

ADVANCEMENTS IN CERUMEN REMOVAL

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

Soham Roy MD, FACS, FAAP
Otolaryngologist



Who suffers from earwax 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.¹ While epidemiological studies vary, it is generally accepted that about 10% of children, 5% of normal healthy adults, and up to 57% of older patients in nursing homes will experience impacted cerumen.¹

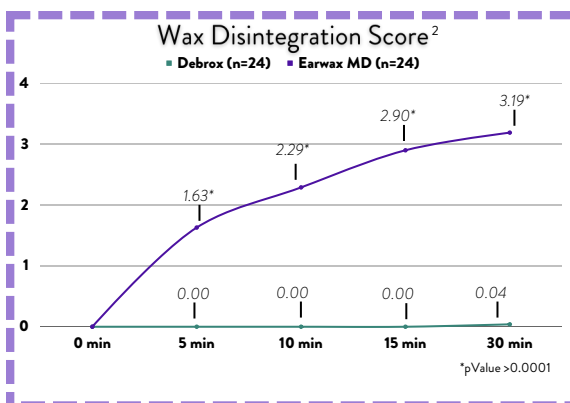
Earwax MD® - an innovative solution to clean ears

Scientists at Eosera developed Earwax MD, a novel, patented 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 the cerumen. Traditional over-the-counter products work by softening the wax over multiple days.

In vitro study design

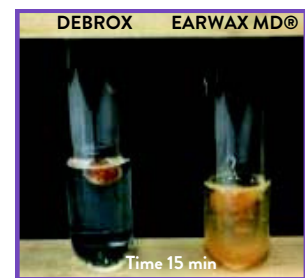
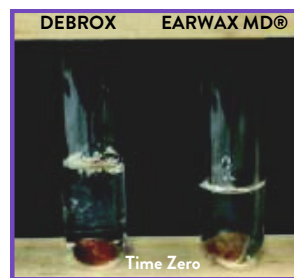
Human cerumen was collected following a protocol approved by an external ethics review board.³ Once collected, similar-sized samples were placed into test tubes. One set of samples received 1 mL of Earwax MD, and the other set received 1 mL of Debrox* and was allowed to incubate at room temperature for 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 evidence of success



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 treated with Earwax MD demonstrated significantly higher disintegration scores than the comparator at every time point measured ($P < 0.0001$). Photographic representation of human cerumen samples also shows rapid disintegration in the samples treated with Earwax MD.



The Conclusion

Earwax MD provides rapid disintegration of human cerumen samples with breakdown beginning as early as 5 minutes. Conversely, the commercially available product, Debrox*, containing carbamide peroxide 6.5%, had minimal effects on the cerumen samples.

In a separate clinical study

A separate clinical study in humans demonstrated the significant 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 full clearance after 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 earwax.

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.

