

# ASSESSMENT OF THE EFFICACY OF A 3% CHLORHEXIDINE SHAMPOO\* IN THE CONTROL OF ELEVATED CUTANEOUS *MALASSEZIA* POPULATIONS AND ASSOCIATED CLINICAL SIGNS (*MALASSEZIA* DERMATITIS) IN DOGS

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## INTRODUCTION

In certain conditions, related to cutaneous and/or immune-mediated factors, *Malassezia* may proliferate within the *stratum corneum*. The subsequent yeast overgrowth may then acquire a real pathogenic capacity and initiate a true dermatitis.<sup>1-4,10,11</sup> Since *Malassezia* are frequently associated with other dermatoses (which are also often pruritic) and since the subsequent lesional aspect is far from specific, the component of the clinical signs due to the yeast can only be determined after an efficient treatment.<sup>4</sup>

## OBJECTIVES

It has already been demonstrated that chlorhexidine containing topical products<sup>7</sup> and the 3% chlorhexidine containing shampoo\* tested in this study<sup>5,6</sup> are effective *in vitro* against bacteria and the yeast *Malassezia pachydermatis*. Moreover it has been demonstrated that chlorhexidine alone is as effective as when combined use with azoles molecules (miconazole)<sup>6</sup> and that the formulation of a shampoo can highly influence its activity.<sup>5</sup> The objectives of this study were to evaluate *in vivo*, the tolerance and the antimicrobial and clinical efficacy of a 3% chlorhexidine shampoo\*, in the control of abnormally high cutaneous *Malassezia* populations (*Malassezia* overgrowth) and the associated clinical conditions (associated dermatitis).

## MATERIALS AND METHODS

**Animals.** Dogs (of any breed or sex) included were affected with pruritic dermatitis associated with elevated population of *Malassezia*. Concurrent superficial pyoderma was treated with a 3-week course of systemic antibiotic. Dogs with deep pyoderma (furunculosis, cellulitis), parasitic skin diseases (demodicosis and Sarcoptic mange) and flea allergy dermatitis (where pruritus and lesions were not controlled by topical and/or environmental treatment with parasiticidals) and dogs treated with systemic or topical antifungal, antibacterial and anti-inflammatory products within the last week were not included in the study.

**Treatment.** The shampoo was used twice weekly for three weeks. The hair coat was massaged over the entire body (including foots, face, ear pinnae, tail, perineal area). It was rinsed off, followed by a second application, which was left on for 10 minutes. This was followed by a thorough final rinse to ensure total elimination of the remaining foam and product. Then the hair coat was dried with a clean towel. The only concurrent treatments allowed were ear cleansing with Epi-Otic® (Virbac S.A.) and antibiotic therapy in cases with associated superficial pyoderma (mainly bacterial folliculitis). No other topical or systemic agents were allowed.

**Protocol design.** General and dermatological examinations and cytological examinations were performed on the initial visit (D0) and 3 weeks later at the end of the treatment (D21). Six clinical parameters were scored using a 0-4 scale (absence to severe): pruritus, excoriations, erythema, exudation, keratoseborrhoeic disorder (KSD) and the total extent of affected body surface. A total clinical score was calculated by adding all 6 clinical parameters. Impression smear or scotch tape techniques were done on two sites selected at D0 and rechecked at the end of the study and cytological examinations of 20 high power fields (X100 objective) were performed to score the *Malassezia* population using a 0-4 scale (normal flora to very numerous *Malassezia*).

**Assessment of efficacy and statistical analyses.** The principal assessment criterion of efficacy was the reduction of the *Malassezia* population on the two selected sites after 3 weeks of treatment. The second assessment criterion of efficacy was the improvement in the general condition of the dog, assessed by the reduction of the scores recorded for the clinical parameters. Non parametric Wilcoxon Signed-Rank tests were used to analyse the scores evolution over the study period and Wilcoxon Sum-Rank tests to compare D0 scores and percentages of reduction in different sub-populations (concurrent pyoderma or not).

## RESULTS

**General data.** Thirty four dogs with *Malassezia* dermatitis were included in the study, 28 were analysed. Three cases were lost to follow-up and 3 were excluded: 2 for missing data and 1 due to deviation from the protocol because of concurrent corticosteroid treatment. There were 14 females and 14 males, mean age was  $5.65 \pm 3.85$  years and mean weight  $15.81 \pm 13.83$  kg; 14 dogs had concurrent bacterial folliculitis treated with systemic antibiotics.

**Clinical efficacy.** All scores and total clinical score decreased over the study period with high statistic significance ( $p \leq 0.0001$ ), **table 1** and **figures 1 and 2**. the clinical scores were reduced by 78% to 92% over the study period, with the total clinical score being reduced by close to 85% and the *Malassezia* population by more than 97% (**figure 3**). Twenty six dogs (93%) reached a zero score for the *Malassezia* population (**figure 4**) and those dogs had a total clinical score reduction of 88%. Comparable results were obtained whether dogs were affected with concurrent pyoderma or not, showing that the antibiotic treatment had no influence on the *Malassezia* dermatitis evolution. However, interestingly, clinical signs were significantly higher in dogs with associated folliculitis at D0, maybe due to an additional effect of the *Malassezia* dermatitis and the pyoderma (**figure 5**). 100% of good tolerance was reported.

## CONCLUSIONS

The 3% chlorhexidine shampoo\* tested, used twice a week for three weeks, was well tolerated and highly effective in the control of elevated *Malassezia* populations, and associated skin lesions and pruritus. This clearly demonstrates that efficacy of this shampoo is not only limited to the antibacterial activity of chlorhexidine but antifungal activity as well. This study, once again, points out that when dealing with a dog affected by a pruritic dermatitis, particularly when an allergic dermatitis is suspected, it is absolutely necessary to check for possible presence of secondary cutaneous infections (bacterial overgrowth and/or *Malassezia* dermatitis and/or pyoderma).<sup>8-11</sup> Efficient treatment of these may lead to a dramatic (if not complete) remission of clinical signs.

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Table 1: Evolution of means scores of clinical parameters over the study period

Clinical parameters	D0	D21
Pruritus	2.75	0.64
Excoriations	1.86	0.29
Erythema	2.00	0.29
Exudation	1.25	0.14
Keratoseborrhoeic disorder (KSD)	0.86	0.11
Total surface of affected body	2.18	0.39
Total clinical score	10.90	1.86
<i>Malassezia</i> populations	2.50	0.07

Significant reductions were noted for all the scores at D21 ( $p \leq 0.0001$ ).

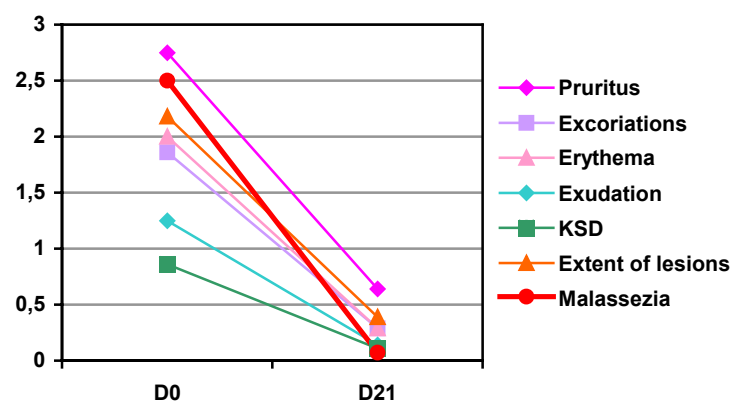


Fig.1: Evolution of the means of the clinical and of the *Malassezia* population scores (n=28)

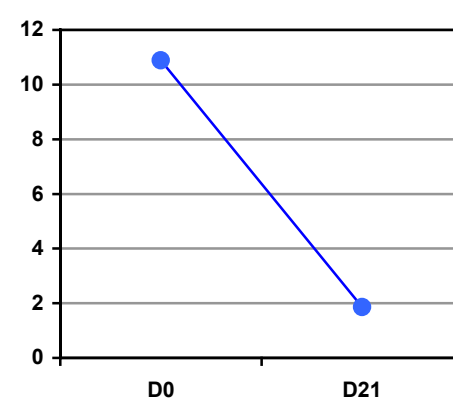


Fig.2: Evolution of the mean of the total clinical score (n=28)

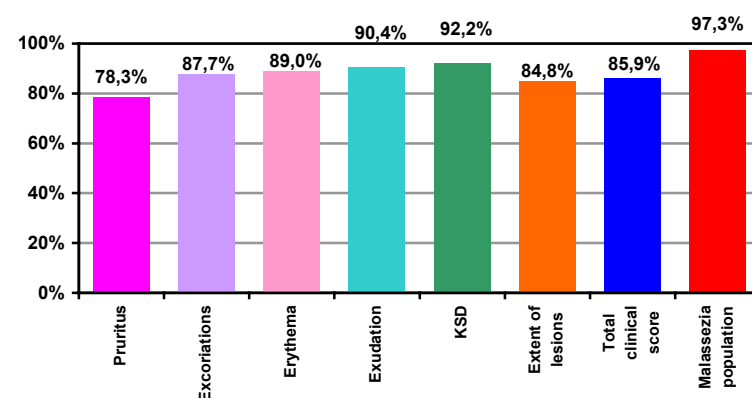


Fig.3: Percentages of reduction of the clinical and of the *Malassezia* population scores (n=28)

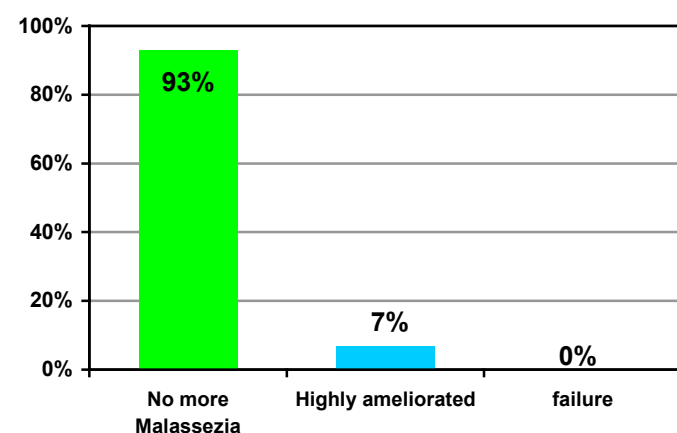


Fig.4: Percentage of success after three weeks of treatment (n=28)

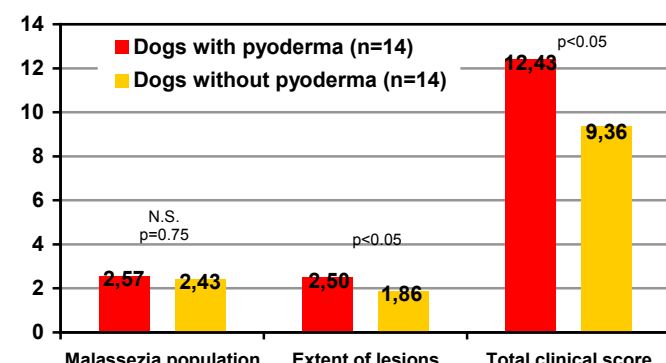


Fig.5: Comparison at D0 of the means of the *Malassezia* population, extent of lesions and total clinical scores in dogs with (n=14) and without (n=14) concurrent pyoderma

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