

Innovations in Cerumen Removal

Earwax MD™, a novel cerumen removal aid, shows promise in clinical study

By Douglas Fullington, MD



The problems with ear wax

Cerumen impaction is one of the most common ear-related reasons to seek medical attention, affecting 1 in 10 children, 1 in 20 adults, and 1 in 3 elderly patients. Moreover, patients with hearing aids are particularly susceptible to cerumen accumulation, and 60% to 70% of all hearing aid repairs are caused by contact with cerumen. Symptoms of cerumen impaction include hearing loss, feeling of fullness, pain, itching, tinnitus, odor, and dizziness. General practitioners are becoming more reluctant to manually extract cerumen due to complications like bleeding, perforated eardrums, dizziness, and infections, making cerumen management a growing segment of the audiologist's practice.

Cerumenolytics: Are they effective?

Along with irrigation and manual extraction, cerumenolytic agents are recommended in the American Academy of Otolaryngology-Head and Neck Surgery Foundation clinical practice guidelines on cerumen removal, and it is encouraged that these techniques be used in combination with one another. The problem with current cerumenolytics is their questionable efficacy. Multiple studies have demonstrated that these products are no more effective than distilled water at solving the problem of impacted cerumen.

Earwax MD™ – the one-two punch

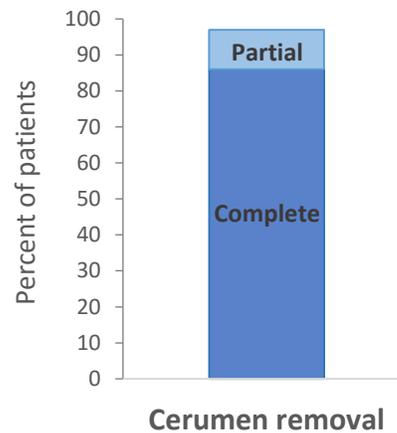
Scientists at EOSERA™ have developed Earwax MD™, a novel, patent-pending topical drop that uses Earase™ technology, a dual-action approach to dissolve cerumen. Earase™ technology solubilizes the lipids and wax while simultaneously disrupting the sheets of skin cells (keratinocytes) that are continually shed from the ear canal. In laboratory studies, this one-two punch is substantially more effective at breaking down human cerumen samples than currently available cerumenolytics, such as Debrox® and Murine® Ear Wax Removal Systems.

Earwax MD™ clinical study design

Recently, a clinical study evaluated the efficacy and safety of Earwax MD™. A total of 30 ears with at least 50% cerumen impaction at the time of enrollment were dosed with Earwax MD™ for 15 minutes prior to low-pressure irrigation with warm water. This procedure could be repeated one time, if needed.

Success in cerumen removal

After one treatment with Earwax MD™, a majority of ear canals (53%) were completely clear of cerumen, with 100% tympanic membrane visualization. Greater than 85% of all ears had total clearing of cerumen after 1 or 2 treatments. All but one ear tested showed a substantial reduction in cerumen.



Dramatically reduced symptoms

Before treatment, 90% of ears were symptomatic, with more than half having 2 or more ear-related symptoms. After treatment, symptoms were dramatically reduced by 82%. Specific symptoms demonstrating a statistically significant reduction after treatment were impaired hearing, fullness, itching, and tinnitus.

Use as a prophylactic?

In 11 of 12 patients with partial cerumen occlusion (which allowed the product to reach behind the wax plug), Earwax MD™ was highly successful at clearing the ear. This suggests that Earwax MD™ may be effective as a prophylactic agent for those patients suffering from repeated cerumen accumulation.

Conclusion

The clinical study results of this new product, Earwax MD™, demonstrated promising success at cerumen removal when used in combination with irrigation. This efficacy translated into a dramatic reduction in symptoms for these patients and should be considered for both in-office and at-home treatment of impacted cerumen.

Evaluation of a Novel Product for the Removal of Impacted Cerumen



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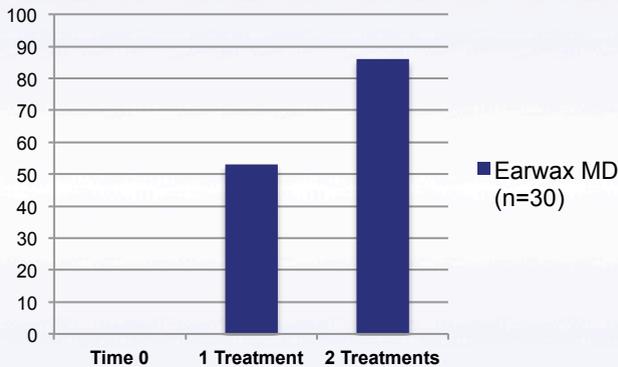
BACKGROUND

Cerumen impaction is one of the most common ear-related reasons to seek medical attention, affecting 1 in 10 children, 1 in 20 adults, and 1 in 3 elderly patients. Patients with hearing aids have an increased rate of cerumen accumulation. Studies report that up to 70% of all hearing aid malfunctions are caused by cerumen build-up. Common symptoms of cerumen impaction include hearing loss, feeling of fullness, itching and tinnitus.^{1,2}

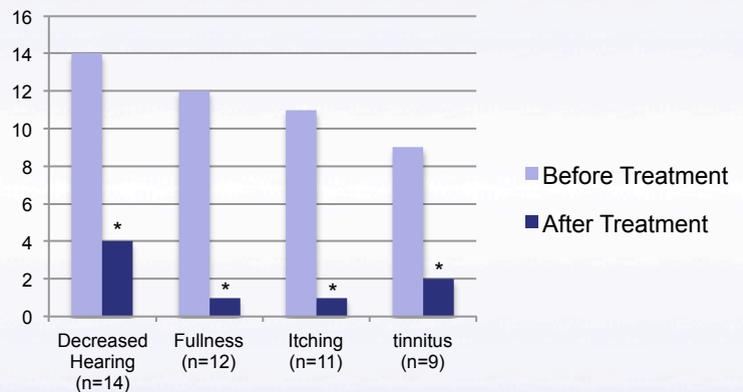
METHOD

IRB approved clinical evaluation of the efficacy and safety of Earwax MD™ in a total of 30 ears with at least 50% cerumen impaction at the time of enrollment. Severity of cerumen impaction was graded using a 5-point scale. Improvement in tympanic membrane visualization was assessed after instillation and rinse. Subjects were dosed with Earwax MD™ for 15 minutes prior to irrigation with warm water. This procedure could be repeated one time, if needed.

Percent of Subjects with Total Wax Clearance



Improvement in Cerumen Impaction Symptoms



RESULTS

After one treatment with Earwax MD™, a majority of ear canals (53%) were completely clear of cerumen, with 100% tympanic membrane visualization. Greater than 85% of all ears had total clearing of cerumen after 1 or 2 treatments. All but one ear tested showed a substantial reduction in cerumen. Before treatment, 90% of ears were symptomatic. After treatment, symptoms were reduced by 82%. Specific symptoms demonstrating a statistically significant reduction after treatment were impaired hearing, fullness, itching, and tinnitus. Only one mild adverse event (ear pruritis) occurred that was related to treatment. In 11 of 12 patients with partial cerumen occlusion (which allowed the product to reach behind the wax plug), Earwax MD was highly successful at clearing the ear. This suggests that Earwax MD may be effective as a prophylactic agent for those patients suffering from repeated cerumen accumulation.

CONCLUSION

The clinical study results of this new product, Earwax MD™, demonstrated success at cerumen removal when used in combination with irrigation. This efficacy translated into a dramatic reduction in symptoms for these patients and should be considered for both in-office and at-home treatment of impacted cerumen. In addition, evidence suggests prophylactic benefits in patients with chronic cerumen accumulation.

REFERENCES

1. Roland PS, Smith TL, Schwartz SR, Rosenfeld RM, Ballachanda B, Earll JM, et al. Clinical practice guideline: cerumen impaction. *Otolaryngol Head Neck Surg.* 2008 Sep;139(3 Suppl 2):S1-S21
2. Kochkin S. Customer satisfaction with hearing instruments in the digital age. *Hear J* 2005;58:30-43