Contact Lens and Anterior Eye 42 (2019) 526–532

Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Prosthetic replacement of the ocular surface ecosystem for corneal irregularity: Visual improvement and optical device characteristics

Preetam Kumar[a,b], Ashik Mohamed[c], Faiza Bhombal[a,b], Srikanth Dumpati[a,b], Pravin K. Vaddavalli[a,*]

[a] Contact Lens Services, Tej Kohli Cornea Institute, L V Prasad Eye Institute, Hyderabad, India
[b] Brien Holden Institute of Optometry and Vision Sciences, L V Prasad Eye Institute, Hyderabad, India
[c] Ophthalmic Biophysics, L V Prasad Eye Institute, Hyderabad, India

ARTICLE INFO

Keywords:
Contact lens
Keratoconus
Topography
Apical clearance
Three-point touchn

ABSTRACT:

Purpose: To describe patterns of prescribing Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) in irregular corneas and compare various components of lens design.

Methods: Design: Retrospective, observational case series. 244 eyes of 173 patients with keratoconus (n = 178), pellucid marginal degeneration (n = 21), keratoglobus (n = 6), following refractive surgery (n = 19) and following keratoplasty (n = 20) fitted with the PROSE device were retrospectively analyzed. Simulated keratometry value along the steep meridian (Steep-K) and anterior chamber depth (ACD) were measured using Scheimpflug imaging. Improvement in visual acuity and parameters of lens design such as vault, front surface eccentricity (FSE) and toricity were analyzed and compared across all conditions.

Results: PROSE improved visual acuity, both uncorrected (median, 1.30 logMAR) and spectacle-corrected (median, 0.60 logMAR), to a median of 0.22 logMAR. Positive correlation was observed between Steep-K and ACD with lens vault, especially in keratoconus. Multiple regression analysis established ACD as the most reliable factor while choosing vault. FSE value of 0.6 was the most common across diagnostic subgroups. The distribution of FSE values did not differ between keratoconus patients with Steep keratometry of < 60D or those > 60D. In every diagnostic subgroup, at least 20% of eyes required a lens design of with-the-rule toricity of haptic.

Conclusion: The PROSE device resulted in significant improvement in vision in this population. A trend of prescribing higher lens vault with increased keratometry value was evident especially in keratoconus. ACD appeared to be more important than Steep K in vault selection. An FSE of 0.6 and vertical peripheral lens toricity were used most frequently in this subset of patients.

1. Introduction

The importance of the Prosthetic Replacement of Ocular Surface Ecosystem (PROSE) devices in the treatment of complex corneal conditions has been growing since the turn of the 21st century. This could be attributed to the steady improvement in the design of large diameter lenses and growing awareness among contact lens practitioners, especially in the last decade [1]. Multiple reports on the importance of these lenses for conditions such as dry eyes in Steven-Johnsons syndrome [2], graft vs host disease [3], limbal stem-cell deficiency in chemical injury [4], degenerative changes such as keratoconus [5], pellucid marginal corneal degeneration (PMCD) [6], keratoglobus [7], and high irregular astigmatism exist in literature. Several recent case reports have documented the expansion indications for usage of scleral lenses in diverse ocular conditions such as exposure keratitis resulting from facial nerve palsy [8], corneal anesthesia resulting from fifth cranial nerve damage [8] as well as helping in staged reconstruction in patients with large eyelid defects [9]. A recent review by Richard Allen has comprehensively summarized the expanding role and wider acceptance of scleral contact lenses in the medical community [10].

The PROSE device is made up of a gas permeable fluorosilicone-acrylate material (Equalens II, Boston XO2, Contamac's Optimum Extra and Extreme, Polymer Technology Corporation, Bausch & Lomb, Rochester, New York, USA) [11]. The use of spline function in the software provides the lens with unique features such as smoother transition across all the junctions of several curves along with complete control of sagittal height of the lens irrespective of its base curve. These characteristics help to maneuver a lens fit onto any of the ocular

* Corresponding author at: Tej Kohli Cornea Institute, L V Prasad Eye Institute, L V Prasad Marg, Banjara Hills, Hyderabad, 500034, Telangana, India.
E-mail address: pravin@lvpei.org (P.K. Vaddavalli).

https://doi.org/10.1016/j.clae.2019.05.001
Received 2 December 2018; Received in revised form 7 May 2019; Accepted 15 May 2019

surfaces with the kind of precision that may not be achieved by other commercially available scleral lens designs.

In view of their therapeutic impact along with optical benefits, the approach to care is rapidly changing with the medical community and their support of scleral lenses as mentioned above. For ocular surface diseases, the scleral lenses are usually considered after topical treatment and prior to any surgical intervention. However, for irregular corneas, where patient primarily requires optical correction, the scleral contact lens is usually ranked second in terms of order of preference, next to the corneal gas permeable contact lenses [12]. Large diameter scleral lenses serve more as a useful fall back option in situations where the clinician is unable to achieve a satisfactory lens fit or where comfort of patient is significantly compromised with conventional modalities [13].

Fitting of these lenses is subjective for the most part and often involves a lengthy process of trial and error that depends greatly on the practitioner's experience [14,15]. The selection of the ideal lens parameters for these conditions is sparingly described in literature [15,16]. The goals of fitting a scleral lens are to achieve complete clearance of the corneal surface and to rest the lens periphery on the sclera with minimum pressure on the overlying conjunctival vessels. The range of acceptability within which the lens parameters can be maneuvered and still provide maximum visual acuity and ocular comfort can vary among the practitioners. Hence, this work primarily focused on a baseline description of the parameters of PROSE lenses prescribed in conditions with irregular corneas and understanding how these parameters are varied across these different disorders.

One could easily argue that topography is irrelevant for PROSE treatment since the lens is designed to vault over rather than align with the cornea. This conviction has become stronger from the reports by Shornack et al and Sonsino et al where no correlation was found between lens vault and keratometry values while fitting Jupiter scleral contact lenses in normal corneas as well as in keratoconus [17,18]. Though corneal topography is not always helpful in fitting scleral lenses, it is usually the first reference point and an important tool in assessing and monitoring the progression of irregular corneas. Ocular parameters such as anterior corneal curvature, especially at the steepest point of the cornea, corneal asphericity and anterior chamber depth are some of the quantifiable measures derived from corneal topography, which can help selecting the first trial lens. The hypothesis was that some of these topographic features could even potentially serve as useful objective points of reference for initiating a PROSE lens trial and helping the fitting process. In this study, the aim was to describe the prescribing patterns of PROSE lenses in irregular corneas.

2. Materials and methods

This is a retrospective observational case series and the study was approved by the Institutional Ethics Committee, L V Prasad Eye Institute, Hyderabad, India. The study adhered to the tenets of Declaration of Helsinki. Medical records of all patients who underwent a PROSE lens trial between March 2009 and March 2016 and were dispensed PROSE lenses were considered for analysis. Patient with ocular surface disease were excluded and patient with keratoconus, pellucid marginal degeneration, keratoglobus, irregular astigmatism post-refractive surgery or post-penetrating keratoplasty were included.

2.1. Lens parameters and fitting algorithm

Ideal fitting characteristics of a PROSE device include a well-centered lens that settles on sclera and overlying conjunctiva with minimum blanching on conjunctival vessels and allows minimum debris collection under the device following four hours of lens wear along with a complete clearance of the back surface of the lens over the front surface of cornea.

As per the clinical protocol, lens vault was the first parameter that was factored in while selecting the first trial lens. This was primarily chosen on a subjective basis by the practitioner based on the appearance of the height of the corneal apex on slit lamp examination. A change of lens vault was made based on the amount of lens clearance from anterior corneal surface. No further changes in the vault were made if the thickness of lens clearance appeared to be at least the same thickness as that of the central lens thickness on slit lamp biomicroscopy. Fig. 1 shows a representative clinical picture of PROSE lens fit in a patient with keratoconus where a central corneal clearance equal to the corneal thickness.

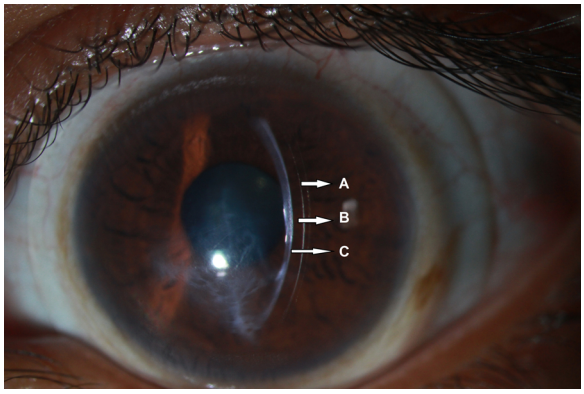

Fig. 1. PROSE in advanced keratoconus: This figure shows an advanced keratoconus eye fitted with a PROSE lens. The clinical vault of the dispensed lens is compared with the lens thickness. (A: Back surface of the PROSE lens; B: Clinical measure of the Vault; C: Front surface of the cornea).

Deviation from a conventional spherical front surface in the form of eccentricity is a unique feature of the PROSE lenses. Apart from having a spherical front surface of zero eccentricity, these lenses are also available with three other degrees of eccentricity with values of 0.3, 0.6 and 0.8. The initial trial was with a PROSE lenses with a random front surface eccentricity (FSE) value (0, 0.3, 0.6 or 0.8) from a trial lens set. On completion of an extended trial wear (comprising of a 4-hs long wear time), visual acuity was assessed with the trial lens and three other lenses of differing FSE values. The lens with the value of eccentricity that resulted in the best visual acuity was considered as the final lens. The lens was always dispensed with spherical back vertex power (BVP) and a spectacle prescription for additional astigmatism.

The haptic of the scleral contact lens is the segment of the lens that is in contact with the ocular surface. A lens with a spherical haptic was always chosen as the first trial lens and toricity was incorporated in the design based on assessment of the lens edge alignment. The first trial was almost always initiated with a lens diameter of 18.5 mm and lens diameter was increased or reduced subsequently based on fitting characteristics such as lens centration and movement. The base curve of device did not play a role in its selection.

Demographic and clinical details such as patient's age, gender and laterality of the eye were included. Clinical features such as diagnosis, uncorrected visual acuity (UCVA), Spectacle corrected visual acuity (SCVA) and prosthetic device corrected visual acuity (PDVA) were noted. For the purpose of analysis, Snellen notation of visual acuity was converted to the logarithm of minimum angle of resolution (logMAR) values.

Corneal topography was measured using the WaveLight® Oculyzer II (Alcon, Fort Worth, TX, USA) topography system. Simulated keratometry values along the steep (Steep K) and flat (Flat K) meridians, average simulated keratometry value (Avg K), corneal astigmatism (D) and anterior chamber depth (ACD) were noted. Vault, radii of curvature of optic zone (base curve) and haptic, total diameter, back vertex power, front surface eccentricity (FSE), magnitude and direction of toricity of the haptic were noted from the final lens dispensed to patients. Additional clinical details such as number of trials needed,

average lens wearing time (AWT) during follow-up visits and number of follow-up visits completed during time period were also noted.

Statistical analysis was performed using the software Origin v7.0 (OriginLab Corporation, Northampton, MA, USA). Normality of the dataset was checked using Shapiro-Wilk test. Parametric data were represented in the form of mean ± standard deviation (SD). Non-parametric data were represented in the form of median with inter-quartile range (IQR). Categorical data were presented in proportions and were compared using Chi-square test. While comparing different groups of continuous data, the equality of variance was assessed using Levene's test. When comparing more than two groups of continuous data, analysis of variance (ANOVA) was used if the data were parametric and there was equality of variance. If the data were non parametric or in cases of unequal variance, Kruskal-Wallis test was performed. A p-value of < 0.05 was considered to be statistically significant. Post-hoc pair wise comparisons were performed using *t*-test (parametric data with equal variance) or Mann-Whitney test (non-parametric data or data with unequal variance) and Bonferonni correction was applied (p-value was adjusted to $0.05/4 = 0.0125$). Regression analysis was performed to assess the relationships Steep K vs lens vault and anterior chamber depth (ACD) vs lens vault for all corneal conditions.

3. Results

A total of 244 eyes of 173 patients (127 males and 46 females) were included in the study. The PROSE device improved visual acuity, both UCVA [median of 1.30 logMAR (IQR, 1.00–1.50 logMAR); $p < 0.0001$] and SCVA [median of 0.60 logMAR (IQR, 0.40 to 0.92 logMAR); $p < 0.0001$], to a median of 0.22 logMAR (IQR, 0.00 to 0.30 logMAR) following device wear. The demographics and clinical information of the corneal conditions are shown in Table 1. The correction modalities that patients were using for visual rehabilitation prior to using the PROSE lenses are detailed in Table 2. The parameters of the PROSE lens used in various corneal conditions are summarized in Table 3.

Table 2
Lens modalities in the past – this table shows the contact lens modalities used in the past prior to the usage of PROSE lenses.

Lens modality prior to PROSE	Number of eyes
Never Worn	82 (34.1%)
RGP lens	68 (28.2%)
Rose K2 lens	47 (19.5%)
Spectacles	14 (5.8%)
SCL	9 (3.7%)
Piggy Back lens	16 (6.6%)
MSD/Other Scleral lens	5 (2.1%)

MSD: Mini-scleral design; PROSE: prosthetic replacement of the ocular surface ecosystem; RGP: rigid gas permeable; SCL: soft contact lens.

Among the different indications, keratoconus (72.9%) was the most common. Based on the Amsler-Krumeich classification, 43 of these eyes had moderate keratoconus (Steep k < 60D) and 72 eyes had severe keratoconus (Steep k > 60D). Eyes post refractive surgery had the best level of uncorrected visual acuity (median 0.92 logMAR; IQR, 0.50–1.30 logMAR) compared to the other conditions. The maximum improvement in vision with the PROSE device was achieved in eyes with PMCD. However, the quantum of visual improvement with PROSE device was comparable among the different subgroups. Cases of keratoglobus showed the highest amount of corneal astigmatism (median -12.8D; IQR -14.4 to -5.1D) and anterior chamber depth (median 4.90 mm; IQR 4.30–5.20 mm) compared to other groups (Table 1).

The number of trials required to dispense a lens was comparable among all the subgroups. Similar was the case when the number of follow up visits was considered. In terms of the duration of contact lens wear during the day (AWT), eyes with keratoconus wore lenses the most (median 10 h/day; IQR 8–12 hours/day) and eyes post corneal transplant wore them the least (median 6 h/day; IQR 5–8 hours/day)

Table 1
Study demographics – this table summarizes the demographics and clinical details of various corneal ectatic conditions.

	Keratoconus (n = 178)	PMCD (n = 21)	Post-corneal transplant (n = 21)	Post-refractive surgery (n = 19)	Keratoglobus (n = 6)	p-value
Age at diagnosis (years), median (IQR)	18 (14 to 23)	35 (27 to 44)	26.5 (24 to 39.5)	23 (22 to 32)	20 (16 to 28.7)	< 0.0001[a]
Age at dispensing (years), median (IQR)	26 (19.7 to 32)	40 (30 to 47)	43.5 (31 to 53.2)	37 (30 to 44)	23 (16 to 40.3)	< 0.0001[b]
UCVA (logMAR), median (IQR)	1.30 (1.00 to 1.52)	1.30 (1.00 to 1.40)	1.10 (0.92 to 1.60)	0.92 (0.50 to 1.30)	1.40 (1.37 to 1.40)	0.01[c]
SCVA (logMAR), median (IQR)	0.70 (0.40 to 1.00)	0.40 (0.30 to 0.60)	0.65 (0.60 to 0.80)	0.50 (0.30 to 0.70)	0.55 (0.50 to 0.60)	0.04[d]
PDVA (logMAR), median (IQR)	0.22 (0.00 to 0.30)	0.00 (0.00 to 0.20)	0.22 (0.00 to 0.60)	0.10 (0.00 to 0.40)	0.20 (0.10 to 0.42)	0.08
Steep K (D), median (IQR)	62.4 (57.2 to 66.4)	54.1 (50.6 to 58.1)	53 (48.8 to 58.1)	44.8 (39.9 to 49.1)	59 (54.5 to 65.1)	< 0.0001[e]
Corneal astigmatism (D), median (IQR)	−6.4 (−9.6 to −3.6)	−8.7 (−13.4 to −6.4)	−7.0 (−12.4 to −2.8)	−4.2 (−9.7 to −1.4)	−12.8 (−14.4 to −5.1)	0.14
ACD (mm), median (IQR)	3.9 (3.5 to 4.2)	3.8 (3.3 to 4.3)	4.14 (2.8 to 4.9)	3.4 (3.2 to 3.9)	4.9 (4.3 to 5.2)	0.008[f]

(ACD: anterior chamber depth; UCVA: uncorrected visual acuity; PDVA: PROSE corrected visual acuity; IQR: inter-quartile range; PMCD: pellucid marginal corneal degeneration; SCVA: spectacle corrected visual acuity).

[a] Post-hoc analysis showed only keratoconus differed significantly from PMCD, corneal transplant and post-refractive surgery for age at diagnosis, all $p < 0.0125$.

[b] Post-hoc analysis showed keratoconus differed significantly only from PMCD and post-corneal transplant for age at dispensing; similarly, post-refractive surgery differed significantly only from PMCD and post-corneal transplant for age at dispensing, all $p < 0.0125$.

[c] Only post-refractive surgery differed significantly from keratoconus and keratoglobus for UCVA, all $p < 0.0125$.

[d] Post-hoc analysis showed keratoconus differed significantly only from PMCD and post-corneal transplant for SCVA; similarly, post- corneal transplant differed significantly only from PMCD for SCVA, all $p < 0.0125$.

[e] Post-hoc analysis showed keratoconus differed significantly only from PMCD and post-refractive surgery for Steep K; similarly, post-refractive surgery differed significantly only from PMCD and keratoglobus for Steep K, all $p < 0.0125$.

[f] Post-hoc analysis showed keratoconus differed significantly only from post-refractive surgery and keratoglobus for ACD; similarly, keratoglobus differed significantly only from PMCD and post-refractive surgery for ACD, all $p < 0.0125$.

Table 3
PROSE lens parameters – This table summarizes the details of dispensed PROSE lens parameters in various corneal conditions.

		Keratoconus	PMCD	Post-corneal transplant	Post-refractive surgery	Keratoglobus	p-value
Vault (mm), median (IQR)		5.5 (5 to 5.6)	5.35 (5.3 to 5.8)	5.5 (4.9 to 5.6)	4.9 (4.7 to 5.2)	6 (5.8 to 6.3)	< 0.0001[a]
Base curve (mm), median (IQR)		7.9 (7.4 to 7.9)	7.9 (7.4 to 7.9)	7.4 (7.4 to 7.9)	7.9 (7.9 to 8.6)	7.4 (7.4 to 7.5)	0.005[b]
FSE	0	3 (1.7%)	NA	3 (15%)	5 (26.3%)	NA	0.001
	0.3	25 (14%)	1 (4.8%)	2 (10%)	6 (31.5%)	1 (16.6%)	
	0.6	94 (52.8%)	14 (66.6%)	9 (45%)	7 (36.8%)	1 (16.6%)	
	0.8	56 (31.4%)	6 (28.5%)	6 (30%)	1 (5.3%)	4 (66.6%)	
Haptic (mm)		15 (14.4 to 15)	15 (14 to 15)	15 (14 to 15)	14.5 (14.3 to 15)	15 (14.5 to 15.1)	0.35
BVP (D)		−1.3 (−3.0 to +0.4)	−1.1 (−3.3 to −0.8)	−3.1 (−5.5 to −0.7)	−6.3 (−9.3 to −4.5)	−2.4 (−7.4 to −0.6)	< 0.0001[c]
Spherical toricity		129 (72.4%)	17 (80.9%)	15 (75%)	13 (68.4%)	3 (50%)	0.73
Horizontal toricity		9 (5.1%)	NA	NA	1 (5.2%)	1 (16.6%)	
Vertical toricity		40 (22.4%)	4 (19.1%)	5 (25%)	5 (26.3%)	2 (33.3%)	
No of trials required, median (IQR)		1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	0.90
Average wearing time (hours/day), median (IQR)		10 (8 to 12)	8 (7 to 12)	6 (5 to 8)	9 (6 to 10)	6 (4 to 10)	0.009[d]
Number of follow-up visits, median (IQR)		2 (1 to 5)	2 (0 to 3)	2 (1 to 4)	1 (0 to 4)	1 (1 to 8)	0.45

(BVP: back vertex power; FSE: front surface eccentricity; IQR: inter-quartile range; PMCD: pellucid marginal corneal degeneration).
[a] Post-hoc analysis showed both only post-refractive surgery and keratoglobus differed significantly from all the other conditions, all $p < 0.0125$.
[b] Post-hoc analysis showed only post-refractive surgery differed significantly from keratoconus, post-keratoplasty and keratoglobus, all $p < 0.0125$.
[c] Post-hoc analysis showed only post-refractive surgery differed significantly from keratoconus, PMCD and PK, all $p < 0.0125$.
[d] Post-hoc analysis showed only keratoconus was significantly different from post-keratoplasty ($p = 0.002$).

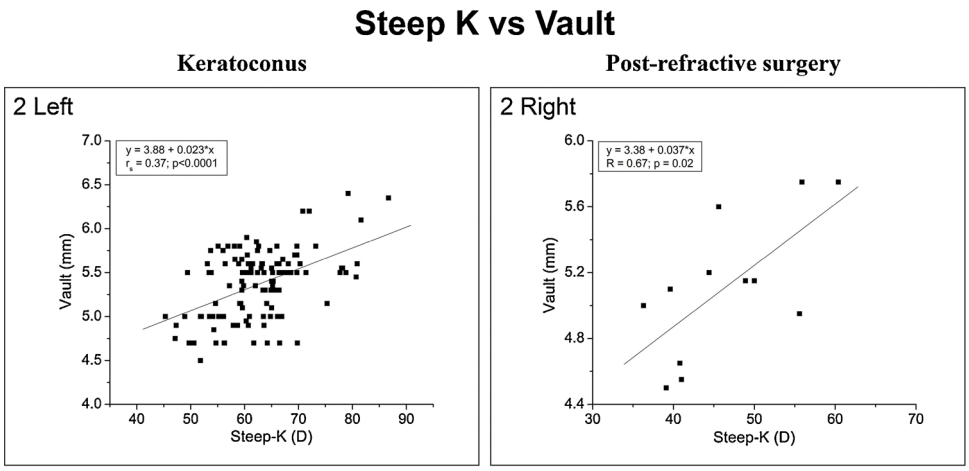

Fig. 2. Steep-K vs Vault in PROSE: This figure shows the relationship between Steep-K and vault of the dispensed PROSE lens in keratoconus (left, n = 115) and post-refractive surgery (right, n = 12).

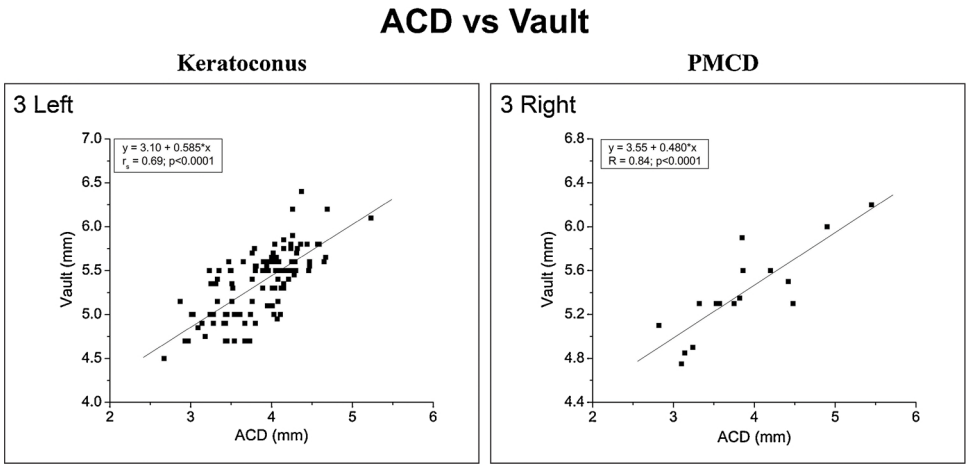

Fig. 3. ACD vs Vault in PROSE: This figure shows the relationship between anterior chamber depth and vault of the dispensed PROSE lens in keratoconus (left, n = 115) and pellucid marginal corneal degeneration (right, n = 17).

(Table 3).

Regression analysis between Steep K and lens vault showed a positive correlation in keratoconus ($p < 0.001$) and post-refractive surgery ($p = 0.02$) (Fig. 2). Regression analysis between ACD and lens vault showed a positive correlation in keratoconus ($p < 0.0001$) and PMCD ($p < 0.0001$) (Fig. 3). Multiple regression analysis (independent variables: steep K and ACD vs dependent variable: lens vault) found only ACD ($p < 0.0001$) to be a significant factor affecting lens vault in keratoconus and not steep K ($p = 0.10$).

4. Discussion

This report focusses on describing the practice pattern of PROSE lenses at a tertiary eye care center and identifying the various parameters of these lenses required for a good fit and to select a trial lens. As expected, a significant improvement in vision with the PROSE lens was observed in all conditions and is in agreement with published data for visual improvement [5,19,20]. The best-corrected visual acuity with the device was also significantly better compared to the spectacle-corrected visual acuity.

Scleral lens vault appears to be one of the fundamental parameters that determine the central corneal clearance; hence this is of primary area of interest for the practitioners during contact lens fitting. A sense of ambiguity persists in selection of this parameter which can vary considerably based on the clinical experience of the practitioner [15]. The report by Arumugam and colleagues has clearly noted the requirement of a significantly higher vault in ectatic conditions (mean value of 5.26 ± 0.43 mm) when compared to eyes with ocular surface disorder where a relatively flatter corneal surface is often experienced (mean value of 4.90 ± 0.25 mm) [20]. In this cohort as well, ectatic corneas required lenses with higher vault when compared to flatter corneas such as those post-refractive surgery (Tables 1 and 3). Additionally, eyes with keratoglobus required significantly higher vault values compared to keratoconus or PMCD (Table 3). However, the maximum vault dispensed in this cohort was 6.3 mm which was still significantly less compared to the 7.6 mm vault device dispensed in the case reported by Mahadevan and colleagues [21]. A positive correlation was found between curvature of steepest corneal point and lens vault in keratoconus indicating requirement of steadily increasing vault with steeper corneal curvature (Fig. 2). A similar correlation was found in post-refractive surgery corneas but no relationship was found between these two parameters in other ocular conditions.

Anterior chamber depth (ACD) was identified as an independent parameter that correlated with lens vault. Shornack et al, in their report, speculated that understanding the relationship between depth of anterior chamber and highest point on cornea would probably be a better indicator in terms of selection of lens with adequate sagittal height over cornea [17]. A positive correlation was evident between ACD and lens vault, and interestingly, multivariate analysis showed a significant correlation only between ACD and vault but not between corneal curvature and lens vault (Fig. 3). This result complies with the results from the recent work by Weber and colleagues that suggested anterior chamber depth is an important predictor in terms of selection of sagittal depth of Esclera scleral contact lens [22]. In addition, the present report with the PROSE lenses further consolidate the repeatable nature of the finding across the different designs of scleral lenses. It appears that the lens vault can range from 4.9 mm (when ACD is 3 mm) to 5.7 mm (when ACD is 4.5 mm), the increase being 0.6 mm per unit mm increase in ACD. However, prospective validation with a more direct measurement with the help of anterior segment tomography would confirm this observation.

A unique feature designed to enhance the quality of vision that sets these devices apart from other scleral lenses is an addition of eccentricity on the front surface of lens. Eccentricity (e) values are used to represent a conic section and to demonstrate its deviation from a perfect circle. Addition of this feature is thought to compensate for issues such as magnitude of the cone and any deviation of the apex of cone from the optical center of device [23]. Three different FSEs are available along with its spherical form; 0.3, 0.6 and 0.8.

In the present study, the overall distribution of different FSE values was significantly different among the groups. Keratoconus, PMCD and post-penetrating keratoplasty eyes followed a similar trend where 0.6 FSE was most commonly dispensed followed by 0.8 and 0.3. The result follows a trend similar to that of a case series of five patients with keratoconus by Hussoin et al where 0.6 and 0.8 eccentricity values yielded better visual performance than 0.3 FSE [23]. In the present series, an FSE of 0.8 was most useful in eyes with keratoglobus, while a 0.6 FSE was mostly useful in eyes with astigmatism post-refractive surgery, closely followed by an FSE of 0.3 in the rest. The use of a non-eccentric spherical front surface lens was less common across all the groups and accounted for a minority of patients post-refractive surgery (26.3%) followed by PMCD (15%) and keratoconus (1.7%) (Table 3).

The role of FSE of the device is still ambiguous and perhaps not fully understood in practice. As described in several mathematical models of cornea, this abnormal shape is best explained by the term asphericity (Q) that defines the rate of change in curvature from the apex to the periphery of the cornea [24–26]. The report by Tummanapalli et al used corneal asphericity as a highly sensitive descriptor for diagnosing PMCD, where a positive 'Q' value indicated a more oblate cornea when compared with keratoconic cornea [27]. Understandably, these two subsets (keratoconus and PMCD) of patients are supposed to experience higher order aberrations (HOAs) A report by Gumus et al has shown that FSE has the greatest impact on spherical aberration among all HOAs [19].

In post refractive surgery cases, FSE of 0.6 (36.8%), 0.3 (31.5%) and 0 (26.3%) were prescribed more than 0.8 (5.3%). Interestingly, usage of a device with lower eccentricity values and spherical devices were more common in these cases compared to the other subgroups. This result could be explained by a relatively oblate form of cornea presented after a refractive surgery, causing a genuine difference in the overall asphericity of cornea compared to the other aforementioned ocular conditions.

An increase in negative asphericity indicates a more advanced form of keratoconus [28]. Woodward et al has postulated a higher rate of corneal flattening from the apex of cone to periphery in more advanced forms of keratoconus [29]. Theoretically, one can expect higher FSEs for more advanced forms of keratoconus. In this cohort, although the pattern of distribution of FSE values was not statistically different between the groups with 0.6 eccentricities occupying the major share of dispensed devices, the number of lenses with an FSE value of 0.8 were higher in more advanced forms of keratoconus (Table 4).

This cohort of cases required a significantly high number of devices with eccentricity incorporated on the front surface 95.4% compared to only 28.6% of devices reported by Gumus et al. [19]. This difference could be due to the clinical evaluation methods used in the respective PROSE lens practices. In this practice, effort was made in keeping the other lens parameters (i.e. vault, base curve, diameter and back vertex power) constant while switching between devices with different FSE

Table 4
FSE in keratoconus – this table summarizes the distribution of various front surface eccentricity (FSE) values in the sub-groups of 'mild-moderate' and 'advanced' form of keratoconus.

Severity of keratoconus	Front Surface Eccentricity (FSE)				
	0	0.3	0.6	0.8	
Steep K < 60 D (n = 43)	1 (2.3 %)	8 (18.6%)	28 (65.1%)	6 (13.9%)	P = 0.13
Steep K > 60 D (n = 72)	N/A	13 (18%)	37 (51.3%)	22 (30.5%)	

N/A: Not available.

values. In addition, incorporating visual assessment with low contrast acuity chart could potentially yield better result in making a judgment on subjective preference of patient as noted by Hussoin and colleagues [23]. However, a prospective observation in a controlled experimental set up could provide further insight for this particular feature of the lens.

Use of anterior optical coherence tomography has helped in understanding the shape of the anterior ocular surface beyond the extent of the cornea (limbus). Reports have clearly established the rotationally asymmetric nature of the corneo-scleral curvature as well as anterior scleral curvature [30–32]. Customization at the haptic region of the scleral lens in the form of toricity addition facilitates closer approximation of the lens to the anterior scleral shape, making the lens more stable and patients more comfortable in this process [33]. Though spherical haptic were most frequently used in this series, 67 devices (27.4%) required toricity to be incorporated in haptic region. A similar trend was noted, i.e. vertical toricity over horizontal was more frequently prescribed indicating a similar scleral anatomy irrespective of the type of corneal ectasia, which complies with theoretical assessments made by van der Worp [34]. Arumugam et al. have reported a higher proportion of devices (72.9%) that required a customization in the form of toricity in haptic portion [20]. The differing proportion from this study could be due to the variability in indications of PROSE lenses in the clinics or subjectivity involved in the assessment of lens fitting characteristics such as understanding the compression of mid-haptic portion on superficial conjunctival blood vessels and impingement of lens periphery on ocular surface [15]. Reports have suggested that the measurement of scleral curvature along the horizontal meridian is easier and more reliable compared to the measurements along the vertical meridian due to the difficulties in capturing and interpreting the tomography image [31]. However, a greater proportion of devices dispensed with vertical toricity might indicate a natural tendency of these lenses to decenter inferiorly as described by Walker et al. [35]. Additionally, cases with ocular surface disorders may incur surface irregularity such as scarring of bulbar conjunctiva, formation of symblepharon and fornicial changes that may require more manipulation of the haptic design compared to ectatic corneas.

In this report, reasons for prescribing these lenses in ectatic conditions were multi-dimensional. Inability to achieve a well fit conventional or a specially designed RGP contact lens and intolerance to wearing them were the main reasons. Five patients were prescribed PROSE lenses following signs of exacerbation of ocular allergy after prolonged use of conventional lenses. Among piggy back contact lens users, inconvenience in using two lens systems was the main reason to shift to PROSE lenses. In patients already using mini-scleral and scleral designs, a greater compression on underlying conjunctival vessels and inability to use lenses for a prolonged period were the main reasons for switch over to PROSE lenses. For post-keratoplasty eyes, the major indication for corneal transplant was keratoconus and these patients were uncomfortable with rigid contact lenses. The post-refractive surgery patients, who were soft contact lens users prior to surgery, were not comfortable with the idea of having a rigid contact lenses over the eye.

Patients with keratoconus wore the lenses for maximum duration (median 10 h a day) while post-corneal transplant patients wore them for the least duration (median 6 h a day). The overall impression was similar to a range between 8 to 11 h mentioned by Tan et al. [36] and the report from Kenpullum's group where a significantly large retrospective report from 538 patients showed 59% of them worn lenses for more than 10 h a day [37]. A report by Severinsky et al has shown a greater AWT (11.8 h a day) compared to this cohort of post-penetrating keratoplasty cases [38]. This difference could be attributed primarily to the health of the grafts that were fit with these lenses at the time of trial as well as during the lens usage. An association of dispensing a toric haptic and devise usage has not been looked into in this report. However, it can be argued that an increase in volume of devices dispensed with toricity at the haptic would probably have resulted in an increase in hours of lens usage as mentioned by Visser and colleagues [33].

The number of visits that patients needed for follow up was the most in post-transplant cases. While the straight forward reason for this could be medical management of graft health, the underlying causes could be multifactorial in nature. A change in the osmotic gradient in the corneal stoma due to the release of lactic acid in cases of reduced oxygen availability on the anterior corneal surface [35], event of micro trauma due to the constant usage of device, a tightly fit lens causing a substantial reduction in the tear exchange and an increase in metabolic waste beneath the lens [38], a possible effect of an ongoing systemic management of the underlying condition with immunosuppressive [39] or even a poor compliance in terms of lens care regimen [38] could all potentially initiate an inflammatory event in an already compromised post-transplant cornea.

One of the limitations of this study is the fact that the report describes the practice pattern with a particular type of scleral lens, which can not necessarily be extrapolated to the other commercially available scleral lens designs. In addition, the retrospective nature of the study warrants further prospective investigations to validate the finding regarding various lens fitting parameters such as lens vault, front surface eccentricity and haptic toricity. However, with the growing stature of the practice of scleral contact lenses, it is useful to gather information of different practice patterns, especially with one of the most decorated scleral lens designs such as PROSE devices.

In summary, this study looked at various parameters of the PROSE lens in detail and tried to identify the key ones required to make selection of the primary trial lenses easier. Anterior chamber depth appeared to be a better predictor for selecting the vault of the trial lens over corneal curvature. An FSE value of 0.6 appeared to be more frequently used in this cohort. Overall, this study supports the growing role of these devices as a promising alternative in diseases with irregular corneas where conventional contact lens wear may fail.

Conflicts of interest

None of the authors have any proprietary interests or conflicts of interest related to this submission.

Source(s) of support

None.

References

[1] C.B. Nau, J. Harthan, E. Shorter, et al., Demographic characteristics and prescribing patterns of scleral lens fitters: the SCOPE study, Eye Contact Lens 44 (September (Suppl 1)) (2018) S265–S272.
[2] P. Rosenthal, J. Cotter, The Boston Scleral Lens in the management of severe ocular surface disease, Ophthalmol Clin North Am 16 (2003) 89–93.
[3] D.S. Jacobs, P. Rosenthal, Boston scleral lens prosthetic device for treatment of severe dry eye in chronic graft-versus-host disease, Cornea 26 (2007) 1195–1199.
[4] J.D. Ling, A. Gire, S.C. Pflugfelder, PROSE therapy used to minimize corneal trauma in patients with corneal epithelial defects, Am J Ophthalmol 155 (2013) 615–619 619.e1-2.
[5] I. Baran, J.A. Bradley, F. Alipour, et al., PROSE treatment of corneal ectasia, Cont Lens Anterior Eye 35 (2012) 222–227.
[6] V.M. Rathi, S. Dumpati, P.S. Mandathara, et al., Scleral contact lenses in the management of pellucid marginal degeneration, Cont Lens Anterior Eye 39 (2016) 217–220.
[7] R. Mahadevan, A. Fathima, R. Rajan, et al., An ocular surface prosthesis for keratoglobus and Terrien's marginal degeneration, Optom Vis Sci 91 (4 Suppl 1) (2014) S34–39.
[8] M. Weyns, C. Koppen, M.J. Tassignon, Scleral contact lenses as an alternative to tarsorrhaphy for the long-term management of combined exposure and neurotrophic keratopathy, Cornea 32 (March (3)) (2013) 359–361.
[9] D.B. Samimi, G.B. Chiu, M.A. Burnstine, PROSE scleral lens: a novel aid for staged eyelid reconstruction, Ophthalmic Plast Reconstr Surg 30 (September–October (5)) (2014) e119–21.
[10] R.C. Allen, Controversies in periocular reconstruction for facial nerve palsy, Curr Opin Ophthalmol 29 (September (5)) (2018) 423–427.
[11] W.B. Stason, M. Razavi, D.S. Jacobs, et al., Clinical benefits of the Boston ocular surface prosthesis, Am J Ophthalmol 149 (2010) 54–61.

[12] E. Shorter, J. Harthan, C.B. Nau, et al., Scleral lenses in the management of corneal irregularity and ocular surface disease, Eye Contact Lens 44 (November (6)) (2018) 372–378.
[13] P.S. Mandathara, F.J. Stapleton, M.D.P. Willcox, Outcome of keratoconus management: review of the past 20 years' contemporary treatment modalities, Eye Contact Lens 43 (2017) 141–154.
[14] A.D. Nixon, J.T. Barr, D.A. VanNasdale, Corneal epithelial bullae after short-term wear of small diameter scleral lenses, Cont Lens Anterior Eye 40 (April (2)) (2017) 116–126.
[15] J. Harthan, E. Shorter, C. Nau, et al., Scleral lens fitting and assessment strategies, Cont Lens Anterior Eye 42 (February (1)) (2019) 9–14.
[16] J.C. Lee, G.B. Chiu, D. Bach, et al., Functional and visual improvement with prosthetic replacement of the ocular surface ecosystem scleral lenses for irregular corneas, Cornea 32 (2013) 1540–1543.
[17] M.M. Schornack, S.V. Patel, Relationship between corneal topographic indices and scleral lens base curve, Eye Contact Lens 36 (2010) 330–333.
[18] J. Sonsino, D.S. Mathe, Central vault in dry eye patients successfully wearing scleral lens, Optom Vis Sci 90 (2013) e248–251 Discussion 1030.
[19] K. Gumus, A. Gire, S.C. Pflugfelder, The impact of the Boston ocular surface prosthesis on wavefront higher-order aberrations, Am J Ophthalmol 151 (2011) 682–690 e2.
[20] A.O. Arumugam, R. Rajan, M. Subramanian, et al., PROSE for irregular corneas at a tertiary eye care center, Eye Contact Lens 40 (2014) 71–73.
[21] R. Mahadevan, A. Fathima, R. Rajan, et al., An ocular surface prosthesis for keratoglobus and Terrien's marginal degeneration, Optom Vis Sci 91 (4 Suppl 1) (2014) S34–9. April.
[22] S.L. Weber, R. Ambrósio Jr., C. Lipener, et al., The use of ocular anatomical measurements using a rotating Scheimpflug camera to assist in the Esclera® scleral contact lens fitting process, Cont Lens Anterior Eye 39 (April (2)) (2016) 148–153.
[23] T. Hussoin, H.G. Le, K.G. Carrasquillo, et al., The effect of optic asphericity on visual rehabilitation of corneal ectasia with a prosthetic device, Eye Contact Lens 38 (2012) 300–305.
[24] A.K. Lam, W.A. Douthwaite, Derivation of corneal flattening factor, p-value, Ophthalmic Physiol Opt 14 (1994) 423–427.
[25] W.A. Douthwaite, The asphericity, curvature and tilt of the human cornea measured using a videokeratoscope, Ophthalmic Physiol Opt 23 (2003) 141–150.
[26] H. Burek, W.A. Douthwaite, Mathematical models of the general corneal surface, Ophthalmic Physiol Opt 13 (1993) 68–72.
[27] S.S. Tummanapalli, V. Maseedupally, P. Mandathara, et al., Evaluation of corneal elevation and thickness indices in pellucid marginal degeneration and keratoconus, J Cataract Refract Surg 39 (2013) 56–65.
[28] J.T. Holladay, Corneal topography using the holladay diagnostic summary, J Cataract Refract Surg 23 (1997) 209–221.
[29] D.A. de Cunha, E.G. Woodward, Measurement of corneal topography in keratoconus, Ophthalmic Physiol Opt 13 (1993) 377–382.
[30] L.A. Hall, C. Hunt, Young, et al., Factors affecting corneoscleral topography, Invest Ophthalmol Vis Sci 54 (May (5)) (2013) 3691–3701.
[31] H.J. Choi, S.M. Lee, J.Y. Lee, et al., Measurement of anterior scleral curvature using anterior segment OCT, Optom Vis Sci 91 (July (7)) (2014) 793–802.
[32] B. Tan, A.D. Graham, G. Tsechpenakis, et al., A novel analytical method using OCT to describe the corneoscleral junction, Optom Vis Sci 91 (June (6)) (2014) 650–657.
[33] E.S. Visser, R. Visser, H.J. Van Lier, Advantages of toric scleral lenses, Optom Vis Sci 83 (April (4)) (2006) 233–236.
[34] E.A. van der Worp, Guide to Scleral Lens Fitting, Version 2.0. Forest Grove, Pacific University, OR, 2015.
[35] M.K. Walker, J.P. Bergmanson, W.L. Miller, et al., Complications and fitting challenges associated with scleral contact lenses: a review, Cont Lens Anterior Eye 39 (April (2)) (2016) 88–96.
[36] D.T. Tan, K.W. Pullum, R.J. Buckley, Medical applications of scleral contact lenses: 2. Gas-permeable scleral contact lenses, Cornea 14 (March (2)) (1995) 130–137.
[37] K.W. Pullum, M.A. Whiting, R.J. Buckley, Scleral contact lenses: the expanding role, Cornea 24 (April (3)) (2005) 269–277.
[38] B. Severinsky, S. Behrman, J. Frucht-Pery, et al., Scleral contact lenses for visual rehabilitation after penetrating keratoplasty: long term outcomes, Cont Lens Anterior Eye 37 (2014) 196–202.
[39] P. Rosenthal, J.M. Cotter, J. Baum, Treatment of persistent corneal epithelial defect with extended wear of a fluid-ventilated gas-permeable scleral contact lens, Am J Ophthalmol 130 (July (1)) (2000) 33–41.