

Semifluorinated Alkanes Enhance the Lipid Layer for Dry Eye Therapy

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Background

Dry Eye Disease (DED) is one of the most prevalent ocular surface disorders causing significant pain and discomfort to patients. The semifluorinated alkane, Perfluorohexyloctane (NovaTears®), has recently been introduced as a preservative-free eye drop for management of DED symptoms.

This study was performed to evaluate the mechanism by which Perfluorohexyloctane exerts a lubricating effect on the ocular surface.

Methods

The rabbit model was used for this study as rabbit tear fluid dynamics are comparable to humans (Table 1). The influence of Perfluorohexyloctane on tear fluid dynamics was studied after instillation into healthy rabbit eyes twice daily (b.i.d.) for seven days and was compared to the instillation of saline.

Table 1. Comparison of human and rabbit tear fluid dynamics¹⁻⁴

Parameter	Humans	Rabbits
Lipid layer thickness (nm)	<60-180	>180
Tear volume (mm)	>20	15-27
Osmolarity (mmol/kg)	282.50±24.32	375.83±18.17

The lipid layer grade (LLG) was observed daily by interferometry using a Keeler Tearscope® Plus (Fig. 1A). Tear fluid evaporation rate (TFER), measured using a modified Delfin VapoMeter (Fig. 1B), and tear volume, measured as per the phenol red thread test, were also observed daily during the course of treatment. Tear osmolarity was measured before and after the seven-day study period using the TearLab® Osmolarity System.

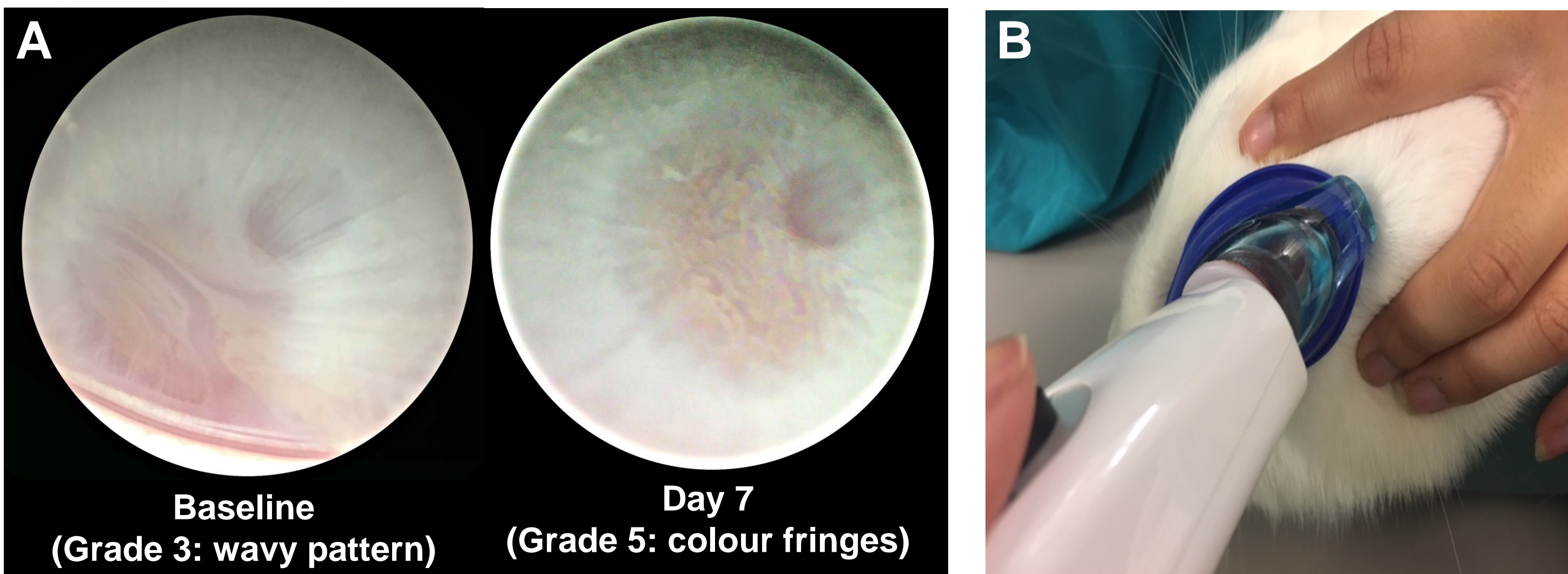


Figure 1. Clinical tear film testing for A. LLG using the Keeler Tearscope at baseline (left) and on Day 7 (right); and B. TFER measurement using a modified Delfin VapoMeter.

Ocular safety was monitored throughout the test period and corneal and conjunctival integrity were assessed by sodium fluorescein staining at baseline and at the end of the study.

Results

A cumulative increase in LLG was observed after instillation of Perfluorohexyloctane with statistically significant improvement from baseline being evident from Day 5 onwards (Fig. 2). No significant changes were seen after instillation of saline.

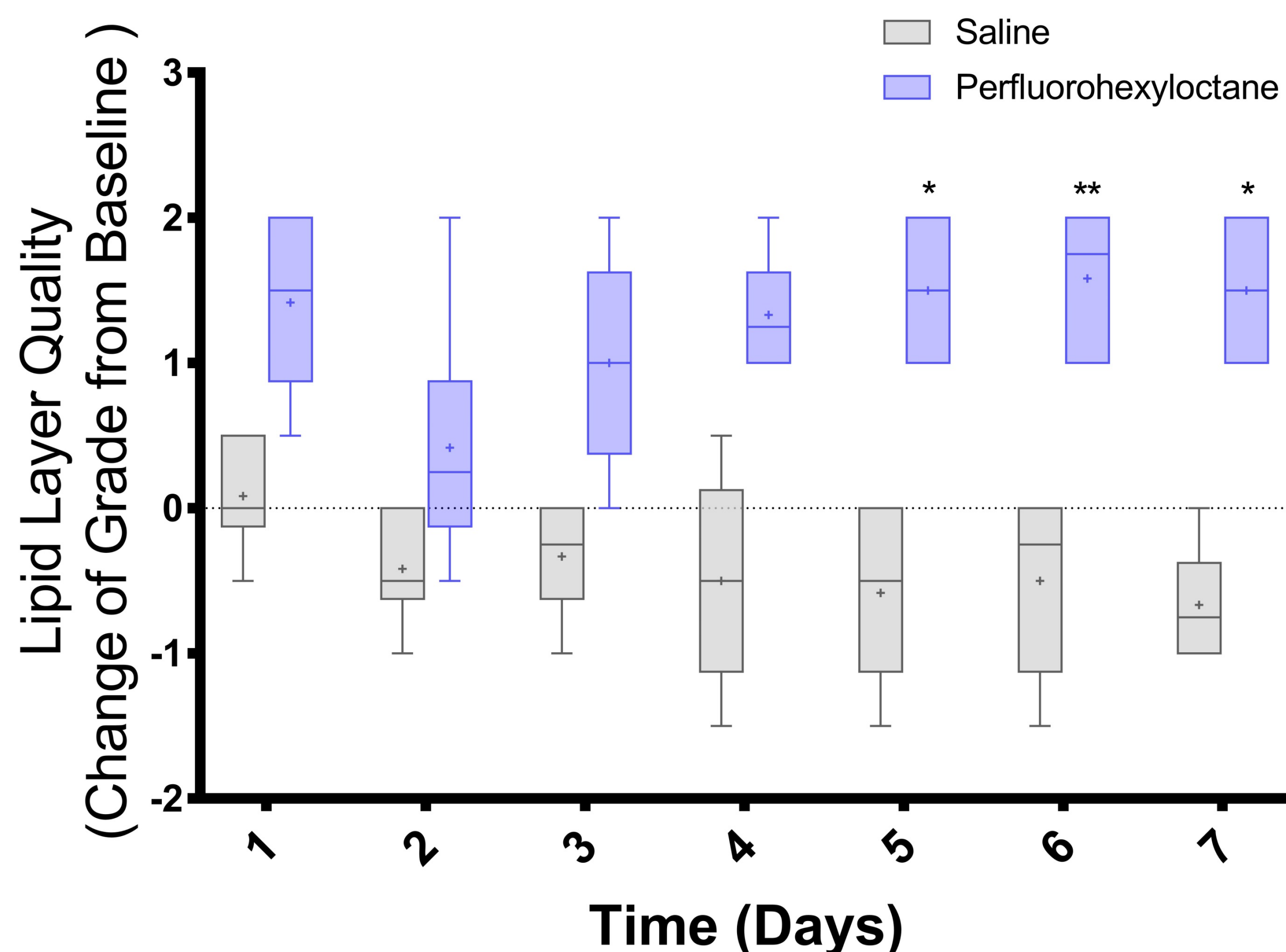


Figure 2. Change in LLG observed after b.i.d. instillation of saline and Perfluorohexyloctane over seven days (n=6). Significance of difference from baseline, if observed, is denoted as *: $p \leq 0.05$ **: $p \leq 0.01$.

No significant change in the TFER, tear volume and tear osmolarity was observed over the seven day test period after instillation of both Perfluorohexyloctane and saline (Fig. 3).

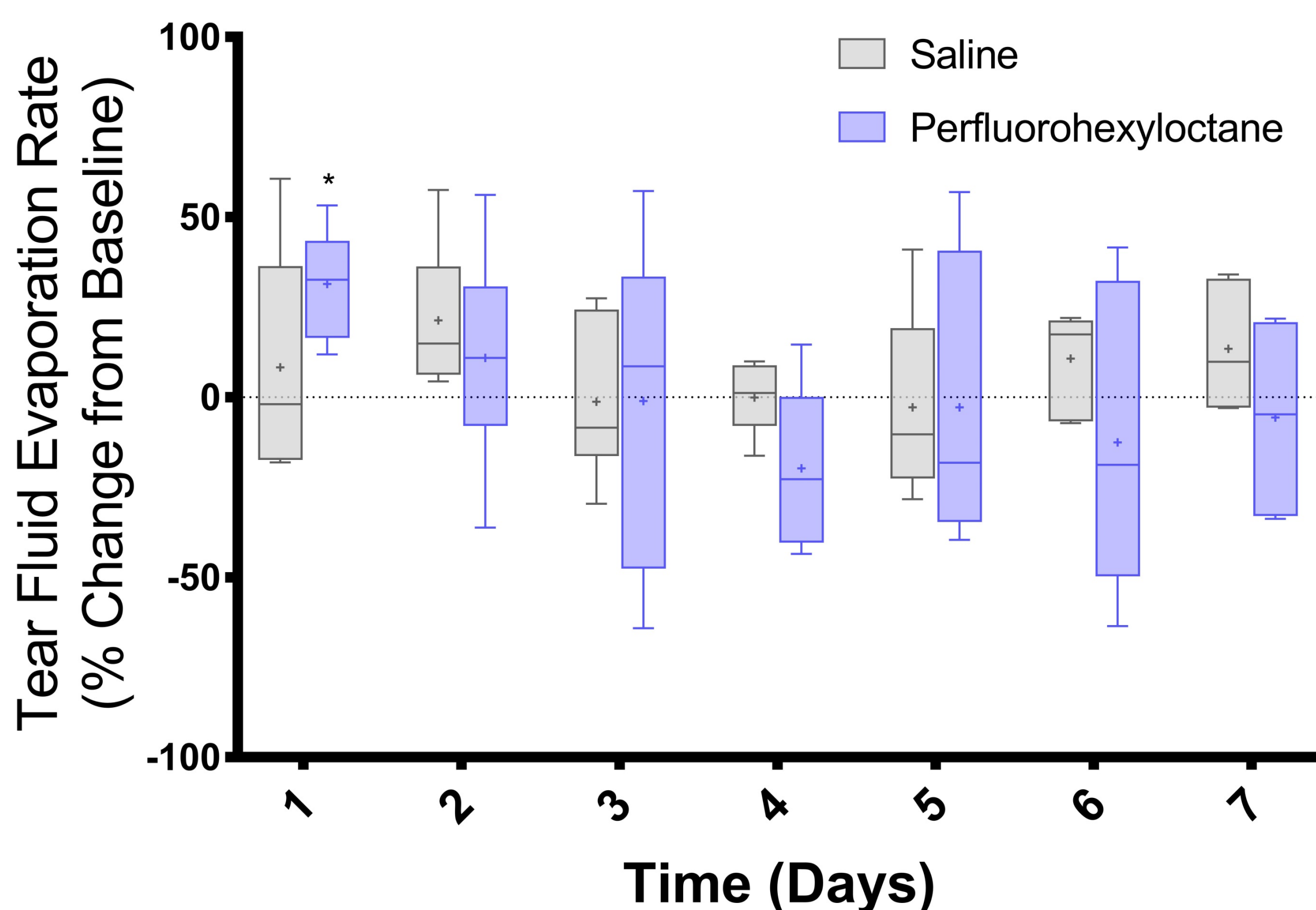


Figure 3. Percentage change in TFER observed after b.i.d. instillation of saline and Perfluorohexyloctane over seven days (n=6). Significance of difference from baseline, if observed, is denoted as *: $p \leq 0.05$.

Finally, no signs of ocular discomfort or adverse effects, such as corneal opacity, erythema, conjunctival swelling or discharge were observed at any point during the study. Corneal and conjunctival integrity were maintained after instillation of Perfluorohexyloctane and saline for seven days.

Conclusion

Perfluorohexyloctane progressively improved the LLG and thus the lipid layer thickness after twice daily topical application supporting its lubricating effect to provide symptomatic relief in dry eye patients. No significant difference in TFER or tear volume could be observed in healthy rabbit eyes after seven days.

References:

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