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Original Article

Treatment of dry eyes with lifitegrast 5% before cataract surgery: A prospective trial

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Abstract

Objective: The objective of the study was to evaluate the impact of dry eye treatment on intraocular lens (IOL) biometry measurements and postoperative refractive outcome.

Design: This study involves a prospective interventional study.

Participants: Consecutive patients with dry eye disease undergoing cataract surgery were included in the study.

Materials and Methods: All participants underwent a comprehensive dry eye assessment including the ocular surface disease index (OSDI) questionnaire, Schirmer's test without anesthesia, corneal fluorescein staining, and conjunctival lissamine green staining. Optical biometry was performed using swept-source optical coherence tomography (IOL Master® 700, Zeiss), and corneal aberrometry was measured using a scanning-slit aberrometer (OPD SCAN III, Nidek). Diagnosis of dry eye was made according to Dry Eye Workshop II. Patients received 6 weeks of treatment of lifitegrast 5% and preservative-free artificial tear eye drops and had repeat testing at the end of 6 weeks. The change in subjective and objective dry eye tests and biometry measurements and the difference in target and postoperative refraction before and after treatment were compared.

Results: Forty eyes of 21 patients were included in the study. Subjectively, OSDI improved from 26.35 ± 6.24 at baseline to 20.97 ± 8.41 after treatment ($P = 0.03$). Objectively, corneal staining improved from 1.42 ± 1.78 at baseline to 0.39 ± 0.67 after treatment ($P = 0.006$). No changes were observed in Schirmer's test without anesthesia, conjunctival staining, or corneal aberrometry ($P > 0.05$). Repeated biometry after dry eye treatment showed a change in IOL power difference ≥0.5 diopters in 50% (20) of eyes. Mean absolute error was within 0.25D in 87.5% (35) of eyes after treatment compared to 67.5% at baseline ($P = 0.05$).

Conclusion: Dry eye treatment leads to subjective symptom improvement and changes in IOL power calculations and postoperative refractive outcomes. Assessing and treating patients for dry eyes before cataract surgery is important in maximizing refractive outcomes.

Keywords: Biometry, cataract surgery, dry eye

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INTRODUCTION

Dry eye is one of the most prevalent ocular surface diseases worldwide; it is a multifactorial disease of tears and the ocular surface, resulting in symptoms of discomfort, tear film instability, and increased ocular surface inflammation.[1] Cataract surgery has been shown to exacerbate dry eye disease (DED) postoperatively. Several mechanisms have been proposed, including transection of corneal nerves, toxicity from topical eye drops, exposure to microscope illumination intraoperatively, and increased inflammatory mediators.[2] Previous studies have also shown a significant decrease in goblet cell density after surgery, which is important in maintaining the tear film.[3,4]

The prevalence of dry eye has been estimated to vary between 7% and 33% of the population and is probably more common in cataract surgery patients given risk factors such as advanced age and medications.[5] A recent study in the United States found that 77% of patients scheduled to undergo cataract surgery had objective findings of dry eye, although only 30% of them were symptomatic.[6] It has been shown that dry eye symptoms correlate strongly with patient satisfaction postoperatively, more so than objective clinical measures of visual acuity.[7] In a sample of 74 eyes that were dissatisfied after cataract surgery, 35% of patient dissatisfaction was due to dry eye symptoms.[8] In addition, poor ocular surface also affects preoperative planning including intraocular lens (IOL) power calculation, keratometry, and topography measurements.[9] An abnormal tear film can lead to imprecise IOL power calculations due to inaccurate preoperative biometry measurements. In fact, it has been found that eyes with DED have greater variability in keratometry readings, and IOL power calculations can vary as much as 0.5 D, which can impact visual outcomes, especially in toric IOLs.[10]

Treatment for DED included artificial tears, cyclosporine, corticosteroids, and more recently, lifitegrast 5%. Lifitegrast is an integrin antagonist that reduces corneal inflammation by decreasing T-cell inflammatory response and the release of inflammatory cytokines.[11] A paucity of studies has assessed the impact of DED treatment on ocular biometry measurements. Nevertheless, improved accuracy of IOL power calculations after the installation of artificial tears and DED treatment have been reported.[12-15] Therefore, the aim of the current study was to quantify the impact of dry eye treatment involving lifitegrast 5% and preservative-free artificial tears on IOL biometry measurements, higher-order aberrations (HOAs), and postoperative visual outcome.

MATERIALS AND METHODS

This prospective single-center study recruited patients with DED who were undergoing cataract surgery at the Toronto Western Hospital or Kensington Eye Institute, Toronto, Canada, from July 2019 to December 2020. Ethics approval was obtained from the University Health Network and the University of Toronto Research Ethics Board and adhered to the tenets of the Declaration of Helsinki. Signed informed consent was obtained from all patients following an explanation of the risks and benefits of the study.

Study participants

All eligible patients were first screened for DED according to the Dry Eye Workshop II diagnosis criteria.[16] Participants had to have an ocular surface disease index (OSDI) score ≥13 and one of the following: (1) noninvasive tear break-up time (NiaBUT) shorter than 10 s, (2) tear osmolarity >308 mOsms/L or interocular difference >8 mOsms/L, and (3) ocular surface staining: >5 corneal spots or >9 conjunctival spots. The severity of dry eye was graded according to OSDI, with mild (13–22), moderate (23–32), and severe (≥33). Exclusion criteria included any previous history of refractive surgery, intraocular surgery within the past 3 months, previous corneal or ocular trauma, previous keratoplasty, current use of topical antibiotics, glaucoma, anti-inflammatory or steroid drops, and any ocular comorbidities including uveitis, herpes simplex/zoster infection, glaucoma, corneal dystrophy, and other ocular surface disease besides dry eye. Patients who were already on treatment with cyclosporine 0.05% or lifitegrast 5% were excluded from the study.

Ocular Surface Disease Index questionnaire

The OSDI questionnaire is a 12-item questionnaire to assess symptoms of DED and their impact on quality of life. Each item is graded on a scale of 0–4 for a total score of 100. Higher scores represent greater symptoms.[17]

Tear film osmolarity

Tear film osmolarity was evaluated in both eyes using a lab-on-a-chip system (TearLab Corp, San Diego, CA). A tear sample was collected from the lower temporal canthus tear film meniscus by passive capillary action using a disposable chip. Analysis was performed using maximal tear film osmolarity reading. Values >308 mOsm/L were considered abnormal.

Corneal and conjunctival staining pattern

Corneal and conjunctival staining were both graded using the standard National Eye Institute/Industry (NEI) scale.[18] Corneal fluorescein staining (CFS) was evaluated

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using cobalt blue illumination at the slit-lamp for a maximum possible CFS score of 15. Using the NEI scale, the cornea is divided into five sections and assigned a score from 0 (absent) to 3 (severe) based on the amount, size, and confluence of punctate keratitis. Lissamine green conjunctival staining was evaluated at the slit-lamp 2.5–3 min after instilling 1 drop of 1% sodium lissamine green compounding eye drops into the lower fornix of both eyes. Using the NEI scale, the conjunctiva is divided into six sections and assigned a score from 0 (absent) to 3 (severe) for a maximum score of 18.

Tear film analysis

Tear film quantity and quality were measured using the OCULUS Keratograph device (Oculus, Germany), which measures noninvasive first break-up time and noninvasive average tear film break-up time (NiBUT) in an objective, automated, and noninvasive way.[19] For measuring the NiTBUT, the distortion of the Placido disk mires projected onto the cornea in different segments of the cornea is analyzed.

Corneal aberrometry

Corneal aberrometry was analyzed using the OPD-Scan III (NIdek, Japan), a five-in-one device with topography, keratometry, pupillometry, and wavefront aberrometry functions. Wavefront aberrations are calculated by retinoscopy, and the resulting refractive power map can be separated into total ocular, corneal, and internal components. Total HOAs in root mean squares, and spherical aberration (SA), coma, and trefoil were analyzed.

Optical biometry

Optical biometry was measured using a swept-source optical coherence tomography (IOLMaster® 700, Carl Zeiss, Germany)-based device. Keratometry readings and IOL power calculations using the Barrett Universal II formula software built into the machine were analyzed before and after treatment.

Treatment protocol

All patients were treated with sodium hyaluronate preservative-free artificial tears 4 times a day (CandorVision, Montreal, Canada) and lifitegrast 5% (Xiidra, Novartis./Bausch & Lomb) twice daily. After 6 weeks, dry eye assessment, corneal aberrometry, and optical biometry measurements were repeated in the same order. At the follow-up visit, participants were asked about their compliance as well as any side effects experienced with the eye drops. Participants were encouraged to continue treatment until 1 month after cataract surgery, at which point manifest refraction was obtained.

Intraocular lenses

The Acrysof SN60WF (Alcon Laboratories, Inc.) is a single-piece aspheric hydrophobic acrylic IOL with an overall diameter of 13 mm, an optical zone diameter of 6 mm, and a negative SA of −0.2 μm in the anterior surface. The available power ranges from 6 to +30.00D in 0.50D steps. A constant = 118.7.

Statistical analysis

Data analysis was performed using Microsoft Excel. The demographics of the study population were examined through descriptive statistics. The normality of the data was checked using Shapiro–Wilk test. Changes in dry eye metrics were compared before and after treatment using paired *t*-test, Wilcoxon–signed rank test, and McNemar test as appropriate. Fisher's exact test was used to compare the characteristics of the two groups. The prediction accuracy of optical biometry was determined using mean absolute error to identify % of eyes within 0.25 diopters (D) of the intended target and median and mean numerical error to assess the difference between target spherical equivalent (SE) predicted by biometry and measured postoperative SE. Statistical significance was defined as $P < 0.05$.

RESULTS

Overall, 40 eyes of 21 patients were enrolled in the study. The mean age was 72.73 ± 8.71 years old, with a mean distance corrected visual acuity (DCVA) of 0.43 ± 0.38 LogMar at baseline. All patients completed follow-up until 1 month postoperatively and were included in the analysis [Table 1].

Dry eye disease assessment

Six weeks after treatment, statistically significant improvement was observed in mean OSDI from 26.35 ± 6.24 to 20.97 ± 8.41 ($P = 0.03$) and corneal staining from 1.421 ± 1.78 to 0.39 ± 0.67 ($P = 0.006$).

Table 1: Demographics and dry eye assessment testing at baseline compared to 6 weeks after treatment with lifitegrast 5% associated with preservative-free artificial tears

Parameters	Baseline testing	6 weeks after treatment	*P*
Age (years)	72.73±8.71	-	-
DCVA (LogMAR)	0.43±0.38	0.45±0.37	0.82
Tear osmolarity (mOsm/L)	318.15±16.05	318.08±9.57	0.63
OSDI	26.35±6.24	20.97±8.41	0.03
NiaBUT	8.91±6.37	10.00±6.19	0.40
Corneal staining	1.421±1.78	0.39±0.67	0.006
Conjunctival staining	2.65±3.90	2.28±3.47	0.36

DCVA: Distance corrected visual acuity, OSDI: Ocular surface disease index, NiaBUT: Noninvasive average break-up time

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In fact, the percentage of corneal staining improved from 62.5% (25 eyes) at baseline to 30.0% (12 eyes) after treatment ($P = 0.01$). Although not statistically significant, a trend toward improved NiaBUT was observed (8.91 ± 6.37 and 10.00 ± 6.19; $P = 0.40$). No statistically significant differences from baseline were observed in conjunctival staining (2.65 ± 3.90 and 2.28 ± 3.47; $P = 0.36$) and tear osmolarity (318.15 ± 16.05, 318.08 ± 9.57; $P = 0.63$) [Table 1]. At baseline, no statistically significant difference was found in the conjunctival staining score compared to the corneal staining score (1.42 ± 1.78 vs. 2.65 ± 3.90, $P = 0.1$). However, after treatment, the conjunctival staining score was statistically significantly higher than the corneal staining score (0.39 ± 0.67 vs. 2.28 ± 3.47, $P = 0.03$).

Corneal aberrometry

Compared to baseline, total HOAs improved after treatment in 16 eyes (40%) by a mean of 0.43 ± 0.56 μ ($P = 0.04$), remained the same in 5 (12%), and increased in 13 (33%) by a mean of 0.36 ± 0.24 ($P = 0.07$). No statistically significant differences ($P > 0.05$) were observed after treatment in SA (0.16 ± 0.18, 0.15 ± 0.203), coma (0.28 ± 0.29, 0.30 ± 0.36), and trefoil (0.47 ± 0.40, 0.41 ± 0.38) [Figure 1].

Keratometry

Mean flat keratometry at baseline was 43.64 ± 1.12 diopters (D) compared to 43.65 ± 1.16D after treatment ($P = 0.97$). Mean steep keratometry was 44.29 ± 1.04D compared to 44.33 ± 1.13D after treatment ($P = 0.89$). The average corneal cylinder was 0.65 ± 0.29D at baseline compared to 0.64 ± 0.38 after treatment ($P = 0.91$). The mean absolute difference in flat keratometry was 0.16 ± 0.17D and 0.16 ± 0.18D in steep keratometry. In flat keratometry, 27 eyes (67.5%) had a difference <0.25D, whereas 12 (30.0%) had a difference between 0.25 and 0.5D. The difference in steep keratometry was <0.25D in 26 eyes (65.0%), within 0.25–0.5D in 12 eyes (30.0%), and >0.5D in 2 eyes (5.0%). Twenty-two eyes (55.0%) had a difference in cylinder <0.25D, 12 (30.0%) between 0.25D and 0.5D, and 6 (15.0%) >0.50D.

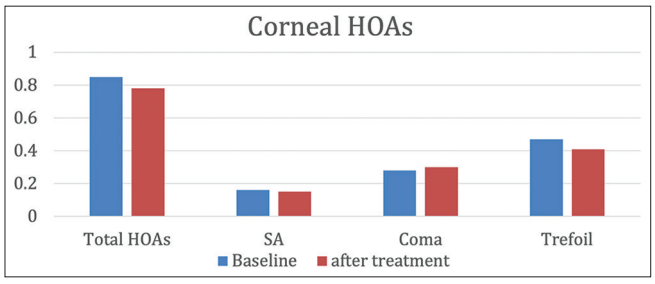

Figure 1: Corneal higher-order aberrations at baseline and after treatment with lifitegrast 5%. No statistically significant differences were observed ($P > 0.05$). HOAs: Higher-order aberrations, SA: Spherical aberration

Optical biometry and postoperative refraction

Compared to the baseline, the calculated IOL power differed ≥0.5 D in 20 eyes (50.0%) after treatment. Postoperative DCVA was 0.04 ± 0.07 LogMar. The mean numerical prediction error was higher at baseline compared to after treatment (0.12 ± 0.21, −0.03 ± 0.18, $P = 0.02$). The percentage of eyes with predicted SE refraction within 0.25D as calculated by the Barrett Universal II formula was higher when using biometric calculations at 6 weeks after treatment compared to baseline (87.5% vs. 67.5%, respectively, $P = 0.05$).

DISCUSSION

Optimizing ocular surfaces has been recognized to be an important factor in improving refractive outcomes. The results show that treatment of DED before cataract surgery led to changes in IOL power selection in 50% of eyes. Compared to baseline, the accuracy of biometry after treatment was within 0.25D for 87.5% versus 67.5% of eyes, respectively. This corroborates the importance of treating ocular surface before cataract surgery.

There has been little published regarding the effect of dry eye treatment on biometry.[13] Compared to the previous study, we used comprehensive testing of dry eye and the standard definition of DED according to DEWS II. We also included patients undergoing surgery with monofocal lenses only to limit the effect on refraction and visual function from premium lenses. However, the results are also relevant for multifocal or toric lenses, as they require greater precision in biometry. We found that a short course of treatment with preservative-free artificial tears and lifitegrast 5% was sufficient in improving the ocular surface. Nevertheless, longer treatment may be beneficial.

A previous study has reported on the repeatability of keratometry and axial length values in eyes with DED compared to normal eyes.[20] It was observed that DED eyes have lower repeatability when measuring steep axis and axial length, which can lead to changes in IOL power calculations. In fact, corneal staining was observed to impact the repeatability of axial length. In our study, we observed statistically significant improvement in corneal staining score after treatment with lifitegrast 5%, which may be one of the reasons for improved ocular biometry results posttreatment, with a higher percentage of eyes within 0.25D of error. Moreover, one explanation for

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the absence of statistically significant differences in keratometry reading observed in this study could be, in fact, the higher variability of keratometry measurements in DED eyes. Furthermore, patients are usually instructed to blink immediately before measurements, which improves ocular surface lubrication and, therefore, positively impacts keratometry measurements.

Few studies that reported increased HOAs in patients with DED, DED attributed it partially from the presence of superficial punctate keratitis (SPK) above the optical zone.[13] We observed improved HOAs in 40% of our patients, which may correlate to improvement in corneal staining. The absence of SPK and improvement in tear film quality reduces scatter and improves the quality of vision, which is directly affected by HOAs.[21]

The strengths of this study include its prospective nature, comprehensive assessment of DED, and use of patients before treatment as their own control. All our patients concluded the study and returned for their 1-month postoperative assessment. In this study, we sought to mimic a routine clinical setting, which is the reason we included artificial tears in the treatment. Although we included both lifitegrast and artificial tears in the treatment, it is possible that artificial tears alone may be sufficient in treating dry eyes and improving IOL calculations. Limitations include the absence of a placebo arm for control, so it is possible that there may be variability in measurements at different visits. However, the improvement in multiple dry eye parameters and refractive outcomes suggests that the differences in outcome are likely due to intervention rather than variability in measurements. Furthermore, it remains unclear, the long-term effect of the improvement in DED assessment and HOAs with lifitegrast 5%. Should patients have received premium IOLs, including presbyopia-correcting IOLs, it is not known if they need to remain on either lifitegrast 5% or other types of DED to minimize positive dysphotopsia postoperatively. In addition, a larger sample size may be needed to detect differences adequately.

CONCLUSION

To our knowledge, this is one of the few studies to assess the impact of treating dry eyes with lifitegrast 5% on biometry before cataract surgery. In summary, DED treatment with lifitegrast and preservative-free artificial tears leads to changes in IOL selection in 50% of patients, improves the quality of vision by improving HOAs, and improves biometry accuracy. Given the increasing availability of premium lenses and the need for precise biometry, optimizing the ocular surface is a key component in improving visual outcomes and patient satisfaction.

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Conflicts of interest

There are no conflicts of interest.

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