

# Cerumen removal – assessment of a new agent

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**Abstract**

**Objective:** To evaluate the efficacy of a novel preparation, CleanEars, combining cerumenolytic and lubricating effects, in the removal of earwax.

**Materials and methods:** Nineteen subjects (age, 65-88, mean: 75.7) were enrolled in the study and treated with CleanEars for one week, 3 times a day. The degree of occlusion of external ear canal was assessed prior to treatment and after the treatment.

**Results:** After treatment, more than two thirds of the 38 ears showed complete to near- complete resolution of their obstruction.

**Conclusions:** It appears that CleanEars is an effective and safe method for removal of cerumen

## **Introduction**

Cerumen is part of the external ear defense mechanism against foreign bodies and infectious agents. It is a combination of epithelial cells, dust and foreign bodies as well as the production of 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 bodies, dust and dirt adhere to the cerumen, and thus are prevented from plugging the ear or reaching the tympanic membrane.

Cerumen impaction is a common problem encountered by the general physician, the family physician and the otolaryngologist almost every day. It has been estimated that each week 150,000 cerumen removals take place in the United States (1). 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 (2).

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 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, vertigo, infection of the external auditory canal, tinnitus and tympanic membrane perforation. Performing this procedure by an inexperienced physician might lead to high rate of complications (1).

Cerumenolytic products act by softening the cerumen and lubricating the canal, thus facilitating cerumen removal from the ear canal. 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 dissolving the cerumen (3,4).

CleanEars (Naveh Pharma, Israel) is a new, spray-applied solution, which was tested in the present report for its efficacy.

### **Subjects and Methods**

The study was approved by the institutional ethics review board. A total of 23 volunteers were examined during March-August 2004. All subjects signed informed consent. Subjects enrolled in the study were over 18 years old, without any previous ear disease, and none had any ear examination or treatment during the previous 6 months. Nineteen subjects were eventually included in the study: two patients were lost for follow up; one patient discontinued treatment after 5 days due to otalgia, and another completed full treatment, had no adverse effects, but refused follow up. The age range of the 19 patients was 65 to 88 years (mean age, 75.7 years). There were 10 males and 9 females.

All together 38 ears were studied. All gradings and treatments were done by the same physician. The degree of occlusion by cerumen was determined using a scale of 0 to 3 (Table 1): 0–no obstruction, 1-mild obstruction, 2-moderate obstruction, 3-complete obstruction. The type or the consistency of the cerumen was determined prior to treatment and afterwards in order to assess the effect of the medication on the cerumen (Table 2).

Otologic signs and symptoms and any possible adverse effects of the treatment were monitored. CleanEars is composed of mineral oil (paraffin), squalane and spiramint oil. The preparation was administered by spray for one week, 3 times a day. Each time 2 puffs were instilled into the ear. After 1 week of treatment, the ears were examined and if any cerumen was left it was removed using suction or Hartman's ear forceps. The duration of the removal procedure was timed, the suction size was documented and the subjects were asked to score their satisfaction on a 1 to 5 scale.

### **Results**

Before treatment, 27 ears were completely occluded (score: 3), 5 ears had moderate occlusion (score: 2), 2 ears were mildly occluded (score:1) and 4 ears had no obstruction (score:0). After completion of the treatment there was no obstruction in 17 ears, mild obstruction (score: 1) in 10 ears, moderate (score: 2) in 4 and complete (score: 3) in seven ears (Table 3, Figure 1).

The consistency of the cerumen, when present, was found to be type A in 5 ears, type B in 15 ears and type C in 14 ears. Following treatment the distribution was type A in 3 ears, type B in 6 ears and Type C in 12 ears (Table 4), showing that in remaining occlusion, of any degree, the cerumen tended to become softer..

The remaining cerumen was completely removed using suction (#13), within less than one minute, in 10 ears; Using suction (#14), within less than one minute, in 1 ear; Using suction (#13), within 1 minute to 5 minutes, in 2 ears; Using Hartman's ear forceps and suction (#13), within 1 minute to 5 minutes, in 6 ears; And using Hartman's ear forceps, within less than one minute, in 2 ears.

The otologic symptoms prior to the treatment with CleanEars and afterwards (before complementary cerumen removal) are described in Table 5: Most symptoms in our study resolved after the treatment period.

All the patients described the use of the preparation as very satisfactory (5 on a 1 to 5 scale) During the treatment period 2 patients had some degree of pain in their ears during the application of the preparation, 1 described ear discharge and the other 16 patients had no symptoms during the use of the preparation.

## **Discussion**

In the present study complete or near- complete resolution of the ear obstruction was achieved in more than two thirds of the ears. In comparison, resolution of cerumen obstruction with Cerumenex, Murine and placebo was respectively observed in 29.2%, 15.4%, and 41.7% of the subjects (5)

In other studies, the efficacy of cerumenolytic agents was evaluated by the need for syringing or other way of cerumen removal after their use. Such a need was found between 70% to 80% of the ears (6-9), whereas in the present study it was only in 55.3%.

The type of cerumen prior to treatment was dry in most ears. After treatment with CleanEars most of the cerumen was soft and easier to remove.

While there are several commercial agents for removing cerumen, none so far has been shown to be superior in efficacy (3,4,9). The superior efficacy of CleanEars might be attributed to its combined mode of action: cerumenolysis along with lubrication. The spray administration may also assist in deeper penetration of the substance to the cerumen layers.

The meticulous attention to the details in the treatment protocol and in the evaluation methodology may have also influenced by aiding to reach a reliable outcome.

Despite some limitations (lack of controls and small group size), it appears that using CleanEars is an effective and safe method for removal of cerumen, combining cerumenolytic and physical properties for the removal of cerumen.

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**Table 1: Scoring degree of obstruction**

Degree of obstruction	Description	Score
No obstruction	External auditory canal not obstructed	0
Mild	Less than 50% of the external auditory canal diameter is obstructed	1
Moderate	More than 50% of the external auditory canal diameter is obstructed	2
Complete	Complete obstruction of the external auditory canal	3

**Table 2: Coding for cerumen type**

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

**Table 3: Pre-treatment and post-treatment obstruction scores**

(n=number of ears; %=percent of all ears)

Obstruction Score	Pre-Treatment n (%)	Post-Treatment n (%)
0	4 (10.5)	17 (44.7)
1	2 (5.2)	10 (26.3)
2	5 (13.2)	4 (10.5)
3	27 (71.1)	7 (18.4)
Total	38 (100)	38 (100)

**Table 4: Pre-treatment and post-treatment cerumen type**

(n=number of ears; %=percent of all ears)

<b>Cerumen Type</b>	<b>Pre-Treatment n (%)</b>	<b>Post-Treatment n (%)</b>
A	5 (14.7)	3 (14.3)
B	15 (44.1)	6 (28.6)
C	14 (41.2)	12 (57.1)
Total	34 (100)	21(100)

**Table 5: Pre-treatment and post-treatment otologic symptoms**

(n=number of ears)

<b>Symptom</b>	<b>Pre treatment n</b>	<b>Post treatment n</b>
Fullness	12	2
Tinnitus	4	4
Pruritus	5	-
Pain	2	-

**Fig. 1: Degree of Obstruction: Pre-treatment and Post-treatment**

