

# EVALUATION OF THE CERUMENOLYTIC EFFICACY OF TWO COMMERCIALLY AVAILABLE EAR DROPS, OLIVE OIL AND OTEX EXPRESS

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## Introduction

Hardened earwax is a common problem that affects 2-6% of people in the UK. Various treatments for this condition exist, and their main aim is to soften or break down the earwax in the ear. Their action is mechanical, not pharmacological. Consequently, these products tend to be listed as medical devices. Surprisingly, very limited information exists on the comparative cerumenolytic efficacy of commercially available ear drops.

## Aim

The aim of this study was to compare the cerumenolytic efficacy of two commercially available medical devices in the UK, Olive Oil and Otex Express ear drops.

## Materials and Methods

Artificial earwax was prepared and used to form compacted wax barriers in tubes designed to mimic in vivo conditions. 3 drops of each product, Otex Express and Olive Oil ear drops, were applied onto the top of each formed earwax barrier as per the manufacturers' instructions. Test tubes were incubated at 36.5 °C for up to 40 minutes, and all mechanical changes in earwax structure were recorded. For the purpose of assessing the ability of products to distort and destroy the wax barrier, two parameters were defined: 'First visual change' and 'Breakthrough time'. First Visual Change in earwax composition is recorded as the time at which the first visible changes in the earwax structure were observed. The main experimental endpoint, Breakthrough time, is recorded as the time at which the compacted earwax barrier was sufficiently crumbled and moved to the other end of the tube. It indicates the full cerumenolytic effect of the product.

Statistical analysis was performed by Qi Statistics Ltd, Reading, UK. In order to determine if the data are normally distributed, the Anderson–Darling test was applied. Analysis of variance (ANOVA) was then carried out on the mean number of seconds for the First visual change and Breakthrough time, as measured in seconds, to compare the mean value for each product.

Rheological assessment was performed on Anton Paar Rheometer MCR 302. Rotational test was performed on a parallel plate–plate system with the upper geometry radius of 25 mm and a distance between plates of 1 mm. Viscosity was presented via controlled shear rate in the range 0.1 to 100 1/s. Test temperature was 36.5 °C.

Field emission scanning electron microscopy (SEM) was used to study the surface morphology of the samples (model SU8030 Hitachi).

## Results and Discussions

The comparative effects of Otex Express and Olive Oil ear drops on the earwax barrier are presented in Figure 1. Mean values of First visual changes and Breakthrough times are presented in Table 1.

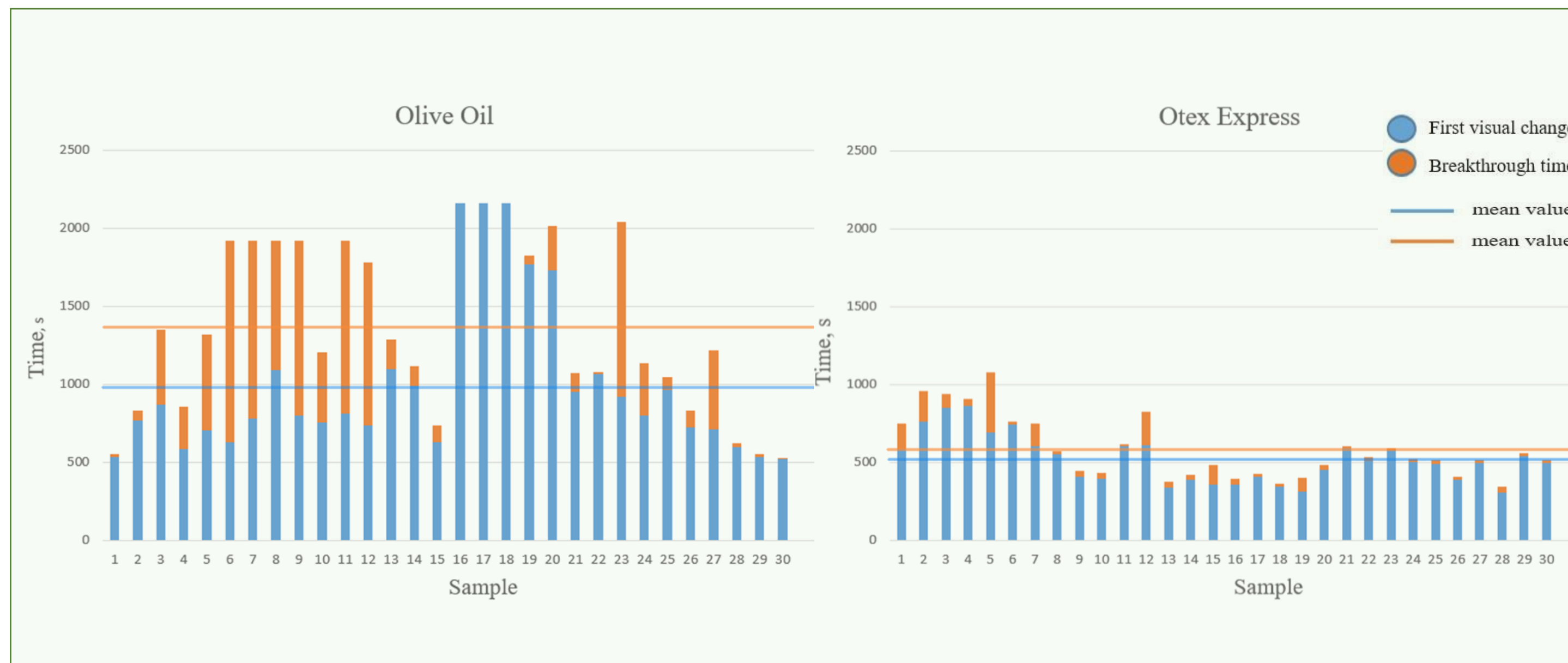


Figure 1. Olive Oil and Otex Express ear drops results, First visual change and Breakthrough time (n = 30)

Table 1. Olive Oil and Otex Express ear drops results, First visual change and Breakthrough time, mean value  $\pm$  Sd

| Product      | First visual change<br>(mean $\pm$ Sd) (s) | Breakthrough time<br>(mean $\pm$ Sd) (s) |
|--------------|--------------------------------------------|------------------------------------------|
| Otex Express | 517 $\pm$ 154                              | 583 $\pm$ 198                            |
| Olive Oil    | 984 $\pm$ 494                              | 1369 $\pm$ 555                           |

The First visual change in earwax composition started at least 1.5 times faster, and the Breakthrough time was more than 2 times faster for samples treated with Otex Express in comparison to Olive Oil ear drops.

Otex Express ear drops managed to produce visual changes in earwax in less than 600 s (517  $\pm$  154 s). The total collapse of compacted earwax followed shortly after that (583  $\pm$  198 s). We could visually observe that Otex Express ear drops break down the hardened earwax into smaller particles.

Olive Oil ear drops took longer than Otex Express to produce visual changes in earwax, and this difference was statistically significant. It took, on average, over 1200 s for this effect to take place (1369 s  $\pm$  555 s). The difference in ability to break down the hardened wax between these two commercial products was also statistically significant. Interestingly, Olive Oil ear drops did not have the ability to break down hardened earwax into smaller particles, but it softened it, making it more able to move.

Viscoelastic properties of earwax are fundamental for its removal. Therefore, viscosity profiles of untreated and treated earwax samples were analysed, data shown in Figure 2. The earwax samples treated with Otex Express resulted in earwax becoming significantly softer than the control, neat samples. The same effect, but to a lesser extent, was observed with Olive Oil ear drops.

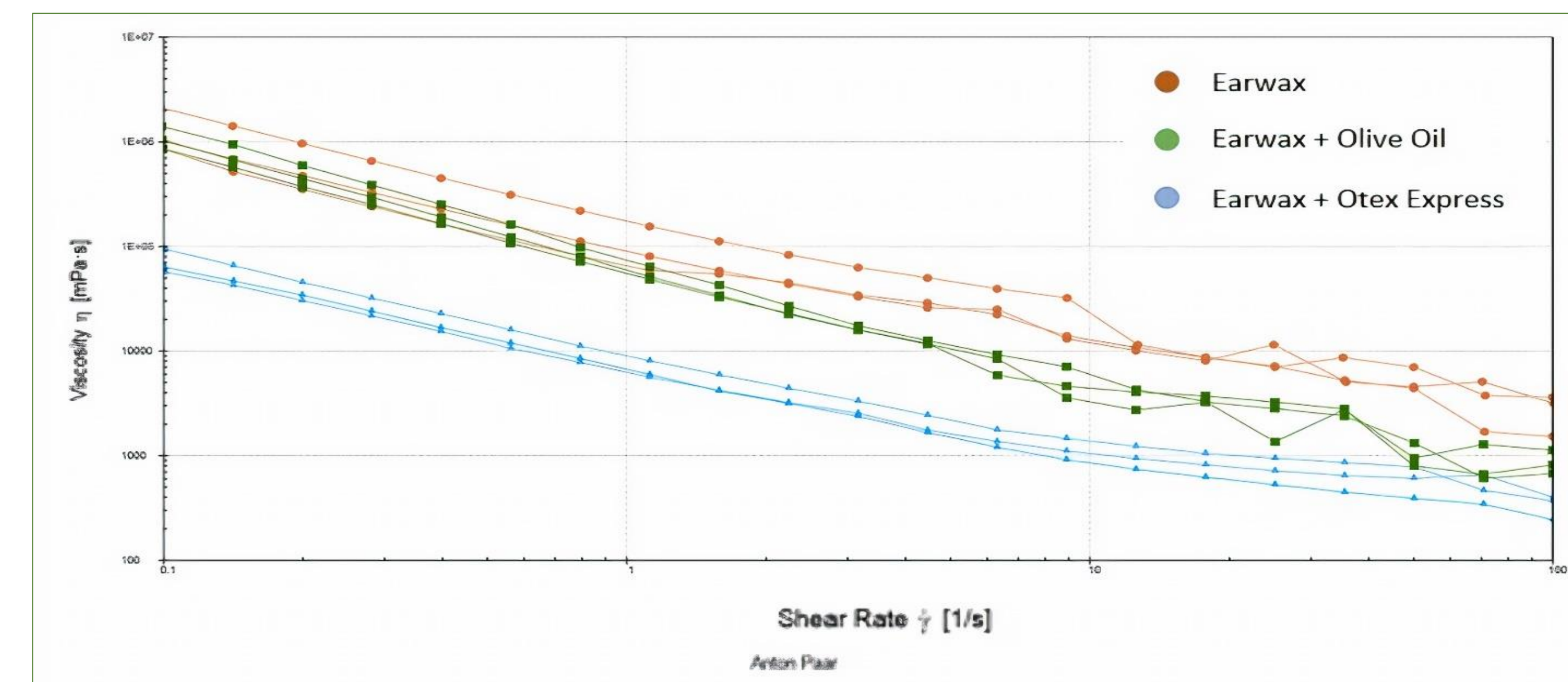


Figure 2. Viscosity curves of earwax as prepared (red dot), earwax and Olive Oil (green dot), earwax with Otex Express (blue dot).

After treating earwax samples with Olive Oil and Otex Express ear drops, SEM highlighted a significantly greater level of wax being 'broken' into smaller particles when treated with Otex Express in comparison to Olive Oil (Figure 3). Olive Oil treatment produced smoother surfaces, whilst Otex Express treatment resulted in more morphologically rough surfaces being observed.

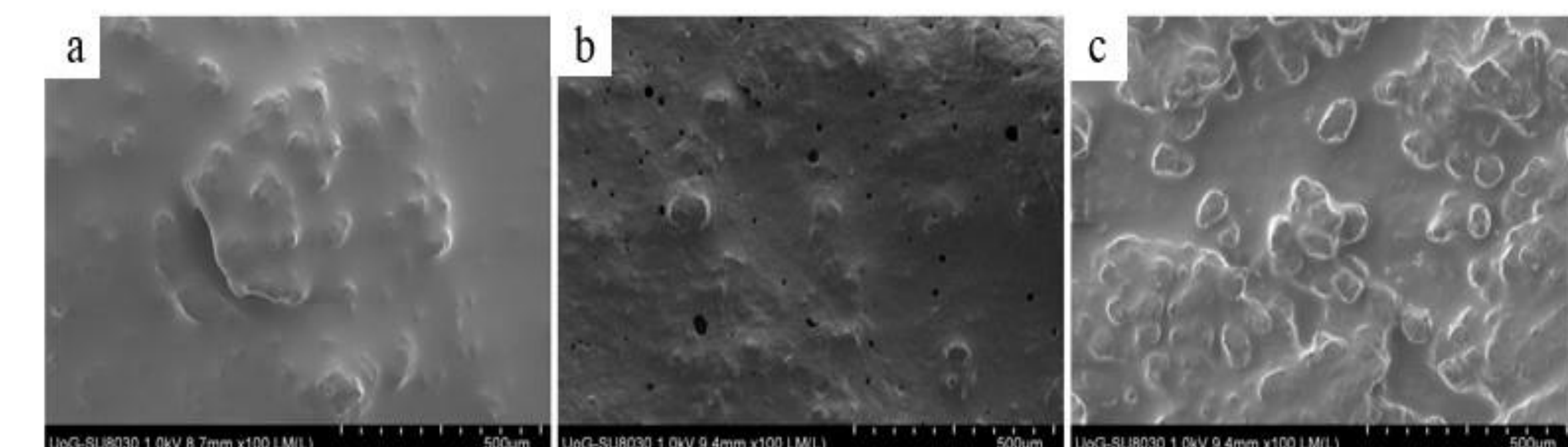


Figure 3. Representative SEM sample images at 100x magnification, a) Earwax with Olive Oil; b) Earwax (neat); c) Earwax with Otex Express.

## Conclusion

This study has confirmed the cerumenolytic efficacy of Otex Express and Olive Oil ear drops. There are statistically significant differences in the performance between these two products, with Otex Express being more than twice as fast as Olive Oil in breaking the earwax and unblocking the tubes. This formulation also induced quicker changes (1.5 x faster) in the structure of earwax.