Visual and physiological outcomes of scleral lens wear

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ABSTRACT

Purpose: To describe patient-specific outcomes of scleral lens wear utilizing a variety of lens designs across multiple practice settings as reported in an international practitioner survey.

Methods: An electronic survey was administered to eye care providers who prescribe scleral lenses in which they were asked to describe their most recently examined established scleral lens patient. Data was collected on patient characteristics, lens designs, wearing schedules, care products, and visual and physiological outcomes of lens wear. Descriptive analysis of data was performed.

Results: A total of 292 responses were received. Participants represented 26 countries. The most commonly reported indication for scleral lens wear was corneal irregularity (87%) followed by ocular surface disease (8%), refractive error (4%) and 1% with multiple indications. Visual acuity improved from 0.4 ± 0.4 (mean $\pm$ SD) to 0.1 ± 0.2 in eyes with corneal irregularity ($p < 0.001$), from 0.3 ± 0.3 to 0.1 ± 0.3 in eyes with ocular surface disease ($p < 0.001$), and from 0.1 ± 0.1 to $0.0 \pm [0.1]$ in eye with refractive error ($p = 0.01$). Prior to scleral lens wear, corneal staining was present in 55% of patients; staining was present in only 35% of patients following scleral lens wear. The number of topical ophthalmic drops needed decreased from 1.7 ± 0.9 to 0.8 ± 0.8 in patients with corneal irregularity ($p < 0.001$) and from 3.5 ± 1.7 to 1.1 ± 1.0 in patients with ocular surface disease ($p < 0.001$). The number of drops used by patients with refractive error remained stable, with these patients using an average of 2.0 ± 1.0 drops prior to scleral lens wear and 1.7 ± 1.5 drops following scleral lens wear.

Conclusions: Patients with corneal irregularity experienced the greatest improvement in visual acuity, but patients with ocular surface disease and refractive error also achieved better visual acuity with scleral lenses. Ocular surface condition improved in patients with both corneal irregularity and ocular surface disease; patients with ocular surface disease experienced the most dramatic improvement. Patients who wore scleral lenses to correct uncomplicated refractive error did not experience an improvement in signs or symptoms of ocular surface disease.

1. Introduction

There has been a dramatic increase in the number of scleral publications from 2012 to 2016 compared to the previous 5-year period based on a recent study on the body of scleral lens-related scientific research [1]. Recent literature includes single-center, retrospective case series which generally describe a single lens design and unified fitting philosophy [2–7]. Studies on observed or potential impact of scleral lenses on ocular surface structures have also been published within the past 5 years [8,9], as has research on the structure and contour of conjunctival, episcleral, and scleral tissue [10–13]. Phenomena related to scleral lens fitting characteristics have also been described [14–16].

There is a lack of published data describing outcomes of scleral lens wear for patients within the general eye care community. Single-center retrospective reviews provide some insight into prescribing patterns and outcomes of scleral lens wear, but most of these studies originate from tertiary care centers or specialty contact lens practices. The results of these single-center studies may not be generalizable to other lens designs, practice modalities and fitting philosophies. Results of a worldwide survey of general scleral lens prescription and management strategies were recently reported [17–19]. While these studies provided a better understanding of the indications for scleral lens use along with

information on lens designs being prescribed, care products recommended, and demographics of scleral lens prescribers, they do not offer insight into outcomes of scleral lens wear. This cross sectional study was designed to evaluate patient-specific outcomes of scleral lens wear across a broad population, gathering data from multiple providers using a wide variety of lens designs.

2. Methods

A web-based, REDCap (Research Electronic Data Capture) survey was designed and hosted at the University of Illinois at Chicago [20]. This study was reviewed and deemed exempt by the University of Illinois Institutional Review Board. The survey was available between December 13, 2016 and March 31, 2017. Direct email invitations were sent to 2790 members of the Scleral Lens Education Society, 604 participants of the original SCOPE (Scleral Lenses in Current Practice Evaluation) study who had indicated willingness to participate in future studies, and to 37 scleral lens prescribers that were suggested by study participants. Links to the survey were also included in the I-Site and BCLA (British Contact Lens Association) monthly e-newsletters.

Respondents were asked to provide information on the established scleral lens patient ($\geq$6 months of lens wear) that they had most recently evaluated in their clinics. They were specifically asked to reference the patient's medical record while completing the survey. De-identified demographic information, indications for lens wear, ocular history, visual acuity prior to and after scleral lens fitting, presence or absence of corneal staining prior to scleral lens wear and at the most recent visit, use of topical medications before and after scleral lens use, and complications were reported. (Survey, see Appendix 1). Data was analyzed using descriptive statistics. Paired *t*-test was used to compare pre- and post-lens values.

3. Results

A total of 352 responses were received. Of those, 21 were excluded due to lack of scleral lens use in either eye and 39 were excluded as they only included patient demographic data. The remaining 292 responses were analyzed for the purposes of this study.

A total of 26 countries were represented with 60% of responses from the United States, 5% from Canada, 5% from Italy, 4% from India, 3% from Switzerland, 3% from South Africa, 2% from Spain and 1% or less from 19 other countries. Respondents were asked to provide information on their primary mode of practice (n = 233), years of experience in fitting scleral lenses (n = 233), and the year that they completed their training (n = 229). A majority of respondents (72%) reported working primarily in private or group practice. An additional 21% worked in academic practice settings. Other modalities representing less than 3% each included lens manufacturing and corporate/retail, hospital-based, military, HMO, and multidisciplinary practice settings. Forty-two percent of respondents reported $\leq$5 years of experience fitting scleral lenses, 37% reported 6–10 years of experience, 12% reported 11–15 years or experience, and the remaining 9% reported $\geq$16 years of experience. The mean date of training completion was 1997 $\pm$ 12 (mean $\pm$ SD) years (range 1970–2016).

The mean patient age was 45 [14] years with a range of 18–86 years (n = 285). Gender distribution was 63% male and 37% female (n = 292). Race was reported for 291 patients: 66% white, 16% Hispanic or Latino, 7% Black or African American, and 7% Asian/Pacific Islander. Other races represented less than 2% each, including Indian, Middle Eastern, European African, and South African. Major indications for lens wear were reported for 291 patients, and the specific condition being treated was reported for 289 patients. Table 1 shows the number of patients included in each general indication, along with the number of patients with specific conditions.

Surgical history was reported for all 292 patients; 45% had undergone at least one prior surgical procedure. Thirty three percent (n = 96)

Table 1

Overall percentages of patients with corneal irregularity, ocular surface disease, refractive error, and multiple indications are 87%, 8%, 4%, and 1% respectively. Keratoconus was the most common diagnosis reported, representing 61% of the total number of patients in the study.

Indications for Scleral Lens Wear		
(n = 291)		
General Indication	Specific Condition	Number of Patients
Corneal Irregularity (n = 253)[a]	Keratoconus	176
	S/P corneal surgery	52
	Pellucid marginal corneal degeneration	18
	Corneal scarring	3
	Corneal dystrophy	2
	Irregular astigmatism	1
Ocular Surface Disease (n = 24)	Dry eye syndrome	10
	Ocular graft versus host disease	4
	Exposure keratopathy	2
	Chemical/thermal injury	1
	Limbal stem cell deficiency	1
	Neurotrophic keratopathy	1
	Neuropathic pain	1
	Radiation keratopathy	1
	Recurrent corneal erosion	1
	Sjögren's syndrome	1
	Stevens Johnson syndrome	1
Refractive Error (n = 11)[a]	High myopia	4
	High hyperopia	2
	Astigmatism	2
	Low hyperopia	1
	Presbyopia	1
Multiple Indications (n = 3)	All 3 indications	1
	Keratoconus and Stevens Johnson syndrome	1
	Keratoconus and ocular graft versus host disease	1

[a] Specific conditions were not identified for one patient with corneal irregularity and one patient with refractive error.

of patients had previous bilateral surgery; 18 patients had undergone surgery in their right eye only, and 16 patients had undergone surgery in their left eye only. The most commonly reported surgical procedure in this population was corneal transplantation (n = 97 eyes), followed by refractive surgery (n = 62), corneal crosslinking (n = 41), cataract surgery (n = 31), and intracorneal ring segments (n = 25). Other procedures reported included lid surgery (n = 5), keratoprosthesis (n = 3), conductive keratoplasty (n = 2), pterygium excision (n = 2), trabeculectomy (n = 1), electrolysis (n = 1), strabismus surgery (n = 1), and repair of retinal tear (n = 1).

Of 292 patients, 233 wore lenses bilaterally. Unilateral right eye lens wear was reported in 27 patients, and unilateral left lens wear was reported in 32 individuals. Duration of lens wear was reported for 291 patients: mean duration of lens wear was 2.5 $\pm$ 2.0 years (range 0.5–16 years, median 1 year). The population represented a total of 734.3 patient years of scleral lens wear.

Respondents were asked to identify the form of optical correction that the patient was wearing at the time of scleral lens fitting. Habitual correction was reported for 255 patients (451 eyes). Information on habitual correction was available for 222 right eyes and 229 left eyes. Table 2 shows the number of eyes wearing each form of correction by indication.

3.1. Visual outcomes of scleral lens wear

Both pre- and post-scleral lens visual acuity was reported in a total of 246 patients (434 eyes); 188 patients wore scleral lenses bilaterally, 27 wore a scleral lens in the right eye only, and 31 wore a scleral lens in

Table 2
Habitual correction worn in each eye prior to scleral lenses, by indication.

	Corneal Irregularity		Ocular Surface Disease		Refractive Error	
	(221 patients)		(22 patients)		(9 patients)	
	(391 eyes)		(38 eyes)		(17 eyes)	
	OD	OS	OD	OS	OD	OS
Corneal rigid gas permeable lenses	93	88	0	0	2	2
Glasses alone	41	44	12	10	3	3
No correction	18	22	6	6	0	1
Glasses and contact lenses	12	13	1	1	2	1
Soft contact lenses	17	20	1	1	2	1
Hybrid lenses	8	9	0	0	0	0
Piggyback lenses	1	3	0	0	0	0
Other scleral lens design	1	1	0	0	0	0

Three patients (5 eyes) for whom information on habitual correction was provided are not included in the table above. One patient with multiple indications for bilateral scleral lens wear wore glasses and contact lens correction in both eyes. Another patient with multiple indications for bilateral scleral lens wear wore no correction in either eye. A third patient for whom the indication for scleral lens wear was not provided wore soft contact lens correction in the left eye only.

the left eye only. Visual acuity was reported in Snellen notation (or equivalent), and was converted to logMAR for statistical analysis. Mean visual acuity in all right eyes (n = 215) prior to scleral lens wear was 0.4 ± 0.4, range −0.12 to 2. With scleral lenses, mean visual acuity in all right eyes improved to 0.1 ± 0.2, range −0.3 to 2; this improvement was statistically significant ($p < 0.001$). Mean visual acuity in all left eyes (n = 219) prior to scleral lens wear was 0.4 ± 0.4, range −0.3 to 2. With scleral lenses, mean visual acuity in all left eyes was 0.1 ± 0.2, range −0.3 to 1; this improvement was also statistically significant ($p < 0.001$). Changes in visual acuity were then calculated for each major primary indication. (Three patients (6 eyes) were not included in this analysis as a single primary indication was not provided by survey respondents.) In all eyes with corneal irregularity (n = 377), mean visual acuity was 0.4 ± 0.4 prior to lens wear and improved to 0.1 ± 0.2 with scleral lenses ($p < 0.001$). In all eyes that were being treated for ocular surface disease (n = 34), mean visual acuity was 0.3 ± 0.3 prior to lens wear, and improved to 0.1 ± 0.3 with scleral lenses ($p < 0.001$). In all eyes fit with scleral lenses primarily for correction of uncomplicated refractive error (n = 17), mean visual acuity was 0.1 ± 0.1 prior to lens wear, and was 0.0 ± 0.1 with scleral lenses ($p = 0.01$).

Fig. 1 illustrates the number of eyes per major indication for which changes in the number of lines of Snellen acuity were reported following scleral lens wear. Of the 14 eyes that achieved worse visual acuity with scleral lenses compared to habitual correction, 12 were fit with scleral lenses for management of corneal irregularity and 2 used scleral lenses to manage ocular surface disease. Correction prior to scleral lens wear in those eyes was distributed as follows: 7 wore corneal rigid gas permeable lenses, 4 wore no correction, 2 wore soft contact lenses, and 1 wore glasses and contact lenses. All of the 21 eyes that experienced 10 or more lines of improvement in visual acuity were fit with scleral lenses for management of corneal irregularity. Prior to scleral lenses, 10 of these eyes wore no correction prior to scleral lens wear, 6 wore spectacle correction, 2 wore soft contact lenses, 2 wore corneal rigid gas permeable lenses, and 1 wore glasses and contact lenses.

Overall, 56% of right eyes and 60% of left eyes achieved Snellen-equivalent visual acuity of 20/20 or better. Ninety percent of right eyes
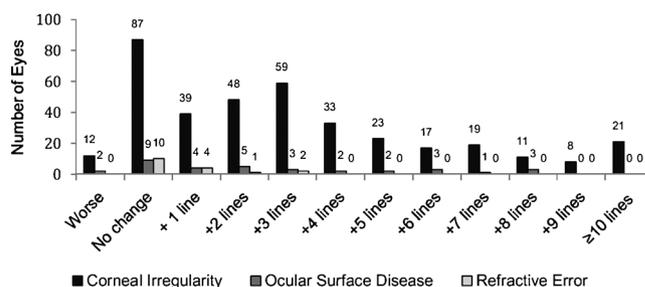

Fig. 1. The changes in Snellen-equivalent visual acuity in each eye are shown for each of the three major indications for scleral lens wear (corneal irregularity, ocular surface disease, refractive error).

and 95% of left eyes achieved visual acuity of 20/40 or better. All but 4 right eyes and 4 left eyes achieved visual acuity of 20/70 or better. Of 252 respondents who indicated whether their patients wore supplemental spectacle correction over their scleral lenses, 4 reported that their patients were reported to wear distance spectacle correction over scleral lenses, 10 patients were reported to wear spectacle correction for near tasks, and 7 patients were reported to wear multifocal glasses over their scleral lenses.

3.2. Physiological outcomes of scleral lens wear

Physiological outcomes of scleral lens wear were ascertained by comparing presence or absence of corneal staining prior to lens wear with staining at the most recent examination. Respondents were asked to indicate the degree of staining on a 6-level scale (none, trace, 1+, 2+, 3+, or 4+); primary analysis of data was conducted by looking at presence or absence of staining only. The degree of staining was then analyzed as a secondary endpoint in patients who experienced corneal staining both prior to and following scleral lens wear. Pre- and post-scleral lens assessments of corneal staining were available for 246 patients (435 eyes). By indication, corneal status was reported for 214 patients with corneal irregularity, 20 patients with ocular surface disease, 9 patients with refractive error, 3 patients with multiple or no indications listed. Overall, corneal staining was noted prior to lens wear in 136 (55%) of patients (224 eyes). Pre-lens corneal staining was reported in 113 (53%) patients (188 eyes) with corneal irregularity, 18 (90%) of patients (30 eyes) with ocular surface disease, 4 (44%) patients (6 eyes) with refractive error, and 3 (100%) patients (6 eyes) with multiple or no indications identified.

At the study visit, staining was present in a total of 86 (35%) patients (127 eyes). Distribution by indication is as follows: 73 patients (108 eyes) with corneal irregularity, 8 patients (13 eyes) with ocular surface disease, 5 patients (6 eyes) with refractive error, and 2 patients (4 eyes) with multiple indications. Corneal staining had been noted in 51 of these patients prior to initiating scleral lens wear. Continued presence of staining did not necessarily indicate that scleral lenses provided no ocular surface protection. Comparing pre- and post-lens levels of severity for patients in whom corneal staining was noted both prior to and following scleral lens wear, decreased severity was noted in 24 patients (37 eyes) with corneal irregularity, all 8 patients (12 eyes) with ocular surface disease, 3 patients (4 eyes) with refractive error, and both patients (4 eyes) with multiple indications. Corneal staining did not always improve with scleral lens wear, however. In 6 patients (6 eyes) with corneal irregularity and 1 patient (1 eye) with refractive error for whom pre-lens staining was noted, more severe staining was reported following lens wear. Furthermore, post-lens staining was reported in a number of patients whose corneas had been clear prior to scleral lens wear. Twenty patients (32 eyes) with corneal irregularity

Pre- and Post-Scleral Lens Corneal Staining
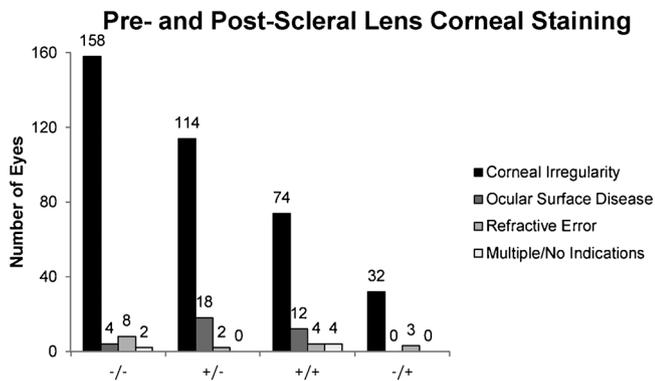
Fig. 2. Presence or absence of corneal staining prior to scleral lens wear compared to presence or absence of staining at study visit.
" − / − ": no staining was present prior to or following scleral lens wear.
"+/− ": corneal staining was noted prior to scleral lens wear, but was not noted at the study visit.
"+/+": corneal staining was present both prior to scleral lens wear and at the study visit.
"−/+": corneal staining was not present prior to scleral lens wear, but was noted at the study visit.

and two patients (3 eyes) with refractive error developed corneal staining following scleral lens wear. Fig. 2 shows the number of eyes with corneal staining prior to and/or following scleral lens wear per indication.

Physiological outcomes of scleral lens wear were also assessed by comparing the number of topical medications used prior to and after scleral lens use. Prior to scleral lens fitting, 84 patients were reported to use topical eye drops (58 patients with corneal irregularity, 21 patients with ocular surface disease, 3 patients with refractive error, and 2 patients with multiple indications). The mean number of topical preparations utilized before scleral lens fitting among these patients was 2.2 ± 1.5, and the maximum number of topical agents used was 7 (in one patient). Average number of topical ophthalmic drops used prior to scleral lens wear per indication was 1.7 ± 0.9 for corneal irregularity, 3.5 ± 1.7 for ocular surface disease, and 2.0 ± 1.0 for refractive error.

Following scleral lens wear, the average number of topical agents used by this group of patients was 1.0 ± 1.1; the difference in the number of drops used was statistically significant (p < 0.001).

The patient who had been using 7 topical agents prior to scleral lens fitting was still using all 7 agents while wearing scleral lenses. Thirty of the patients who were using drops prior to scleral lens wear no longer needed to use them after being fit with scleral lenses. Average number of topical ophthalmic drops used following scleral lens wear per indication decreased to 0.8 ± 0.8 for corneal irregularity (p < 0.001), decreased to 1.1 ± 1.0 for ocular surface disease (p < 0.001), and decreased to 1.66 ± 1.5 for refractive error (p = 0.4). In the thirty patients who were able to discontinue the use of topical medications, primary indications for scleral lens wear were corneal irregularity in 21 patients, ocular surface disease in 7 patients, refractive error in 1 patient, and multiple indications in 1 patient. Specific topical ophthalmic preparations used prior to and after scleral lens fitting are shown in Table 3.

In addition to the 54 patients who used drops both prior to and after scleral lens fitting, 20 patients who had not used drops prior to scleral lens wear were reported to use one or more of these agents with scleral lenses. The primary indication for scleral lens wear was corneal irregularity in 19 of these patients and refractive error in the remaining patient. Average number of drops used by this group of patients following scleral lens wear was 1.6 ± 0.8. Topical ophthalmic preparations used by these individuals included artificial tears (n = 11), topical steroids (n = 7), antihistamines (n = 5), cyclosporine (n = 3),

lubricant gel (n = 2), lubricant ointment (n = 1), antibiotics (n = 1) and ocular hypotensive agents (n = 2).

Respondents were also asked to identify the number of patients who had experienced adverse events or issues associated with scleral lens wear. One or more abnormal findings had been observed during at least one visit in one or both eyes in 124 (42%) patients. Primary indications for scleral lens wear in patients who had experienced adverse events were as follows: corneal irregularity, 106 (42%); ocular surface disease, 12 (50%); refractive error, 6 (54%). No cases of microbial keratitis were reported in this population. Adverse events reported are summarized by indication in Table 4.

4. Discussion

This multicenter, cross-sectional study confirms previous reports of positive visual and physiological outcomes of scleral lens wear. These results suggest that the positive outcomes of scleral lens wear reported in retrospective case reviews from tertiary care clinics and medical centers are being achieved across a wide spectrum of practices throughout the world. The study also provides further insight into specific conditions for which scleral lenses are being prescribed and potential issues or adverse events that may be associated with scleral lens wear.

Overall, patients experienced significant improvements in visual acuity with scleral lenses. Given that a majority of patients represented in this study wore lenses for management of corneal irregularity, this is certainly encouraging, but not surprising. However, patients who wore lenses for management of ocular surface disease also achieved significant improvements in visual acuity. Improvement in visual acuity in patients with ocular surface disease has been previously reported [21]. The present study provides further evidence that scleral lenses may improve visual acuity in patients with ocular surface disease by improving and maintaining the integrity of the ocular surface. Patients for whom scleral lenses were primarily prescribed to correct refractive error did not experience significant improvements in visual acuity, but this small group of patients generally achieved normal levels of visual acuity with their habitual correction. It must be noted, however, that the number of patients wearing lenses for correction of refractive error represented less than 4% of all patients in this study. It is possible that improvements in visual acuity may be found with a larger sample size.

While overall evaluation of data shows a significant improvement in visual acuity, not all patients achieve improvements in acuity. A majority of patients for whom improvements in visual acuity were not achieved with scleral lenses were capable of resolving 20/25 or better with habitual correction prior to lens wear. This suggests that scleral lenses may confer some other benefit (improvement in comfort, improved quality of vision) even in patients with reasonable visual acuity with another form of correction. A small number of patients actually achieved poorer visual acuity with scleral lenses than with their habitual correction. In patients with ocular surface disease, a slight loss of acuity may be a reasonable trade-off for the ocular surface protection provided by a scleral lens. Improved comfort compared to corneal rigid gas permeable lenses may justify fitting a patient with corneal irregularity with a scleral lens, even if visual acuity does not improve.

The number of patients with corneal irregularity who were wearing no correction prior to being fit with scleral lenses was surprising. It is possible that these patients achieved adequate visual acuity with one eye, and had not found a mode of correction that provided enough improvement in visual acuity in their poorer eyes to justify the added burden of care associated with contact lens wear. It is also possible that these patients had tried unsuccessfully to wear other contact lens modalities, and had simply given up trying to see well. Regardless of the reason for the lack of correction reported here, these results suggest that scleral lenses may be able to provide better vision for patients who have not been able to achieve success with other types of contact lenses.

Assessment of physiological outcomes of scleral lens wear through

Table 3
The number of patients reported to use each of the topical ophthalmic drops, gels, or ointments prior to scleral lens wear and at study visit are shown above. Pre- and post-scleral lens drop use was also reported for two patients with multiple indications. One patient used artificial tears only prior to scleral lens wear and used no drops after initiating scleral lens wear. The other patient used artificial tears, steroids, lubricant gel, cyclosporine, antihistamine, lubricant ointment, antibiotics and NSAID's both prior to and after scleral lens wear.

	Corneal Irregularity		Ocular Surface Disease		Refractive Error	
	Pre-Lens ($n = 58$)	Post-Lens ($n = 37$)	Pre-Lens ($n = 21$)	Post-Lens ($n = 14$)	Pre-Lens ($n = 3$)	Post-Lens ($n = 2$)
Artificial tears	32	21	17	9	2	2
Steroids	28	14	16	2	1	1
Lubricant gel	6	4	12	4	0	0
Cyclosporine	6	1	10	5	0	0
Allergy drops	13	6	0	1	2	2
Lubricant ointment	4	1	8	0	0	0
Antibiotics	5	0	7	0	1	0
Serum tears	0	0	3	2	0	0
Topical NSAID's	1	0	1	0	0	0
Ocular hypotensive drops	6	4	1	1	0	0

Table 4
A total of 164 adverse events were reported during 734.3 patient years of lens wear. The most common adverse finding was conjunctival injection, followed by handling/application error.

	Corneal Irregularity	Ocular Surface Disease	Refractive Error	Total
Conjunctival Findings				
Injection	64	7	2	73
Prolapse	13	2	0	15
Hypertrophy	5	0	0	5
Subconjunctival hemorrhage	1	0	0	1
Giant papillary conjunctivitis	5	0	0	5
Corneal Findings				
Stromal edema	14	0	0	14
Neovascularization	9	1	0	10
Bullae	2	0	0	2
Infiltrates	1	0	0	1
Limbal edema	8	1	0	9
Limbal hypoxia	2	0	0	2
Other Findings				
Handling/application error	19	2	2	23
Uveitis	2	0	0	2
Toxic keratopathy	1	0	0	1
Increased intraocular pressure	0	1	0	1
Total	**146**	**14**	**4**	**164**

comparison of pre-lens corneal staining to that which was described at the study visit highlighted a substantial improvement in ocular surface integrity in patients with ocular surface disease. Although corneal staining did not completely resolve in all patients, the degree of staining decreased in all patients with ocular surface disease for whom corneal staining was recorded prior to scleral lens wear. Interestingly, improvements in ocular surface health were also found in patients who were fit with scleral lenses for management of corneal irregularity. A majority of these patients had worn corneal rigid gas permeable lenses prior to scleral lenses. These patients were refit into scleral lenses because their small-diameter lenses were causing corneal compromise. Epitheliopathy associated with corneal lens wear could reasonably be expected to improve with scleral lens wear. Evaluation of corneal staining associated with scleral lens wear for correction of uncomplicated refractive error presents a somewhat more complex picture. Corneal staining improved, but did not completely resolve, in 3 of the 4 patients who exhibited staining prior to being fit with scleral

lenses. Additionally, 2 patients who had not shown signs of corneal compromise prior to scleral lens wear were reported to have some level of corneal staining after wearing scleral lenses. These patients had generally healthy eyes before being fit with scleral lenses, and therefore would be more likely to show subtle signs of corneal stress associated with scleral lens wear. The sample size is too small to allow for rigorous statistical analysis, but this finding certainly deserves further evaluation.

Reasons for persistence of corneal staining in some patients have yet to be fully explained. Some patients may have been filling the bowl of the lens with a solution that was not compatible with the ocular surface prior to application. A previous study found that some providers actually recommend that patients use preserved saline, multipurpose soft contact lens solution, or even tap water to fill the bowl of the lens prior to application [17]. Even if a provider specifically recommends that a patient use only non-preserved products for this purpose, some patients choose to use preserved solutions to fill their lenses. Use of these products could certainly cause some degree of epitheliopathy. Use of topical medications or preserved artificial tears could also contribute to findings of corneal punctate staining. If the scleral lens does not completely clear the cornea and limbus, mechanical interaction between the lens and the ocular surface could also result in corneal compromise. The current trend in scleral lens fitting is to limit the amount of corneal clearance in an attempt to provide an adequate oxygen supply to the cornea. However, if the lens settles to the extent that it is actually in contact with the cornea, epithelial damage may occur. Although we are not able to determine the cause of the staining in these patients, the persistence of corneal staining in some patients, along with appearance of new corneal staining in previously healthy individuals illustrates the importance of checking the ocular surface following removal of the lens at each visit. Additional work is needed to identify solutions and fitting parameters that are least likely to cause corneal damage.

Given the small percentage of individuals in this sample who wore scleral lenses for ocular surface disease, the relatively low overall percentage of patients using any kind of topical eye drops or lubricant agents (29% of total patients described) is not surprising. In patients with ocular surface disease, most (88%) were using some eye drops, gels, or ointments prior to initiating scleral lens wear, but 23% of individuals with corneal irregularity and 27% of individuals with refractive error were also using one or more topical ophthalmic agents prior to lens wear. This suggests that ocular discomfort may be a secondary indication for scleral lens wear in at least some patients. Although a majority of individuals who required topical ocular medications prior to scleral lens wear still needed to use at least one eye drop, ointment, or gel even when wearing scleral lenses, our results do suggest that scleral lens wear may allow them to reduce the number of

drops used. While we did not assess frequency of use; it is also possible that patients who find it necessary to use lubricant drops while wearing scleral lenses may need to use them less frequently than they did prior to initiating lens wear. It was interesting to note that 20 individuals who had not needed to use topical ophthalmic drops, ointments or gels prior to scleral lens wear found it necessary to do so while wearing lenses. Reasons for this finding are unclear. These patients may have developed some degree of tear film dysfunction independent of scleral lens wear. However, it may be prudent to advise patients who are considering scleral lenses that there is a slight possibility that they may need to use lubricant drops while wearing scleral lenses, even if they do not find it necessary to do so prior to scleral lens fitting.

Scleral lens related issues and adverse events were reported in 42% of patients in this study. Fortunately, most of these issues appear to be relatively benign. The most commonly reported adverse finding was conjunctival injection. While complete avoidance of conjunctival injection may be preferable, most providers would likely agree that this finding generally does not indicate a sight-threatening problem. Despite concerns that prolonged corneal hypoxia could lead to unacceptable levels of corneal swelling or other signs of corneal stress, corneal edema was reported in less than 5% of patients in this study, and corneal neovascularization was noted in less than 4% of these patients. No cases of microbial keratitis were reported in this population, but the total number of patient years of scleral lens wear represented is relatively low (734.3 years). A larger study will be necessary to determine the incidence of microbial keratitis in scleral lens wearers.

Speculation that scleral lens wear may cause an increase in intraocular pressure is a matter of some concern within the eye care community [22,1–24]. In this population, only one patient was reported to experience a significant increase in intraocular pressure in one eye. However, two patients who had not been using ocular hypotensive drops prior to scleral lens wear were reported to be using glaucoma medications at the study visit. While the assumption that scleral lens wear was solely responsible for the elevation of intraocular pressure that may have necessitated the use of ocular hypotensive medication in these patients, the finding is worth noting. More study in this area would certainly be welcome, particularly in populations of patients who may be at higher risk for developing glaucoma.

This study may not accurately represent scleral lens outcomes worldwide, as data was collected using an English language survey. However, a larger percentage of responses in this study were from international prescribers (40%) compared to the original SCOPE study [18], in which 23% of prescribers reported residency outside of the United States. Lack of standardized methods of measuring visual acuity or assessing corneal staining may also represent a weakness in this retrospective study. In a prospective study, standardization of visual acuity measurement and application of photographic grading scales for assessment of corneal or conjunctival staining could be implemented. For this retrospective study, we made the assumption that each provider would be internally consistent in visual acuity assessment and documentation of corneal staining. Since our primary interest was change in visual acuity and corneal staining following initiation of scleral lens wear rather than an absolute value for visual acuity or corneal staining at a single point in time, we would submit that trends observed in this study represent general outcomes of scleral lens wear reasonably well.

Despite these limitations, the current study does provide information for scleral lens prescribers that will allow them to better educate their patients as to what to expect with scleral lens wear. Data presented here may also be used in the design of future prospective multicenter studies that will further elucidate visual and physiological outcomes of scleral lens wear.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.clae.2018.07.007.

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