Diagnoses and Outcomes of Prosthetic Replacement of the Ocular Surface Ecosystem Treatment—A Canadian Experience

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Objectives: To investigate underlying diagnoses and outcomes of patients undergoing Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment at the first Canadian PROSE center.

Methods: A retrospective chart review was conducted on patients referred for PROSE treatment and fitted with PROSE devices from 2018 to 2020. Data were collected on diagnoses, presenting symptoms, previous lens modalities attempted, best-corrected visual acuities (BCVAs) pre-PROSE and post-PROSE, daily wear time, and failure rates. Best-corrected visual acuities pre-PROSE and post-PROSE were compared to evaluate visual improvement.

Results: In total, 78 patients (126 eyes) were analyzed. The most common diagnoses were keratoconus (n=39 eyes) and postcorneal graft (n=15) in the distorted cornea group, and limbal stem cell deficiency (n=17) and graft versus host disease (n=15) in the ocular surface disease (OSD) group. Most frequent symptoms included blur, photophobia, and pain. Most common lens modalities attempted pre-PROSE were conventional scleral lenses and glasses. The overall mean BCVA improvement was 0.40 logarithm of the minimal angle of resolution (logMAR) (4-lines Snellen) ($P<0.0001$). Best-corrected visual acuities improvement in the distorted cornea group (0.52 logMAR, 5-lines) was significantly greater than in the OSD group (0.29 logMAR, 3-lines) ($P=0.004$).

Conclusions: Prosthetic replacement of the ocular surface ecosystem treatment can provide significant visual improvement for patients with distorted corneal surfaces and OSDs who failed other lens modalities.

Key Words: Keratoconus—Ocular surface disease—PROSE—Symptoms—Visual acuity.

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Corneal conditions such as ectasias, degenerations, and ocular surface diseases (OSDs) are a leading cause of ocular morbidity and vision loss.[1,2] These conditions can cause a variety of symptoms including impaired vision, glare, and ocular discomfort which may be very debilitating and severely reduce patients' quality of life (QOL).[3] Often, patients with complex corneal disorders have exhausted a wide range of therapies such as preservative free artificial tears, anti-inflammatories, and punctal occlusion for OSDs, or multiple spectacle and contact lens options as well as procedures including corneal crosslinking and transplantation for severely distorted corneal surfaces.

For patients who are still symptomatic despite these treatments, scleral contact lenses (CLs) are an option to manage symptoms of both distorted corneas and OSDs. Scleral lenses are large gas permeable (GP) CLs that completely vault over the cornea and limbus, with haptics resting on the sclera. They are filled with saline before insertion, so the ocular surface is bathed to maintain hydration and mask any corneal irregularities causing distorted vision and irregular astigmatism. Although scleral lenses may provide improved comfort to those who are intolerant to smaller corneal GP lenses,[4] some patients may still not tolerate conventional sclerals because of irregular corneal or scleral shape resulting in irregular lens fit, lens suction, decentration, discomfort, or inadequate vision.[5]

The BostonSight Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) device (BostonSight, Needham, MA) is a custom-designed scleral lens approved in 1994 by the Federal Drug Administration for the management of corneal disorders.[6,7] It uses proprietary computer software based on mathematical spline functions to design and manufacture lenses with greater customizability to each eye.[7] Their technology, along with radial venting channels,

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creates lens shapes that minimize scleral compression, improves control of the lens vault independent of base curve radius, and reduces lens suction.[7,8] The PROSE treatment has been reported by several studies to be an effective therapy for a wide range of complex corneal conditions including keratoconus,[9,10] postcorneal grafts,[11] and severe OSD from Stevens–Johnson syndrome (SJS),[12,13] graft versus host disease (GVHD),[14,15] and Sjogren syndrome.[16]

The purpose of this study was to investigate the various diagnoses and outcomes of patients undergoing PROSE treatment in the first PROSE program established in Canada in 2017, at the Kensington Eye Institute (KEI, Toronto, Canada). We report on diagnoses, presenting symptoms, previous lens modalities attempted, and reasons for failure in those modalities to gain a more thorough understanding of patient experiences before PROSE wear. With the results from this study, we aim to inform clinicians, researchers, administrators, and policy makers about the broad clinical and public health impact of PROSE treatment, and to support the continuation of PROSE programs to improve access for patients requiring therapy for complex corneal conditions.

METHODS

A retrospective chart review was performed for patients who presented to the KEI PROSE clinic from March 2018 to March 2020. This study protocol was approved by the University of Toronto Research Ethics Board and followed the tenets of the Declaration of Helsinki.

Study Participants

Ninety-two patients were identified, and their medical records were reviewed. Only new PROSE fittings performed at KEI were included for analysis. Patients who were previously fitted successfully with PROSE devices at external clinics were excluded. In Ontario, Canada, funding for PROSE devices was available only for patients who had a history of failure with CLs and a visual acuity (VA) of 20/40 or worse in their better eye.

Prosthetic Replacement of the Ocular Surface Ecosystem Device Fitting

On presentation for their initial fitting consult, each patient completed an intake form reporting their medical and ocular history, symptoms, and previous lens modalities attempted. Patients were examined by an optometrist (S.R. or J.L.) trained in the fitting of PROSE devices and who received their PROSE Fellowship training at BostonSight (Needham, MA). Corneal tomography scans were obtained with Pentacam (Oculus, Wetzlar, Germany) to assess the extent of corneal irregularity, and anterior segment optical coherence tomography (OCT) scans were obtained with Cirrus HD OCT (Carl Zeiss Meditec, Inc., Jena, Germany) to capture lens clearance over the ocular surface and assess haptic alignment, especially over areas of aberrant conjunctival tissue. Although PROSE device fitting was not dependent on the OCT scans, they were helpful to monitor changes in device fit over time. Patients were fitted with PROSE devices from a fitting set, and the lens was allowed to settle on the eye for between 30 min and 2 hr. Personalized adjustments to lens parameters were then decided based on assessment of the lens fit on each patient's eye and overrefraction over the lens. The customized PROSE device was then ordered and fitted on the patient at a follow-up visit to confirm adequate fit, vision, and comfort. When the PROSE fit was appropriate for the patient to take home, they were educated on the proper care and handling of the lens and thoroughly trained in the application and removal of the lens before it's dispense. Patients returned for follow-up appointments over several months after dispensing to monitor for successful lens wear and make any necessary minor adjustments to the lens parameters.

Data Collection

For each patient, the following data were collected from their medical records and intake form: age, sex, referring practitioner type, diagnoses underlying PROSE device wear, relevant ocular history, presenting symptoms, ocular medications and therapies, previous vision devices tried, and reasons for failure in previous devices. Diagnoses were separated into two main groups: distorted corneal surface and OSD. In the distorted cornea group, specific diagnoses included keratoconus, pellucid marginal degeneration, Terrien's marginal degeneration, postradial keratotomy, postrefractive ectasia, postcorneal graft, and corneal scar. In the OSD group, diagnoses included limbal stem cell deficiency (LSCD), ocular GVHD, SJS/toxic epidermal necrolysis (TEN), Sjogren syndrome, neurotrophic keratopathy, exposure keratopathy, neuropathic pain, chemical burn, and severe dry eye from other etiologies.

Additional details from the fitting process were collected for each eye, including central corneal thickness, keratometric values from Pentacam scans, habitual best-corrected VA (BCVA) pre-PROSE device, BCVA with PROSE device, time from initial fitting to dispense of the first lens, total follow-up period, average daily wear time, and lens parameters. Data were also recorded on the number of patients who were lost to follow-up (defined as an inability to present to any follow-up appointment in over 9 months), failed fittings (defined as definitively discontinuing PROSE device wear, based on clinical recommendation of the managing ophthalmologist or optometrist), and the time to discontinuation for failed fittings.

Statistical Analysis

Data on diagnoses, previous lens modalities, and presenting symptoms were analyzed by descriptive statistics. The BCVA values were converted from Snellen to logarithm of the minimal angle of resolution (logMAR) acuity values to allow for statistical analysis. Paired *t* tests were conducted between mean BCVA before and with PROSE device for all patients, as well as within the two subgroups. Two-sample *t* tests were also performed to assess any differences in BCVA, K_{max}, and corneal astigmatism between the subgroups. Chi-square tests were performed to assess the proportion of eyes achieving 20/50 BCVA or better with PROSE device compared with before PROSE fitting, as well as to compare the proportion of eyes achieving at least 5 hr of daily wear between the two subgroups. *P*-values of 0.05 or less were considered statistically significant. Data collection and analyses were performed on Microsoft Excel (Microsoft Corporation, Redmond, WA).

RESULTS

In total, the charts of 92 patients were reviewed. Fourteen were excluded because they were successfully fitted with a PROSE

device at an external clinic, and only presented to KEI for follow-up care. Included in the final analysis were 126 eyes in 78 patients with a mean age of 52.2±18.2 years (range 15–86 years) of which 50% (n=39) were female. Patients were referred from ophthalmologists (n=66), optometrists (n=11), and a rheumatologist (n=1). The average total follow-up time (defined as time from the first to most recent appointment) was 40.22±24.92 weeks, with a range of 4 to 121 weeks.

Eyes were categorized into distorted corneal surface or OSD subgroups based on their diagnoses indicating PROSE treatment. In the distorted cornea group, the most common condition was keratoconus (n=39 eyes), followed by postcorneal graft (n=15), then corneal scar (n=11). In the OSD group, the most common diagnoses were LSCD (n=17), ocular GVHD (n=15), and SJS/TEN (n=14) (Table 1). The mean K_{max} in the distorted cornea group was 49.20±6.73 D, whereas in the OSD group, it was 44.06±2.94 D. The mean corneal astigmatism in the distorted cornea group was 6.38±4.48 D, whereas in the OSD group, it was 2.59±3.65 D. Other relevant comorbid ocular conditions and procedural histories were also recorded for each eye, the most common being glaucoma (n=14) and corneal grafts over 10 years old (n=7) (Table 2).

The most frequent presenting symptoms were blurry vision (n=67 patients, 85.9%), photophobia (n=55, 70.5%), pain (n=42, 53.8%), wateriness/burning (n=39, 50.0%), fluctuating vision (n=37, 47.4%), and glare or rainbow around lights (n=36, 46.2%). The top three symptoms in the OSD group were the same as in all patients, whereas in the distorted cornea group, glare or rainbows around lights was more commonly reported than pain (Table 3).

The most common lens modalities previously attempted before PROSE consultation were conventional scleral lenses (n=59 eyes, 46.8%), glasses (n=59, 46.8%), and corneal GPs (n=41, 32.5%). Previous attempts in other CLs included soft (n=31, 24.6%), hybrid (n=17, 13.5%), piggyback (n=13, 10.3%), and EyePrint-PRO prosthetic sclerals (Advanced Vision Technologies, Lakewood, CO) (n=2, 1.6%). Failure in these modalities was usually because of lens discomfort (n=52 eyes, 41.3%), inadequate visual improvement (n=45, 35.7%), and lens decentration (n=12, 9.5%) (Table 4).

The mean presenting BCVA in habitual correction was 0.58±0.54 logMAR, (Snellen 20/76). After fitting and customizing PROSE devices based on patients' individual ocular anatomy and refractive status, the mean BCVA achieved with PROSE treatment was 0.17±0.24 logMAR (Snellen 20/30). The mean improvement in BCVA was −0.40±0.44 logMAR (4-line improvement on Snellen chart) ($P<0.0001$) (Table 5). The pre-PROSE BCVA was significantly worse in the distorted cornea (0.68±0.47 logMAR, Snellen 20/96) compared with the OSD group (0.48±0.58 logMAR, Snellen 20/60; $P=0.04$). Visual improvement for both groups was significant, with the distorted cornea group improving to 0.14±0.18 logMAR, Snellen 20/28 ($P<0.0001$), and the OSD group improving to 0.19±0.29 logMAR, Snellen 20/31 ($P<0.0001$). Improvement in the BCVA was significantly greater in the distorted cornea group (−0.52±0.45 logMAR, 5-line improvement) than the OSD group (−0.29±0.41 logMAR, 3-line improvement; $P=0.004$). After PROSE fitting, a total of 108 eyes (85.71%) achieved 20/50 BCVA or better, compared with only 64 eyes (50.79%) pre-PROSE ($P<0.0001$). Furthermore, 91 eyes (72.2%) achieved a BCVA of 20/30 or better.

Overall mean K_{max} across all patients was 46.56±5.74 D, with a range from 35.5 to 70.1 D. Mean corneal astigmatism was 4.44±4.48 D. Compared with the OSD group, the distorted cornea group had significantly steeper K_{max} (44.06 vs. 49.20 D, respectively; $P<0.0001$) and more severe corneal astigmatism (2.59 vs. 6.38 D, respectively; $P<0.0001$) (Table 5).

During the fitting process including the initial consultation, it took on average 2.18 appointments, over 11.81±7.75 weeks, for a patient to be dispensed their first PROSE device. An average of 3.31±1.66 lenses were ordered per eye over the entire follow-up period, with minor adjustments made to lens parameters after the first dispense to achieve optimal vision and fit.

For patients who returned to follow-up and had data available on average daily wear time, 29 eyes (38.2%) achieved at least 9 hr per

TABLE 1. *Ocular Diagnoses Indicating PROSE Wear*

	Number of Diagnoses	% (n=126)
Distorted corneal surface		
Keratoconus	39	30.95%
Postcorneal graft	15	11.90%
Corneal scar	11	8.73%
Terrien's marginal degeneration	6	4.76%
Radial keratotomy	4	3.17%
Pellucid marginal degeneration	3	2.38%
Postrefractive ectasia	2	1.59%
Ocular surface disease		
Limbal stem cell deficiency	17	13.49%
Ocular graft versus host disease	15	11.90%
Stevens–Johnson syndrome/toxic epidermal necrolysis	14	11.11%
Severe dry eye from other etiologies[a]	14	11.11%
Neurotrophic keratopathy	11	8.73%
Sjogren syndrome	10	7.94%
Exposure keratopathy	2	1.59%
Neuropathic pain	2	1.59%
Chemical burn	1	0.79%

Of 126 eyes, a total of 166 diagnoses were made. 88 eyes had only 1 diagnosis, 36 had 2 diagnoses, and 2 had 3 diagnoses.

[a]Other etiologies: severe meibomian gland dysfunction, rheumatoid arthritis, Bell's palsy, post-LASIK (laser in situ keratomileusis), glaucoma medications, and suspected phlyctenular keratitis.

TABLE 2. *Comorbid Ocular Conditions and Procedural Histories*

Comorbid Eye Conditions/Procedures	Number of Eyes	% (n=126)
Glaucoma (or suspect)	14	11.11%
Most recent corneal graft>10 years ago	7[a]	5.56%
Trichiasis	6	4.76%
Radial keratotomy	4	3.17%
Pinguecula/pterygium	3	2.38%
Fuch's dystrophy	2	1.59%
Glaucoma surgery/device	2	1.59%
Past retina surgery/laser	1	0.79%

[a]Age of graft in four additional eyes was unknown.

day, 28 eyes (36.8%) achieved 5 to 8 hr per day, whereas 19 eyes (25%) achieved less than 5 hr per day. Overall, 57 eyes (75%) had at least 5 hr daily wear time, and this proportion was comparable between the distorted cornea and OSD groups (71.1% and 78.9%, respectively) (P=0.427).

The characteristics of the final customized lens for each patient were as follows: mean diameter of 18.2±0.6 mm, meridians of toricity of four in 75.4% of lenses and 8 in 24.6%, and eccentricity measurements of 0.6 in 97.6% of lenses, and 0.8 in 2.4%. Materials used include Contamac Optimum Extra (59.5%), Contamac Optimum Extreme (15.1%), BOSTON XO2 (11.1%), and BOSTON EQII (14.3%). In some cases, advanced technologies of PROSE were used to facilitate better fit and function of the device. 13.5% of devices used 1 channel, whereas 11.9% used 2 channels to improve fluid ventilation and oxygen exchange in cases where the haptics fit too tightly over the conjunctiva. In addition, Hydra-PEG coating was used in 8.7% of lenses to improve surface wettability.

From 2018 to 2020, 10 eyes (7.94%) of six patients were lost to follow-up, and three eyes (2.38%) of two patients failed PROSE treatment. The average time to failure was 7.29±4.70 weeks, and reasons for failure were disease progression requiring surgery, lens discomfort, and difficulty with insertion and removal.

DISCUSSION

This study aimed to assess multiple characteristics in a group of Canadian patients undergoing PROSE treatment including diagnoses, presenting symptoms, previous lens modalities attempted, and visual outcomes after fitting. We found PROSE treatment to be indicated for a multitude of corneal conditions, most commonly keratoconus, LSCD, postcorneal graft, and ocular GVHD. Similarly, several other studies reported keratoconus being the most frequent diagnosis requiring PROSE device wear.[7,10,16–18] By contrast, a large study conducted by Parra found dry eye disease to be the leading diagnosis requiring PROSE treatment.[19] Comparable with our results, other studies reported their common diagnoses to be GVHD, SJS, severe dry eye syndrome, postcorneal graft, and corneal scars.[19,20]

In our study, some patients had multiple diagnoses indicating PROSE treatment. Many of these corneal conditions may also have an associated dry eye component (such as meibomian gland dysfunction or aqueous deficient dry eye disease). However, because cases of mild dry eye are so prevalent[21] and patients were referred to the PROSE clinic for treatment of more visually threatening ocular conditions, cases of nonsevere dry eye were not reported in this study. Consequently, dry eye could potentially be a secondary, tertiary, or quaternary diagnosis in some patients, and the number of eyes with multiple indicated diagnoses may possibly be higher than reported.

To the best of our knowledge, this is one of the largest studies to date assessing a variety of subjective patient symptoms before PROSE device wear, with the most frequently reported being blurry vision, photophobia, and pain. A previous study also found photophobia and pain to be major symptoms in ectasia and OSD patients, although the prevalence of these symptoms was lower than in our study.[18] Some notable differences in symptoms were found between the distorted cornea and OSD groups. For instance, glare/rainbow around lights was reported more often by the distorted cornea group, whereas pain, injection, and sandiness/grittiness were described more frequently by the OSD group. Although few other studies have systematically recorded the

TABLE 3. *Number and Percentage of Patients Reporting Each Presenting symptom.*

Presenting Symptom	Overall (n=78)	Distorted Cornea Group (n=38)	OSD Group (n=40)
Blurry vision	67 (85.9%)	33 (86.8%)	34 (85.0%)
Photophobia	55 (70.5%)	23 (60.5%)	32 (80.0%)
Pain	42 (53.8%)	14 (36.8%)	28 (70.0%)
Watery/burning	39 (50.0%)	16 (42.1%)	23 (57.5%)
Fluctuating vision	37 (47.4%)	15 (39.5%)	22 (55.0%)
Glare/rainbow around lights	36 (46.1%)	20 (52.6%)	16 (40.0%)
Injection	33 (42.3%)	12 (31.6%)	21 (52.5%)
Sandy/gritty	32 (41.0%)	9 (23.7%)	23 (57.5%)
Double/distorted vision	32 (41.0%)	17 (44.7%)	15 (37.5%)
Frequent headaches	25 (32.1%)	9 (23.7%)	16 (40.0%)
Discharge	18 (23.1%)	7 (18.4%)	11 (27.5%)

All patients reported at least one symptom.

OSD, ocular surface disease.

TABLE 4. *Reasons for Failure in Previous Lens Modalities*

Reason for Failure	Number of Eyes (n=126)
Lens discomfort	52 (41.3%)
Inadequate vision with lens	45 (35.7%)
Lens decentration	12 (9.5%)
Corneal edema	7 (5.6%)
Poor surface wetting	6 (4.8%)
Tight lens	4 (3.2%)
Difficulty handling	4 (3.2%)
Corneal neovascularization	2 (1.6%)
Microcystic edema	1 (0.8%)

various symptoms patients initially presented with, the studies that mentioned associated symptoms similarly described pain, photophobia, and burning sensation as the most prominent in OSD patients, whereas reduced vision was the main one found in distorted corneas.[7,8,10] Because our study found blur to be the predominant symptom overall (85.9% of patients) and in both subgroups, it is encouraging that PROSE treatment can provide a clinically and statistically significant improvement in vision, with an average four-line improvement in Snellen acuity and allowing 72.2% of eyes to achieve a BCVA of 20/30 or better.

Overall, the 0.40 logMAR improvement in BCVA that we found with PROSE treatment was slightly greater but comparable with values described in other studies by Parra (0.28 logMAR), Arumugam (0.30 logMAR), and Stason (0.39 logMAR).[10,18,19] Divided into subgroups, our results were similar to those reported by Parra and Stason, with the distorted cornea group achieving greater visual improvement than the OSD group.[18,19] These are in contrast to Arumugam's study, which found a greater improvement in OSD compared with distorted cornea groups, although this difference between groups was small.[10] It is worth noting that the post-PROSE BCVA used in our analysis was the best VA value recorded in the entire post-PROSE period after dispense of the first device. This was performed to assess the potential improvement in vision with the device.

With respect to lens modalities attempted before PROSE treatment, our findings of conventional scleral CLs and glasses being the top modalities differed from previous studies (that reported corneal GPs as the most common and conventional sclerals as the least common modality tried).[9,10,22] Our results may be explained by the recent surge in accessibility and popularity of fitting conventional sclerals for patients with corneal ectasias and OSDs.[23] This increased interest can be attributed to greater commercial availability of large diameter CL buttons of GP materials, improved corneal imaging systems, and more precise computer-driven lathe cut manufacturing of lenses.[24] Canadian patients have access to two Canadian conventional scleral lens manufacturing laboratories, but a significant number of US manufactured scleral lens options are also available, subject to international logistics and shipping regulations to Canada (which may limit some options). Despite this increased interest, our finding that corneal GPs were the third most common modality used still supports corneal lenses as the traditional gold standard CL in managing corneal ectasias.[4] The main reasons for failure in previous modalities in our study were also comparable with those reported by Arumugam, which include lens intolerance, poor fit, and pain.[10] However, because our study comprises a greater proportion of past scleral CL wearers compared with corneal GP wearers, the mechanisms behind poor fit in our case may be more specific to scleral lenses (such as asymmetric sclerae, conjunctival prolapse, and limbal bearing).[5] In addition, in more complex cases, the experience of the contact lens fitter may potentially be one of the factors in fitting success of the conventional scleral lens. Accordingly, the wide range in experience of the clinicians who refer to the PROSE clinic may cause some variability in previous failed fittings. However, because of the retrospective nature of this study, we can only speculate as to whether successful fitting with the PROSE was due to clinician experience or the inherent properties of the treatment itself.

Reasons that PROSE treatment could be beneficial for patients who have failed in conventional scleral lenses include the unique ability to use the computer software to manipulate specific points in various meridians on the lens design on a micron level. Also, contrary to standard scleral lenses, which usually have sizes in one or two diameters, PROSE lenses can be created in any diameter from 13 to 23 mm. These features allow for greater customization for anatomical obstacles such as pterygia or glaucoma blebs, ultimately improving lens fit and aiming to reduce suction and compression forces that can stress ocular surface function.

Although 75% of the eyes with available data achieved at least 5 hr of daily wear time, our finding that only 38.2% of eyes achieved over 9 hr was less compared with other studies.[25,26] This may indicate that a greater proportion of patients in our study are in the process of building up "wear time" to full-time daily wear,

TABLE 5. *Best-corrected visual acuity Pre-PROSE, With PROSE, Change (PROSE BCVA – Pre-PROSE BCVA), Maximal Corneal Curvature (K_{max}), and Corneal Astigmatism*

Group	Pre-PROSE BCVA, logMAR (Mean±SD), Snellen	PROSE BCVA, logMAR (Mean±SD), Snellen	*P*	ΔBCVA, logMAR (Mean±SD), Snellen	K_{max}, D (Mean±SD)	K_{max} Range, D	Corneal Astigmatism, D (Mean±SD)
Overall	0.58±0.54 20/76	0.17±0.24 20/30	2.21 × 10^−17	−0.40±0.44 4-line improvement	46.56±5.74	35.5–70.1	4.44±4.48
Distorted corneal surface	0.68±0.47 20/96	0.14±0.18 20/28	5.22 × 10^−12	−0.52±0.45 5-line improvement	49.20±6.73	35.5–70.1	6.38±4.48
OSD	0.48±0.58 20/60	0.19±0.29 20/31	2.89 × 10^−7	−0.29±0.41 3-line improvement	44.06±2.94	37.4–55.8	2.59±3.65
P-value	**0.0382**	0.2391		**0.0044**	1.99 × 10^−6		3.96 × 10^−6

Bolded P-values indicate statistically significant differences (α=0.05).

BCVA, best-corrected visual acuity; logMAR, logarithm of the minimal angle of resolution; PROSE, prosthetic replacement of the ocular surface ecosystem; OSD, ocular surface disease.

which one study defined as 8 hr per day.[25] A possible reason for this could be the shorter follow-up period for these patients (with the KEI PROSE clinic only being established 3 years ago and the average patient only having a follow-up time of 40.22 weeks). Accordingly, some patients may have still been adapting or fine-tuning their lens parameters to achieve an optimal fit, especially during their first few follow-up visits.

Furthermore, because most patients were referred by corneal specialists with expertise in OSD, referral bias could have resulted in our patient population having more cases of severe OSDs relative to previous studies.[25,26] Complex OSDs can result in more compromised tear composition, poorer lens surface wetting, and lens fogging because of debris buildup, which could all be reasons for a more gradual progression in improving daily wear time.[5] These eyes with shorter daily wear times are not necessarily failed fittings, but require close follow-up, assessment, and education to resolve any potential issues with fit, vision, or comfort in the lens so wear time can be increased. For instance, strategies to reduce midday lens fogging include modifying the PROSE device material or using a higher viscosity saline solution. However, one of the most effective methods is to educate patients to remove their lenses partway through their day and replenish them with fresh saline solution to avoid the midday fogging caused by debris buildup. The failure rate in our study (2.38%) was slightly lower, but still comparable with what Schear reported (6.8%) in a similar-sized study.[17]

Most patients who were lost to follow-up did not return to the clinic after their first lens was dispensed, so any problems they may have had with the device were not reported. To the best of our knowledge, no patient failed PROSE device wear or was lost to follow-up solely because of difficulties with application and removal. Additional contributing reasons included disease progression necessitating surgery, or lens discomfort, which comprises a foreign body sensation or unpleasant feeling with the lens on a patient's eye that they cannot become habituated to over time. This sensation can potentially be due to inadequate lens fit, a patient's OSD, or both. To facilitate PROSE wear, it is essential to educate patients that gaining comfort with application and removal takes time, and to arrange appointments for them to become proficient at it before dispensing the device.

This study has several limitations to consider. Its retrospective nature precluded a more rigorous assessment of symptom improvement after PROSE fitting. In addition, lack of QOL data in the form of validated questionnaires prevented more in-depth analyses of visual function. Another limitation of the study is the lack of data regarding prior fitting attempts performed by scleral lens fitters from external clinics. Furthermore, because the PROSE program at KEI was recently established, a longer follow-up time is required for patients in this study to obtain a more accurate image of successful wear and failure rates.

Strengths of this study include its large size and data on a Canadian population of PROSE patients not previously reported. Moreover, this study collected detailed subjective data on symptoms before PROSE treatment. Along with a patient's diagnosis, this provides additional valuable information on indications for PROSE fittings. Prospective studies are planned in the future to evaluate patient symptoms over time, along with a validated QOL questionnaire (such as the Ocular Surface Disease Index or the Visual Function Questionnaire), and with measures to follow any long-term effects of PROSE lenses to better determine the extent that PROSE treatment improves visual functioning.

To conclude, in addition to providing information on the variety of diagnoses underlying PROSE treatment, as well as reinforcing its successful visual outcomes and tolerability at the only Canadian center to date, this study also provides a more thorough understanding of subjective patient experiences before PROSE wear to better inform clinicians on symptoms to assess. The significant improvement in vision found with PROSE treatment supports its successful use for patients with complex distorted corneal conditions and OSDs who have previously failed other lens modalities.

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