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Evaluation of Perfluorohexyloctane Eyedrops in Habitual Contact Lens Wearers

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Background: Dry eye disease is one of the most common disorders we see in practice today. Perfluorohexyloctane (PFHO) ophthalmic solution (MIEBO®) (©Bausch + Lomb) is a novel, non-aqueous, single entity, preservative-free ophthalmic drop recently approved by the FDA for treatment of the signs and symptoms of dry eye disease.

Purpose: While the safety and efficacy of PFHO has been demonstrated in non-contact lens wearers, its safety and potential benefits in habitual contact lens wearers have not been explored. This report presents the results of a trial designed to evaluate the safety of PFHO and its effect on contact lens comfort, specifically in established contact lens wearers.

Patients and methods: The study included 47 patients who were adjusted contact lens wearers with a best corrected visual acuity of 20/25 or better at distance. All the patients were healthy contact lens wearers with no dry eye symptoms.

Results: A significant improvement in comfort scoring was observed without any significant changes in osmolarity, meibography scores, and total fluorescein staining.

Conclusion: These findings suggest that PCHO is safe for contact lens wearers to use and shows promise to reduce contact lens dropout.

Keywords: perfluorohexyloctane, dry eye disease, meibomian gland dysfunction, total corneal fluorescein staining, osmolarity

Introduction

Dry eye disease (DED) is one of the most common disorders we see in practice today. The incidence of DED has been increasing over the past several years. Studies estimate that between 5% and 15% of the US population is affected by DED and that DED costs the US economy approximately $55.4 billion each year.[1,2] There are two major subgroups of DED, aqueous-deficient DED, which results from reduced lacrimal gland secretions, and evaporative DED, which results from excessive evaporation of the tear film.[3] The majority of DED cases have an underlying evaporative component, and the primary cause of evaporative DED is meibomian gland dysfunction (MGD).[4–8] MGD, which potentially impacts one billion people globally, causes alterations in the tear film lipid layer which contributes to tear film instability and increased evaporation of the aqueous layer.[1,9,10] Tear film instability associated with MGD leads to tear hyperosmolarity, resulting in apoptosis and inflammation of the ocular surface.[11,12]

Patients suffering from DED complain of symptoms including irritation, dryness, burning or stinging and visual disturbances. These symptoms may adversely affect the patient's quality of life and work productivity.[13,14] Signs of DED include tear film instability (eg, reduced tear film breakup time (TBUT)), and conjunctival redness.[15] Many therapies are being used to help treat MGD, including physical therapies (eg, gland expression, thermal pulsation, intense pulsed light), oral medications (eg, doxycycline, azithromycin) with the intention of reducing inflammation or lowering meibum viscosity, and over the counter lipid based tears to replenish the tear film lipid layer temporarily. Immunomodulatory or anti-inflammatory drugs such as cyclosporine, lifitegrast, and loteprednol etabonate are also being used for the treatment of DED but are not approved for the treatment of MGD.

According to the TFOS DEWS II Iatrogenic Report, contact lenses can significantly impact dry eye syndrome (DES). The mechanical interaction between the lens and the ocular surface can disrupt the tear film, leading to increased

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evaporation and instability. Contact lens wear can also reduce corneal sensitivity and alter tear production. Long-term use of contact lenses is associated with meibomian gland dysfunction, further contributing to DES symptoms. Specifically, contact lens-induced dry eye (CLIDE) and contact lens-associated dry eye (CLADE) are recognized conditions where lens wear exacerbates dry eye symptoms.[16]

Perfluorohexyloctane (PFHO) ophthalmic solution (MIEBO®) (Bausch + Lomb) is a novel, non-aqueous, single entity, preservative-free ophthalmic drop recently approved by the FDA for treatment of the signs and symptoms of dry eye disease. This sterile, clear, colorless liquid containing 100% perfluorohexyloctane is approved for topical ophthalmic use four times daily. Although its exact mechanism in DED is unknown, PFHO is effective in reducing tear film evaporation by forming a monolayer at the tear film's air–liquid interface. Its low surface tension facilitates rapid spreading across the tear film, causing minimal visual disturbance due to its refractive index similar to water.[17]

Both Phase 3 trials (GOBI and MOJAVE) demonstrated significant improvements in both signs and symptoms of DED compared to hypotonic saline, with good tolerability.[18] In addition, 100% of the patients enrolled in both trials also had clinically diagnosed meibomian gland dysfunction.[18] While the safety and efficacy of PFHO has been demonstrated in non-contact lens wearers, its safety and potential benefits in habitual contact lens wearers have not been explored. This report presents the results of a trial designed to evaluate the safety of PFHO and its effect on contact lens comfort, specifically in established contact lens wearers.

Methods

Study Design

This was an open-label, double-arm, 4-week trial (ClinicalTrials.gov identifier NCT06176651) with no control and no randomization. The study took place at a single site in La Jolla, CA, from October 2023 to March 2024 and consisted of 3 visits: screening and 2 follow-up visits at weeks 1 and 4. The study included 47 patients who were adjusted contact lens wearers with a best corrected visual acuity of 20/25 or better at distance. The patients were all healthy contact lens wearers with no dry eye symptoms. The patients were divided into two arms based upon their contact lenses being daily disposables or reusable contact lenses. Patients were instructed to instill 1 drop of PFHO into each eye four times a day with their contact lenses removed before each installation as directed by the package insert. Patients waited at least 30 minutes before reinserting their contact lenses after instilling PFHO.

The trial was conducted utilizing the International Council for Harmonisation (ICH)/Good Clinical Practice (GCP) guidelines. This Study complies with the Declaration of Helsinki. The trial protocol was approved by the Salus Institutional Review Board. All patients provided written informed consent before initiation of any trial-related procedures.

Patients

Participants consisted of patients ≥18 years of age with a history of soft contact lens usage for at least 60 days, and a best corrected visual acuity of 20/25 or better in both eyes. Exclusion criteria included non-contact lens wearers, previous use or known allergy to PFHO, and any corneal abnormality that would affect the study outcome in the investigator's opinion.

Outcome Measures

A thorough assessment of the anterior segment, including total corneal fluorescein staining (tCFS), was performed via slit-lamp biomicroscopy at screening, week 1 and week 4. The tCFS score was determined by the National Eye Institute (NEI) grading scale and adding the 5 regions together. Each visit also included an assessment of visual acuity with contact lenses and contact lens fit. Tear film osmolarity, meibography, and comfort score via Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) were assessed at screening and week 4. Meibography measurements were obtained with removal of lenses and utilizing a Lipiview instrument.

The primary endpoint was to limit the increase (worsening) of the tCFS score baseline at week 4. The secondary endpoint was to limit the increase (worsening) of the CLDEQ-8 score baseline at week 4. tCFS scores will increase with more corneal staining, while the CLDEQ-8 score will also increase with more discomfort.

Safety assessments included adverse events (AEs), slit-lamp biomicroscopy, and best-corrected visual acuity.

Statistical Methods

The analysis population included all enrolled patients who received PFHO, had no significant protocol deviations, and completed the study. The primary and secondary endpoints (tCFS, CLDEQ-8 score) were evaluated in the analysis population using paired *t*-tests to compare changes from Day 1 to Day 30, with significance set at $p < 0.05$.

Results

Patients

The analysis population included 46 of the 47 patients who participated in the study. A total of 26 patients wore daily disposable contact lenses and the other 21 patients wore reusable contact lenses, both groups wore varied lens materials (hydrogel and silicone hydrogel). No major protocol deviations occurred, so no patient data exclusions were required.

Endpoints

Primary Endpoint (Safety)

Patients treated with PFHO experienced no significant change in tCFS score from screening at week 4, thereby meeting the primary safety endpoint (Table 1). At screening, the mean tCFS score was 0.36, and decreased to 0.25 by week 4, indicating a mean change of −0.11 ($p = 0.387$). Slit-lamp examination and BCVA were performed at all visits of the study and revealed no abnormal results. These findings suggest that no statistically significant adverse changes occur to the ocular surface of contact lens wearers while using PFHO at the prescribed dosage.

Secondary Endpoint (Efficacy)

At screening, the mean comfort score, as measured by CLDEQ-8 was 14.26. By week 4, this score significantly improved to 8.45, reflecting a mean change of −6.04 ($p < 0.000001$) (Table 1). These findings suggest an improvement in contact lens comfort when patients use PFHO.

Other Secondary Endpoints

Tear film osmolarity decreased from 300.17 mOsm/L at screening to 293.23 mOsm/L at week 4, with a mean change of −6.94 mOsm/L ($p = 0.297$) (Table 1). The mean meibography score showed negligible change, with a screening mean of 1.11 to a week 4 mean of 1.14, with a mean change of 0.03 ($p = 0.687$) (Table 1). These findings support the lack of statistically significant adverse changes to the ocular surface of contact lens wearers while using PFHO at the prescribed dosage. There was no change noted in visual acuity over the course of the study.

Table 1 Demographic and Clinical Characteristics

Characteristic	Baseline	Week 4	Mean Change (Baseline - Week 4)	*T*-test
tCFS score (NEI), mean OU, mean (SD)	0.36 (1.49)	0.25 (0.75)	−0.11	0.387213
CLDEQ-8 score, mean (SD)	14.26 (8.07)	8.48 (5.45)	−5.78	0.000001
Tear Osmolarity Score, mean OU, mOsm/L, mean (SD)	300.17 (11.19)	293.23 (44.81)	−6.94	0.297023
Meibography Score, mean OU, mean (SD)	1.11 (1.16)	1.14 (1.18)	0.03	0.687647

Notes: Demographics: Mean (range), age (y): 38.5 (23–71). Female, n (%): 33 (70.2).
Abbreviations: tCFS, total corneal fluorescein staining; NEI, National Eye Institute; SD, standard deviation; CLDEQ-8, Contact Lens Dry Eye Questionnaire-8; mOsm/L, milliosmoles per liter.

Safety

One subject experienced a mild ocular adverse event (AE) of unilateral allergic conjunctival hyperemia. The patient that experienced the ocular AE elected to temporarily discontinue wearing their contact lenses, resulting in their withdrawal from the study. The unilateral nature of this AE indicates an unlikely correlation between AE and the use of PFHO, although previous studies have indicated a rare occurrence of conjunctival hyperemia while using PFHO. There were no serious AEs during the study. No clinically meaningful safety concerns were observed in slit-lamp examination, tCFS, meibography, visual acuity or CLDEQ-8 scores.

Discussion

This single-site, open-label, double-arm trial enrolled patients who were established soft contact lens wearers. The trial met both the primary endpoint (increase (worsening) of tCFS score at week 4) and the secondary endpoint (increase (worsening) of CLDEQ-8 score at week 4) (Table 1). Contact lens wearers often do not realize their lenses may not be as comfortable as they could be. This may add to the amount of contact lens dropouts. Using a drop which may increase lens comfort and wearing time could be a great help in improving patients lens wearing ability.

PFHO, administered 4 times daily for 4 weeks in patients wearing soft contact lenses, has shown to be safe and well tolerated when used as directed by the manufacturer. These findings are noteworthy, given that demonstration of safe use of PFHO in soft contact lens wearers has not been evaluated from other studies. PFHO also demonstrated a significant improvement in contact lens comfort. These results are even more interesting given that these patients were not dry eye patients. There were no serious ocular or nonocular AEs reported in patients treated with PFHO in this study.

Limitations of the current study include the relatively short treatment period of 4 weeks and not exclusively evaluating contact lens wearers with dry eye disease. Further research is needed to explore the mechanisms driving changes in comfort and their relation to tear film stability. A future study where patients do not remove their contact lenses when instilling PFHO could also be considered.

Conclusion

Our conclusion in this study is that PFHO is a safe product to utilize for soft contact lens wearers when used as directed by the manufacturer. The study demonstrated no statistically significant adverse changes to the ocular surface while showing statistically significant improvement in comfort.

Data Sharing Statement

Once published the data will be shared at various educational meetings from the podium. Only the published data will be made available for an indeterminate time frame.

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Disclosure

The authors report no conflict of interest in this work.

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