



An *ex vivo* comparison of over-the-counter cerumenolytics for ear wax

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Background: Ear wax (cerumen) impaction is a common reason why patients present to general practitioners (GPs) and ear, nose and throat (ENT) specialists. However, there is no consensus on the effectiveness of the variety of cerumenolytics commonly available. Currently, there are no investigations on the effectiveness of cerumenolytics against cerumen of varying consistencies.

Methods: This prospective *ex vivo* study analysed cerumen from twelve patients who visited an Ear, Nose Throat clinic for impaction over a 1-month period. Four separate samples of cerumen of varying consistency ratings (soft, medium or hard) were compared. A punch biopsy was used to standardise the test sample size of the cerumen, which was placed in a tube containing 0.5 mL of 1 of 10 different cerumenolytics. Agents used were Waxsol[®], hydrogen peroxide, Aqua Ear[®], Earclear[®], CleanEars[®], olive oil, Cipro[®]HC, Sofradex[®], Co-phenylcaine[™] Forte and sterile water. Photo documentation of the cerumen samples was performed at 1, 2, and 5 minutes. Outcome measures were based on dissolving and softening scales.

Results: Water-based cerumenolytics resulted in the greatest extent of cerumen dissolvability and softening. Sterile water had the greatest effect. Oil-based agents had limited effect. Non-water-/non-oil-based cerumenolytics were comparable with water-based agents in dissolving and softening the cerumen across all consistencies.

Conclusions: Cerumenolytic agents commonly available in most Australian pharmacies were compared against cerumen of different consistencies. Water-based agents were found to be the most effective. Oil-based cerumenolytics commonly used in the outpatient setting were found to be ineffective. Sterile water was the most effective agent across most consistencies, raising questions about the worth of expensive cerumenolytic products. Cerumen consistency did not significantly alter the effectiveness of the cerumenolytics.

Keywords: Cerumen; cerumenolytics; firmness; consistency; softening; dissolving

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Introduction

Problematic ear wax (cerumen) is a common presentation to the primary care physician and is the most frequent reason for presentation for ear pain (1). Cerumen impaction is estimated to affect 6–20% of the Australian population,

with higher rates observed in elderly persons and those with disability (2). The health burden of cerumen-related procedures in the United States is reported to be US \$50 million, making this a significant burden on the health system (1,3). Although the total annual cost of managing cerumen in Australia is not readily available, it is

likely to have similar health-related expenses because of the common lifestyles amongst the countries.

The external auditory canal is predominately self-cleaning due to specialised epithelium, glandular function and anatomy. Impaction can occur when these physiological processes fail or simply as a result of attempted removal itself (4). Impacted cerumen can be associated with symptoms of hearing loss, pain, itchiness, tinnitus, dizziness and cognitive impairment in elderly patients (1,5). Cerumen impaction can also be asymptomatic but can obstruct visualisation and assessment of the tympanic membrane, which can lead to a delay in either diagnosis or management of other otological problems (6).

The common treatment methods for clearing impacted cerumen include cerumenolytics, irrigation by syringe and microsuction. Cerumenolytics is the most common first-line management by both general practitioners (GPs) and ear, nose and throat (ENT) specialists (7). The success rate for managing cerumen impaction by irrigation has been reported to range from 68% to 92% (1). Irrigation complications can include pain, external auditory canal injury, otitis externa, vertigo and, rarely, tympanic membrane perforation (1,8). Manual removal of impacted cerumen using a binocular microscope for visualisation has a reported success rate of 90% (1) but can cause trauma to the external auditory canal, including pain, bleeding and tympanic perforation and, rarely, infection (1,9). Both methods require increased procedural and equipment costs or ongoing input from a GP with adequate training and experience and availability of equipment or input from an ENT specialist (1).

In Australia, there are many different types of commercially available ear drops. These can be separated into oil-based compounds (e.g., olive oil, CleanEars[®]), water-based compounds (e.g., Waxsol[®], hydrogen peroxide) or non-water-/non-oil-based solutions, such as carbamide peroxide (Earclear[®]). Water-based cerumenolytics function by drawing water into the cerumen, resulting in its fragmentation, whereas oil-based preparations lubricate and soften the cerumen (1). Antibiotic drops are also commonly used in the outpatient setting as an adjunct infection-preventive measure. The commonly used topical antibiotics are Sofradex[®] and Cipro[®]HC. Cerumenolytic agents are commonly prescribed for managing cerumen impaction and are known to be associated with a relatively low incidence of adverse effects when used in patients without active ear infection and an intact tympanic membrane (10). Cerumenolytics reduce the need for syringing or manual

removal of the impacted cerumen and can also improve the efficacy of manual removal and irrigation (1). There is little evidence to support the use of one cerumenolytic across both adult and paediatric populations (4,11). The relative success rates of different cerumenolytics for treating different cerumen consistencies are also unknown. There have been some comparisons of cerumenolytics conducted *in vitro* and *in vivo* (12-16); however, most of these investigations compared only a very small number of agents or tested some agents not commonly available in Australia.

The degree of consistency of the patient's cerumen (hard, medium and soft) is clinically relevant to the medical practitioner. Both hard and soft cerumen are known to be a problem in the population and may require different treatments. Several studies have included consistency ratings of the cerumen (17,18); however, no investigation has directly studied whether the effectiveness of cerumenolytics is affected by cerumen consistency.

This investigation aims to compare the effectiveness of the commonly prescribed cerumenolytic agents available in Australia in softening or dissolving cerumen. We also examined whether the consistency of the cerumen influences the efficacy of each cerumenolytic agent. The hypothesis tested was that water-based cerumenolytics would be more effective than oil-based agents and that the consistency rating of the cerumen would alter the effectiveness of the cerumenolytic agent.

We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/ajo-20-50>).

Methods

This investigation was a prospective study performed in accordance with STROBE requirements (19). This exploratory study included the analysis of cerumen samples collected from 12 patients over a 1-month period from an outpatient ENT clinic in a Queensland hospital. All patients were referred by GPs as a result of problems associated with bothersome cerumen. All patients consented to their cerumen being used and were given a patient information sheet. Patients were excluded from the study if they had concurrent ear pathology. No demographic details were recorded.

Using a Jobson Horne ear probe, cerumen was extracted manually, placed in a collection jar and stored at room temperature. Two independent observers subjectively categorised the cerumen into three different consistency

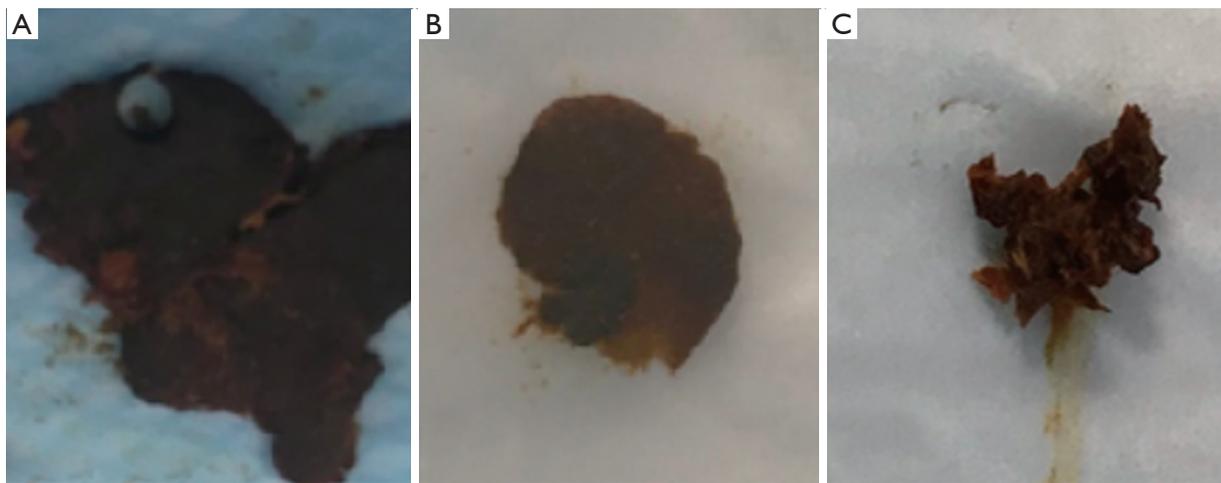


Figure 1 Photographic images of different types of cerumen. (A) Hard cerumen; (B) medium cerumen; and (C), soft cerumen.

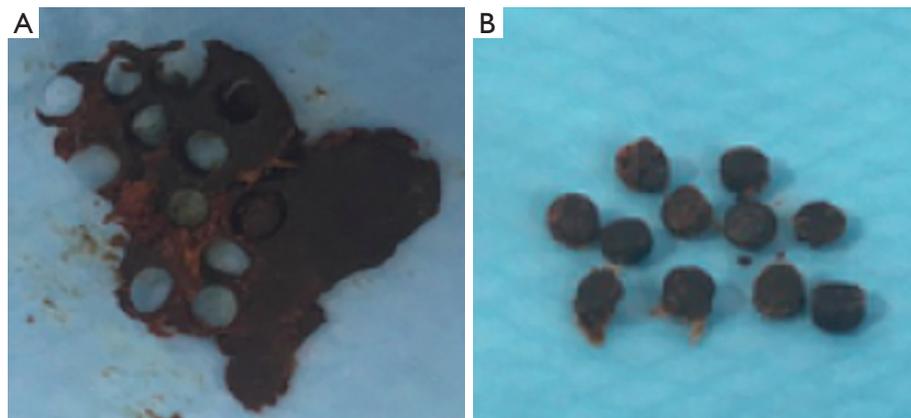


Figure 2 Punch biopsy of a hard cerumen sample. (A) Hard cerumen sample post 3 mm punch biopsy; (B) standard samples of extracted hard cerumen.

ratings: soft, medium or hard (*Figure 1*). Cerumen analysis was performed on the same day as collection. A punch biopsy was used to standardise the size of the test sample (*Figure 2*). Cerumen analysis involved placing 0.5 mL of cerumenolytics with each cerumen sample. The cerumenolytics used were Waxsol[®], hydrogen peroxide, Aqua Ear[®], Earclear[®], CleanEars[®], olive oil, Cipro[®]HC, Sofradex[®], Co-phenylcaine[™] Forte and sterile water (water). Photo documentation was performed at one, two and five minutes. Test tubes were then drained of their solution, and the remaining cerumen was placed onto a sheet of paper. Outcome measures for the treated cerumen were based on a dissolving scale (ranging from 0, unchanged; 1, <25%; 2, 25–75%; and 3, >75%) and a

softening scale (from one swipe with a Jobson Horne probe; ranging from 0, unchanged; 1, partially softened; and 2, completely softened). Two independent investigators rated each cerumen sample for dissolvability and softening ratings. In cases of discrepancy, the average value was recorded. The softening scale was a comparison with baseline consistency of the cerumen. Because the consistency ratings were heterogeneous, the softening scale comparisons were made within groups rather than between groups.

Data was recorded in an Excel spreadsheet. *Post hoc* analysis was performed on the outcome variables using the Kendall Tau-b coefficient for correlation. A Fisher's exact test was used to compare individual agents against each other for difference in dissolvability and softening.

Table 1 Cerumenolytics tested

Categories	Brand name	Active ingredient
Water-based	Waxsol®	Sodium docusate
	Aqua Ear®	Acetic acid/isopropyl alcohol solution
	Hydrogen peroxide	Hydrogen peroxide solution
	Co-phenylcaine™ Forte	Lignocaine/phenylephrine
	Sterile Water	Water
	Cipro®HC	Ciprofloxacin/hydrocortisone
	Sofradex®	Gramicidin/framycetin/dexamethasone
Oil-based	Olive oil	Olive oil
	CleanEars®	Mineral oil, squalane, spearmint oil
Non-water-/non-oil-based (other)	Earclear®	Carbamide peroxide

Logistical regression analysis was performed with two independent variables (initial cerumen rating and agent) to assess their influence on the level of dissolving and softening. Stata V16.2 (StataCorp, 2019, Stata Statistical Software: Release 16, College Station, TX, USA) was used for statistical comparisons. A P value of <0.05 was considered significant. Because this was a prospective research, there were no missing data.

Ethics approval was obtained via low-risk ethics submission through the Metro South Ethics Committee. Research was performed based on the standard of Ethical Considerations in the Conduct and Reporting of Research: Privacy and Confidentiality. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This ex-vivo study did not impact on individual patient care or their future management.

Results

This exploratory study utilised a convenience sampling, which obtained wax from twelve patients which was comparable to previous studies in sample size (13,14,16). Exploratory research was conducted as a number of agents used in this study have not been investigated in prior studies. *Table 1* lists the names and characteristics of the 10 cerumenolytics tested for their abilities to dissolve and soften cerumen of hard, medium and soft consistencies. The cerumenolytics fell into three categories: water-based, oil-based and non-water-/non-oil-based. Data collected included mean dissolvability and softening indices for each sample tested.

The correlation between the dissolving and softening indices of the different agents was assessed using Kendall Tau-b correlation coefficients. Values of Kendall Tau-b expressed as percentages are illustrated in *Tables 2,3*. These percentages could range from -100% to +100%, where zero indicated no association. This shows there are strong correlations between the individual water-based cerumenolytics (including the water-based antibiotic drops) and non-water-/non-oil-based cerumenolytics. There were also strong negative correlations between the water-based and oil-based cerumenolytics across all baseline cerumen consistency ratings, indicating an inverse relationship.

As illustrated by *Figures 3,4* water-based agents (with the exception of Aqua Ear®) had greater mean dissolvability and softening indices compared with oil-based agents. The only non-water-/non-oil-based agent Earclear® dissolved and softened cerumen to the same extent as water-based agents.

Waxsol® is the number one selling product on the market in Australia (20). A Fisher's exact test was performed comparing each agent to Waxsol® in terms of dissolving and softening indices. A statistically significant difference in the dissolving index was noted comparing Waxsol® to Aqua Ear® (P=0.00), CleanEars® (P=0.00) and olive oil (P=0.00). There was no statistical difference in the dissolving index between Waxsol® and other agents. A Fisher's exact test was performed on the softening index comparing Waxsol® to the other agents across all baseline cerumen consistencies, and a statistically significant difference was demonstrated for Aqua Ear® (P=0.005), CleanEars® (P=0.001) and olive oil (P=0.00). There was no statistically significant difference between Waxsol® and other agents for the softening index

Table 2 Correlation of the cerumenolytic agents for dissolving index*

Agents	Waxsol [®]	H ₂ O ₂	Aqua Ear [®]	Earclear [®]	CleanEars [®]	Olive oil	Cipro [®] HC	Sofradex [®]	Co-phenyl. [™]	Water
Waxsol [®]	100%									
H ₂ O ₂	0%	100%								
Aqua Ear [®]	-62%	36%	100%							
Earclear [®]	-6%	11%	39%	100%						
CleanEars [®]	-6%	36%	-9%	-53%	100%					
Olive oil										
Cipro [®] HC	-9%	29%	33%	60%	-52%		100%			
Sofradex [®]	28%	3%	18%	48%	-49%		54%	100%		
Co-phenyl. [™]	-8%	2%	13%	72%	-42%		42%	35%	100%	
Water	25%	-5%	5%	63%	-37%		21%	52%	70%	100%

*, Correlation value is represented as a percentage for Kendall Tau-b coefficient. Correlations between 0% and 25% are yellow and 50% and 99% are green.

Table 3 Correlation of the cerumenolytic agents for softening index*

Agents	Waxsol [®]	H ₂ O ₂	Aqua Ear [®]	Earclear [®]	CleanEars [®]	Olive oil	Cipro [®] HC	Sofradex [®]	Co-phenyl. [™]	Water
Waxsol [®]	100%									
H ₂ O ₂	34%	100%								
Aqua Ear [®]	-31%	-21%	100%							
Earclear [®]	38%	38%	35%	100%						
CleanEars [®]	84%	19%	-12%	25%	100%					
Olive oil	68%	54%	-29%	12%	82%	100%				
Cipro [®] HC	-37%	-37%	-31%	-65%	-60%	-49%	100%			
Sofradex [®]	12%	6%	-84%	-20%	-13%	0%	48%	100%		
Co-phenyl. [™]	-8%	-3%	8%	4%	-16%	-26%	-8%	-16%	100%	
Water	-36%	-28%	-25%	-24%	-43%	-52%	25%	21%	67%	100%

*, Correlation value is represented as a percentage for Kendall Tau-b coefficient. Correlations between 0% and 25% are yellow and 50% and 99% are green.

across all baseline cerumen consistency ratings.

Water was the most efficacious agent used (Figures 3,4). A Fisher’s exact test was performed for water (most cost-effective and potentially most efficacious) agent comparing it with the other agents in terms of both dissolving and softening abilities. A statistically significant difference was noted for Waxsol[®] (P=0.016), Aqua Ear[®] (P=0.00), CleanEars[®] (P=0.000) and olive oil (P=0.00) in dissolving index. A Fisher’s exact test was performed on the softening index comparing water to the other agents across all

baseline cerumen consistencies, and a statistically significant difference was found for Waxsol[®] (P=0.27), Aqua Ear[®] (P=0.00), CleanEars[®] (P=0.000), olive oil (P=0.00), Cipro[®]HC (P=0.027) and Sofradex[®] (P=0.009).

Logistical regression was used for further analysis. Our dependent variable was the dissolving index (<25%, ≥25%), and independent variables of initial cerumen rating and agent were used to assess their influence on the level of dissolvability. When examining water and Waxsol[®], water was more likely to result in a dissolving level ≥25% (AdjR²

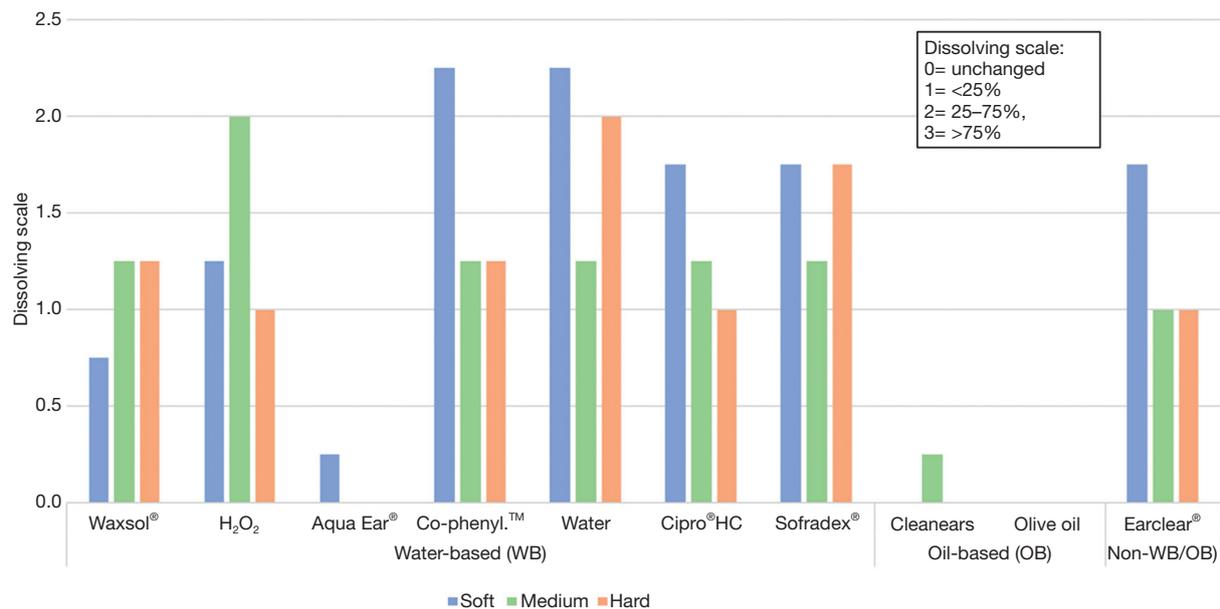


Figure 3 Dissolving effectiveness of cerumenolytics for each cerumen type. The mean dissolving indices (n=4 participants/group) of each cerumenolytic is shown for soft, medium and hard cerumen.

=0.3832, $P=0.011$). We also assessed the influence on the softening index using a logistical regression with two independent variables (initial cerumen rating and agent) and a single dependent variable (softening index). Water was 26 times more likely than Waxsol® to completely soften the cerumen, which was statistically significant ($\text{AdjR}^2=0.3716$, $P=0.018$). Because this was an exploratory analysis, no corrections were made for multiple hypothesis testing.

Discussion

In Australia, there is a growing number of cerumenolytic agents currently on the market used for treating bothersome cerumen impaction. The interest in over-the-counter cerumenolytics has remained steady because of patient comfort and the relative cost of microsuction therapies. The 2017 American Academy of Otolaryngology guideline on cerumen stated that ‘there are a limited number of well controlled, high quality, homogenous studies demonstrating the efficacy of topical agents’ (1).

It is widely accepted in the available literature that treatment with any form of water- or oil-based cerumenolytic is more effective than no treatment (21). A Cochrane review of the published evidence for cerumenolytics concluded that cerumenolytic drops were effective, but the authors of the study did not find any difference amongst agents (11).

The current investigation used a methodology similar to previous research in this area, with key adjustments made to more accurately assess the effectiveness of cerumenolytics and to replicate real-life application. Cerumen size and volume of the solution were standardised to improve consistency of results. Although Srisukhumchai *et al.* [2019] combined cerumen samples from multiple patients, which potentially confounded the interpretation of results (16), we performed a separate investigation of patient samples. Our study also used a greater variety of commonly used cerumenolytics available in Australia, some of which had not been previously tested. No known studies have examined Cipro®HC, Sofradex® or Co-phenylcaine™ Forte, which are commonly used treatments.

A 5-minute period for evaluating the effect of cerumenolytics was used deliberately by examiners as it was felt that this reflected the physiological time frame in which most ear drops would be instilled in a patient’s ear. There is no consensus in the literature on a time period to determine cerumenolytic effect. Srisukhumchai *et al.* [2019] used a period of 60 minutes, Saxby *et al.* [2013] assessed the effect after 12 hours and Whatley *et al.* [2003] assessed the cerumenolytic effect after 15 minutes (14,16,18).

Other similar studies have examined the degree of cerumen disintegration but did not use a softening scale. This was considered an important measure because of the

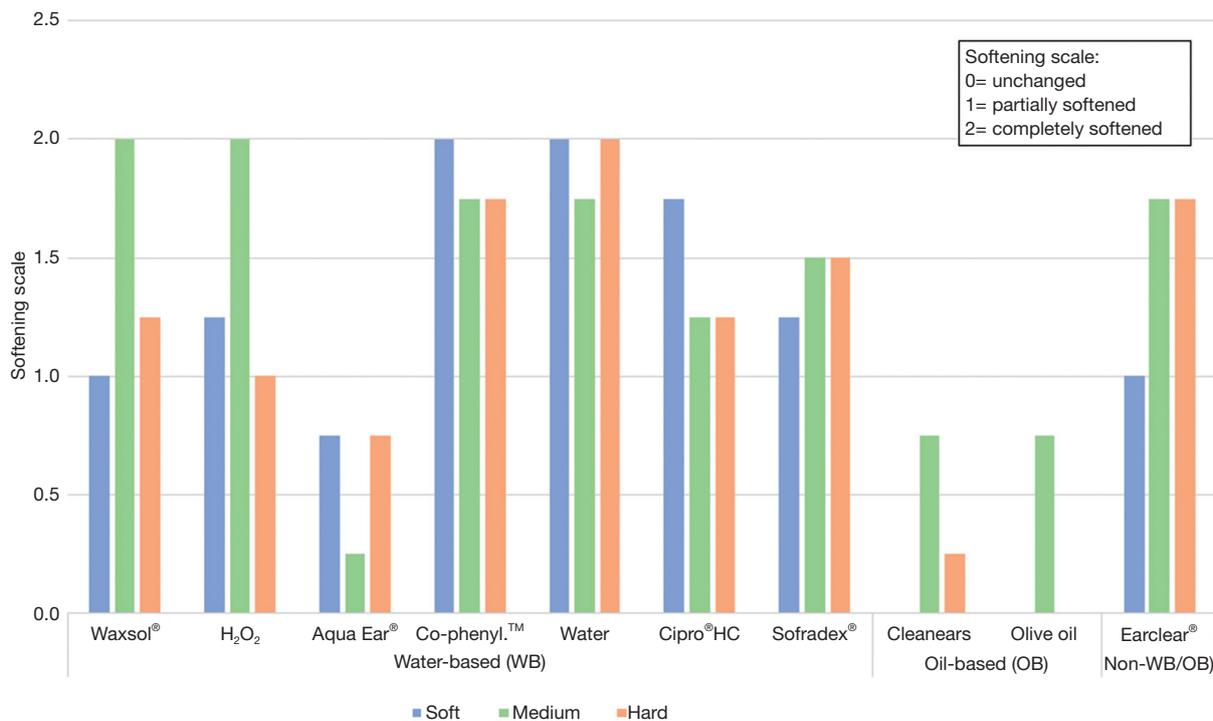


Figure 4 Mean softening indices for cerumenolytic effectiveness across each cerumen consistency rating (n=4 participants/group) of each cerumenolytic is shown for soft, medium and hard cerumen.

different proposed cerumenolytic mechanisms of water- and oil-based drops. Water-based preparations are thought to draw in water via osmosis and fragment the cerumen, whereas oil-based agents lubricate and soften the cerumen without fragmentation (1).

This investigation examined the effect of different cerumenolytics against cerumen of various consistencies. The results of this study showed a similar effectiveness and no statistically significant difference with agents against soft, medium and hard cerumen consistencies. To our knowledge, no other prior studies have compared this variable.

Across the three broad categories of agents, non-water-/non-oil-based agents were comparable with water-based products, and oil-based cerumenolytics had limited effect. The results of this study indicate that water-based cerumenolytics were more effective than oil-based cerumenolytics. Some studies have reported similar results (13,14). However, there is no consensus in the literature; some studies reported no significant difference between water-based and non-water-based agents, which was the same finding of the Cochrane review (11,21).

Olive oil is readily available in the home environment

and is still commonly used for treating impacted cerumen. In our study, oil-based agents, especially olive oil, were ineffective cerumenolytics. Similarly, Saxby *et al.* [2013] reported that oil-based products were relatively ineffective, a result Chalishazar *et al.* [2007] also found with the added conclusion that olive oil was totally ineffective (13,14).

Sterile water is an inexpensive, readily available cerumenolytic agent. In our study, sterile water alone had higher dissolving and softening indices than all other agents studied. Saxby *et al.* [2013] also found that distilled water was associated with the greatest degree of cerumenolysis (14). A recent Cochrane review found no evidence that using water alone was better or worse than commercial cerumenolytic products (11). However, the prolonged use of water in the external ear canal may predispose the patient to otitis externa (2).

In this study, water was more effective than Waxsol® in softening and dissolving cerumen, and this difference was statistically significant. According to the IMS Health Australia Pharmaceutical Index (July 2018), Waxsol® was the best-selling product (20). The effectiveness of sodium docusate (the active ingredient in Waxsol®) has been described in three previous studies. One *in vitro* study

found substantial cerumen disintegration by Waxsol[®] (12). Another *in vitro* study that compared sodium docusate to sodium bicarbonate found superior results with sodium bicarbonate (16). An *in vivo* randomised controlled trial compared docusate sodium to triethanolamine polypeptide (Cerumenex[®]) and found that docusate sodium solution was a more effective cerumenolytic than Cerumenex[®]; however, this finding has little relevance to Australian practitioners, because Cerumenex[®] is not commonly available in Australian pharmacies (15). Aqua Ear[®] was the least effective water-based agent in our research, but its primary prescribed function is for the treatment of inflammation and infection, rather than cerumenolysis.

Excluding sterile water, when evaluating the other water-based agents, there was no statistically significant difference observed. There is similar effectiveness of the other water-based preparations and more readily available agents included Waxsol[®] and hydrogen peroxide.

A limitation of our study was the sample size. However, the number of samples was comparable with that of other *in vitro/ex vivo* studies in this field. In some of these published studies, the cerumen was pooled and mixed, and the researchers made no attempt to subclassify cerumen consistencies (14,16). Future studies using larger patient numbers would provide more statistically robust results. The current investigation was an *ex vivo* study; therefore, the major conclusions need to be validated in clinical *in vivo* trials and potential complications associated with each agent should be evaluated.

Conclusions

Cerumen impaction is a common and significant health problem. This study provides an Australian-specific, up-to-date trial comparing the effectiveness of commonly available cerumenolytics in Australian pharmacies. There is a lack of consensus in the literature on the most appropriate cerumenolytic, and in many instances, the choice of cerumenolytic is based on the practitioner's individual experience. Oil-based cerumenolytics are still commonly prescribed by GPs and ENT specialists. Adding to the growing evidence base, we found that oil-based agents, more specifically, olive oil, were ineffective cerumenolytics. Water-based cerumenolytics were the most effective across all consistencies.

While there are a growing number of over-the-counter, relatively expensive agents on the market, none in this study were more effective than sterile water. However, due

to potential increased risk of otitis externa, further *in-vivo* studies are required. The authors have concluded for everyday practice, oil-based agents should be avoided and any of the water-based cerumenolytics, including Waxsol[®] and hydrogen peroxide, would be the next best treatment regardless of cerumen consistency.

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/ajo-20-50>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the research are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Metro South Ethics Committee (HREC/2020/QMS/61086) and informed consent was taken from all individual participants.

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