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Influence of perfluorohexyloctane containing eye drops on tear film thickness in patients with mild to moderate dry eye disease

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Purpose

Recently introduced new water-free perfluorohexyloctane eye drops (NovaTears®, Novaliq, Germany) have demonstrated to improve clinical signs and symptoms in patients with dry eye disease (DED). This formulation is a completely non-aqueous liquid, in which microbial growth is not possible and therefore requires no preservatives.

Further, the agent shows significant spreading abilities that reduce shearing forces between surfaces. In a recent observational study in patients with DED, treatment with perfluorohexyloctane eye drops significantly improved subjective and objective symptoms and signs of the disease.[1] In the present study, the effect of perfluorohexyloctane eye eye drops on tear film thickness (TFT) in patients with mild to moderate DED was investigated.

Methods

A total of 48 patients with mild to moderate DED were included in this randomized, single-masked, observer-blinded parallel group study. Patients were randomized to receive either NovaTears®, or unpreserved 0.9% saline solution eye drops (Hydrabak® eye drops) 4 times daily in both eyes for 4 weeks. TFT was assessed before treatment start and 6 times after first instillation to determine short time effect as well as after 2 and 4 weeks, respectively. The study design is shown in Figure 1.

A custom built and validated ultra-high resolution OCT system was used to assess TFT, the primary endpoint of the study. Details on the instrument have been published previously.[2] The precorneal lipid layer thickness (LLT) was measured based on a commercially available white-light interferometer. Further, standard clinical tests to assess signs and symptoms including break up time (BUT), fluorescein staining and ocular surface disease index (OSDI) were performed.

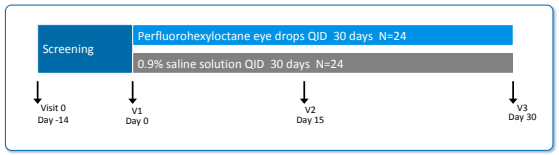

Figure 1: Study design

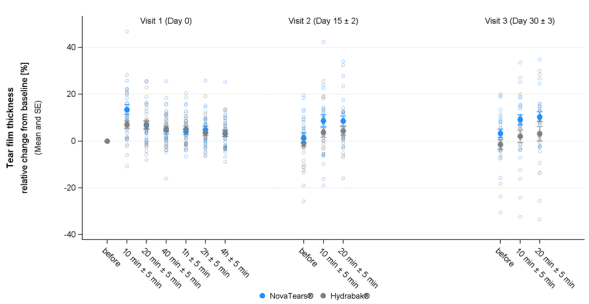

Figure 2: Effect of perfluorohexyloctane eye drops (NovaTears®) and 0.9% saline solution (Hydrabak®) on the relative change in tear film thickness from baseline at all different measurement time-points (n=48, mean +- SD)

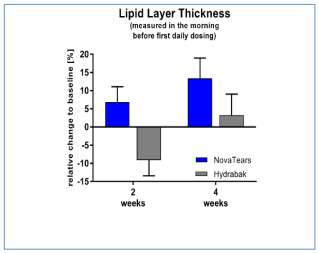

Figure 3: Lipid layer thickness measured 2 and 4 after treatment start. Data are presented as means+-SD.

Results

Mean TFT and LLT at baseline were comparable in the two treatment groups. The primary efficacy analysis showed that the relative change (%) in TFT from baseline was significantly higher with perfluorohexyloctane eye drops than saline solution over all postdose measures with an estimated LS mean difference of 3.33% (95% CI [0.44; 6.23]; p=0.025). As shown in Figure 1, after a single dose on Visit 1 perfluorohexyloctane eye drops temporarily increased TFT immediately after drop instillation. However, at all subsequent timepoints on Day 1 no apparent change between the two treatment groups were evident.

After multiple dosing, perfluorohexyloctane eye drops gradually increased TFT over time with a maximum effect at the end of the study after 4 weeks treatment (LS mean difference: 1.29%; p=0.4901 at Day 1, 4.33%; p=0.0547 at Week 2, 6.42%; p=0.0142) at week 4 (Figure 2).

4 Weeks after study start, LLT values showed a more pronounced increase in LLT for perfluorohexyloctane eye drops (perfluorohexyloctane: 13.36%±26.33% saline: 3.21% ±28.65%; p=0.001, Figure 3).

The secondary endpoints fluorescein staining, BUT and OSDI improved in both treatment groups with no statistical difference between groups in the current study design.

Conclusions

The study demonstrates that perfluorohexyloctane eye drops increase TFT as well as LLT over time and reaches its maximum at the end of study treatment. These tear film restoring properties are in line with the mode of action of perfluorohexyloctane preventing evaporation by stabilizing the lipid layer.

References

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Disclosures

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