



Perfluorohexyloctane Ophthalmic Solution in Patients with Dry Eye Disease Undergoing Cataract Surgery: A Prospective Multicenter Study

John A. Hovanesian · Eva Liang · Neel R. Desai · Gregg J. Berdy · Kayla Karpuk ·

Justin Schweitzer · Adam Alexander · Jason L. Vittitow · John Berdahl · Jason Bacharach

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ABSTRACT

Introduction: Dry eye disease (DED) is a common comorbidity in patients undergoing cataract surgery. Perfluorohexyloctane ophthalmic solution (PFHO) forms a protective layer on the tear film surface to reduce evaporation and is approved for treatment of signs and symptoms

Prior presentation: An interim analysis of baseline data from this study was presented at the American Society of Cataract and Refractive Surgery (ASCRS) held on April 25–28, 2025, in Los Angeles, California, USA, and the American Academy of Optometry (AAO) held on October 8–11, 2025, in Boston, Massachusetts, USA.

J. A. Hovanesian
Harvard Eye Associates, Laguna Hills, CA, USA

E. Liang
Center for Sight, Las Vegas, NV, USA

N. R. Desai
The Eye Institute of West Florida, Largo, FL, USA

G. J. Berdy
Ophthalmology Associates, St Louis, MO, USA

K. Karpuk · J. Schweitzer · J. Berdahl
Vance Thompson Vision, Sioux Falls, SD, USA

A. Alexander · J. L. Vittitow
Bausch + Lomb, Bridgewater, NJ, USA

J. Bacharach (✉)
North Bay Eye Associates, Inc., 104 Lynch Creek
Way, Suite 15, Petaluma, CA 94954, USA
e-mail: jbacharach@northbayeye.com

of DED. Because PFHO has a long ocular surface residence time, it was of interest to assess whether PFHO interfered with preoperative biometry and keratometry measurements to affect postoperative refractive accuracy in patients undergoing cataract surgery. This study evaluated the perioperative use of PFHO in patients undergoing cataract surgery.

Methods: This phase 4, multicenter, open-label, single-arm study enrolled patients with DED who were candidates for phacoemulsification with posterior chamber intraocular lens (IOL) implantation. Patients instilled PFHO bilaterally four times daily for 30 days preoperatively and received a second 30-day PFHO treatment approximately 1 month after surgery. The primary endpoint was the mean difference in absolute deviations between the manifest refraction spherical equivalent and predicted refractive error.

Results: Ninety-seven patients were enrolled (mean age: 68.6 years; female: 75.3%). The mean difference in absolute deviations between manifest refraction and predicted refractive error was -0.027 ± 0.167 D ($p=0.1385$). The difference in predicted refractive error at baseline versus post-PFHO treatment was within ± 0.3 D for 94.2% of study eyes. More patients had a calculated IOL power within ± 0.50 D of the correct IOL power post-PFHO treatment than pre-PFHO (83.7% vs. 72.1%). Treatment with PFHO significantly improved DED signs and symptoms,

including total and central corneal fluorescein staining, eye dryness, and Ocular Surface Disease Index scores, before and after cataract surgery ($p < 0.0001$ for all). The percentage of patients with best-corrected visual acuity of 20/20 or better was 86.0% at first postsurgical assessment and 91.8% after 30 days of subsequent PFHO treatment. Two adverse events were considered related to treatment (mild eye pruritus and mild noninfectious conjunctivitis).

Conclusions: In patients with DED undergoing cataract surgery, PFHO did not affect the accuracy of preoperative biometry and keratometry measurements or the predicted refractive error. Patients experienced significant reductions in signs and symptoms of DED.

Trial registration: ClinicalTrials.gov identifier, NCT06346340.

Keywords: Cataract surgery; Dry eye; Ocular surface disease; Perfluorohexyloctane ophthalmic solution

Key Summary Points

Why carry out this study?

Dry eye disease (DED) is a common comorbidity in patients undergoing cataract surgery.

Perfluorohexyloctane ophthalmic solution (PFHO) forms a monolayer at the tear film–air interface and has a long ocular surface residence time; a single drop was detectable in the tear film for at least 8 h in a rabbit pharmacokinetic study.

This study evaluated the impact of PFHO treatment prior to cataract surgery on the accuracy of preoperative biometry measurements and predicted refractive error, and the impact of pre- and postoperative treatment with PFHO on the signs and symptoms of DED.

What was learned from this study?

Though not statistically significant, preoperative PFHO treatment showed a positive trend towards improving predicted refractive error, indicating no alteration to expected refractory outcomes with PFHO use.

The functional properties of PFHO, including the formation of an ultrathin barrier on the tear film and lengthy ocular surface residence time, had no impact on the predictability of preoperative measurements or postoperative refractive accuracy.

Significant reductions were observed in signs and symptoms of DED prior to cataract surgery, and further improvements were noted during postsurgical treatment with PFHO.

These results support a role for PFHO in the pre- and postoperative management of DED in patients undergoing cataract surgery.

INTRODUCTION

Nearly 30 million cataract surgeries are performed each year, making it the most common surgical procedure worldwide [1]. Although the overall success rate for cataract surgery is high [2], visual outcomes are dependent on the accuracy of preoperative assessment, including intraocular lens (IOL) power calculation and selection [3]. Biometry is one of the most important factors determining postsurgical outcomes and patient satisfaction [3, 4]. Ensuring the accuracy and predictability of IOL power is particularly important for lenses that are multifocal or toric, or have an extended depth of focus, and in cases of keratoconus, irregular cornea, prior refractive surgery, or ocular surface disorders such as dry eye disease (DED) [5, 6]. DED disrupts tear film homeostasis and causes ocular surface inflammation and damage [7], which can interfere with biometric measurements and corneal topography assessments [8, 9]. Moreover, the presence of DED has been shown to increase the variability in preoperative biometric measurements [6, 10], and greater variability increases the error between predicted and postoperative refraction [6].

DED is a considerable burden to patients, adversely affecting health-related quality of life and interfering with daily activities [11]. It is estimated that more than 16 million adults in the United States have diagnosed DED, and an additional six million have symptoms consistent with DED but are undiagnosed [12]. As the incidence of both DED and cataract increase with age, they often coexist [13]. In addition, cataract surgery can disrupt the tear film, thereby exacerbating pre-existing DED or inducing de novo DED [8, 13]. For most patients undergoing cataract surgery, tear film abnormalities and corneal staining are present preoperatively, although many patients may be asymptomatic [14, 15]. Tear film issues can not only affect the accuracy of IOL power determination, but also slow the healing and vision recovery process, impair visual quality, and reduce postoperative satisfaction [14]. Expert guidance advocates for the preoperative evaluation and management of DED in patients undergoing lens-based surgery (including cataract surgery) to optimize surgical outcomes [13, 14, 16, 17].

Perfluorohexyloctane ophthalmic solution (PFHO; Miebo®; Bausch + Lomb, Bridgewater, NJ, USA) is a water-free, preservative-free, topical ophthalmic medication indicated for treatment of the signs and symptoms of DED [18, 19]. PFHO is thought to act as a functional stabilizer for the native tear film, forming a long-lasting anti-evaporative barrier at the air-tear interface [19]. PFHO is a single-component product consisting of 100% perfluorohexyloctane; it has low surface tension, which allows it to spread rapidly across the ocular surface upon instillation and between blinks, and may reduce friction at the ocular surface [18–20]. A rabbit pharmacokinetic study demonstrated that a single drop of PFHO was detectable in the tear film for at least 8 h [21]. The efficacy and safety of PFHO for reducing signs and symptoms of DED were demonstrated in two phase 3 randomized controlled trials [22, 23] and in a long-term, open-label extension study [24].

The distinctive physicochemical properties of PFHO (forming a long-lasting monolayer on the surface of the tear film) spurred inquiries about the potential for PFHO to interfere with preoperative biometry and keratometry measurements

and affect the accuracy of predicted refractive error. In a biometry study conducted in healthy volunteers, the lens power selection was stable in 75% of participants when comparing measurements taken before and 60 min after instillation of PFHO [25]. The present study was conducted to evaluate the effects of PFHO in patients with DED who were undergoing cataract surgery. We evaluated the impact of PFHO treatment prior to cataract surgery on the accuracy of preoperative biometry measurements and predicted refractive error. We hypothesized that preoperative treatment with PFHO would not interfere with the accuracy of preoperative biometry measurements. We also explored the effect of pre- and postoperative treatment with PFHO on DED signs and symptoms in patients with DED who underwent cataract surgery.

METHODS

Study Design and Patients

This phase 4, multicenter, open-label, single-arm study (NCT06346340), conducted from April 2024 through February 2025 at 11 sites in the United States, enrolled adult patients with DED who were scheduled to undergo routine, uncomplicated surgery (phacoemulsification with posterior chamber IOL implantation) for removal of a visually significant cataract in at least one eye. Patients must have had, in the investigator's opinion, the potential for postoperative pinhole Snellen best-corrected visual acuity of at least 20/200 in both eyes. Required indicators of DED presence at baseline included a tear film break-up time of ≤ 10 s, a total corneal fluorescein staining (CFS) score between ≥ 2 and ≤ 11 using the National Eye Institute scale, and an Ocular Surface Disease Index (OSDI) score of ≥ 23 .

Participants were excluded from the study if they had clinically significant ocular surface slit-lamp findings in the study eye or other ocular findings that could interfere with trial parameters, including history of eye trauma, Stevens–Johnson syndrome, or herpetic keratitis; active blepharitis or lid margin inflammation; DED secondary to scarring, irradiation, alkali

burns, cicatricial pemphigoid, or destruction of conjunctival goblet cells; abnormal lid anatomy causing incomplete lid closure; abnormal cornea shape (keratoconus); corneal epithelial defect or significant confluent staining or filaments; ocular or periocular rosacea; pterygium in either eye; active ocular allergies; or active ocular or systemic infection. Participants were prohibited from using specified ocular therapies (e.g., topical ocular steroids, prescription dry eye therapies) in the past 30 days, using any eye drops in the study eye or intranasal tear neurostimulator 24 h prior to baseline, and wearing contact lenses within the past month. Moreover, patients could not have undergone a procedure affecting the meibomian glands within the past 3 months or had intraocular surgery or ocular laser surgery on the study eye within the past 3 months or refractive surgery on the study eye within the past 2 years.

All patients who met the eligibility criteria instilled PFHO four times per day (QID) bilaterally for 30 days preoperatively (starting at visit 1/baseline; Fig. 1). Biometry and other study evaluations were repeated at visit 2, and patients were instructed to continue PFHO treatment

until the evening before cataract surgery. Thirty days after cataract surgery in the study eye, patients returned for a postoperative follow-up visit to finalize the manifest refraction. At visit 3, patients were instructed to resume bilateral QID PFHO treatment for another 30 days. If the study eye was the patient's second eye to undergo cataract surgery or if the patient required unilateral cataract surgery on the study eye only, the manifest refraction was performed at visit 3. If the study eye was the patient's first eye to undergo cataract surgery, the manifest refraction was performed at a standalone visit 30 days after cataract surgery in the study eye, and visit 3 occurred 30 days after cataract surgery on the patient's fellow eye. The last study evaluation was performed 60 days after cataract surgery (visit 4). Patients were instructed to instill PFHO at least 30 min and no longer than 4 h prior to the start of visits 2 and 4.

The study was conducted in accordance with the Helsinki Declaration of 1964, its later amendments, and the principles of Good Clinical Practice. The study protocol was approved by a central institutional review board (Advarra IRB;

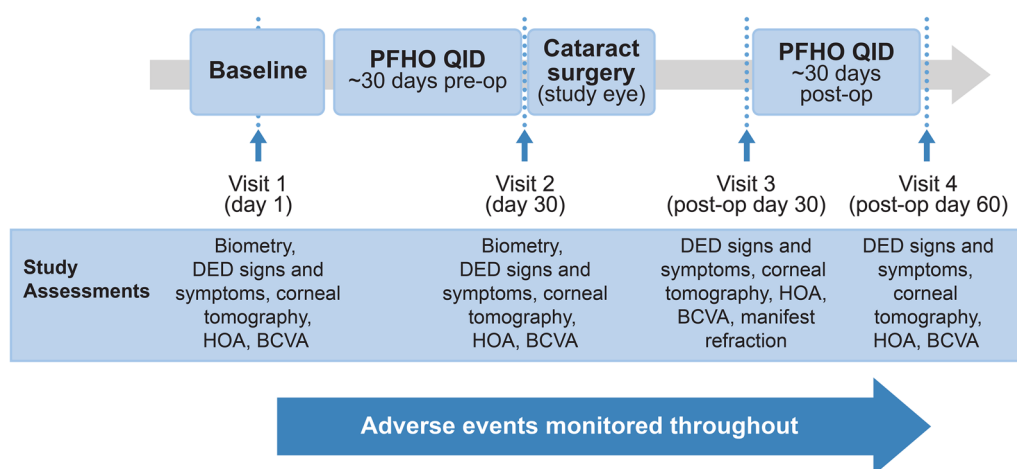


Fig. 1 Study design.* *For patients undergoing surgery on both eyes, cataract surgery on the second eye was performed approximately 7–14 days after surgery on the first eye. If the study eye was the patient's second eye to undergo cataract surgery or the patient required cataract surgery on the study eye only, then refractive outcome (manifest refraction) was determined at visit 3. If the study eye was

the patient's first eye to undergo cataract surgery, manifest refraction was determined at a standalone visit 30 days after cataract surgery in the study eye, and visit 3 occurred 30 days after cataract surgery on the patient's fellow eye. *BCVA* best-corrected visual acuity; *DED* dry eye disease; *HOA* higher-order aberrations; *PFHO* perfluorohexyloctane; *QID* four times daily

Columbia, MD, USA). All patients provided written informed consent.

Assessments

Efficacy was measured by predicted refractive error and IOL power calculation accuracy as well as changes in CFS, eye dryness score, OSDI, best-corrected visual acuity (Snellen), root mean square (RMS) higher-order aberrations (HOAs), and corneal tomography. Biometry for the calculation of predicted refractive error and IOL power calculation was performed (with an IOLMaster [Zeiss; Dublin, CA, USA], Lenstar [Haag-Streit; Germany], or Argos [Movu; a Santec Company, NJ, USA]) at baseline and visit 2 (after 30 days of preoperative PFHO treatment). The total CFS score was the sum of the inferior, superior, central, nasal, and temporal CFS scores, each graded on a scale of 0 to 3, with a maximum possible total CFS score of 15; higher scores indicate a greater extent of staining [26]. Eye dryness was measured on a visual analogue scale (VAS), wherein patients were asked to indicate their severity of ocular dryness from 0 (none) to 100 (worst severity possible). The OSDI is a 12-item questionnaire in which patients rate each item on a scale of 0 (none of the time) to 4 (all of the time) [27]. The total score represents a percentage of the possible 48 points and is reported on a scale of 0 to 100, with higher scores indicating greater ocular surface disease severity. The OSDI score is categorized as normal (range 0–12) or indicative of mild (13–22), moderate (23–32), or severe (33 and above) ocular surface disease [28]. The HOA and corneal tomography were assessed over the central 6.0 mm of the cornea. Safety and tolerability were assessed via continuous monitoring of treatment-emergent adverse events (TEAEs). For ocular adverse events, both eyes were assessed.

Data Analysis

The primary efficacy endpoint was the mean difference in absolute deviations between the manifest refraction spherical equivalent and the predicted refractive error in the study eye. The two deviations were calculated by subtracting the predicted refractive error determined

(1) at baseline (visit 1) and (2) after 30 days of preoperative PFHO treatment (visit 2) from the manifest refraction spherical equivalent measured at 30 days after cataract surgery (visit 3). Exploratory efficacy endpoints included percentage of patients within a ± 0.50 D deviation between calculated IOL power and correct IOL power (the correct IOL power is determined after finalization of postoperative manifest refraction and represents the IOL power that would have resulted in 0.00 D deviation from the desired manifest refraction and actual manifest refraction; study eye), percentage of patients reaching predicted refraction (within 0.25 D, 0.5 D, and 0.75 D; study eye), mean change from baseline in total and central CFS (study eye), eye dryness, and OSDI at visits 2 and 4, mean change from baseline RMS HOA in the central 6.0 mm of the cornea (study eye), and stability of postoperative RMS HOAs and postoperative corneal tomography in the central 6.0 mm of the cornea (study eye) based on calculations at visit 2 and visit 4.

A sample size calculation determined that enrollment of 77 patients would yield 80% power to detect an effect size of 0.325 standard deviations (SD) for the primary endpoint using a paired *t*-test with a 5% two-sided significance level. To accommodate the potential for up to 23% missing data, target enrollment was set at approximately 100 patients. Summary statistics (e.g., percentages, means, SDs) were calculated for study variables. A two-sided paired *t*-test with a significance threshold of less than 0.05 was used for statistical comparisons. All efficacy analyses utilized the full analysis set. No imputation was performed for missing data. Statistical analyses were performed using SAS® software version 9.4 or higher (SAS Institute Inc, Cary, NC, USA).

RESULTS

A total of 103 patients were screened for enrollment, and 97 patients met the inclusion criteria and received study treatment. Eighty-five patients (82.5%) completed the study. Reasons for study discontinuation included patient withdrawal ($n=6$), TEAE not related to treatment

($n=3$), treatment-related TEAE ($n=2$), and visit 2 outside of the study window ($n=1$). Data were available for 97 patients at visit 1 (baseline), 91 patients at visit 2 (after 30 days of preoperative PFHO treatment), 86 patients at visit 3 (30 days post-cataract surgery in the study eye; no PFHO treatment), and 85 patients at visit 4 (60 days post-cataract surgery, following 30 days of postoperative PFHO treatment). Self-reported compliance with PFHO was $96.9\% \pm 10.7\%$ during the preoperative treatment period and $94.6\% \pm 17.0\%$ during the postoperative treatment period.

Patients were primarily female (75.3%) and white (80.4%); the mean age was 68.6 ± 6.8 years (Table 1). Baseline measures of DED signs and symptoms, including CFS, eye dryness score, and OSDI, indicated a study population with primarily moderate DED, as is regularly seen in clinical settings, although patients across the range of DED severity (mild to severe) were represented [11, 26, 27]. Mean baseline RMS HOA in the central 6.0 mm optic zone (0.66 ± 0.21) was consistent with previous observations among patients with cataracts [29]. Most patients (68.0%) had best-corrected visual acuity of 20/32 or better.

Refractive Accuracy

The primary endpoint was the difference in absolute deviations between manifest refraction spherical equivalent and predicted refractive error as determined via biometry after 30 days of preoperative PFHO treatment (visit 2; 0.278 ± 0.205 D) versus baseline (visit 1; 0.305 ± 0.217 D). The mean difference was -0.027 ± 0.167 D, which was not statistically significant ($p=0.1385$), indicating that refractive outcomes were stable and not affected by PFHO treatment. The difference between the baseline predicted refractive error and the predicted refractive error post-PFHO treatment (as determined by the biometry assessments at visit 1 and visit 2) was within ± 0.3 D for 94.2% of study eyes. Prior to PFHO treatment, 80.2% of patients had a manifest refraction spherical equivalent within ± 0.50 D of predicted, and 95.3% were within ± 0.75 D. After PFHO treatment, 82.6% of patients were within ± 0.50 D of predicted

Table 1 Patient demographics and baseline characteristics

Parameter	Patients ($n=97$)
Age, years, mean $\pm$ SD	68.6 ± 6.8
Sex, n (%)	
Male	24 (24.7)
Female	73 (75.3)
Race, n (%)	
White	78 (80.4)
Black/African American	7 (7.2)
Asian	6 (6.2)
Other/multiracial	6 (6.2)
Ethnicity, n (%)	
Hispanic or Latino	21 (21.6)
Not Hispanic or Latino	76 (78.4)
Study eye, n (%)	
Right eye (OD)	53 (54.6)
Left eye (OS)	44 (45.4)
Central CFS score, mean $\pm$ SD	0.9 ± 0.8
Total CFS score, mean $\pm$ SD	5.0 ± 2.7
Eye dryness (VAS score), mean $\pm$ SD	62.3 ± 19.0
OSDI overall score, mean $\pm$ SD	51.9 ± 16.9
RMS HOAs of central 6.0 mm of cornea, μm , mean $\pm$ SD	0.66 ± 0.21
Best-corrected visual acuity (Snellen), n (%)	
20/16 or better	2 (2.1)
20/20 or better	26 (26.8)
20/25 or better	45 (46.4)
20/32 or better	66 (68.0)
20/40 or better	80 (82.5)
20/80 or better	93 (95.9)
20/200 or better	97 (100.0)

CFS corneal fluorescein staining; HOA higher-order aberrations; OSDI ocular surface disease index; RMS root mean square; VAS visual analogue scale

and 97.7% were within ± 0.75 D (Fig. 2). In an exploratory efficacy analysis, the proportion of patients who were within a ± 0.50 D deviation between calculated IOL power and correct IOL power was greater post-PFHO treatment (visit 2; 83.7%) than pre-PFHO (visit 1; 72.1%).

Signs and Symptoms of DED

Thirty days of preoperative PFHO treatment resulted in significant reductions from baseline in total and central CFS scores ($p < 0.0001$; Fig. 3). At visit 2, the mean total CFS score (2.1 ± 2.2) was approaching the lower limit for inclusion (2.0) in this study and had improved by -2.9 ± 2.5 from baseline ($p < 0.0001$). At visit 4, the mean total CFS score (1.3 ± 1.8) was below the lower limit for inclusion in this study, a 74% reduction from the baseline value (5.0 ± 2.7). Postoperative PFHO treatment further reduced total CFS (-0.5 ± 2.2 from visit 3 to visit 4; $p = 0.0509$). The proportion of patients with a central CSF score of 0 increased from 33.0% at baseline to 75.8% after 30 days of preoperative PFHO and 84.7% after 30 days of postoperative PFHO.

Preoperative PFHO treatment significantly reduced the mean eye dryness score

(-25.2 ± 21.9 from baseline to visit 2; $p < 0.0001$; Fig. 3), and the mean eye dryness score further decreased during postoperative PFHO treatment (-9.3 ± 22.0 from visit 3 to visit 4; $p = 0.0002$). Eye dryness score at visit 4 (25.9 ± 23.3) was less than half of the baseline value (62.3 ± 19.0).

Treatment with PFHO significantly reduced the OSDI score from baseline to visit 2 by 21.4 ± 16.8 ($p < 0.0001$; Fig. 3), and further improvement was observed during successive study visits ($p < 0.05$). Postoperative PFHO treatment decreased the mean OSDI score by an additional 2.4 ± 9.8 from visit 3 to visit 4 ($p = 0.0257$). Overall, the mean OSDI score was reduced by 39.4 ± 18.2 ($p < 0.0001$) from baseline to visit 4. The severity of DED as determined by the mean OSDI score improved from severe (51.9 ± 16.9) at baseline to moderate (30.1 ± 17.6) at visit 2 and from mild (14.4 ± 11.2) at visit 3 to normal (11.9 ± 10.9) at visit 4.

Other Exploratory Endpoints

The majority of patients (74.5%) experienced improved (38.9%) or stable (35.6%) RMS HOAs after 30 days of preoperative PFHO (Fig. 4). These findings were maintained throughout the study. Mean RMS HOA did not change significantly from baseline at any point, indicating the stability of the outcome. Findings from corneal tomography indicated stability across all visits.

The proportion of patients with best-corrected visual acuity of 20/20 or better was increased after 30 days of postoperative PFHO treatment, from 86.0% at visit 3 to 91.8% at visit 4 (Fig. 5). Slit-lamp examination findings were mostly unremarkable, as two or fewer patients per category were reported to have clinically significant findings for the eyelids, cornea, conjunctiva, anterior chamber, iris, and lens at visit 4.

Safety

Ten patients experienced 14 ocular TEAEs, 12 of which were considered by the investigator to be unrelated to study treatment. The two

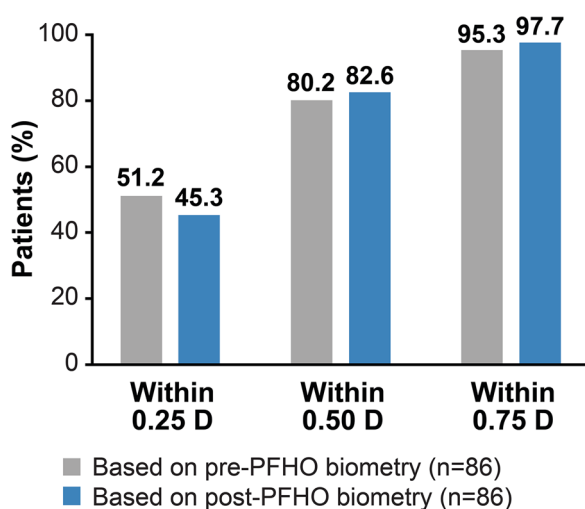


Fig. 2 Predictive accuracy of preoperative biometry performed before and after PFHO treatment. *PFHO*, perfluorohexyloctane

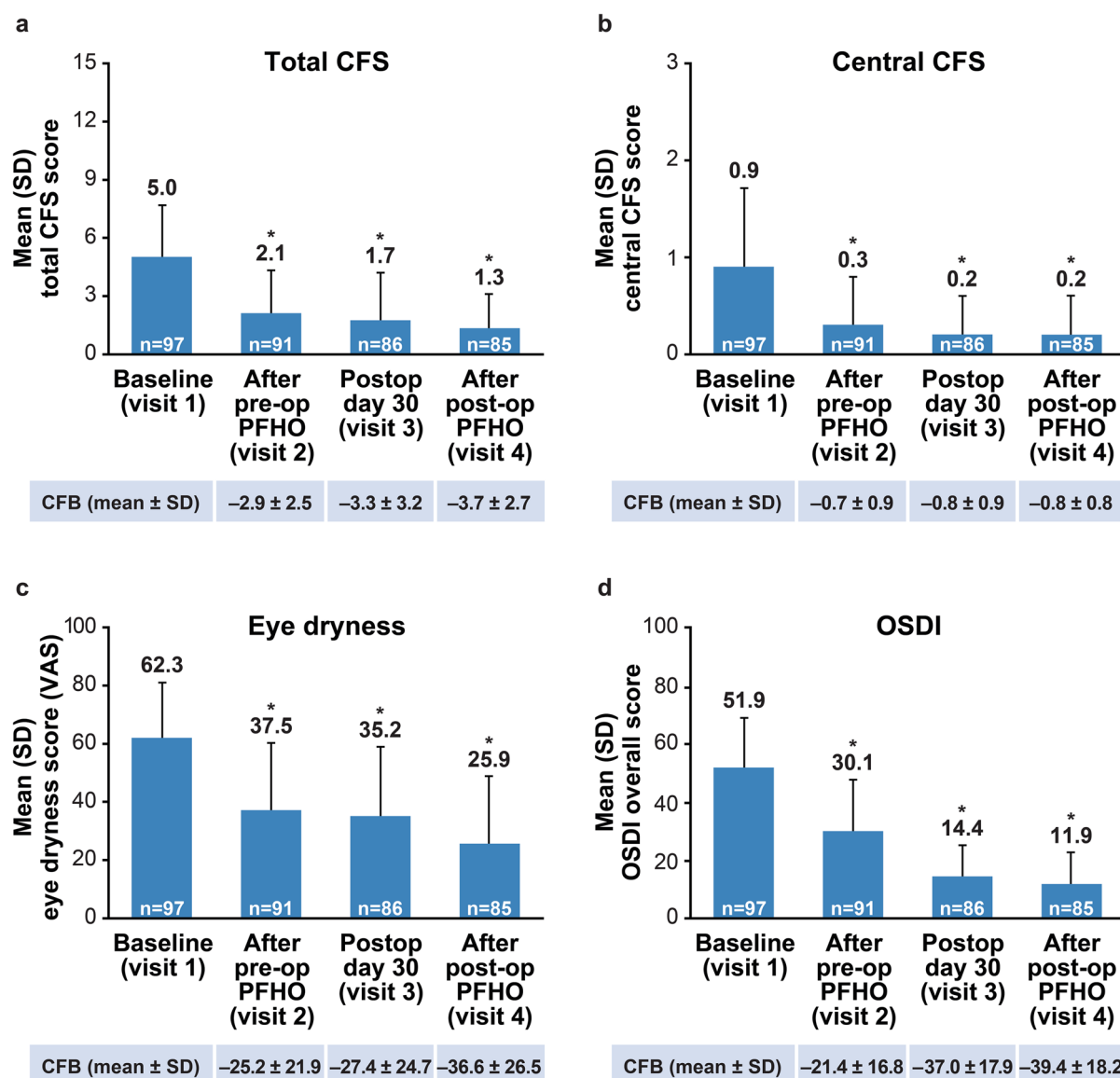


Fig. 3 DED signs and symptoms at each study visit. **a** Total CFS score, **b** central CFS score, **c** eye dryness score (VAS), and **d** OSDI overall score. * $p < 0.0001$ versus baseline. CFB change from baseline; CFS corneal fluorescein

staining; DED dry eye disease; OSDI Ocular Surface Disease Index; PFHO perfluorohexyloctane; VAS visual analogue scale

events considered related to treatment, eye pruritus and noninfectious conjunctivitis, were mild in intensity. For both events, PFHO was withdrawn, and the patient discontinued the study. Two serious TEAEs were reported during the study: pneumonia and severe iridocyclitis, both of which were judged to be not related to study treatment.

DISCUSSION

This phase 4, multicenter, open-label, single-arm study demonstrated that treatment with PFHO for 30 days prior to cataract surgery did not affect the accuracy of preoperative biometry and keratometry measurements or the

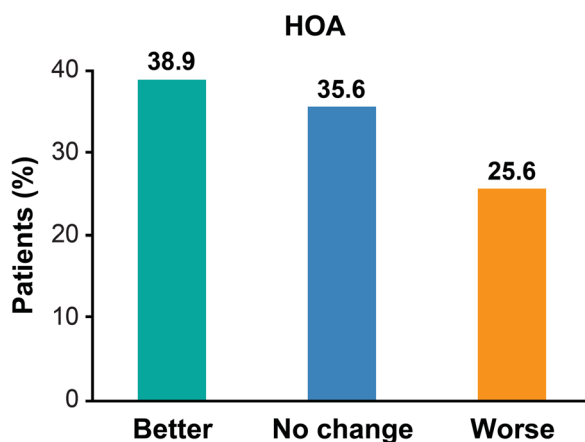


Fig. 4 Change in corneal higher-order aberrations after 30 days of preoperative PFHO treatment ($n=90$). The outcomes for patients with no change, decrease, or increase in RMS HOA value from baseline were categorized as stable, better, or worse, respectively. *HOA* higher-order aberrations; *PFHO* perfluorohexyloctane

predicted refractive error in patients with DED, notwithstanding PFHO's physicochemical properties of forming a long-lasting anti-evaporative monolayer on the tear film surface. Moreover, improvements were observed in the accuracy of IOL power determination after preoperative PFHO treatment. Additionally, patients experienced significant reductions in signs and symptoms of DED during preoperative PFHO treatment, which were maintained or further

enhanced through the postoperative PFHO treatment period. These findings support a role for PFHO in the pre- and postoperative management of DED in patients undergoing cataract surgery.

Though not statistically significant, the difference in absolute deviations between manifest refraction spherical equivalent and predicted refractive error, as determined via biometry after preoperative PFHO treatment versus baseline, showed a positive trend. Because postoperative refractions are measured in increments of 0.25 D and rely on subjective inputs, and IOL power calculations are produced in steps of 0.50 D, it is possible that a larger or differently powered study may have detected a statistically significant improvement in the accuracy of preoperative biometry measurements with PFHO treatment in patients with DED.

Consistent with prior PFHO clinical trials [22–24], treatment with PFHO significantly improved signs and symptoms of DED and was well tolerated in this population of patients with comorbid DED and cataract. The magnitude of improvement in dry eye signs and symptoms is notable in this population, as the response to a different water-free dry eye treatment was previously shown to be less robust in patients with cataract than those without cataract [30]. Our study also demonstrated that, in addition to the continued amelioration of dry eye signs and symptoms after cataract surgery,

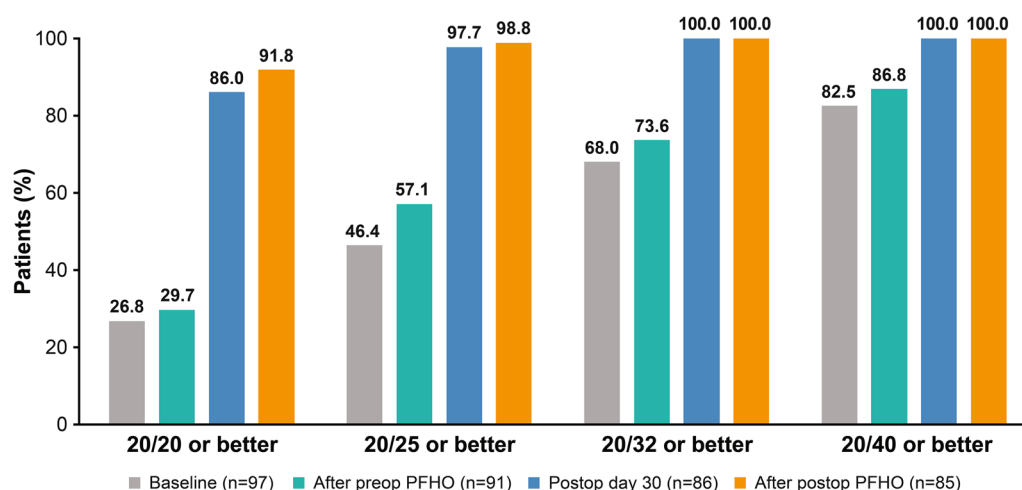


Fig. 5 Best-corrected visual acuity categorization at each study visit. *PFHO* perfluorohexyloctane

postoperative PFHO treatment improved visual outcomes beyond what was achieved with cataract surgery alone. Data suggest that most patients experience signs and/or symptoms indicative of dry eye after undergoing cataract surgery [31]. Indeed, the presence of DED is a key contributor to patient dissatisfaction and visual discomfort after cataract surgery [17, 32]. Previous clinical evidence has demonstrated that initiating treatment prior to cataract surgery prevents iatrogenic DED in patients with a normal ocular surface or who have mild DED [33]. Our study expands on this finding by establishing a postoperative benefit of PFHO treatment after cataract surgery for patients with pre-existing DED ranging from mild to severe.

This study has several strengths, including the involvement of multiple study centers, the evaluation of treatment both before and after cataract surgery, and the assessment of measures that reflect both surgical outcomes and signs and symptoms of DED. In addition, compliance with treatment was high during both the pre- and postoperative periods.

Limitations of the study include the lack of an untreated control arm, exclusion of certain surgical techniques (i.e., limbal relaxing incisions) and IOL types (i.e., IC-8 Aphera, light-adjustable lens), the potential inclusion of patients who had previously undergone refractory surgery and were at least 2 years post-surgery, a modest sample size, and a limited postoperative treatment period. Future studies could explore lengthened and/or standalone postoperative DED treatment periods to better understand the potential long-term positive impacts on patient outcomes.

CONCLUSION

The results of this study indicate that preoperative treatment of DED with PFHO has no impact on the predictability of preoperative measurements or postoperative refractive accuracy. Though not statistically significant, 30 days of preoperative PFHO treatment showed a positive trend towards improved predicted refractive

error. Additionally, the results support the benefit of PFHO treatment before and after cataract surgery to improve CFS score and diminish patient-reported DED symptoms. Further, postoperative DED treatment increased the proportion of patients with best-corrected visual acuity of 20/20 or better. Inadequate visual quality and DED symptoms are known sources of patient dissatisfaction after cataract surgery. Clinicians should be aware of the impact of DED on the patient experience, evaluate patients prior to cataract surgery for the presence of signs and symptoms of DED, and manage the condition appropriately to optimize postsurgical outcomes.

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Data Availability. The datasets generated during and/or analyzed during the current study

are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. John A. Hovanesian reports serving as a consultant to Bausch+Lomb. Eva Liang reports serving as a consultant to Bausch+Lomb. Neel R. Desai reports serving as a speaker/consultant for Alcon, Bausch+Lomb, Biotissue, Dompé, E-Swin, Glaukos, Johnson and Johnson, LayerBio, LensAR, RxSight, Sight Sciences, and Spyglass; and being a shareholder of Alcon, Biotissue, Glaukos, LayerBio, and Sight Sciences. Gregg J. Berdy reports serving as a consultant or as a member of advisory boards for Alcon Laboratories, Inc, Allergan, Avellino Labs, Bausch+Lomb, Dompé, Novartis (Alcon Pharmaceuticals), Sun Pharma, and TearScience; and receiving honoraria for lecturing as part of the speaker's bureau for Alcon Laboratories, Allergan, Avellino Labs, Bausch+Lomb, Dompé, Novartis (Alcon Pharmaceuticals), and Sun Pharma. Kayla Karpuk reports serving as a consultant for Tarsus. Justin Schweitzer reports serving as a consultant or speaker for Alcon, Allergan/AbbVie, Bausch+Lomb, Bruder, Dompé, Glaukos, Iveric Bio, LKC Technologies, MediPrint Ophthalmics, Ocuphire Pharma, Inc, Reichert Technologies, ScienceBased Health, Sight Sciences, Sun Pharmaceutical Industries Ltd, Tarsus Pharmaceuticals, Théa, Topcon Healthcare, Trukera Medical, Visus Therapeutics, and Zeiss; and serving as Chief Medical Editor for Modern Optometry. Adam Alexander and Jason L. Vittitow are employees of Bausch+Lomb. John Berdahl reports serving as a consultant/advisor for AbbVie, Aerpio, ALJ Health, Alcon, Aldeyra, Allergan, Aquea Health, Aurea Medical, Aurion Biotech, Avelinno, Balance Ophthalmics, Bausch+Lomb, Belkin, Centricity Vision, CorneaGen, Dakota Lions Eye Bank, Elios Vision, Equinox, Expert Opinion, Glaukos, Gore, Greenman, Horizon Surgical, Iacta Pharmaceuticals, Ilevro, Imprimis, Interfeen, iRenix, Iveric Bio, Johnson and Johnson, Kala, Kedalion, MELT Pharmaceuticals, MicrOptx, New World Medical, Ocular Surgical Data, Ocular Therapeutix, Omega Ophthalmic, Orasis, Oyster Point, RxSight, Santen,

Sight Sciences, Surface, Tarsus, TavoBio, Tear Clear, Tissue Gen, Vance Thompson Vision, Versea Biologics, Vertex Ventures, ViaLase, Visionary Ventures, Visus, Vittamed, and Zeiss; serving as a lecturer for AbbVie, Alcon, Glaukos; having equity ownership or stock options in Aurion Biotech, Balance Ophthalmics, CorneaGen, Equinox, Expert Opinion, Glaukos, Interfeen, LayerBio, Ocular Surgical Data, Omega Ophthalmic, Surface, True North CRO, Vance Thompson Vision, Verana Health, and Zeiss; and receiving royalties from Imprimis. Jason Bacharach reports being a consultant and conducting research for Bausch+Lomb.

Ethical Approval. The study was conducted in accordance with the Helsinki Declaration of 1964, its later amendments, and the principles of Good Clinical Practice. The study protocol was approved by a central institutional review board (Advarra IRB; Columbia, MD, USA).

Informed consent. All patients provided written informed consent.

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