SUCCESSFUL TREATMENT OF KERATOCONJUNCTIVITIS SICCA (KCS) IN DOGS WITH PIMECROLIMUS EYE DROPS: A COMPARISON WITH CYCLOSPORIN A (CyA) OPHTHALMIC OINTMENT.

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Purpose. The aim of this study was to conduct a clinical trial, testing the efficacy of topical administration of pimecrolimus in alleviating the clinical signs of KCS in dogs and to compare it with the veterinary commercial form of CyA (Optimmune®). **Methods**. The study was an open-label, multicenter, randomized, 8-week outpatient clinical study and included 44 dogs (77 eyes) that had never been treated with CyA. KCS was diagnosed based on a Schirmer Tear Test I (STT) value ≤ 10 mm/min. and an aggregate score ≥ 4 in grading clinical signs of corneal and/or conjunctival inflammation (9 signs were evaluated and scored from 0=none to 4=severe). Dogs were randomly assigned to a treatment group, to be medicated twice daily with 1% pimecrolimus oil-based eye drops or 0.2% CyA ophthalmic ointment. Rechecks were conducted 2, 4 and 8 weeks after enrollment. The STT values and the ocular sign scores were analyzed by using ANOVA and the Wilcoxon rank sum test, respectively. As there were no substantive differences between the worst-eye (with the lowest STT value at baseline) and best-eye analyses, the results for only the worst-eye analyses are summarized.. **Results**. At baseline, the mean STT values in the pimecrolimus and CyA groups were 3.8 ± 0.7 mm/min. (mean ± sem; n = 20) and 4.6 ± 0.7 mm/min. (n = 24), respectively. Statistically significant improvements from baseline were observed within both groups ($P \leq 0.001$) at all follow-up visits. After 8 weeks of treatment, mean increases of 9.2 and 5.8 mm/min were observed in the pimecrolimus and CyA groups, respectively. The difference between the 2 groups was marginally significant ($P = 0.085$). Both drugs also caused a significant improvement in clinical signs of corneal and conjunctival inflammation ($P \leq 0.001$) at all follow-up visits. At baseline, the mean total scores in the pimecrolimus and the CyA groups were 16.0 ± 1.1 and 13.9 ± 1.4, respectively. After 8 weeks of treatment, there was a significantly larger reduction in the total score in eyes treated with pimecrolimus (mean decrease of 10.3) as compared to eyes treated with CyA (mean decrease of 7.6; P = 0.024). Two dogs assigned to the pimecrolimus group were discontinued a few days after enrollment because of severe local irritation. **Conclusions**. The results of this study show that 1% pimecrolimus oily eye drops are more effective than the commercial 0.2% CyA ophthalmic ointment in controlling KCS in dogs. These findings confirm the interest to develop pimecrolimus for the treatment of dry eye in humans. **Support.** Funded by Novartis Pharma AG, Basel, Switzerland. CI: C (RO, IA, UG, TP, BS), E (EL, GL).