CleanEars

EAR WAX REMOVAL SYSTEM

- SUPERIOR PROVED EFFICACY
- INNOVATIVE
- DOUBLE ACTION: IRRIGATION & DISSOLUTION
- HIGH SAFETY PROFILE
- NATURAL
- USER FRIENDLY
- PRESERVATIVE FREE

The Problem

- Cerumen impaction is a common problem
- Cerumen impactation may decrease hearing, causing difficulties in communication (social isolation, depression!)
- Cerumen impactation prevalence:
  2-6% of the general population in the UK
  6-18 million people in the Us (Roland et.al.2008)
- It is estimated that each week 150,000 cerumen removals take place in the US (Grossan 1998)
- Removal of cerumen using physical methods by physician (loop, suction, irrigation) might end up with complications such as lacerations of the external auditory canal, pain, infection, vertigo, tinnitus and timpanic membrane perforation (Grossan 1998).

Ear wax accumulation average prevalence, is 4% of the total population

CleanEars vs. Competitors

Tested Parameter:

The change in the degree of ear canal occlusion

Contents lists available at ScienceDirect

Archives of Gerontology and Geriatrics

journal homepage: www.elsevier.com/locate/archger

Cerumen removal: Comparison of cerumenolytic agents and effect on cognition among the elderly

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Objective

Cerumen impaction may affect hearing and decrease hearing acuity, thus decreasing cognitive functions among the elderly.

The objective of this study was to compare the safety and the efficacy of three cerumenolytic agents and to assess the effect of cerumen removal on cognition.

Thirty eight elderly subjects (mean age: 78 years, total 76 ears) were treated with either **Auro (Debrox), Cerumol** or the newer **CleanEars** , and the change in the degree of ear canal occlusion was examined after a week.

In addition, a change in cognition following cerumen removal was evaluated using Raven's standard progressive matrices (RSPM) test.

Introduction

Cerumen is part of the external ear defense mechanisms against foreign bodies and infectious agents.

Cerumen impaction is a common problem encountered by the general physician, the family physician and the otolaryngologist almost every day.

Some 2–6% of the general population in the United Kingdom suffers from cerumen impaction at any given time which suggests a prevalence of 6–18 million individuals in the United States (Roland et al., 2008). It has been estimated that each week 150,000 cerumen removals take place in the United States (Grossan, 1998).

Cerumen impaction has important clinical implications on the general well-being of the patient and might **cause hearing loss, pain, itching, tinnitus, vertigo, external otitis and even chronic cough** (Roeser, 1997).

It is also more common among the elderly and in patients with cognitive impairments, **with up to 65% of patients over 65 years old having cerumen impaction** (Grossan, 1998).

Cerumenolytic Agents

Cerumenolytic products act by softening the cerumen and lubricating the canal, thus facilitating cerumen removal from the ear canal or by disintegrating the cerumen.

Over the years, a large number of agents have been proposed and tested, including tap water, olive oil, hydrogen peroxide, acetic acid, sodium bicarbonate and other commercially available products.

None of these agents was found to be effective in totally dissolving the cerumen

(Browning, 2002; Burton and Doree, 2003). No particular cerumenolytic agent was found to be more effective than any other (Roland et al., 2008).

In the present report **CleanEars, Auro (Debrox) and Cerumol** were compared to each other in their **cerumenolytic effects**.

CleanEars (Naveh Pharma, Israel) is a new spray-applied cerumenolytic solution which is composed of mineral oil (paraffin), squalane and spearmint oil. CleanEars provides combined mode of action, namely cerumenolysis along with lubrication. The spray administration may also assist in deeper penetration of the substance to the cerumen layers.

Auro is a FDA-approved drops composed of carbamide peroxide and anhydrous glycerin.

Cerumol, another FDA approved drops, contains arachis oil (peanut oil), chlorobutanol and dichlorobenzene.

Method

- 38 patients, 76 Ears,
- Mean age 67-92 (ave 78)
- 3 groups – for 3 products
- **Scale of Occlusion**

0 - 1 - 2 - 3

No occlusion Complete occlusion

Test Results

Cerumen Types

Table 1
Coding for cerumen types.

Type of cerumen	Coding
Dry, gurgled	A
Dry, bulky	B
Thin	C
Soft	D

Test Results

Average Occlusion

Table 2
Average occlusion pre- and post-treatment (both ears, *n* = number of ears, score: 0–3 per ear by occlusion severity), mean ± SD.

Intervent.	Number	Pre-treatment	Post-treatment
Auro®	24	4.08 ± 1.73	2.17 ± 2.04
Cerumol®	26	4.54 ± 1.76	3.08 ± 2.87
CleanEars®	26	4.31 ± 1.75	2.0 ± 2.41

Only in the **CleanEars** group a
complete resolution of obstruction
in both ears was achieved, in some of the ears .

Test Results

Degree of Occlusion

Degree	Pre-treatment			Post-treatment		
	Auro®	Cerumol®	CleanEars®	Auro®	Cerumol®	CleanEars®
0	0	0	0	10 (41.6)	10 (38.5)	14 (53.8)
1	8 (33.3)	7 (27)	8 (30.8)	6 (25)	4 (15.4)	3 (11.5)
2	7 (29.2)	5 (19.2)	6 (23.1)	4 (16.7)	0 (0)	4 (15.4)
3	9 (37.5)	14 (53.8)	12 (46.1)	4 (16.7)	12 (46.1)	5 (19.3)
Total (*n*)	24	26	26	24	26	26

CleanEars was the only agent found in the current study to bring upon complete resolution of obstruction in both ears.

Test Results

Differences between the pre- and post-treatment occlusion scores

Table 4
The mean differences between pre- and post-treatment occlusion scores.

	Mean ± SD	Range
Auro®	1.92 ± 1.24	0–4
Cerumol®	1.46 ± 1.71	0–5
CleanEars®	2.30 ± 1.75	0–6
Total	1.89 ± 1.59	0–6

Test Results

The time needed to remove the remaining cerumen

Table 5
Average duration of the treatment.

	Keyed duration
Auro®	1.58
Cerumol®	2.46
CleanEars®	1.23

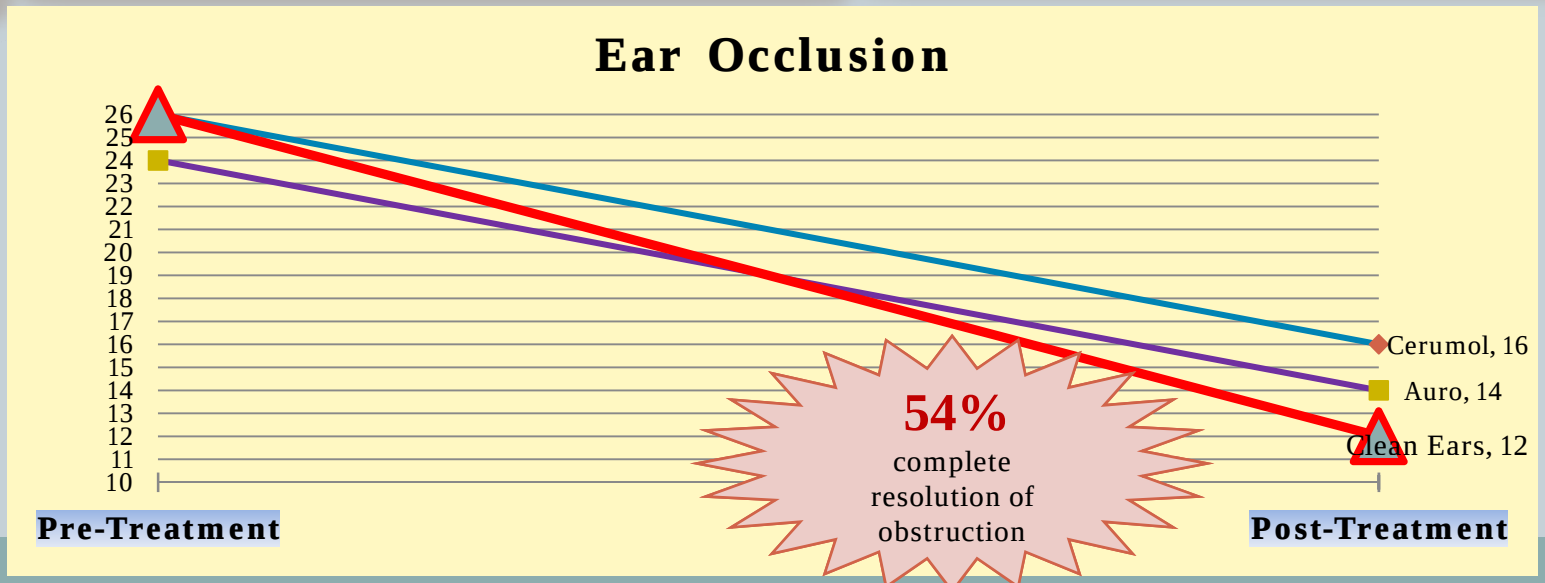
Meaning of keys: 1 <1 min; 2 >1 min and <5 min; 3 >5 min.

Only in 46.2% cases of the CleanEars group
and in **61.5%** and in **58.4%** in the Cerumol and Auro groups,
there was a need for additional treatment

Test Results

Results

Type	Pre-treatment			Post-treatment		
	Auro®	Cerumol®	CleanEars®	Auro®	Cerumol®	CleanEars®
A	4 (16.7)	6 (23.1)	2 (7.7)	2 (8.3)	0	0
B	14 (58.3)	14 (53.8)	18 (69.2)	6 (25)	5 (19.2)	3 (11.5)
C	2 (8.3)	2 (7.7)	0	2 (8.3)	2 (7.7)	2 (7.7)
D	4 (16.7)	4 (15.4)	6 (23.1)	4 (16.7)	9 (34.6)	7 (26.9)
Total	24	26	26	14 (58.3)	16 (61.5)	12 (46.2)



Test Results

Over 80% Efficacy

Superior Efficacy of Clean Ears

Type	Pre-treatment			Post-treatment		
	Auro®	Cerumol®	CleanEars®	Auro®	Cerumol®	CleanEars®
A	4 (16.7)	6 (23.1)	2 (7.7)	2 (8.3)	0	0
B	14 (58.3)	14 (53.8)	18 (69.2)	6 (25)	5 (19.2)	3 (11.5)
C	2 (8.3)	2 (7.7)	0	2 (8.3)	2 (7.7)	2 (7.7)
D	4 (16.7)	4 (15.4)	6 (23.1)	4 (16.7)	9 (34.6)	7 (26.9)
Total	24	26	26	14 (58.3)	16 (61.5)	12 (46.2)

Among the 20 **CleanEars** users with severe wax accumulation in the group ranked A-B, only 3 (15%) remain (in type B), thus the efficacy of **CleanEars** is considered as over **80%**

Conclusion

In the present study, resolution of the ear occlusion was achieved in 38–54% of the treated ears.

Only in the **CleanEars** group a complete resolution of obstruction in both ears was achieved.

A statistically significant difference between the RSPM score before and after the removal of cerumen was found.

Using **CleanEars** is as effective and safe as other agents and may be advantageous due to its spray application.

Removal of cerumen significantly improves the well-being of elderly patients.

Archives of Gerontology and Geriatrics xxx (2010) xxx–xxx

Contents lists available at ScienceDirect

Archives of Gerontology and Geriatrics

journal homepage: www.elsevier.com/locate/archger

Cerumen removal: Comparison of cerumenolytic agents and effect on cognition among the elderly

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ARTICLE INFO

Article history:
Received 13 August 2009
Received in revised form 24 February 2010
Accepted 26 March 2010

Keywords:
Ear wax
Cerumen impaction in elderly
Cerumenolysis

ABSTRACT

Cerumen impaction may affect hearing and decrease hearing acuity, thus decreasing cognitive functions among the elderly. The objective of this study was to compare the safety and the efficacy of three cerumenolytic agents and to assess the effect of cerumen removal on cognition. Thirty eight elderly subjects (mean age: 78 years, total 76 ears) were treated with either Auro®, Cerumol® or the newer CleanEars®, and the change in the degree of ear canal occlusion was examined after a week. In addition, a change in cognition following cerumen removal was evaluated using Raven's standard progressive matrices (RSPM) test. There was no difference regarding the eventual degree of occlusion between the three treatment groups. Only in the CleanEars® group a complete resolution of obstruction in both ears was achieved. A statistically significant difference between the RSPM score before and after the removal of cerumen was found. Using CleanEars® is as effective and safe as other agents and may be advantageous due to its spray application. Removal of cerumen significantly improves the well-being of elderly patients.

1. Introduction

Cerumen is part of the external ear defense mechanisms against foreign bodies and infectious agents. It is a combination of epithelial cells, dust, foreign bodies as well as the secretions of the sebaceous glands and apocrine glands. Cerumen lubricates and cleans the ear canal. The lubrication is the effect of lipids, found in high concentration in the sebum, produced by the sebaceous glands. The cleaning function of cerumen is the result of constant migration of the cerumen towards the outer part of the external auditory canal. On its way out, foreign materials adhere to the cerumen and thus are prevented from plugging the ear or reaching the tympanic membrane (McCarter et al., 2007).

Cerumen impaction is a common problem encountered by the general physician, the family physician and the otolaryngologist almost every day. Some 2–6% of the general population in the United Kingdom suffers from cerumen impaction at any given time which suggests a prevalence of 6–18 million individuals in the United States (Roland et al., 2008). It has been estimated that each week 150,000 cerumen removals take place in the United States (Grossan, 1998). Cerumen impaction has important clinical implications on the general well-being of the patient and might cause hearing loss, pain, itching, tinnitus, vertigo, external otitis and even chronic cough (Roeser, 1997). It is also more common among the elderly and in patients with cognitive impairments, with up to 65% of patients over 65 years old having cerumen impaction (Grossan, 1998).

Cerumen impaction may affect hearing (Lewis-Cullinan and Janken, 1990) and decrease hearing acuity by 40–45 dB (Meador, 1995). Such hearing impairment among the elderly causes difficulties in communication, social isolation, depression and even physical immobility (Jones et al., 1984; Murlow et al., 1990). Moreover, decreased hearing in old age, either gradual or acute, is perceived by the patients or their caregivers as a natural, almost expected, phenomenon, which does not merit examination or intervention. Thus old people with reversible deafness, as caused by cerumen impaction, may not reach intervention for a very long period of time (Arlinger, 2003).

Older people tend to have hearing impairments not only due to presbycusis (that is, high-frequency hearing loss caused by aging processes in the cochlea and the cochlear nerve) but also due to the effects of aging on the brain temporal processing (Pichora-Fuller and Souza, 2003). These two cause reduced hearing ability both in quiet and in noisy environment and can cause a significant

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0167-4943/$ – see front matter © 2010 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.archger.2010.03.025

impairment in the ability of the elderly people to communicate with his or her surroundings. In addition to that, cognitive impairments have their effect on hearing capabilities among the elderly (Martin and Jerger, 2005). These effects may explain the fact that, despite adequate amplification of sound, some elderly patients with hearing loss do not seem to benefit from hearing aids, especially in everyday life, and not in quiet environment.

Cognitive function was also found to be decreased in individuals with hearing loss (Uhlmann et al., 1989). In one small study both hearing and cognition (as measured by the mini-mental state examination = MMSE) were improved after elimination of cerumen impaction (Moore et al., 2002). Improvement of hearing ability may actually improve intelligence: use of cochlear implant in children brings their IQ scores to that of normal healthy children (Wu et al., 2008).

Removal of cerumen from the external auditory canal can be accomplished using physical methods, chemical methods (cerumenolysis) or any combination of them. The physical removal of cerumen using loop, suction, irrigation or forceps is a common procedure done by the physician. However, it is time consuming and might end up with complications, such as lacerations of the external auditory canal, pain, infection, vertigo, tinnitus and tympanic membrane perforation. Performing this procedure by an inexperienced physician might lead to high rate of complications (Grossan, 1998).

Cerumenolytic products act by softening the cerumen and lubricating the canal, thus facilitating cerumen removal from the ear canal or by disintegrating the cerumen. Over the years, a large number of agents have been proposed and tested, including tap water, olive oil, hydrogen peroxide, acetic acid, sodium bicarbonate and other commercially available products. None of these agents was found to be effective in totally dissolving the cerumen (Browning, 2002; Burton and Doree, 2003). No particular cerumenolytic agent was found to be more effective than any other (Roland et al., 2008).

In the present report CleanEars®, Auro® and Cerumol® were compared to each other in their cerumenolytic effects. CleanEars® (Naveh Pharma, Israel) is a new spray-applied cerumenolytic solution which is composed of mineral oil (paraffin), squalane and spiramint oil. CleanEars® provides combined mode of action, namely cerumenolysis along with lubrication. The spray administration may also assist in deeper penetration of the substance to the cerumen layers.

Auro® is a FDA-approved drops composed of carbamide peroxide and anhydrous glycerin. Cerumol®, another FDA-approved drops, contains arachis oil (peanut oil), chlorobutanol and dichlorobenzene.

An additional goal of the present study was to assess cognition, as a more comprehensive reflection of quality of life (Nota et al., 2007), using the RSPM. This is a multiple choice test of intelligence, requiring inductive reasoning about abstract geometric patterns. In each test item, the respondent is asked to identify the missing segment required to complete a larger geometric pattern. Many items are in the form of a 3×3 or 2×2 matrix, giving the test its name. It is a widely used test, first, because it is non-verbal and hence is relatively more culture-free than the standard IQ test or the MMSE and, second, because it correlates well with other measures of intelligence and hence is valid. It appears to cover a broad range of mental abilities, especially abstract intelligence which was found to be impaired in individuals with hearing loss (Oleron, 1950). The test is applied widely and is usable with individuals irrespective of age, sex, nationality, or education. Most importantly, it is a non-threatening and friendly instrument that may be used in the doctor's office without evoking any special surprise. We could not find any studies investigating the relationship between the Raven test and hearing.

2. Patients and methods

2.1. Ethics

The study took place at the Rehabilitation Department of a geriatric hospital and was approved by the institutional ethics review board. All subjects signed informed consent.

2.2. Study population

Subjects enrolled in the study were well over 18 years old, without any previous ear disease, and none had any ear examination or treatment during the previous 6 months. A total of 41 volunteers were enrolled in the study between February and September 2008. They were chosen after routine screening otoscopy, done in most inmates, revealed that they had cerumen impaction, after it was ascertained that they were cooperative enough to do a cognition evaluation, and that they were not on the verge of discharge to their home or to another institution. Thirty eight subjects were eventually included in the study: one subject was discharged from the hospital prior to the post-treatment examination, another discontinued the application after 1 day of treatment due to feeling of fullness in the ears, and the third subject was transferred to another hospital due to general health deterioration. The age range of the remaining 38 subjects was 67–92 years (mean age = 78 years). The study included 22 male and 16 female subjects. Altogether 76 ears were studied.

2.3. Study design

All grading and treatments were done by the same physician. The degree of occlusion by cerumen was determined using a scale of 0–3: 0 – no occlusion, 1 – mild occlusion (less than 50% of the canal diameter), 2 – moderate occlusion (more than 50% of the canal diameter), and 3 – complete occlusion. The type or the consistency of the cerumen was determined prior to treatment and afterwards in order to assess the physical effect of the medication on the cerumen (Table 1). Color and smell of cerumen were not scored. Otologic signs and symptoms and any possible adverse effects of the treatment were monitored and recorded.

The subjects were randomly assigned to be treated by Auro®, Cerumol® or CleanEars®. The examining physician was blind to the chosen treatment. The selected preparation was administered during 1 week, 3 times a day. Each time 3 drops or 3 puffs were instilled into each ear. After 1 week of treatment, the ears were examined and if any cerumen was left it was removed using #13 or #14 needle suction or Hartman's ear forceps. The duration of the removal procedure was timed (minutes).

The RSPM were presented to the subjects by the same author prior to the initiation of the treatment, and again 1 week later, after the ears were completely clean of cerumen. Each time, 9 different matrices were presented to the subjects and scored on a scale between 0 and 9.

2.4. Statistical analyses

Statistical analysis was performed with SPSS™ for Windows version 15.0. χ^2 analysis and 2-way analysis of variance with repeated measures were used, $p < 0.05$ was considered significant.

Table 1
Coding for cerumen types.

Type of cerumen	Coding
Dry, gurgled	A
Dry, bulky	B
Thin	C
Soft	D

Please cite this article in press as: Oron, Y., et al., Cerumen removal: Comparison of cerumenolytic agents and effect on cognition among the elderly. Arch. Gerontol. Geriatr. (2010), doi:10.1016/j.archger.2010.03.025

Table 2
Average occlusion pre- and post-treatment (both ears, n = number of ears, score: 0–3 per ear by occlusion severity), mean ± SD.

Intervent.	Number	Pre-treatment	Post-treatment
Auro®	24	4.08 ± 1.73	2.17 ± 2.04
Cerumol®	26	4.54 ± 1.76	3.08 ± 2.87
CleanEars®	26	4.31 ± 1.75	2.0 ± 2.41

3. Results

Twelve participants were treated with Auro®, 13 participants were treated with Cerumol® and 13 participants were treated with CleanEars®. Altogether 76 ears were examined. There were no statistical differences regarding age, gender and cognitive impairments between the three treatment groups. Tables 2 and 3 summarize the mean degree of occlusion and distribution of occlusion between the three treatment groups before and after the treatment. There were no differences regarding the degree of occlusion and type of cerumen found prior to the treatment between the three treatment groups.

The mean differences between the pre- and post-treatment occlusion scores are summarized in Table 4. Treatment with ear drops did affect the occluded ears and improved the degree of occlusion, but there was no difference regarding the degree of occlusion after the treatment between the three treatment groups. Only in the CleanEars® group a complete resolution of obstruction in both ears was achieved, in some of the ears.

In 46.2% cases of the CleanEars® group and in 61.5% and in 58.4% in the Cerumol® and Auro® groups, respectively, there was a need for additional treatment (suction or removal of cerumen with Hartman forceps). These differences were not statistically significant ($p = 0.75$).

The time needed to remove the remaining cerumen after 1-week use of cerumenolytics is summarized in Table 5. The duration of treatment was not statistically different between the three treatment groups ($p = 0.21$).

The type of cerumen in each group prior to and after the treatment is summarized in Table 6. Among the CleanEars® and Cerumol® groups the frequency of soft cerumen was higher after the treatment, but this change was not statistically significant ($p = 0.656$).

The otologic symptoms prior to the treatment with the cerumenolytics and afterwards (before complementary cerumen removal) are described in Table 7. The most common complaint was hearing loss, and except for one subject there was no change in the subjects' feeling of hearing loss after the treatment. However, the treatment did improve symptoms of irritation, pressure and fullness in the ears.

Only two subjects described side effects during the treatment period. Both of them were treated with Cerumol®. One subject described foul smell from his ears, and the other complained of mild pruritus and discharge from his ears. Both subjects completed the treatment.

The mean pre-treatment RSPM score was 3.67. The mean post-treatment score was 4.44 ($p = 0.836$). When controlled for age and the degree of ear occlusion, there was no statistically significant difference between the RSPM score before and after the removal of cerumen. There was, however, a significant difference between the outcome of the first set of 3 matrices completed before the removal of cerumen and the first set of 3 matrices completed after the removal of cerumen ($p = 0.011$).

Table 4
The mean differences between pre- and post-treatment occlusion scores.

	Mean ± SD	Range
Auro®	1.92 ± 1.24	0–4
Cerumol®	1.46 ± 1.71	0–5
CleanEars®	2.30 ± 1.75	0–6
Total	1.89 ± 1.59	0–6

Table 5
Average duration of the treatment.

	Keyed duration
Auro®	1.58
Cerumol®	2.46
CleanEars®	1.23

Meaning of keys: 1 <1 min; 2 >1 min and <5 min; 3 >5 min.

4. Discussion

This is a prospective, blinded study, in which a single investigator examined and evaluated the subjects. Each subject was his own control with regard to both the effect of the cerumenolytic agent on the cerumen and the effect of the removal of the impacted cerumen on the RSPM score.

4.1. Cerumenolysis

In the present study, resolution of the ear occlusion was achieved in 38–54% of the treated ears. Complete resolution of both ears' occlusion was achieved only among the CleanEars® treatment group. In comparison, in another study, resolution of cerumen occlusion with Cerumenex®, Murine® and placebo was respectively observed in 29.2%, 15.4%, and 41.7% of the subjects (Roland et al., 2004). In other studies, the efficacy of cerumenolytic agents was evaluated by the need for syringing or other ways of cerumen removal after their use. Such a need was found in 70–80% of the ears (Chaput de Saintonge and Johnstone, 1973; Mehta, 1985; Lyndon et al., 1992; Hand and Harvey, 2004), whereas in the present study it was only in 46.2% in the CleanEars® group and in 61.5% and in 58.4% in the Cerumol® and Auro® groups, respectively. This reflects higher efficacy of the cerumenolysis used in the current study, and may also reflect the improved methodology of evaluation, breaking it down into several and different aspects. We believe that future studies should adhere to those measures to allow comparisons.

While there are several commercial agents for removing cerumen, none so far has been shown to be superior in efficacy (Meador, 1995; Browning, 2002; Hand and Harvey, 2004; Roland

Table 3
Degree of occlusion, n (%).

Degree	Pre-treatment			Post-treatment		
	Auro®	Cerumol®	CleanEars®	Auro®	Cerumol®	CleanEars®
0	0	0	0	10 (41.6)	10 (38.5)	14 (53.8)
1	8 (33.3)	7 (27)	8 (30.8)	6 (25)	4 (15.4)	3 (11.5)
2	7 (29.2)	5 (19.2)	6 (23.1)	4 (16.7)	0 (0)	4 (15.4)
3	9 (37.5)	14 (53.8)	12 (46.1)	4 (16.7)	12 (46.1)	5 (19.3)
Total (n)	24	26	26	24	26	26

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Table 6
Pre- and post-treatment cerumen type, *n* (%).

Type	Pre-treatment			Post-treatment		
	Auro®	Cerumol®	CleanEars®	Auro®	Cerumol®	CleanEars®
A	4 (16.7)	6 (23.1)	2 (7.7)	2 (8.3)	0	0
B	14 (58.3)	14 (53.8)	18 (69.2)	6 (25)	5 (19.2)	3 (11.5)
C	2 (8.3)	2 (7.7)	0	2 (8.3)	2 (7.7)	2 (7.7)
D	4 (16.7)	4 (15.4)	6 (23.1)	4 (16.7)	9 (34.6)	7 (26.9)
Total	24	26	26	14 (58.3)	16 (61.5)	12 (46.2)

Table 7
Pre- and post-treatment otologic symptoms (*n* = number of subjects, complaining for both ears, except for dizziness).

Symptom	Pre-treatment	Post-treatment
Tinnitus	1	1
Pruritus	1	0
Hearing loss	9	8
Pressure	1	0
Fullness	1	0
Dizziness	1	1

et al., 2008). The same conclusion is reached in the present study, since we found no difference among the three treatment groups regarding the degree of obstruction after the treatment. CleanEars® was the only agent found in the current study to bring upon complete resolution of obstruction in both ears. Softer cerumen was found after treatment with CleanEars®, although this was not statistically significant. Both Cerumol® and CleanEars® contain oil as their main component, yet CleanEars® is a spray. The relatively superior efficacy of CleanEars® might be attributed to its spray administration which may provide deeper penetration into the cerumen layers. This mode of administration is certainly more convenient for the patients, and in our experience this is even more pronounced in children.

4.2. Hearing loss

The most common complaint associated with cerumen impaction is hearing loss, as was the case in our study. Surprisingly, except in one subject, treatment did not improve the feeling of hearing loss. It did improve though symptoms of irritation, pressure and fullness in the ears. The lack of effect on hearing sensation can be due to the fact that the degree of blockage of the external auditory canal might not have a significant effect on the participants' hearing. Hearing acuity is not hampered until 80% of the cross-sectional area of the external auditory canal is occluded (Chandler, 1964). We did estimate the degree of occlusion but cannot confirm the effect on hearing acuity since we did not conduct an audiometry prior to the treatment or afterwards. Another possible explanation may be related to the complex mechanism of hearing loss among the elderly, which is not dependent only upon the ear itself but also upon the central processing. It is also possible that some of the subjects had such reduced hearing that eliminating the reversible conductive component made no functional difference. Thus, removal of blocking cerumen may prevent hearing loss; nevertheless it may not be evident in the ability of the elderly patient to hear fully and properly in everyday life. This important procedure is required, yet it does not guarantee alone sufficient hearing.

4.3. RSPM

Contrary to the hearing loss, the RSPM score did improve significantly after removal of the cerumen. This particular test has its advantages since it is neither education- nor culture-dependent. A possible bias is the training-effect due to which the subjects may become familiar with the test and therefore score better on average in the second test. This possibility was neutralized by splitting the original test and looking only into the first three matrices. The significant difference between these sets of matrices could be attributed to the immediate effect of the removal of cerumen. This effect underscores the importance of a routine ear examination and cerumen removal when needed. This simple procedure may contribute to the rehabilitation and well-being of the hospitalized patients.

4.4. Recommendations

This study should by no means be interpreted as a call to complete or thorough removal of cerumen from all ears of elderly people. Since the protective role of the ear wax was emphasized, the recommended procedure when and if occlusion is found would be to remove some of the cerumen, sufficiently to provide passage of sound.

4.5. Implications

Although in the current study no single agent was found to significantly do better than the other, it appears that CleanEars® may be effectively and safely used. Removal of cerumen may improve the well-being of elderly patients and hasten their rehabilitation, since it can improve understanding of hearing, provide relief of symptoms and improve quality of life.

Conflict of interest statement

None.

Acknowledgements

The support of The Morris Slivka Legacy, to honor the memory of Leo Aryeh Greenberg, is gratefully acknowledged.

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Please cite this article in press as: Oron, Y., et al., Cerumen removal: Comparison of cerumenolytic agents and effect on cognition among the elderly. Arch. Gerontol. Geriatr. (2010), doi:10.1016/j.archger.2010.03.025

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Please cite this article in press as: Oron, Y., et al., Cerumen removal: Comparison of cerumenolytic agents and effect on cognition among the elderly. Arch. Gerontol. Geriatr. (2010), doi:10.1016/j.archger.2010.03.025