



FIELD EVALUATION OF THE CLEANSING AND DEODORIZING EFFICACY OF A PHYSIOLOGICAL EAR CARE SOLUTION

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C.A. Rème and H. Gatto

Virbac Laboratories, Medical Department, 06 511 Carros, France

OBJECTIVES

- Evaluate objectively, under real conditions of use, the efficacy of a new ear care solution in removing cerumen from the ear canal of dogs and neutralizing associated unpleasant aural smells.
- Check the perfect tolerance of the cleanser for ears under sustained frequent use.

TEST PRODUCT

VIRBAC PHYSIOLOGICAL EAR CLEANSER®:

- Transparent non-foaming isotonic micellar solution, pH 7
- Micelles of non-ionic surfactants, EDTA, patented anti-odor aldehyde complex

METHODS

Animals

Forty-two dogs were included at 5 veterinary clinical centers in France.

Inclusion criteria: cerumen (yellowish-brown, greasy, smelly material) readily visible at the ear canal openings, owners' informed consent.

Exclusion criteria: obvious signs of otitis externa requiring medical treatment, any type of ear disease, systemic or local treatment in the previous week with antibiotic, antifungal, antiseptic or anti-inflammatory agents.

Treatment

One of the dog's ears was allocated to the cleanser treatment group and subjected to regular cleaning by the owner (1 ml of test solution in ear once a day for 15 days). The remaining ear was left untreated (control group).

Allocation of ears to treatment or control group was performed according to a pre-established randomisation list by the nurse. Veterinarians were unaware of the ear that was treated. No other treatment was allowed.

Evaluation

Complete physical and otoscopic examination of the ears was performed before (Day 0) and 24h after the end of the treatment period (Day 15). Quantity of cerumen in ears, aural odour and associated erythema were each graded on a scale from 0 to 4, according to severity.

Samples for cytological examination were performed using cotton-tipped swabs and Diff-Quik® staining. Representative areas on slides were selected at x10 and x40 objective magnification. Counts of *Malassezia* yeasts were performed on 10 contiguous high power fields (x100 oil immersion objective).

Any adverse event occurring during the study period, or shortly afterwards, was to be reported. An adverse event was defined as any harmful or unintended response associated with the use of the test product, whether or not considered to be product related.

RESULTS

- **Dogs** with pendulous ears presented most often with "dirty ears" (78.6% of cases). Breeds most represented were bassets, Labradors, poodles, spaniels and setters (57.1% of dogs). Dogs of any age (4 months to 15 years), size (4 to 40 kg) and sex (18 females, 24 males) were included in the study.

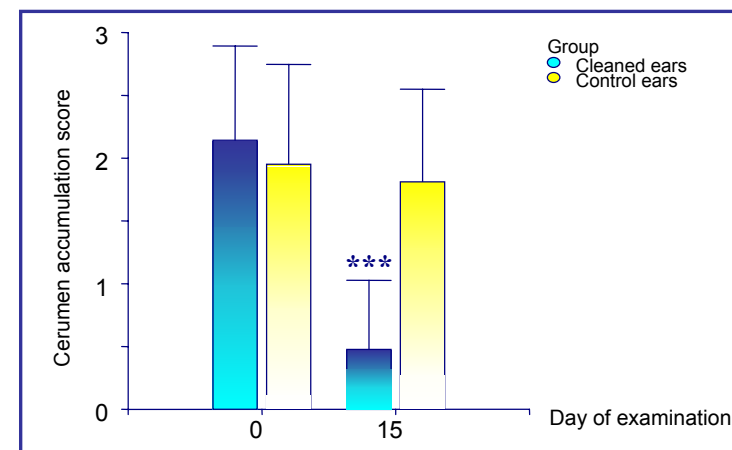


Figure 1. Quantity of cerumen in ears

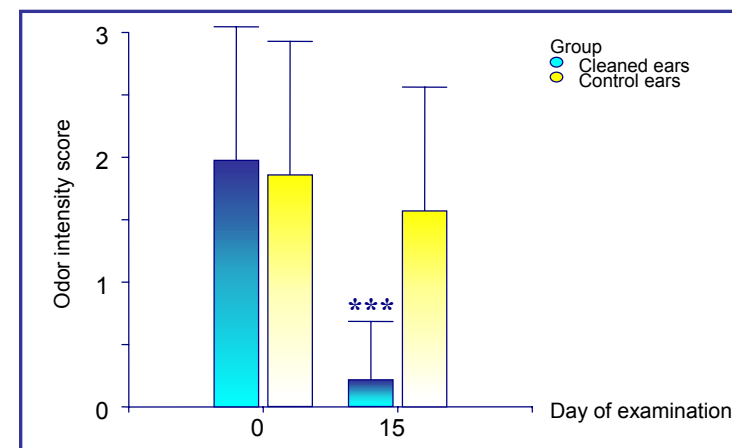


Figure 2. Intensity of odor from ears

- **At baseline**, abundant cerumen (score 3 to 4) was recorded in 76.2% of ear canals. The cerumen was mostly of soft consistency (74.7% of ears) and yellowish to brown colored (respectively 65.1% and 22.9% of ears). Moderate to marked rancid odor was detected for 59.5% of ear canals. Associated erythema was evidenced in 26.2% of ears. Mean numbers of *Malassezia* were lower than 1 organism per microscopic field for 62.7% of samples (≤ 5 yeasts per high power field in all cases). Clinical and microbial parameters were not statistically different between paired treated and control ears on Day 0 (Wilcoxon signed-rank tests, $p > 0.05$).
- **Over the 2-week study period**, cerumen, odor and erythema decreased markedly in cleaned ears (Wilcoxon signed-rank tests, $p < 0.003$) but not in untreated control ears (Fig. 1, 2 and Table).
- **No episode of local irritation or hypersensitivity** was recorded over the trial period during which the test product was instilled into the ears daily for 15 consecutive days. **No microbial proliferation** was detected in samples from the cleaned ears (Fig. 3). Indeed, physiological ear cleaning resulted in significant *Malassezia* count reduction at cytology from Day 0 to Day 15 (paired t-test, $p = 0.009$), whilst a trend for increased yeast counts was observed in untreated ears.

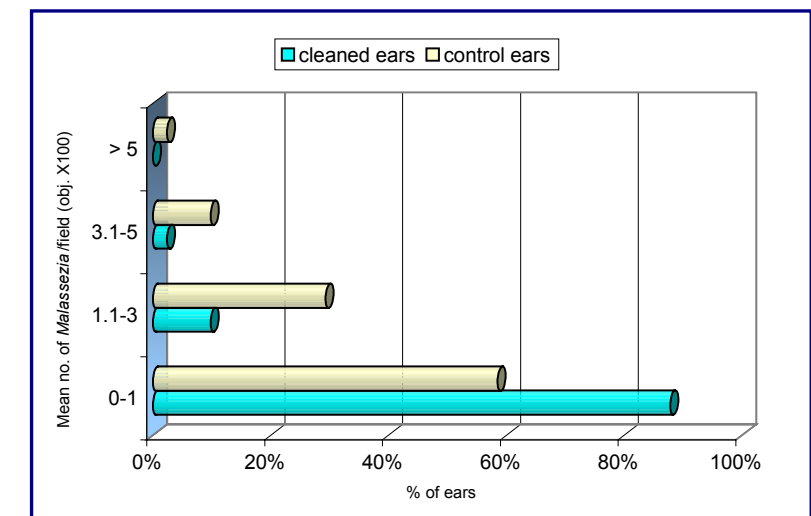


Figure 3. Breakdown of *Malassezia* populations in ears on day 15

Mean % reduction (95% conf. interv.)	Cleaned ears	Control ears
Cerumen score	76.8 (67; 86)	4.1 (-6; 14)
Odor score	90.6 (84; 97)	14.3 (3; 26)
Erythema score	72.8 (57; 89)	25.4 (7; 44)

CONCLUSIONS

- Excellent efficacy of Virbac Physiological Ear Cleanser® in removing excess cerumen from the ear canal of dogs under field conditions.
- Potent anti-odor effect of the solution, thanks to an innovative odor-neutralizing technology.
- Perfect tolerance of the cleanser under repeated frequent use (formulation preserving the natural balance of canine skin ecosystem)
- Contribution of this new micellar solution to the reduction of pre-existing erythema and the control of yeast populations in the ear canal, probably by very efficient removal of cerumen.