Prosthetic Replacement of the Ocular Surface Ecosystem for Terrien Marginal Degeneration: A Case Series

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Objectives: To assess outcomes of the Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) treatment in patients with advanced Terrien marginal degeneration (TMD).

Methods: This is a retrospective case series of patients with advanced TMD who were assessed and fit with customized PROSE lenses. Data were collected on PROSE fitting details including visual acuity (VA) before and after PROSE, slit-lamp findings, and corneal tomography scans.

Results: Six eyes in four patients were included. All patients attempted at least one other contact lens (CL) modality before PROSE. Some patients had corneal comorbidities such as pseudopterygium and pseudobleb that contributed to intolerance to previous lenses and warranted extra considerations in the fitting process. With PROSE, VA improved in all six eyes. Patients with structural corneal comorbidities achieved improved vision, comfort, and lens tolerance with PROSE. Two eyes had noncorneal ocular comorbidities that limited PROSE efficacy. Another eye discontinued PROSE wear because of limbal stem-cell disease progression necessitating a limbal stem-cell transplant.

Conclusions: PROSE treatment can be an effective option to improve vision and comfort for patients with advanced TMD who are intolerant to first-line therapeutic CL modalities, even in the presence of other corneal comorbidities.

Key Words: PROSE—Terrien marginal degeneration—Scleral lens.

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Terrien marginal degeneration (TMD) is a rare, slowly progressive thinning disorder of the peripheral cornea. It is commonly considered a bilateral condition, although marked asymmetry between eyes has been reported.[1,2] Classically, it involves initial thinning and furrowing of the superior peripheral cornea, resulting in irregular against-the-rule astigmatism.[2] With gradual disease progression, usually over several years, the furrow extends circumferentially around the periphery, then toward the central cornea.[3] This corneal distortion becomes severe and with time, causes substantial visual reduction. This thinning is accompanied by changes in the corneal stroma early in the disease process, including lipid deposition with a well-defined leading edge, superficial neovascularization, and opacification.[4,5] Pseudopterygia are another early clinical feature of TMD and can develop when thinning is still subtle.[5] They differ from typical pterygia as they can grow in a relatively oblique axis and have a broader leading edge.[5]

Patients with TMD often present with decreased visual acuity (VA) and occasionally with mild ocular irritation.[3] Because this degeneration usually occurs slowly, conservative management is often appropriate.[2,6] Spectacle lenses can improve VA in the early stages. With increasing corneal irregularity, patients may benefit from rigid gas-permeable (GP) contact lenses (CLs), followed by scleral CLs.[3] Surgical management is considered when risks arise for rare but serious complications, such as Descemet membrane detachments,[7] corneal hydrops,[8] and perforations.[9–11]

Conventional scleral CLs are large-diameter GP CLs that vault over the cornea and limbus, with haptics that land on the sclera. They are filled with a saline solution before insertion to keep the ocular surface hydrated and to mask any corneal irregularities that cause distorted vision and irregular corneal astigmatism. Any residual astigmatism can also be corrected with additional optical modifications. Scleral CLs may provide improved vision and

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comfort to patients with corneal ectasias who are intolerant to rigid GP CLs.[12] However, more complex eyes with severely irregular corneal or scleral shapes may still become intolerant to conventional scleral CLs due to irregular lens fit, decentration, discomfort, or inadequate vision.[13]

The Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) (BostonSight, Needham, MA) is a custom-designed large-diameter scleral lens approved in 1994 by the Food and Drug Administration for the management of corneal disorders.[14,15] It uses proprietary computer software based on mathematical spline functions to design and manufacture lenses with greater customizability to each eye. This can be achieved through controlling the reservoir thickness/sagittal height independently of the base curve, adding front surface eccentricity that reduces higher-order aberrations,[16] meridional-specific control of base curve and landing zone in up to eight independent meridians, and customizable radial channels. In addition, PROSE maintains an ocular environment that is moisturized and mitigates tear film instability from contributing to blur, discomfort, or further damage to the distorted ocular surface. A previous case report described the use of PROSE to improve vision and comfort in a patient with TMD.[17]

Because TMD is uncommon, there is a scarcity of studies describing PROSE treatment specifically in patients with this condition. We report on four patients with advanced TMD who underwent PROSE treatment. Most of these patients had concurrent corneal and ocular surface pathologies that contributed to challenges with CL fittings in other modalities. We highlight these challenges and the advantages of PROSE in managing patients with these complex corneas.

METHODS

This is a retrospective case series of six eyes in four patients who presented to the Therapeutic Contact Lens and PROSE clinic at the Kensington Eye Institute (KEI, Toronto, Canada). This study was performed with approval from the University of Toronto Research Ethics Board and followed the tenets of the Declaration of Helsinki. All patients were referred by their corneal specialist for a consultation and fitting with either conventional scleral CLs or PROSE. A PROSE lens was considered if a patient's corneal pathology required a scleral lens with parameters (such as lens diameter or oblate design) that were beyond what was available to our Canadian-based clinic.

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 and who received their PROSE fellowship training at BostonSight (Needham, MA). Corneal curvature and central corneal thickness (CCT) were measured with Pentacam (Oculus, Wetzlar, Germany), and anterior segment optical coherence tomography (OCT) scans were obtained with Cirrus HD-OCT (Carl Zeiss Meditec, Inc., Jena, Germany). Patients were fit with PROSE devices from a fitting set, and the lens was allowed to settle on the eye for at least 30 min. Personalized adjustments to lens parameters were then decided based on the assessment of the lens fit on each patient's eye through a thorough slit-lamp examination, as well as manifest refractive status over the lens. The targeted lens apical clearance varies depending on the condition being treated, lens diameter, and practitioner preferences. Larger-diameter lenses tend to be fit with greater clearance. Generally, an adequate central clearance ranges from 100 to 400 μm, whereas the limbal clearance is about one third or one quarter of the central clearance. The main objective is to avoid lens contact with the cornea. The customized PROSE lens was then ordered and fit 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 dispensing. We determined a PROSE lens fit appropriately for a patient based on the following criteria: adequate clearance of at least 300 μm over the corneal apex, no contact between the posterior surface of the lens and the cornea, a smooth landing zone over the limbus with no conjunctival impingement or lens edge lift, no excess movement of the lens over the eye, and a comfortable subjective fit for the patient. After assessing the fit, the lens was removed and the eye was examined again to ensure the health of the cornea and ocular surface was maintained. For some patients, training may have occurred over multiple visits to ensure proficiency and confidence in handling the lens before dispensing. 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.

RESULTS

Case Series

Case 1

A 29-year-old man with advanced TMD and a pseudobleb superiorly in his right eye was referred for a scleral CL fitting. His pseudobleb was stable and had been present for years. He reported decreased vision in his right eye for 9 years, with unbalanced binocular vision and photophobia affecting his driving. He had not previously worn glasses or CLs. Uncorrected Snellen VA was 20/150 in his right eye.

The right cornea showed scarring with superior neovascularization and superonasal peripheral thinning. Pentacam imaging of that eye showed a steep corneal curvature of 51.6 diopter (D) × 78.4°, with 10.1 D of against-the-rule corneal astigmatism. The CCT was 409 μm (Fig. 1).

He was fitted with a trial conventional scleral lens (Zenlens, Bausch & Lomb, Bridgewater, NJ) in only his right eye and achieved a VA of 20/15 with an over-refraction of +9.00 D. This lens had an oblate design, a sagittal height of 4,800 μm, and a base curve of 9.70 mm. However, with this high hyperopic lens prescription necessitating a thicker scleral lens design, there were concerns about reduced oxygen transmission through the lens to the corneal surface. Furthermore, with such a high prescription, the scleral lens would be heavier, creating a greater risk of lens decentration, reduced lens clearance, and inadequate postlens tear film with longer lens wear time. This combination could also potentially put the thin and fragile superior cornea at risk of further iatrogenic damage.

A trial fitting of PROSE was conducted because of an ability to control the lens vault over the peripheral cornea independent of the base curve and to modify the landing zone specifically in the superior meridian, independent of the other meridians. Initially, the

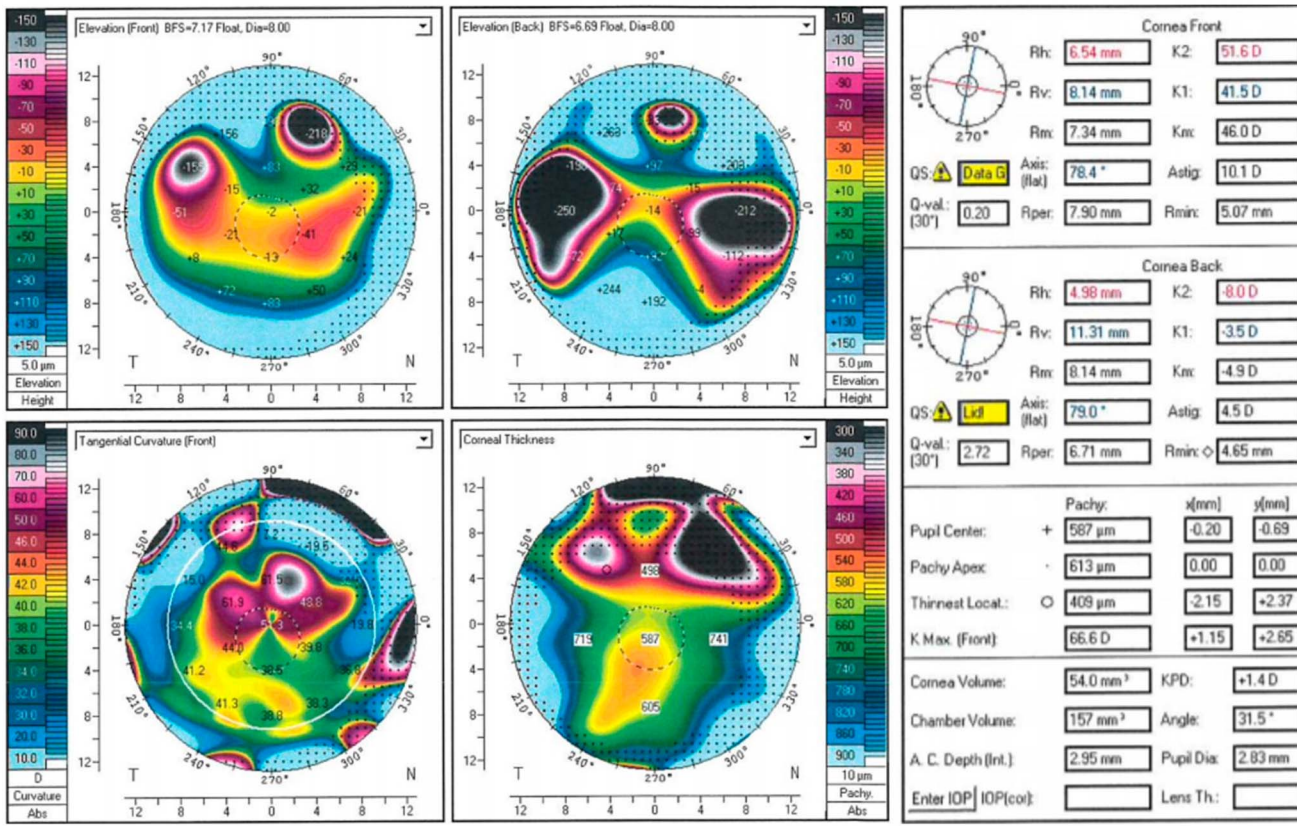

FIG. 1. Pentacam scan of the right eye in *case 1*.

trial lens had good apical clearance but low clearance superiorly over the pseudobleb. Adjustments were ordered to increase the superior limbal clearance by 150 µm. At the lens dispense visit, the PROSE lens attained an improved fit on the eye with a high apical clearance of 634 µm over the cornea and an adequate clearance over the pseudobleb. The VA with this customized PROSE lens was 20/20. At a follow-up appointment 3.5 months after the initial fitting, the patient was able to wear the lens for 6 hr without any noted problems. Mild microcysts were observed on the cornea after removing the PROSE lens. Because this could be an early sign of corneal hypoxia, the corneal vault of the lens was decreased to reduce the postlens tear reservoir and improve oxygenation of the cornea. Although the patient was asymptomatic at this visit, he did not present for a further follow-up appointment after receiving this modified lens.

Case 2

A 44-year-old woman was referred with a diagnosis of advanced TMD in her left eye. The left eye was complicated by a corneal scar, pseudopterygium, and ocular surface disease. She reported blurry and distorted vision, with glare, photophobia, and pain. In addition, the reduced vision in her left eye compared with her right caused significant anisometropia, resulting in difficulty driving at night. She used artificial tear lubrication and did not wear glasses or CLs. Uncorrected VA in her left eye was 20/100, which improved to 20/25 with pinhole. Uncorrected VA in her unaffected right eye was 20/20.

Slit-lamp examination of her left eye showed a large nasal pseudopterygium with pannus nasally and mild corneal ectasia inferiorly. Pentacam imaging of the left eye showed 8.5 D of against-the-rule corneal astigmatism, with a thin CCT of 354 µm (Fig. 2). Slit-lamp examination of her right eye showed presence of inferior pannus.

She was initially fit with a conventional scleral lens (Zenlens, Bausch & Lomb, Bridgewater, NJ) on her left eye only, which provided adequate central corneal clearance. However, it was considered a poor fit due to impaired landing of the nasal haptic on the pterygium, causing significant conjunctival impingement that was not alleviated by multiple haptic modifications.

Given the impingement of the nasal conjunctiva (9 o'clock) with lens edge lift over the inferior nasal conjunctiva (8 o'clock), the PROSE lens was deemed to be a more suitable option for this patient because of the ability to control its landing zone in one of eight meridians, independent of the other meridians. The trial PROSE lens also produced good corneal clearance in addition to noticeably improved comfort relative to the conventional scleral lens. The customized lens was ordered then and dispensed at a later visit, achieving a VA of 20/20.

One week after the lens was dispensed, the patient reported wearing the lens almost every day for an average of 7 hr per day. She reported mild lens sensation inferiorly, which was confirmed with a finding of conjunctival impingement inferior nasally on the slitlamp. A new lens was reordered with adjustments to flatten the inferior nasal landing zone.

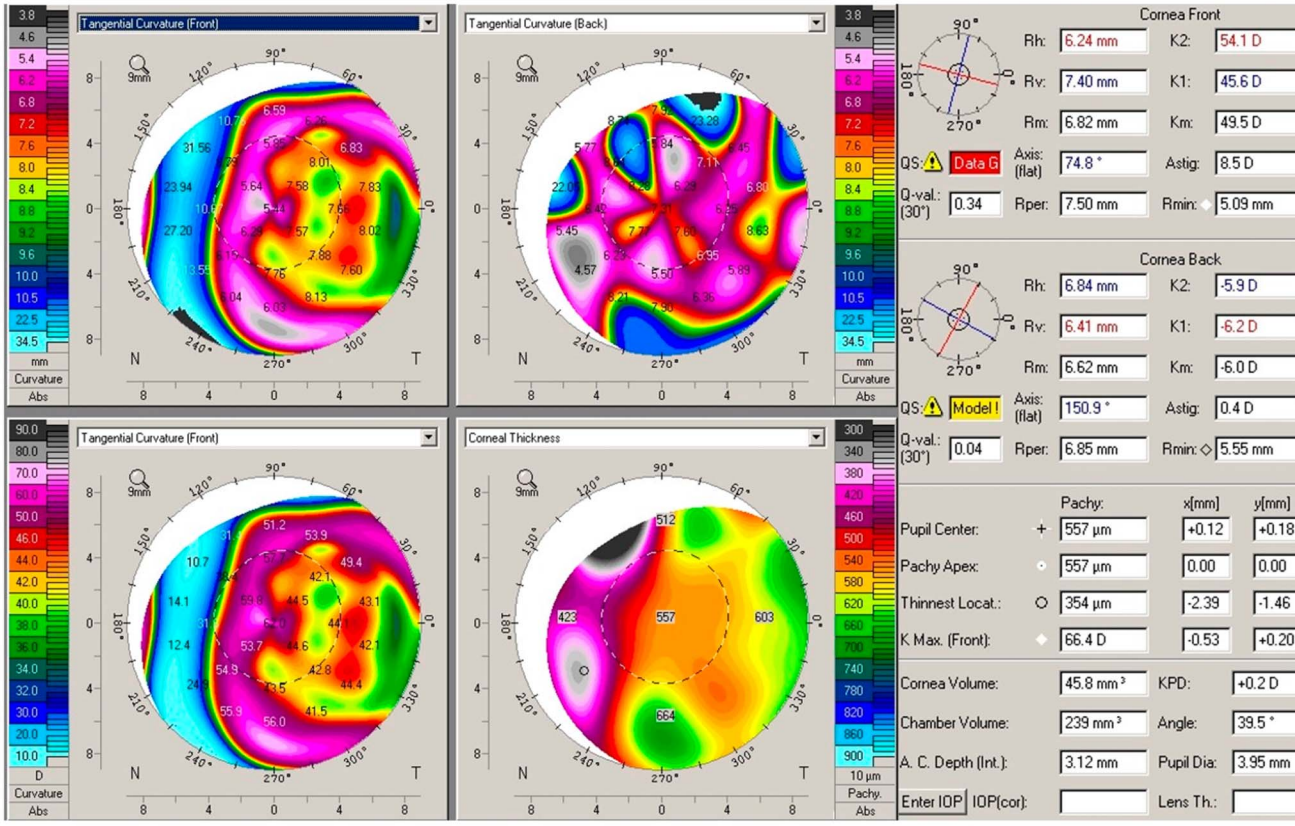

FIG. 2. Pentacam scan of the left eye in *case 2*.

At the 4-month follow-up, the patient reported improved comfort in the lens. However, sensation of fogginess in the lens was affecting her vision. She was advised to add a drop of a more viscous preservative-free artificial tear into the lens bowl before lens application to reduce the fogging. On subsequent visits up to 27 months after her initial fitting, she reported wearing the lens between 8 and 10 hr per day on average, with good visual function. Her examination supported this, with a VA of 20/20 and good lens clearance over the entire cornea. No corneal hypoxic complications were observed.

Case 3

A 75-year-old man was referred with a diagnosis of advanced bilateral TMD. He reported blurry vision even in his rigid (GP) lenses, having previously tried numerous different lens designs. The VAs in his GP lenses were 20/200 in his right eye and 20/80 in his left eye.

Slit-lamp examination revealed peripheral corneal thinning circumferentially and moderate nuclear sclerosis in both eyes. Pentacam scans showed irregular with-the-rule corneal astigmatism of 13.7 D in his right eye with a curvature of 53.8 D along the steep axis. The left eye showed irregular oblique corneal astigmatism of 8.5 D with a curvature of 52.2 D along the steep axis (Fig. 3).

A trial of the PROSE lens was performed because of the ability to incorporate front surface eccentricity to the lens, which could help improve his vision to a more satisfactory level. At the time of fitting, no other scleral lenses available in Canada offered the ability to manipulate front surface eccentricity. Initial Snellen VA with the trial PROSE lenses in both eyes yielded 20/60 in the right eye without any over-refraction and 20/40 in the left eye with an over-refraction of +1.25. The patient reported good comfort and better vision in the PROSE compared with his rigid GP lenses (see Figure 1, Supplemental Digital Content 1, http://links.lww.com/ICL/A225 which demonstrates the PROSE device on the left eye, with peripheral corneal thinning circumferentially).

At the PROSE dispense appointment, the patient noted good comfort but fluctuating vision in the lenses. His VA while wearing the PROSE lens was 20/50 in the right eye and 20/150 in the left eye. On slit-lamp examination, debris was noted in the lens reservoir, particularly with lens movement during blinking. Accordingly, orders for modified lenses were made with steepened superior and inferior peripheral curves on both lenses to improve stability and reduce lens movement and debris buildup in the lenses.

At a follow-up appointment 1 month later, although the lens fit was improved on slitlamp and the patient reported better vision, he still felt that his vision was fluctuating. His VA while wearing the PROSE was 20/80 in his right eye and 20/70 in his left eye. No corneal hypoxic complications were observed. Modified lenses were ordered with adjusted eccentricity parameters. Three months later, with persistent reports of inconsistent vision, he presented for an appointment with his corneal specialist to investigate other potential

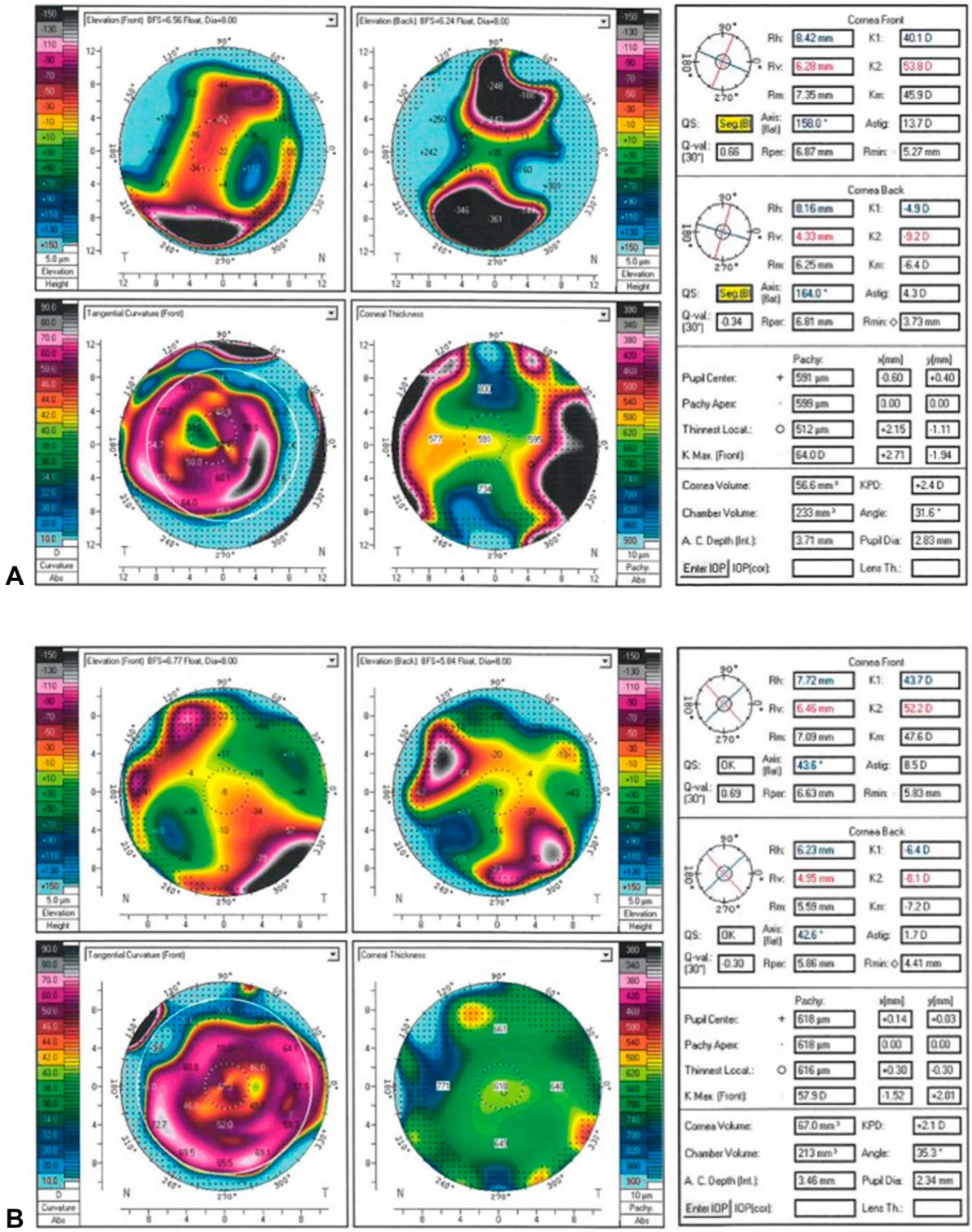

FIG. 3. Pentacam scans of the (a) right eye and (b) left eye in *case 3*.

ocular pathology that could interfere with his vision. After additional workup with macular OCT, an epiretinal membrane (ERM) was noted in his right eye. This, along with the cataract, contributed to the poor vision in his right eye. As a result, the patient was advised to undergo cataract extraction with ERM peel for his right eye, with intended resumption of PROSE wear after surgery.

Case 4

An 80-year-old woman was referred with marked bilateral TMD and limbal stem-cell deficiency (LSCD) as well as a history of deep anterior lamellar keratoplasty in her right eye. She was a previous patient at the KEI Therapeutic Contact Lens Clinic, having been fit with a variety of lens modalities including conventional scleral CLs and piggyback CLs over the course of 2 years before her PROSE fitting. However, these modalities were unsuccessful despite many attempts to modify lens parameters due to her low endothelial cell counts causing corneal edema in conventional scleral CLs and dexterity difficulties with handling small rigid GP CLs within the piggyback system.

Her spectacle-corrected VAs were 20/100 in her right eye and 20/150 in her left eye. Pentacam imaging displayed 14.6 D of against-the-rule astigmatism in her right eye with a corneal curvature of 57.2 D along the steep axis (Fig. 4). Pentacam scans of her left eye could not be reliably obtained because of even greater corneal irregularity.

Slit-lamp examination revealed 360 degrees of vascularization around the peripheral cornea in both eyes, extending 5 mm into the cornea from the periphery. The central cornea was also hazy in both eyes.

With the initial fitting, the patient's right eye had poor wetting with the lens, only achieving a VA of 20/150 with an over-refraction of +3.50. Her left eye achieved better vision with the lens, improving to 20/40 with an over-refraction of −1.50. However, 7 months after her initial PROSE fitting, despite achieving a VA of 20/60 in her left eye with her customized PROSE lens, she was advised by her corneal specialist to undergo a limbal stem-cell transplantation due to progression of her LSCD in that eye. She was advised to discontinue PROSE wear in her left eye, although she was able to continue PROSE wear in her right eye.

After several follow-up appointments for her right eye, the PROSE lens haptics were adjusted to reduce impingement over the fibrovascular tissue, and the lens diameter was reduced to facilitate insertion with her smaller lid apertures. With these modifications, the right eye was able to achieve a fluctuating but improved VA of 20/70. No corneal hypoxic complications were observed. In addition, she was gradually increasing PROSE wear up to 6 hr per day for 5 days per week in that eye, with improving confidence in lens application and removal, which enhanced her day-to-day function.

DISCUSSION

To the best of our knowledge, this is the largest case series reported on patients with TMD undergoing PROSE treatment. We observed that PROSE provided considerable improvement in vision and symptoms as well as being able to mechanistically account for the pseudopterygia and corneal thinning often accompanying the disease process.

With early stages of TMD, there have been multiple reports of associated atypical pterygia or pseudopterygia, which encroach on the cornea from more oblique positions different from the typical

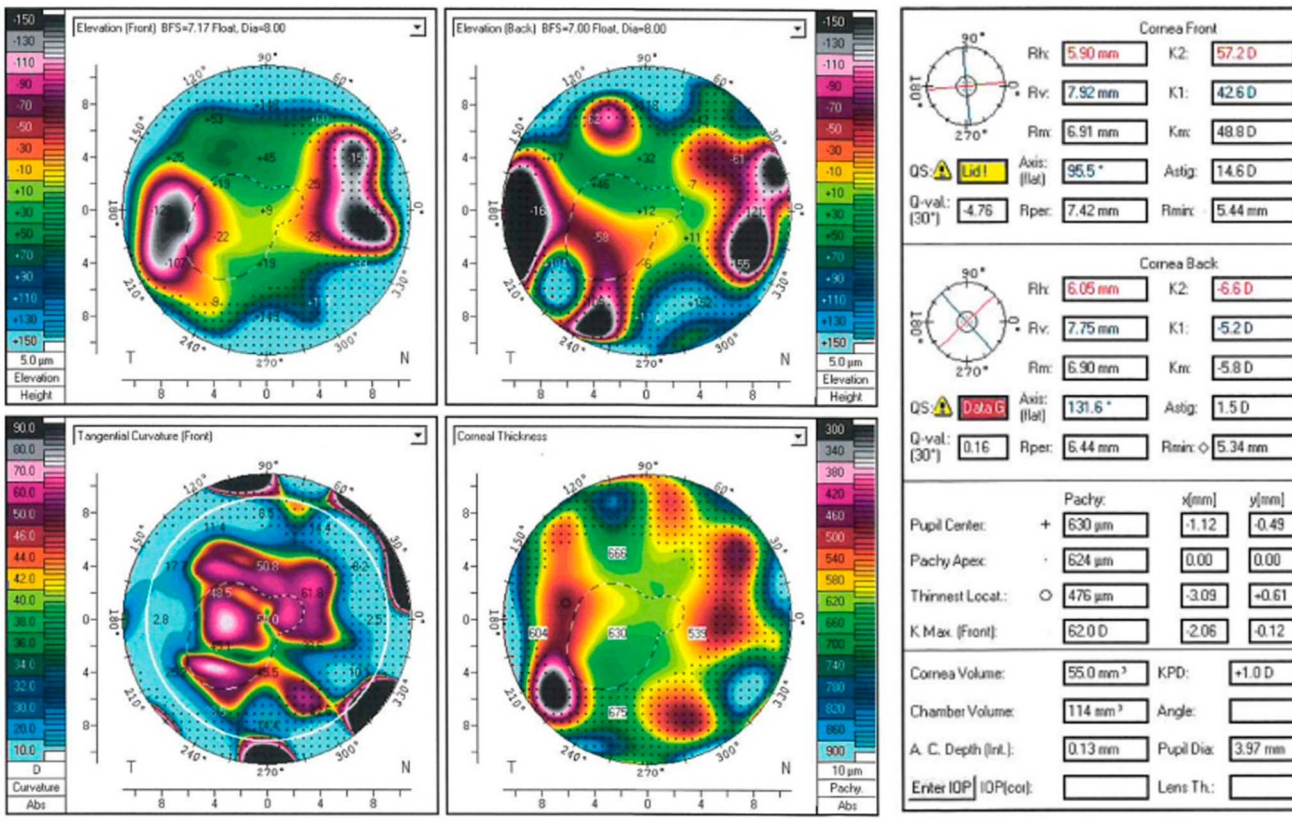

FIG. 4. Pentacam scan of the right eye in *case 4*.

TABLE 1. *Patient Characteristics, Visual Acuity, and Fitting Details in PROSE*

Patient	Eye	Ocular Pathology	Corneal Astigmatism (D)	Pre-PROSE VA	PROSE VA (Customized Lens)	Average Daily Wear Time (hr)	Number of Visits
1	OD	TMD and pseudobleb	10.1	20/150	20/20	6	4
2	OS	TMD, corneal scar, pseudopterygium, and ocular surface disease	8.5	20/100 (20/25 with pinhole)	20/20	10	8
3	OD	TMD, cataract, and epiretinal membrane	13.7	20/200	20/50	Not available	5
3	OS	TMD	8.5	20/80	20/70	Not available	5
4	OD	TMD, LSCD, and post-DALK	14.6	20/100	20/70	6	7
4	OS	TMD and LSCD	Could not measure	20/150	20/60	6 (discontinued)	7

TMD, Terrien marginal degeneration; LSCD, limbal stem-cell deficiency; DALK, deep anterior lamellar keratoplasty; PROSE, Prosthetic Replacement of the Ocular Surface Ecosystem; VA, visual acuity.

three- or nine-o'clock position around the cornea.[2,5,10] Because these fibrovascular growths are described as different and spanning more broadly than typical pterygia, the higher degree of customizability with PROSE may help provide a better fit on patients with TMD with this associated finding. Patient 2 had a pseudopterygium that caused impingement of the nasal conjunctiva with initial fitting of a conventional scleral CL (Table 1). With the PROSE lens, the greater degree of control over lens vault and haptics without affecting the base curve provided better clearance of the fibrovascular tissue, which resulted in a superior fit while still maintaining a good quality refractive correction. This manipulation would be considerably more complex to achieve in conventional scleral lenses. In addition, in contrast to most conventional scleral lenses, which usually offer sizes in only one or two specific diameters, PROSE lenses can be ordered in any diameter ranging from 13 to 23 mm to better fit each individual cornea and facilitate easier lens application for narrow palpebral apertures.

Corneal thinning in TMD can lead to perforation, with rates reported to be approximately 11% to 15%.[2,6] Although overall uncommon, there have been accounts of perforations that were either spontaneous or occurred with minimal trauma.[2,11,18] Because perforated corneas in TMD were found to have worse visual outcomes regardless of surgical intervention,[2] it is important to educate patients about eye protection to prevent potentially devastating vision loss. The initial fitting for patient 1 was complicated by the pseudobleb in his superior peripheral cornea. According to the Pentacam scan (Fig. 1), this area was only 300 μm thick at maximum. There is a concern for perforation, especially because the conventional scleral lens had inadequate centration and clearance over the cornea due to its high prescription and increased weight. Because of their greater customizability, PROSE lenses were a more suitable alternative option to provide greater corneolimbal clearance, better lens centration, and even protection from mechanical forces to reduce the risk of damaging the vulnerable parts of the cornea.

Despite PROSE being a practical treatment for TMD, some ocular comorbidities of patients with complex TMD could potentially limit its viability. Although the right eye of patient 4 illustrated a successful case of improved vision in a patient with TMD postcorneal graft, the underlying LSCD in her left eye continued to progress to the point of requiring a limbal stem-cell transplant. Although PROSE helps to maintain ocular surface hydration and promotes corneal epithelial healing,[19] it does not necessarily definitively halt progression of conditions such as LSCD. Accordingly, routine follow-up with the ophthalmologist is essential to determine whether further interventions are necessary. The ERM and cataracts in patient 3 demonstrates a case where other comorbidities limit the effectiveness of PROSE. Despite his initial visual improvement compared with his GP CLs, he still reported inadequate vision over several months of follow-up. This case serves as a reminder to consider not only corneal findings but also other potential pathologies in an eye when investigating unsatisfactory visual improvement with PROSE.

There are several limitations associated with this case series. Although inclusion of patients with comorbid eye conditions is representative of real-world scenarios (where patients present with multiple comorbidities), these additional conditions can confound outcomes because TMD is not the only condition affecting vision and lens fit. In addition, its retrospective nature constrained complete data collection, with only habitual VA being available in a few of the cases. Moreover, at the time of the fittings, not all US-manufactured conventional scleral lenses were accessible to Canadian clinics, which limited the options available to patients in this case series. Furthermore, the small sample size in this series limits the ability to draw strong conclusions. Prospective studies with larger sample sizes are recommended to better elucidate outcomes in patients with TMD undergoing PROSE treatment. As well, assessing the performance of PROSE lenses in eyes with more complex pterygia and associated higher corneal astigmatism would also be of interest to evaluate the limits of this technology.

To conclude, this case series demonstrates that PROSE can be an effective treatment option for complex corneas with advanced TMD along with its concurrent conditions that also distort the ocular surface such as pseudopterygium and pseudobleb formation. The superior customizability of PROSE can help with improving lens clearance over irregular portions of the cornea. This makes it a potentially better alternative for improving vision and comfort in eyes that are not amenable to first-line therapeutic CL modalities.

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