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Research Article

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Disintegration of cerumen by using several natural cerumenolytic

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Abstract

Objective: To find out the effects of various natural cerumenolytic products (e.g. ascorbic acid, α-tocopherol, rosemary, pine turpentine, pergamote, chestnut, rosehip and rose oils, and onion tincture) as well as distilled water and pure olive oil on the disintegration/dissolution of cerumen.

Method: Cerumen was provided by mechanical removal from adult patients who attended the otolaryngology clinic. Each cerumen sample was placed in a tube containing one of eleven test solutions. The cerumens undissolved were weighed at specific time intervals. e.g., 1 hour, 5 hours, 1 days, 2 days and 5 days. The efficacy of these oils and vitamins were evaluated by measuring the weight of cerumen part disintegrated/undissolved.

Results: The results showed that highest percentage of cerumen disintegration was found for ascorbic acid within 1 hour, followed by pine oil and distilled water in 5 hours, onion tincture in 5 hours, chestnut oil in 2 days, rose oil and α-tocopherol in 5 days, respectively. However, rose, pergamote, chestnut and rosemary oils along with α-tocopherol and onion tincture disintegrated entirely the cerumen within 5 days only, except for olive oil and rosehip oil having the disintegration ratio of about 68% within 5 days.

Conclusion: It could be concluded that the products studied here could be used as cerumenolytic products having different disintegration period depending upon their chemical composition. Furthermore, distilled water showed the greater degree of cerumenolysis compared to oil-based cerumenolytics.

Keywords Cerumen; Disintegration, Ascorbic acid ; Pine oil, *In Vitro*.

Introduction

Cerumen or "earwax," is a naturally occurring substance that cleans, protects, and lubricates the external auditory canal. Cerumen forms when glandular secretions from the outer one-third of the ear canal mix with exfoliated squamous epithelium[1]. It is largely composed of desquamated sheets of keratinocytes. It also contains lipids and peptides, which are secreted by the sebaceous and apocrine glands in the external auditory canal. It acts as a lubricant and creates hydrophobic protective layer on the meatal skin. It also contains lysosomal enzymes and immunoglobulins, which lead it to have bactericidal properties [1]. Normally, cerumen is eliminated or expelled by a self-cleaning mechanism, which causes it to migrate out of the ear canal, assisted by jaw movements [2]. The accumulation of cerumen, caused by failure of the self-cleaning mechanism, is one of the most common reasons that patients seek medical care for ear-related problems [3-4].

Symptoms associated with cerumen impaction include, but are not limited to: hearing loss, tinnitus, fullness, itching, otalgia, discharge, external otitis, or chronic cough. Cerumen impaction can prevent diagnostic assessment by preventing complete examination of the external auditory canal and/or tympanic membrane or by interfering with

diagnostic assessment [5]. Especially, continuous usage of synthetic cerumenolytics for old people can negatively effect on hearing and tympanic membrane.

Multiple methods for removing cerumen exist, including instillation of cerumenolytic agents, manual removal using curettes/hooks/forceps/ suction, and irrigation [6]. Topical therapy is normally used to manage cerumen impactions either as a single therapeutic intervention or in combination with other methods, including irrigation of the ear canal and manual removal of cerumen.

Topical preparations exist in three forms: 1. **Water-based preparation**: 10% Triethanolamine polypeptic oleate condensate, docusate sodium, 3% Hydrogen peroxide, 2.5% Acetic acid, 10% Sodium bicarbonate, water and saline. 2. **Non-water-based/non-oil-based preparation**: Carbamide peroxide (Debrox), 50% Choline salicylate and glycol (Earex plus, Audax), Ethylene oxide, polyoxypropylene glycol (Addax), 0.5% chlorbutol and propylene glycol. 3. **Oil based preparations**: 57.3% Arachis oil, 5% chlorbutol, 2% paradichlorobenzene, 10% oil of turpentine (Cerumol), arachis oil, almond oil, rectified camphor oil (Otocerol, Earex), olive oil, almond oil and mineral oil [7-12].

Water-based agents have a cerumenolytic effect by inducing hydration and subsequent fragmentation of corneocytes. Oil-based preparations are not true "cerumenolytics." They lubricate and soften cerumen without disintegrating cerumen [13]. The mechanism of all the cerumenolytics used has not been defined by in vitro studies in detail [14]. So far, a lot of ceerumenolytic products have been studied. Yet, there is no decision for the most effective cerumenolytic product for all the countries. Each country has used their own formulation for disintegration of cerumen. Principally, olive oil and sodium bicarbonate and hydrogen peroxide and glycerin preparations have been commonly used. Therefore, it is obligatory to find out the best/environmentally-friendly cerumenolytic product.

The aim of this study was to test crumbling or softness the cerumen by using various natural oils and vitamins as replacement of synthetic cerumenolytic products, e.g., hydrogen peroxide in glycerin, having side effects *in vitro*.

Material and methods

Materials

Cerumen was provided by mechanical removal from patients who attended the otolaryngology clinic of Hospital of Medicine Faculty affiliated to Kahramanmaraş Sütçü İmam University, Turkey for about one week period and had ages between 20 and 70 years old for men. In total, thirty three fresh cerumen samples were undertaken in this study. Various vitamins such as ascorbic acid (VC) and α-tocopherol (VE) and six different types of oils (e.g., rosemary, pine turpentine, pergamote, chestnut, rosehip and rose oils) were used as cerumenolytic products and purchased from Talya Company (Antalya, Turkey). Moreover, onion tincture was prepared by using olive oil in the Laboratory of Bio-engineering and Sciences Department, Kahramanmaraş Sütçü Imam University, Turkey. Olive oil and distilled water themselves were also used as reference products.

Method

Five ml of the above-mentioned cerumenolytic products including onion tincture and distilled water was added into each tube containing of cerumen (0.1 gr) via a clean pipette. As for the sample VC in form of powder, 0.1 gr of the vitamin was dissolved in 5 ml distillated water and used as cerumenolytic solvent. All the tubes containing cerumenolytic products (5 ear drops) and cerumen were incubated at room temperature of about 25˚C and observed for various time intervals (e.g., 1 hour, 5 hour, 1 day, 2 days and 5 days) under dark place. The undissolved cerumen particules were removed from the products in petri dishes, dried at room temperature for 3 days and then re-weighed. The experiment was totally conducted three times for each trial. The effectiveness of these oils and vitamins were evaluated by measuring the weight of undissolved cerumen part, and then the percentage of the cerumen part disintegrated/dissolved, that is to say the degree of cerumen disintegration, was calculated according to equation below:

$$\mathbf{S\ (\%) = (S1\text{-}S2)\ x\ 100/\ S1} \qquad \mathbf{(1)}$$

where, S is the percentage of the disintegrated cerumen part, S1 is the initial weight of cerumen provided from the hospital (gr) and S2 is the last weight of undissolved part of cerumen (gr).
For each cerumenolytics, the average of at least three measurements was reported in this study.
On the other hand, Fourier-transform infrared (FTIR/ATR) was used for chemical characterizations of the cerumen collected. The FTIR measurements were performed on Agilant Spectrum ATR Spectrometer from 400 to 4000 cm^{-1}.

Results and Discussion

The results of the effects of various cerumenolytic products on the solubility/disintegration of cerumen as functions of various time intervals are shown in Table 1 and Figs. 1-2.

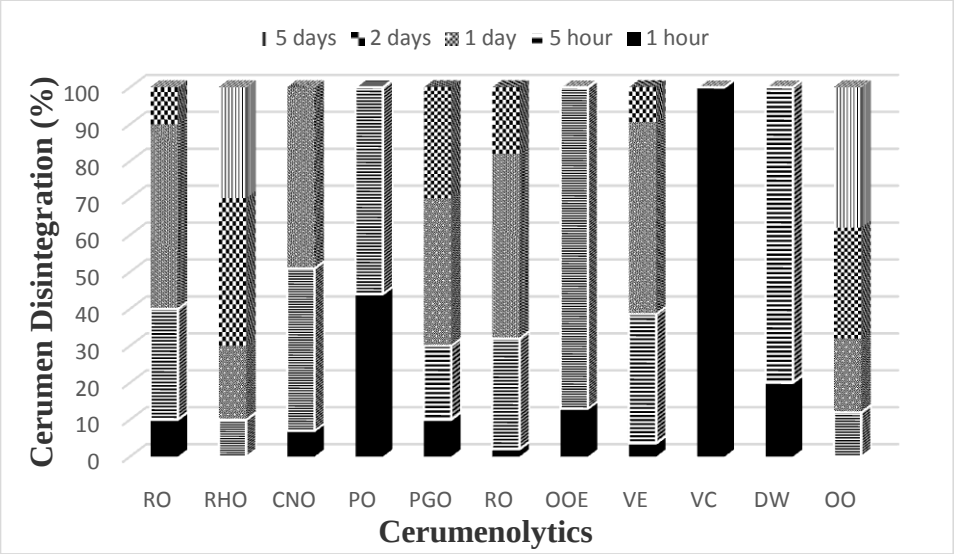

Figure 1: Average disintegration percentage of the cerumen on the basis of time interval

Sample	Before application	After application	First day	Second day	Fifth day
Rosehip oil					
Rose oil					

Figure 2: Photographic example/evidence of cerumen disintegration for the 1st, 2nd and 5th day for rosehip and rose oil

It is evident from Table 1 and Fig. 1 that most effective cerumenolytic is found for the VC product having the highest value of dissolved part percentage of 100 during time interval as short as 1 hour, followed by pine oil (44%) and onion extracted in olive oil (13%), respectively, whereas lower dissolved percentages are obtained from the other oils and vitamins, for example, rose oil (10%) and pergamote oil (10%), chest nut oil (7%), VE (3.5%), rosemary oil (2%), respectively. However, no any disintegration is remarked with rosehip oil at the first time interval of 1 hour.

Table 1: Percentage of dissolved cerumen obtained by using several oil- and non-oil based cerumenolytic products on the basis of various time intervals.

Cerumenolytic products	**Cerumen Disintegration (%)**				
	1 hour	**5 hour**	**1 day**	**2 days**	**5 days**
Rose oil (RO)	10±0.15	30±0.21	50±1.25	80±0.50	100±0.45
Rosehip oil (RHO)	0.0±0.00	10±0.34	20±0.73	40±0.00	67±0.64
Chestnut oil (CNO)	7.0±0.78	44±1.5	67±0.03	100±0.00	-
Pine oil (PO)	44±1.5	100±0.75	-	-	-
Pergamote oil (PGO)	10±0.26	20±0.75	40±2.0	80±0.25	100±0.78
Rosemary oil (RO)	2.0±0.03	30±0.25	50±0.28	70±0.05	100±0.00
Onion tincture (OOE)	13±0.5	100±0.8	-	-	-
α-tocopherol (VE)	3.6±0.05	35±0.93	52±1.5	80±1.5	100±0.5
Ascorbic acid (VC)	100±0.00	-	-	-	-
Distilled Water (DW)	20±0.34	100±0.05	-	-	-
Olive oil (OO)	0±0.00	12±0.84	20±0.5	30±0.75	68±0.23

It was noticed that the effective of decay, for VC, might be due to its acidity. In onion macerated in olive oil, apolar content moved to olive oil during the extraction and caused its activity, and VE has apolar characterizations and oily form, which may strengthen crumbling [15-16].

As shown in Figs 2, it is clear that the percentage of the dissolved cerumen increases with increasing time interval from 1 hour to 5 hours for all the cerumenolytic products used herein (here in). The greatest cerumen dissolved part ratios (100%) at 5 hours were determined for pine oil along with distilled water and onion tincture, followed by chestnut oil (44%), VE (35%), rosemary oil (30%) and rose oil (30%), pergamote oil (20%) and rosehip oil (10%).

As indicated in Fig. 2, at 5 hours, the distilled water and pine oil cause an obvious disintegration of the cerumen, however, the oil-based agents have not yet given any considerable change in the cerumen.

The findings in this study are consistent with those reported in the literature [17-19]. They found that cerumol, containing turpentine and dichlorobenzene, was more effective cerumenolytic when compared with sodium bicarbonate. However, the contents are skin irritants. Therefore, the negative effect of the turpentine oil studied here should be taken into considerations.

As shown in Fig. 2, during the first day, the highest percentage of the dissolved cerumen part is obtained from chestnut oil (67%), followed by VE (52%), rosemary and rose oil (50%), pergamote oil (40%) and rosehip oil (20%), respectively.

It is evident from Fig.1 that the greatest percentage (100%) of the dissolved cerumen is achieved by chestnut oil, the lowest ones are determined for rosehip (40%) and olive oils (30%). The other products used, e.g., rosemary, pergamote, rose oils, and VE, give almost the same solubility ratio (about 80%) of the cerumen.

As can be seen from Fig. 2, it is worthwhile to notice that with the exception of rosehip and olive oils, rosemary, pergamote and rose oils as well as VE result in full disintegration (100%) of the cerumen after a time interval of 5 days. This can be explained by the chemical composition of rosemary, pine, pergamote and rose essential oils having various phenolic components and non-polar terpenes (e.g., alpha terpinol, terpene alcohol, linalool, geraniol, farnesol, etc.). As is also known, they are largely used for various medical applications.

In general, the efficacy of the oils and vitamin used herein is considered to be due to their apolar nature like cerumen component. The using of natural secondary metabolic products from the plant with the remedy is considered as homotherapy, which is one of the most methods to remedy many disorder due to its high activity and has low side effects caused by synthetic medicines.

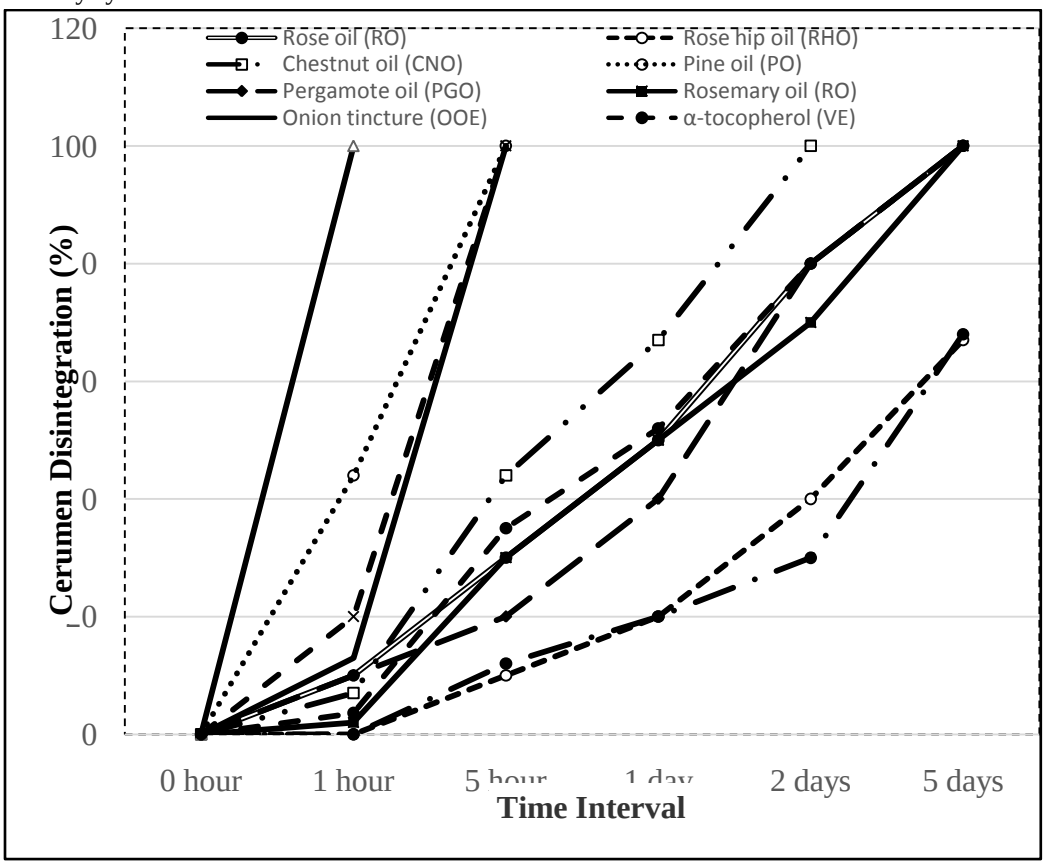

Figure 3: Relationship between time interval and cerumen dsintegration percentage as functions of eleven cerumenolytics

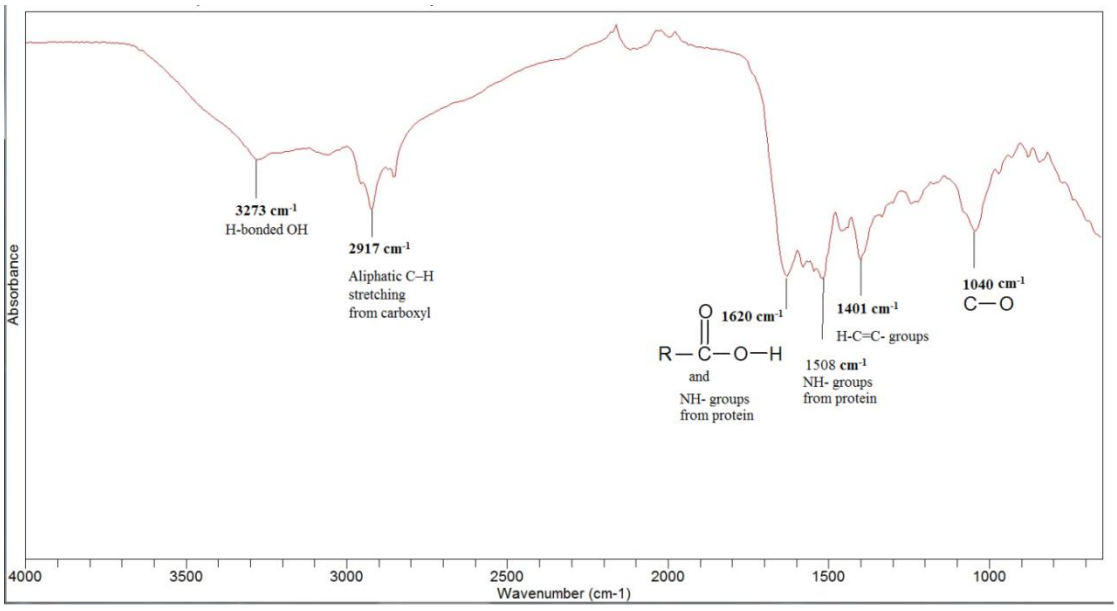

Figure 4: Typical FT-IR/ATR spectrum of the cerumen studied herein

In order to support the data, the photographic example/evidence of cerumen disintegration at the 1st, 2nd and 5th day for rosehip and rose oil are illustrated in Fig. 3. As shown in the figure, the cerumen disintegration increases slowly with prolonging time. On the other hand, the disintegration caused by rose oil is easier than that done by rosehip oil. This phenomenon might be attributed to lees polarity feature of rose oil in comparison to rosehip one.

It is well-known the fact that chemicals/materials can be dissolved in solvent whose structure is similar to the chemical to be dissolved. On this context, the FT-IR study done on the cerumen (Fig. 4) reveals that the cerumen has similarities to the cerumenolytics used herein in having polar and apolar functional groups (e.g. C=O, OH-, NH-, and CH-), leading easy disintegration of cerumen in the cerumenolytics. For instance, the distilled water having huge amount of OH groups caused to disintegrate the cerumen. In conclusion, the cerumen disintegration mechanism can be explained by having similar structures of the cerumenolytics to those of cerumen.

Earwax (cerumen) consists of lipids including long-chain saturated and unsaturated fatty acids, alcohols, wax esters and cholesterol, squalene, and triglycerides; sugars including galactosamine and galactose; and protein material including amino acids, keratin, and desquamated keratinocytes.

As can also be seen from Fig. 3, wide bands are determined in the regions of 3700–3100 cm^{-1} (H-bonded OH groups) and 2917 cm^{-1} (aliphatic C–H stretching from carboxyl). It should be noted that OH- transformation bands are observed between 1420 and 1260 cm^{-1}. Also, two ester bands occur between 1360 and 1075 cm^{-1}, showing strong reaction between COOH- groups with OH- groups. In conclusion, it can be said that cerumen substances have constituted as functional groups from carboxyl, hydroxyl and aldehyde bounds. At the same time NH- groups from protein occur between 1500 and 1700 cm^{-1}.

- The present study aimed to find out the effects of various natural products
- Natural products have low side effects caused by synthetic medicines.
- Natural products may become a helpful addition for cerumenolytic products having different disintegration period depending upon their chemical composition.

Discussion

It was reported by Arikan et al. [17] that a 6% solution of hydrogen peroxide in glycerin and a 10% solution of aqueous sodium bicarbonate resulted in complete disintegration within one hour.

It was also reported by Saxby et al.[18] and Mehta [19] that water-based cerumenolytics was more effective than oil-based ones. The employing water as a cerumenolytic will result in cost-effective way for both patients and the National Health Service.

Robinson [20] noticed that and the most effective ceruminolytic was a 10% solution of sodium bicarbonate, aqueous base. In contrast, those ceruminolytics with an organic base gave little cerumenolytic effect.

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