

CERUMENOLYTIC EFFICACY OF PEROXIDE EAR DROPS: A COMPARATIVE STUDY WITH COMMERCIAL PRODUCTS

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Introduction

Earwax is normally expelled from the ear canal by self-cleaning mechanisms aided by jaw movement. When this fails, earwax can accumulate, become impacted, and block the canal, causing earache, fullness, and hearing impairment. Treatment involves mechanical removal or ear drops/sprays that help break down/soften the wax. One of the most commonly used treatments is the application of Urea Hydrogen Peroxide (UHP) or Hydrogen Peroxide (HP) ear drops. In the ear canal, these ingredients release oxygen that physically disrupts and breaks apart the wax and helps disperse it. As the primary intended mode of action is mechanical rather than pharmacological, UHP and HP ear drops are appropriately considered medical devices. Limited information exists on the comparative efficacy of commercially available ear drops that contain peroxides. Accordingly, the present methodology is designed to assess these mechanistic actions.

Aim

The aim of this study was to compare the cerumenolytic activity of commercially available UHP and HP ear drops, because differences in formulation design and manufacturing may affect peroxide stability and performance, leading to variable efficacy even when the labelled concentration is the same.

Materials and Methods

Six commercial products, shown in Table 1, were tested in this study. Synthetic earwax was prepared and 1 mL was dispensed into each well of a 12-well plate to replicate a clinically relevant scenario of excessive cerumen impaction. For each product, 5 drops/sprays, as per the manufacturers’ instructions, were applied to the top of the respective well containing the wax. Each commercial product was tested in triplicate per well plate with a total of 10 plates used, resulting in 30 replicates per product. Water was used as a negative control, and three wells per plate were also left untreated to ensure the stability of the wax at 37 °C.

Table 1. Commercial products tested in this study and their compositions

Product name	Contents as declared on pack
Otex Express Ear Drops	Glycerol, Urea Hydrogen Peroxide (5%), 8-Hydroxyquinoline
Superdrug Express Ear Drops	Glycerol, Urea Hydrogen Peroxide (5%)
Boots Ear Wax Remover Drops	Glycerol, Urea Hydrogen Peroxide (5%)
Earex Advance Ear Drops	Glycerol, Urea Hydrogen Peroxide (5%)
CI-ear Express Ear Drops	Glycerol, Urea Hydrogen Peroxide (5%)
CI-ear Express Ear Spray	Hydrogen Peroxide (3%), phosphate buffers

The plates were incubated at 37 °C and video recorded for 30 mins. To assess the cerumenolytic activity of the products, the video recordings were analysed to determine the time needed for the ear drops to break through the wax barrier and referred to as the breakthrough time. The rate of cerumen breakdown (mm/s) was also calculated.

A snapshot image was captured at the maximum breakthrough point, when the entire clear zone was visible at the end of breakthrough, and then analysed using ImageJ software to measure the area of clearance in mm² for each well. Statistical analyses were performed in Excel 365 using unpaired t-test to assess differences in cerumenolytic activity between products, using the market leading product (Otex Express) as the primary comparator; statistical significance was set at p < 0.05.

Results

The comparative breakthrough times of Otex Express versus the commercial products are shown in Figure 1. Neither the negative control nor the untreated control exhibited any breakthrough effects and consequently no breakthrough time or area of clearance was recorded, supporting the validity of the study.

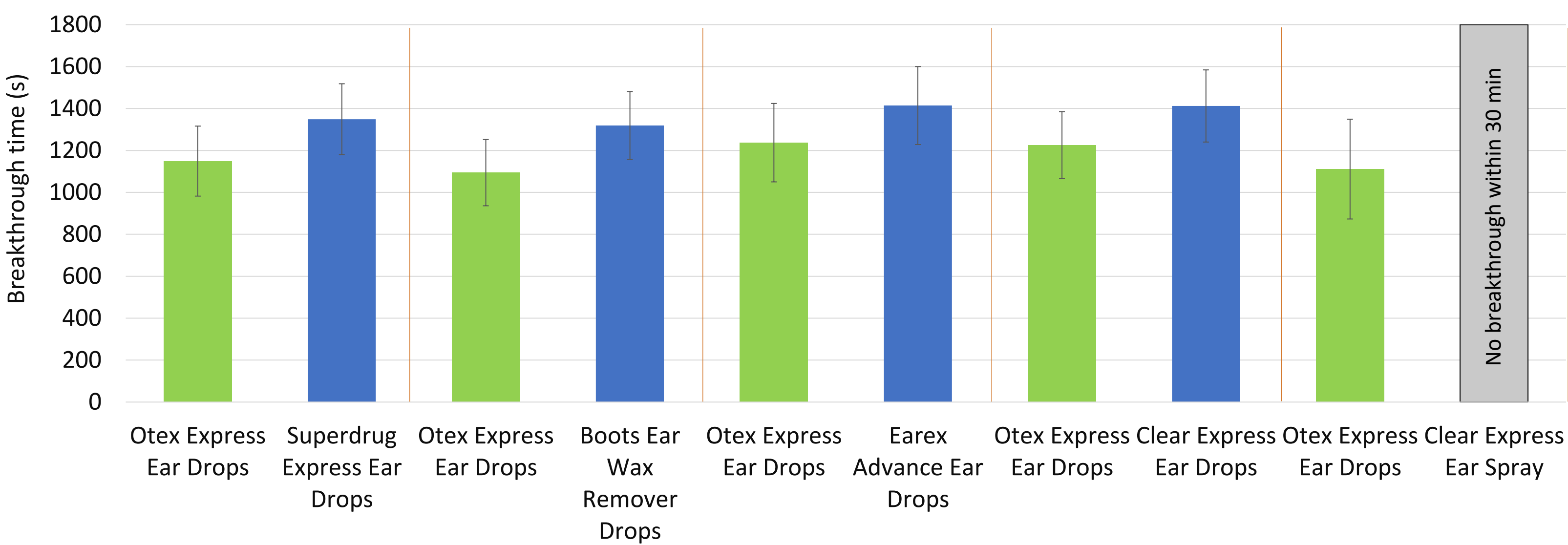


Figure 1. Breakthrough time for Otex Express Ear Drops vs five commercial products. Values represent mean $\pm$ SD, n=30 per product.

Unpaired t-test analysis demonstrated a statistically significant difference in breakthrough time between Otex Express and Superdrug Express, Boots Remover, Earex Advance and CI-ear Express Ear Drops with Otex Express exhibiting a faster breakthrough effect. The relative rates of cerumen breakdown of the commercial products versus Otex Express are shown in Figure 2 with Otex Express acting up to 20 % faster. The faster onset of action observed with Otex Express indicates increased penetration and partitioning into the wax. These differences in the performance of UHP drops may be explained by variation in the extent of UHP overage, the stability of UHP over the product shelf life, and even potential differences in ingredient grades or formulation processes that may influence UHP degradation and release.

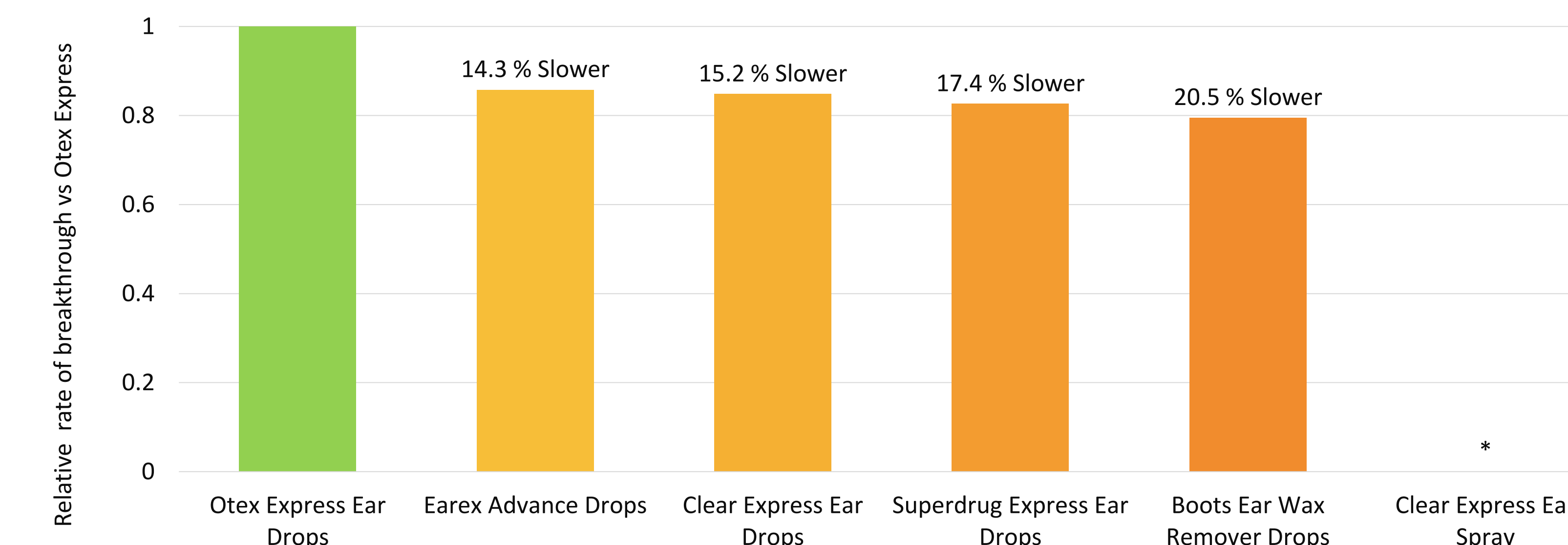


Figure 2. Relative rate of cerumen breakdown of commercial products vs Otex Express. *Clear Express Ear Spray did not exhibit a breakthrough within the 30 min experiment.

The area of clearance measured for each product are shown in Table 2. No significant differences were observed in the area of clearance between UHP commercial products. Surprisingly, CI-ear Express Ear Spray failed to show a breakthrough during the timeframe of the study, hence, Otex Express showed a significantly larger area of clearance compared with Clear Express Ear Spray (p < 0.05). These findings demonstrate that UHP drops possess a stronger cerumenolytic effect than aqueous HP spray, both in terms of the rate of action and the extent of clearance.

Table 2. Comparison of area of clearance (mm²) for Otex Express vs commercial products.

Product name	Area of clearance (mean $\pm$ SD) (mm ²)
Otex Express Ear Drops	70 $\pm$ 14
Superdrug Express Ear Drops	71 $\pm$ 9
Otex Express Ear Drops	61 $\pm$ 10
Boots Ear Wax Remover Drops	66 $\pm$ 11
Otex Express Ear Drops	72 $\pm$ 16
Earex Advance Ear Drops	74 $\pm$ 22
Otex Express Ear Drops	73 $\pm$ 21
CI-ear Express Ear Drops	77 $\pm$ 23
Otex Express Ear Drops	60 $\pm$ 11
CI-ear Express Ear Spray	5 $\pm$ 25

Conclusion

UHP ear drops showed statistically significant differences in performance. Otex Express had a faster onset of action, by up to 20 %, with a similar area of clearance to Superdrug Express, Boots Remover, Earex Advance, and CI-ear Express Ear Drops, and greater overall cerumenolytic activity than CI-ear Express Ear Spray.