Advancements in Cerumen Removal

In vitro model demonstrates significant improvement in the topical treatment of impacted cerumen

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Who suffers from ear wax impaction?

18 million individuals will experience impacted cerumen and at least 8 million ear irrigations are performed each year, according to the 2008 clinical practice guideline. While epidemiological studies vary, it is generally accepted that about 10% of children, 5% of normally healthy adults and up to 57% of older patients in nursing homes will experience impacted cerumen.

Problems associated with ear wax

Cerumen impaction has clinical implications and often affects the well-being of patients. Cerumen impaction is often associated with conductive hearing loss, minor pain, itching and occasionally tinnitus. Removal of impacted cerumen has been shown to positively improve these symptoms, particularly hearing, in many patients.

What are the current treatment options?

There are several cerumen removal products commercially available, including oil-based, water-based, and non-water/ non-oil based formulations. These products often require multiple doses per day over several days and provide very limited efficacy. As a result, millions of patients are driven to their doctor for manual extraction, which is often time-consuming and painful for the patient.

Earwax MD™ – a new innovative treatment

Scientists at Eosera™ have developed Earwax MD™, a novel, patent-pending topical drop that uses a 'dual-action' mechanism to disintegrate human cerumen. The wax ester and fatty acid lipid components of the cerumen are disrupted by one part of the formulation while the second part of the system works to disrupt the keratinocyte component of cerumen.

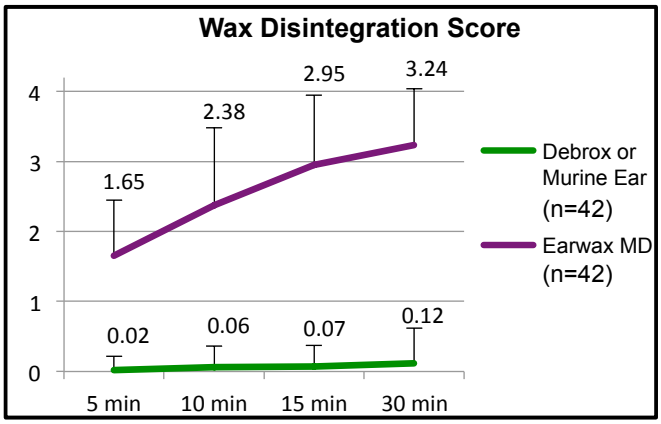
In vitro study design

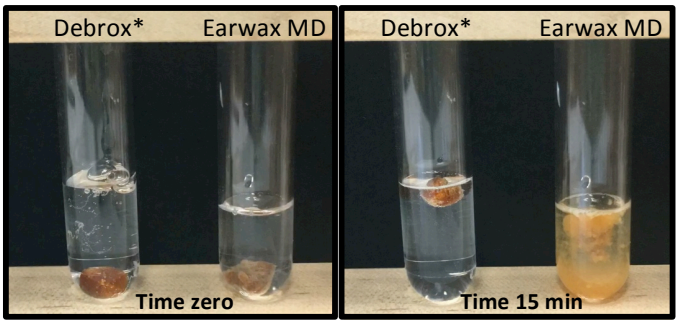
Human cerumen was collected following a protocol approved by an external ethics review board. Once collected, similar sized samples were placed into test tubes. One mL of Earwax MD™, or Debrox*, or Murine Ear* were added to the test tubes and allowed to incubate at room temperature for up to 30 minutes. Disintegration scores were recorded at 5, 10, 15 and 30 minutes. Disintegration was measured on a scale of 0 to 4, with grade 0 showing no disintegration and grade 4 showing complete disintegration.

The statistically significant results

The time course study for disintegration scores demonstrated that Earwax MD™ was effective at quickly breaking down cerumen under room temperature conditions. Samples incubated in Earwax MD™ demonstrated significantly higher disintegration scores than the two comparators at every time point measured ($P < 0.0001$). Photographic representation of human cerumen samples also shows rapid disintegration.

The evidence of success





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The Conclusion

Earwax MD™ provides rapid disintegration of human cerumen samples with breakdown beginning as early as 5 minutes. Conversely, the two commercially available products, Debrox* and Murine Ear*, both containing carbamide peroxide 6.5%, had minimal effects on the cerumen samples. A recent exploratory study in humans demonstrated similar efficacy of Earwax MD in clearing impacted cerumen. Greater than 50% of patients with at least 50% impaction had total clearance after one 15-minute treatment and rinse, with 86% of patients showing total clearance with only 2, 15-minute treatments. The statistically significant results of Earwax MD make this new product a viable option for both in-office and at-home treatment of impacted ear wax.

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Dr. Roy is board certified by the American Board of Otolaryngology-HNS and is a fellow of the American Academy of Otolaryngology-HNS, the American College of Surgeons, and the American Academy of Pediatrics. Dr. Roy is not a paid consultant for Eosera, Inc.

In Vitro Comparison of Three Earwax Removal Formulations for the Disintegration of Earwax

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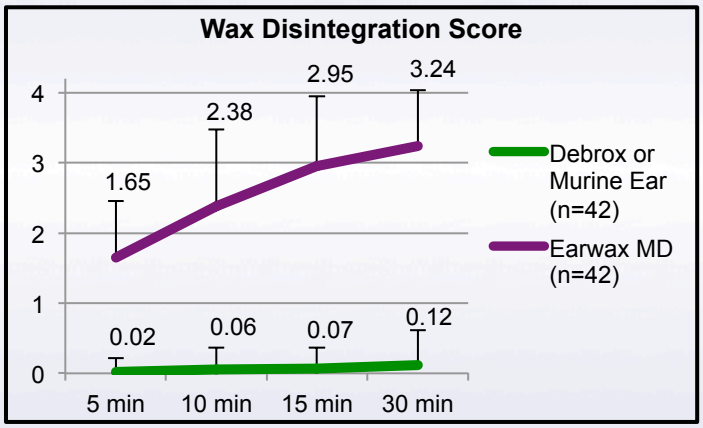
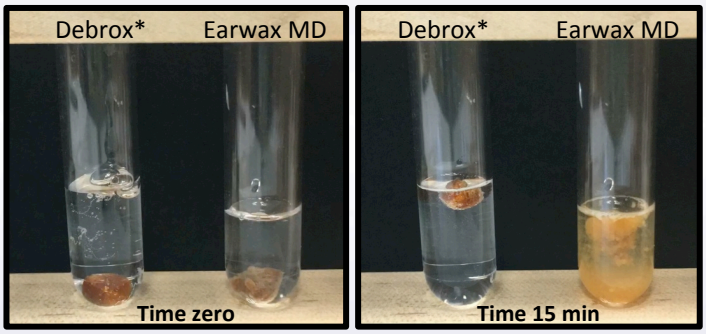
BACKGROUND

According to the 2008 Clinical Practice Guideline for Cerumen impaction, up to 18 million individuals will experience impacted cerumen and at least 8 million ear irrigations are performed each year for this condition. While epidemiological studies vary greatly, it is generally accepted that about 10% of children, 5% of normally healthy adults and up to 57% of older patients in nursing homes will experience impacted cerumen.

METHOD

Human cerumen was collected following a protocol approved by an external ethics review board. Once collected, similar sized samples were placed into test tubes. Approximately 1 mL of Earwax MD™ or Debrox* or Murine Ear* were added to the test tubes and allowed to incubate at room temperature for up to 30 minutes. Disintegration scores were recorded at 5, 10, 15 and 30 minutes. Disintegration was measured on a scale of 0 to 4 (This grading scale was adapted from those of Jimenez et al. and Fraser et al.), zero showing no disintegration and 4 showing complete disintegration. Between-group comparisons were performed using a student's t test. A p value of ≤ 0.05 denoted a statistical difference between treatment groups.





RESULTS

The time course study for disintegration scores demonstrated that Earwax MD™ was effective at quickly breaking down cerumen under room temperature conditions. Samples incubated in Earwax MD demonstrated significantly higher disintegration scores than the two comparators at every time point measured ($P < 0.0001$). Photographic representation of human cerumen samples also shows rapid disintegration.

CONCLUSION

Earwax MD™ provides rapid and statistically significant disintegration of human cerumen samples with breakdown beginning as early as 5 minutes. Conversely, the two commercially available products, Debrox* and Murine Ear*, both containing carbamide peroxide 6.5%, had minimal effects on the cerumen samples. A recent exploratory study in humans demonstrated similar efficacy of Earwax MD in clearing impacted cerumen. Greater than 50% of patients with at least 50% impaction had total clearance after one 15-minute treatment and rinse, with 86% of patients showing total clearance with only two, 15-minute treatments. The statistically significant results of Earwax MD make this new product a viable option for both in-office and at-home treatment of impacted ear wax.

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*Trademarks of another company