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Comparative *in vitro* ceruminolytic activity of 5 commercialized veterinary ear cleaners and a new ear cleaner prototype

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INTRODUCTION

Canine ear disease is a common issue among dogs and represents about 15% of veterinary visits. Ear disease is commonly medically managed by cleaning and use of topical therapy and sometimes systemic therapy. In chronic otitis externa, the quantity of ceruminous glands increases significantly secondary to the inflammatory process[1]. In otitis externa, ear cleaning is frequently performed to maintain normal otic environment, help treat otitis and prevent recurrence in dogs prone to otitis[2, 3]. Effective removal of exudate is fundamental for a successful treatment of otitis externa in dogs. A wide range of ear cleaning preparations and procedures aimed to remove exudates and ceruminous debris has become very popular in veterinary practice. Among other components, most of the commercially available products for routine cleaning contain ceruminolytics agents.

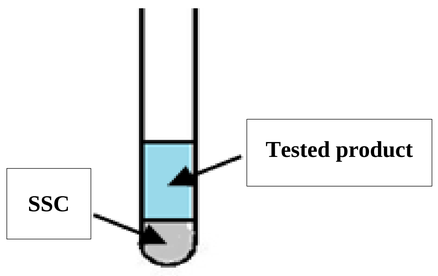
STUDY OBJECTIVE

The objective of the study was to compare the ceruminolytic properties of different commercially available ear cleaners and one new prototype. A previously published *in vitro* method using a standardized synthetic cerumen that mimics the composition and texture of canine cerumen was used[4]. It allows objective and comparable measure of ceruminolytic activity of ear cleaners.

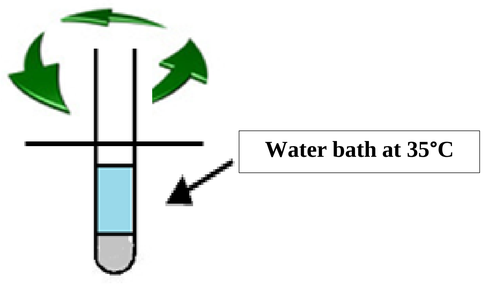
MATERIAL AND METHODS

A standardized synthetic cerumen (SSC) mimicking the lipidic composition and texture of canine cerumen was prepared. The composition of this cerumen was based on the average composition of natural canine cerumen as described in the literature[4, 5]. Aliquots of approximately 500 mg of melted SSC was weighed and placed into individual 10 x 75 mm polypropylene test tubes. Tubes were placed in a vertical position in a test tube rack to allow the melted cerumen to collect homogeneously at the bottom of the tubes. Once the SSC cold and solidified in the tubes, these were weighed and then filled with 2 ml of the tested product. After 20 min incubation in a shaking water bath at 35°C and at a mild agitation of 50 rpm, tubes were removed from the bath and inverted for one hour to allow the dispersed SSC and the tested product mixture to slide out of the tubes. Tubes and remaining SSC were then weighed to estimate the amount of SSC removed. The cycle of adding tested product, agitation, drainage and reweighing was repeated a further three times on each tube simulating consecutive applications of the products. The percentage of SSC removed was then calculated by comparing the initial and final weights of the tubes and SSC.[4, 5] Each of the products was tested in triplicate, by three different operators. Individual results of each replicate were used to calculate the average percentage of removed SSC.

Figure 1 – *In vitro* ceruminolytic activity testing steps



Step 1: addition of the tested product



Step 2: circular tube stirring

Step 3: tube in an inverted position during 1h

This *in vitro* model was originally designed to simulate the diameter of a dog's ear canal, and the temperature, contact time and head shaking that would occur in a real ear canal. The volume of ear cleaner used and number of cleaning repetitions is compatible with recommended ear cleaning practice for owners at home.[5]

Five commercially available ear cleaners and an innovative one (new combination of ceruminolytic agents) were tested. Cleanaural Dog®, Dechra Veterinary Products Limited, UK, Batch Number: 140870 (CLE) ; Douxo® micellular solution, Sogeval, France, Batch Number: 150078B (DOU); Epiotic® Advanced, Virbac, France, Batch Number: 521S (EPI); Otoclean®, Lilly France (Elanco Animal Health), France, Batch Number: 10302 (OTC); Otolane®, Laboratoire TVM, France, Batch Number: M1405F (OTL) and a new prototype (SON), Vetoquinol, France, Batch Number: 150453.

RESULTS

In the present study, the ceruminolytic activity was defined as the weight loss of SSC after consecutive incubation and rinsing of otic preparations (Tests 1 to 4). Ceruminolysis causes disintegration and elimination of cerumen and so is characterized by weight loss. This is represented by a positive value. The negative values indicate impregnation of the product in the SSC without its disintegration and elimination. It is characterized by a weight gain. Results are shown in **Table 1**. The final percentage of SSC elimination was almost complete for SON (85.3%) whereas the 5 other products showed no evident ceruminolytic activity. For these 5 products, all values were negative, meaning that part of the tested product remained in the tube, but without any detectable action on the cerumen plug. Overall, SON was the most efficacious, reaching an *in vitro* ceruminolytic activity of 85%. None of the other products displayed any *in vitro* ceruminolytic activity.

Table 1 – Mean percentage of standardized synthetic cerumen (SSC) removed after each run

Product	Number of samples tested	Test 1	Test 2	Test 3	Test 4
CLE	9	- 6.3%	-7.0%	-5.9%	-6.6%
DOU	9	- 9.9%	-13.4%	-14.1%	-15.3%
EPI	9	-9.5%	-16.2%	-18.4%	-17.8%
OTC	9	-15.0%	-17.7%	-17.1%	-15.2%
OTL	9	-9.5%	-11.2%	-16.9%	-17.5%
SON	9	11.6%	36.7%	68.9%	85.3%

Figure 2 - Appearance of a selection of the tubes after four consecutive incubations showing different degrees of standardized synthetic cerumen (SSC) disintegration. As describe in Table 1, only SON induced an increasing degree of SSC disintegration and removal whereas the 5 other products didn't show any effect on the SSC plug.

Tubes with SSC before beginning the trials

SON tubes after 4 consecutive incubations

CLE tubes after 4 consecutive incubations

DOU tubes after 4 consecutive incubations

EPI tubes after 4 consecutive incubations

OTC tubes after 4 consecutive incubations

OTL tubes after 4 consecutive incubations

CONCLUSION

Ear cleaning in diseased ears allows to remove debris and purulent material, therefore optimizing penetration and diffusion of topical medication to the deeper parts of the horizontal canal. The results obtained indicate that the ceruminolytic effect of each ear cleaning product is not easily deduced by their composition. This study helps the veterinarian to choose the appropriate product based on the ceruminolytic effect. Based on this *in vitro* synthetic canine cerumen model, the new Vetoquinol prototype "SON" appears to have the most efficient ceruminolytic properties of the 6 tested ear cleaners. In the present study the ceruminolytic effect was based on the calculation of the weight loss of the SSC. Previous studies using a similar methodology were performed[4-6]. One of the studies limitation is that synthetic canine cerumen doesn't mimic the composition of cerumen in diseased ear which contains more keratin, inflammatory cells and serum than normal ears. Further studies evaluating the absolute efficacy values, adequately designed *in vivo* studies, should be performed.

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