Laboratory, Wales, UK)

Precision-engineered aluminum Paddington cups (Surgical Material Testing Laboratory, Wales, UK) were assembled to hold water; the aluminum lids were custom-built with a circular aperture, 10 mm thick and 10 mm in diameter, to simulate the ear canal. 30 mL of distilled water, maintained at 28°C to reproduce swimming pool water temperatures, was measured into each cup using a graduated pipette. The earplug materials were inserted from the inner surface of the lids, which were sealed to the cups using a thin layer of vacuum silicone-gel and further secured using Leukoplast Sleek (BSN Medical Ltd., Hull, UK) waterproof adhesive tape. Clamps were applied to further secure the lids, and the cups were weighed prior to testing.

Where applicable, the manufacturers' instructions for insertion of the earplugs were followed. Blu-Tack and cotton wool with petroleum jelly were both inserted by rolling the material into a ball and pressing it against the simulated external auditory meatus. In a climactic chamber set at 37°C/50% relative humidity, a Sartorius ED2202S top-pan balance (Sartorius UK Ltd., Surrey, UK), measuring to the nearest 0.001 g, was set up to hold a collecting vessel and placed beneath a perspex platform. This platform enabled the suspension of the cup above the balance and vessel to record leakage as mass added to the collecting vessel. Testing was begun by inverting the cups to allow water to come into contact with the earplug materials. The collecting vessel contained a thin layer of oil to protect the anticipated leakage reservoir from evaporative effects. Figure 2 illustrates the experimental setup.

The 24-hour temperature and humidity of the incubator was monitored for the duration of testing using a Tinytag data logger (Gemini Data Loggers Ltd., Chichester, UK), and the balance was subjected to precision checks using 1 g, 10 g, and 500 g laboratory check-weights. Additionally, the incubator fan was baffled using a cardboard screen to minimize unwanted airflow that might cause fluctuations in the balance readings. In turn, 720 balance readings were collected at

Figure 1. Test materials (from top left to right): Cotton wool mixed with petroleum jelly (a); cotton wool externally coated with petroleum jelly (b); Blu-Tack; PVC foam earplugs; Mack's silicone putty; "Soggy Froggy" silicone earplug; Mack's AquaBlock flanged earplug; hard silicone custom mould; soft silicone custom mould

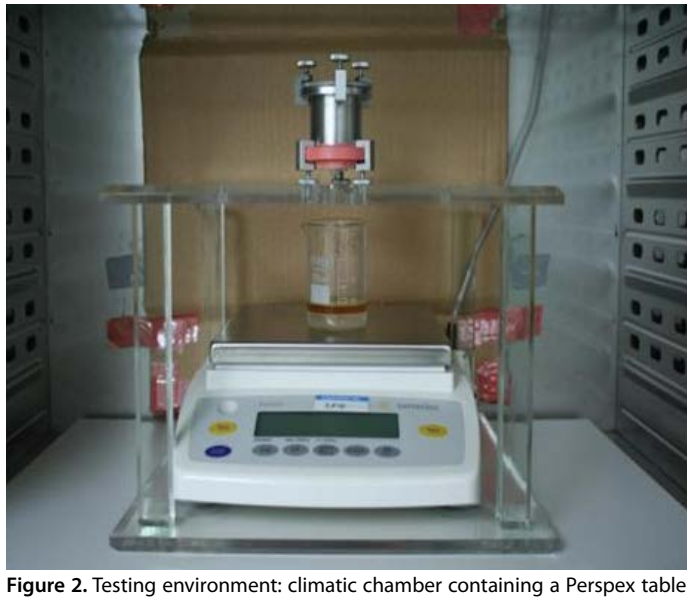

Figure 2. Testing environment: climatic chamber containing a Perspex table with a balance and a beaker. The sealed Paddington cup was suspended and inverted above the beaker through a hole in the table

15-second intervals for each test run. A preliminary test run showed minimal variation in the logged balance readings over 30 minutes.

The test was repeated five times for each material. Data for each test run were collected, and the means were calculated. The final balance readings as well as the rate of leakage over three hours and upon onset of leakage (in milligrams) were assessed.

One way analysis of variance (ANOVA) was used to determine the differences in leakage as the change in balance mass and the rate of leakage upon onset. The data were analyzed using Microsoft Office Excel 2007. A p value <0.05 was considered statistically significant.

Ethics committee approval was received for this study from the ethics committee of the Surgical Materials Testing Laboratory, Wales, UK.

RESULTS

Figure 3 illustrates the mean cumulative water loss through the tested earplug materials over the three-hour test period. The soft custom mould earplugs showed the smallest change in balance readings (water leak), while cotton wool impregnated with petroleum jelly [A], that is, cotton wool mixed with petroleum jelly and then rolled into a ball, demonstrated the most leakage (ANOVA, p = 0.00213). The different composition of cotton wool externally coated with petroleum jelly [B], that is, cotton wool rolled into a ball with petroleum jelly applied to its outer surface, showed some improvement in preventing water loss; however, it proved ineffective overall.

Table 1 denotes the mean times to onset of leakage and the rates of loss from the tested earplugs. Cotton wool mixed with petroleum jelly [A] provided the shortest period of water impermeability of approximately 5 minutes, whereas cotton wool externally coated with petroleum jelly [B] sustained water impermeability for over 20 minutes. Mack's flanged earplugs also showed moderate leakage, with partial flange displacement and mean onset of leakage at approximately 55 minutes. Mack's silicone putty showed minimal water loss at approximately 120 minutes. All other materials showed no evidence of water loss.

From the onset of leakage, cotton wool impregnated with petroleum jelly [A] demonstrated the highest rate of water loss (ANOVA, p < 0.00001). The changes in the rates of leakage from materials, particularly cotton wool and petroleum jelly, showed an obvious plateau after 100 minutes.

DISCUSSION

This study endeavored to accurately investigate the water impermeability properties of some commonly used earplug materials with prolonged water exposure and demonstrated significant differences between the tested materials. All commercial and custom-made earplugs showed prevention of water loss, with custom and putty type earplugs demonstrating the lowest permeability. In addition, Blu-Tack and foam earplugs coated in petroleum jelly also effectively prevented water permeability. That noted, the purpose of this study was to obtain a broad and general comparison between the most effective and least effective earplug materials for prolonged water exposure, with the aim of contributing to clinical advice. Our intent was not in any way to compare specific brands per se, nor does this study claim to be compliant with industry testing standards.

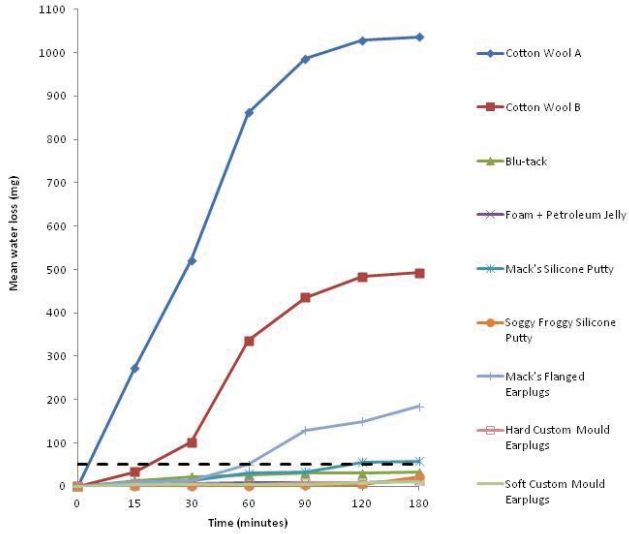

Figure 3. Mean water loss (in milligrams) from earplugs over the three-hour test period. The dashed line indicates the weight of one water droplet. Note that the markers denote the balance readings at the relevant time points; however, the plots are based on readings at 15-second intervals (720 in total for each test run)

Table 1. Time of onset of leakage (up to 180 minutes) and rate of water loss upon leakage for the tested earplugs

Material	Onset of leakage	Rate of loss upon onset of leakage (mg/min)
Cotton wool [A]	5 minutes 45 seconds	5.95*
Cotton wool [B]	23 minutes	3.13
Mack's flanged earplugs	54 minutes 30 seconds	3.27
Mack's silicone putty	120 minutes 45 seconds	0.94
Blu-tack	No leak	N/A
Foam + petroleum jelly	No leak	N/A
Soggy Froggy silicone putty	No leak	N/A
Hard custom mould earplugs	No leak	N/A
Soft custom mould earplugs	No leak	N/A

*p < 0.00001

The data from this study support existing literature reports that cotton wool with petroleum jelly is not an effective barrier against water [4, 12]; instead, the data provide evidence supporting alternative ear protection measures such as mouldable silicone putty [12]. The data also support the use of Blu-tack as an effective home-made solution and re-iterate earlier conclusions that polymeric foam treated with petroleum jelly may prevent the passage of water [4].

Under standardized laboratory-controlled conditions, this study provides valuable insight into the water permeability properties of commonly used materials within a simulated environment. This also allowed accurate, regular collection of data to occur over a much longer time period, giving a new perspective with a broader, clinically relevant test duration, particularly for patients who regularly participate in swimming and water sports.

However, although the conditions were standardized, the inherent limitation of this work is that we were unable to replicate the

shape of the pinna and the movement of the external acoustic meatus that occurs in vivo with temporomandibular joint movement; therefore, we created an excessively and artificially robust environment. In addition, placing the simulated ear canal under a volume of water may in fact be an unfair test of the strength of water exposure prevention, as the human ear is not often exposed to a column of water in this manner. However, this model is comparable to the hydrostatic pressures used in previous similar studies, although we recognize that this may not reflect deeper immersion as experienced in vivo [8].

Furthermore, it should be emphasised that this is an in vitro study, with the limitation of not providing insight into the ease of insertion and comfort of commonly available earplugs and other materials, as has been studied previously by Chisholm et al. [9]. Interestingly, in their study, where the waterproofing qualities of earplugs were assessed by the weight difference of neurosurgical patties after a standardised head wetting regime in 10 patients, cotton wool with petroleum jelly was the most effective earplug; it was also the easiest to insert and the most comfortable for the study subjects.

This waterproofing efficacy is contrary to the findings of the present study. Notably, this may be explained to some extent by the duration of water exposure: a total of one minute of immersion, in comparison to three hours in the current study. That noted, the present study also demonstrated that, counterintuitively, cotton wool externally coated with petroleum jelly appears to offer a longer period of waterproofing than cotton wool mixed with petroleum jelly.

In addition, we showed that the earplug consisting of cotton wool coated with petroleum jelly became significantly less effective with time. This is likely due to the absorbability of the cotton wool over time with constant water exposure. This observation is consistent with the results of Alt and Collins [12] and Laitakari et al. [8], who demonstrated that longer water exposure time was associated with increased leakage for cotton wool coated with petroleum jelly.

Another point for discussion is the use of the weight of water as a measure of the waterproofing efficacy of earplugs. Intrinsically, it may be postulated that lost volume would be a more useful indicator of the water impermeability of earplugs. However, it should be noted that accurate and precise measurement of volume over a relatively long period of time is very difficult; furthermore, previous studies have used changes in weight as a measure of the waterproofing ability of earplugs [9].

An advantage of cotton wool with petroleum jelly is that it is hygienic for ears prone to infection, as the earplugs can be disposed of after each use. Manufactured earplugs include single-use disposable foam earplugs; mouldable silicone putty, which should be applied to clean, dry ears and has a limited usable lifetime; and flanged and custom-mould silicone earplugs, which can be cleaned with mild soap and warm water and dried thoroughly before re-insertion into the ear canal.

Previous studies that have endeavored to investigate the waterproofing efficacy of earplugs have some limitations. An in vivo study used dry green crystal violet dye as an indicator of water penetration without controlling for confounders, such as sweat and sebum, that are naturally found in the external auditory canal [8]. In an in vivo study by Chisholm et al. [9], the weights of pre- and post-water exposure neurosurgical patties were compared to quantify leakage; however, this measurement may have been limited by the maximum volume of water that the neurosurgical patties can absorb. Robinson's in vivo study [10] used pH indicator paper covered with micropore tape as a test for water penetration past earplugs in six swimmers. However, the results were grouped as dry, moist, and wet, which precluded the ability to quantify the water leakage and also precluded any meaningful statistical analysis.

CONCLUSION

This study suggests that there are differences in the water impermeability properties of some commonly advocated earplug materials with prolonged water exposure. In particular, we found that the commonly suggested traditional regimen of cotton wool mixed with petroleum jelly may be inefficacious for substantial periods of water exposure, but that a cotton wool ball externally coated with petroleum jelly is a better preparation method for shorter durations or casual water exposure, such as daily bathing and showering. This study also demonstrates that many available earplugs are effective, including cheaper, readily available alternatives to prescribed custom-mould earplugs. With this data, we hope to provide assistance to clinicians in advising patients on which types of commonly available earplugs to use if indicated. This change in patient use of ear protection may lead to greater accessibility and better aural care for patients and to cost savings for health care services.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of the Surgical Materials Testing Laboratory, Wales, UK.

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REFERENCES

1. Moualed D, Masterson L, Kumar S, Donnelly N. Water precautions for prevention of infection following tympanostomy tube (grommet) insertion in children. Cochrane Database Syst Rev 2016; CD010375.
2. Basu S, Georgalas C, Sen P, Bhattacharyya AK. Water precautions and ear surgery: evidence and practice in the UK. J Laryngol Otol 2007; 121: 9-14. [CrossRef]

3. Poss JM, Boseley ME, Crawford JV. Pacific Northwest survey: posttympanostomy tube water precautions. Arch Otolaryngol Head Neck Surg 2008; 134: 133-5. [CrossRef]
4. Goldstein NA, Mandel EM, Kurs-Lasky M, Rockette HE, Casselbrant ML. Water precautions and tympanostomy tubes: a randomized, controlled trial. Laryngoscope 2005; 115: 324-30. [CrossRef]
5. Marks NJ, Mills RP. Swimming and grommets. J R Soc Med 1983; 76: 23-6.
6. Penny PT. Swimming pool wheezing. Br Med J 1983; 287: 461-2. [CrossRef]
7. Smelt GJ, Monkhouse WS. The effect of bath water, sea water and swimming pool water on the guinea pig middle ear. J Laryngol Otol 1985; 99: 1209-16. [CrossRef]
8. Laitakari K, Sorri M, Pirila T, Lopponen H, Helisten L. Ear protection against water-borne infection: an objective evaluation. J Laryngol Otol 1986; 100: 1337-40.[CrossRef]
9. Chisholm EJ, Kuchai R, McPartlin D. An objective evaluation of the waterproofing qualities, ease of insertion and comfort of commonly available earplugs. Clin Otolaryngol Allied Sci 2004; 29: 128-32. [CrossRef]
10. Robinson AC. Evaluation for waterproof ear protectors in swimmers. J Laryngol Otol 1989; 103: 1154-7. [CrossRef]
11. Johnson DW, Maisel RH. Objective evaluation of earplugs for the control of water-borne infection. Ann Otol Rhinol Laryngol 1981; 90: 89-93. [CrossRef]
12. Alt JA, Collins WO. An objective comparison of leakage between commonly used earplugs. Am J Otolaryngol 2012; 33: 469-72.[CrossRef]