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# Earigate™ for softening ear wax: Is it safe when the eardrum is perforated?

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ABSTRACT

*Objective:* To determine the safety of Earigate™ as an ear wax softening product.
*Study Design:* Prospective, controlled animal study.
*Methods:* Bilateral wide myringotomies were performed in eleven chinchillas. In each animal, Earigate™ was delivered to a randomly selected experimental ear canal as 2 puffs twice a day. Auditory brainstem response (ABR) was used to assess the hearing of the animals before, 3 days and 10 days following the local application of Earigate™. The ABR threshold shifts were compared for both experimental and control ears.
*Results:* The mean hearing threshold shifts in the experimental animals were comparable at all frequencies and at days 3 and 10. No statistically significant differences were observed in the mean threshold shifts for all of the frequencies evaluated, between the control and experimental ears.
*Conclusions:* The administration of Earigate™ to the middle ear of chinchillas did not cause any ototoxicity as assessed by ABR.



## 1. Introduction

Removal of cerumen from the external auditory canal is indicated when there is sufficient cerumen to cause an impaction giving rise to symptoms such as pain, tinnitus and/or the feeling of ear blockage [1–3]. It can also be necessary when performing otoscopic examination of the ear and for audiological investigation [4]. Removal of ear wax can be achieved manually under direct visualization and through irrigation of the ear canal with ear with warm water. Wax softeners are often used as home remedies and are typically available over the counter [5]. The availability of many of wax softeners over-the-counter, and recent reports of ototoxicity from certain cerumenolytic agents, make it necessary to investigate and document the safety of these products being applied in the external auditory canal. The presence of a perforation in the tympanic membrane (TM), not previously diagnosed and which would therefore be unknown to the individual using an ear wax softening product, could lead to the product entering the middle ear cavity. Commonly used ear wax softeners include baby oil, mineral oil, and ceruminex [1,4,6]. Earigate™ is a commercially available, over-the-counter ear cleanser for softening built-up wax. It contains isotonic, 100% natural source sea water, including some electrolytes and trace elements, with no preservatives, bottled and delivered through a nozzle that goes into the external ear canal. Although generally considered innocuous, being similar to commercially available normal saline solutions, there are important differences between the two compounds. Sea water contains trace elements like aluminum, arsenic, cadmium, chrome, cobalt, copper, iron, manganese, nickel, lead and zinc [7]. There are also indications that therapeutic effects of sea water supersede that of normal saline [7]. Furthermore, the endolymphatic fluid in the scala media of the cochlea has a specific electrolyte composition, which is essential for the normal functioning of the outer hair cells. It is not known if the presence of sea water in the middle ear affects the normal electrolyte composition of the endolymph which might affect the physiology of the inner ear and in turn affect hearing function. Safety of this product in the middle and inner ear has not been documented in the literature. This study was therefore conducted to look into the potential ototoxicity of this ear wax softener in the presence of a tympanic membrane perforation.

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## 2. Materials and methods

### 2.1. Animals

The institutional animal care committee and review board of the Research Institute of the McGill University Health Center approved the study. Eleven female chinchillas (*Chinchilla lanigera*) were used in this study.

### 2.2. Composition of Earigate™

The chemical composition of Earigate™ solution was analytically determined on a chemistry analyzer (Beckman UNICEL DXC 600, MA, USA).

### 2.3. Application of product and hearing evaluation

The tympanic membranes and external auditory canals were inspected using an operating microscope. Thereafter, initial ABR measurements were completed to ascertain that the animals had acceptable hearing function. Animals with preexisting hearing loss or any abnormality in the external or middle ear were excluded from the study. Subsequently, bilateral myringotomies were performed following which ABR measurements were repeated: these measurements were referred to as baseline measurements.

The threshold of hearing in each ear at 8 kHz, 16 kHz, 20 kHz and 25 kHz were determined using the Smart EP device (Intelligent Hearing Systems, Miami, FL). In each of the animals, one ear was randomly assigned to receive 2 puffs each of the Earigate™ solution (Schering Plough, Canada), twice in a one-day application. The solution was instilled into the ear canal with the animals head left in place for 10–15 min, tragal compressions were performed to ensure that the test product falls into the middle ear. The control ears did not receive any product. Following the application of Earigate™, ABR measurements were completed at 3 and 10 days post-application. These measurements were then compared to the baseline measurements. All procedures were performed under inhalational anesthesia with isoflurane. The animal model has been previously validated in our laboratory for studying ototoxic effects of otopical products [8,9].

### 2.4. Statistical analysis

The ABR data was analyzed with the Kruskal–Wallis test. Post hoc comparisons were made with Dunn's multiple comparison test. Statistical significance was set at $p$ value $\leq 0.05$.

## 3. Results

### 3.1. Chemical composition of Earigate™

Earigate™ contained: $Na^+$ 141 mmol/L, $K^+$ 3.0 mmol/L, $Cl^-$ 162 mmol/L, $Ca^{2+}$ 3.36 mmol/L, phosphate $< 0.32$ mmol/L, $Mg^{2+} > 2.88$ mmol/L as determined by Beckman Coulter chemistry analyzer.

### 3.2. Auditory brainstem response

The results of ten animals are presented as one animal was eventually excluded because it developed a severe ear infection.

The mean ABR threshold shifts in the control and experimental ears at baseline, 3 and 10 days post-application of Earigate™ were similar for both the control and experimental ears at the various frequencies tested (Figs. 1 and 2). No significant changes were detected between the control and experimental ears at any frequency tested ($p = 0.392$ for 8 kHz, $p = 0.2601$ for 16 kHz, $p = 0.4699$ for 20 kHz and $p = 0.6849$ for 25 kHz).

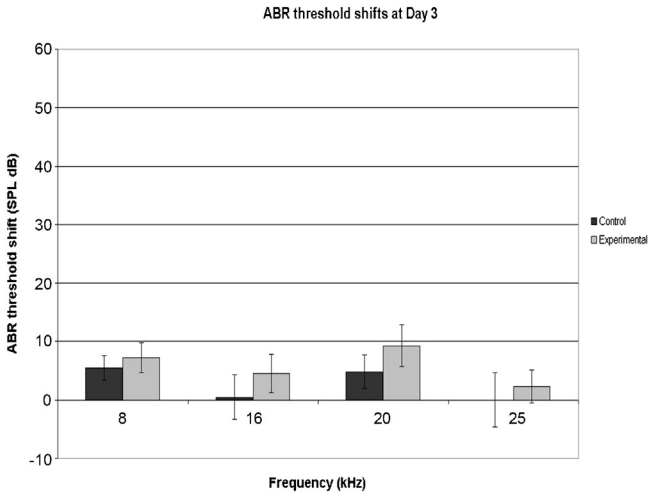


**Fig. 1.** ABR threshold shifts in the control and experimental ears at 3 days post application of Earigate™.

## 4. Discussion

Cerumen accumulation in the ear canal is a very common condition that can affect all of the age groups, though it is said to be more common in the elderly and in very young children [10]. The safety of the products used for softening and removal of the ear wax is therefore as important, if not more important, than the wax removal itself [11]. Various cerumenolytic agents are available over-the-counter and their potential for ototoxicity is not commonly evaluated. It is known that the topical use of different classes of pharmaceutical agents could pose a risk for hearing loss when the eardrum is not intact as the product can enter the middle ear cavity and come into contact with the round and oval window membranes [12,13]. These products can gain access to the membranous labyrinth by permeating through the round window membrane, which is selectively permeable to chemicals with molecular weights below 1000 kD [14,15].

There are studies, which have considered the usefulness and safety of various wax softeners and ears cleansers [1,3,4,6,10,16,17]. Saline was found to be as effective as other commercially available ear products, such as chlorobutanol and potassium carbonate, in softening ear wax, or even more effective [6]. Our group has looked at the potential ototoxicity of triethanolamine polypeptide (Cerumenex®), a product commonly

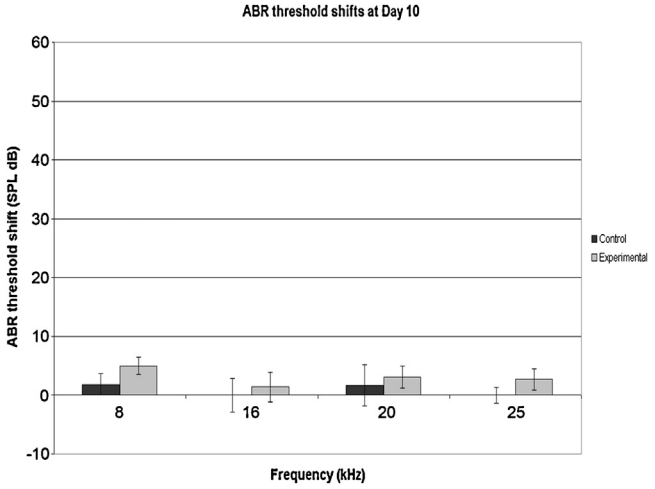


**Fig. 2.** ABR threshold shifts in the control and experimental ears at 10 days post application of Earigate™.

used as an ear wax softener and found it to be toxic to the outer hair cells with inflammatory features on the temporal bone of the tested animals [18]. Saline-based wax softeners have been reported to exhibit no toxicity in the external ear when compared to other wax softeners like triethanolamine and carbamide [19].

The TM represents a seal for the middle ear cavity and, in most cases; products in the outer ear canal should not come into contact with the middle or inner ear. However, perforations in the TM do occur and may be present without the knowledge of the patient [20]. When there is TM perforation, the risk of contact of the product used for ear softening with the middle and inner ear does exist [11]. The principal cations in the endolymph and perilymph are potassium and sodium respectively. Through the round window membrane, it is possible for the constituents of the liquids present in the middle ear to enter into the perilymph. The differences in electrolyte composition of these fluids might then alter the electrolyte milieu of the perilymph. However, the physiological assessment of hearing from this study revealed no untoward effects. Earigate™ did not lead to a significant loss in hearing in all animals tested. There were also no other signs to suggest toxicity to the middle ear, the facial nerve or the vestibule. This supports earlier reports that saline-based ear wax softeners are considered safe even in the presence of a TM perforation.

## 5. Conclusion

The present study suggests that the use of Earigate™ as a wax softening product is safe even in the presence of a tympanic membrane perforation.

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