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Assessment of a practitioner's perception of scleral contact lens complications

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ABSTRACT

Purpose: The purpose of this survey was to better understand scleral lens (SL) practitioners' fitting preferences and minor SL complications and their subsequent treatments.

Method: Practitioners who attended the 2017 Global Specialty Lens Symposium were asked to complete an electronic questionnaire that was created by the investigators, a survey that asked practitioners about their SL fitting experience and preferences, their patients' experience with poor SL wetting, SL fogging, ocular symptoms (redness, pain/discomfort, dryness), and blurred central and side vision, and how the practitioners treated these conditions.

Results: This study analyzed data from 164 SL practitioners. The practitioners had been in practice for 16.3 ± 13.4 years, had been fitting SL for 5.5 ± 5.0 years, and fit 7.4 ± 7.1 SL/month. Practitioners preferred a SL with a final central corneal clearance of ~200 μm and an overall diameter between 15.1 mm to 16.5 mm. Poor SL wetting (90.8% of practitioners documented condition), SL fogging (84.8%), blurred central vision (40.2%), ocular redness (34.8%), ocular dryness (24.4%), ocular pain/discomfort (20.7%), and blurred side vision (12.8%) were encountered by the practitioners. Practitioners preferred treating poor wetting and fogging with lens removal, cleaning, and reapplication, blurred central vision with a lens power change, blurred side (peripheral) vision, ocular redness, and ocular pain with a lens parameter change, and dryness with artificial tears.

Conclusions: Most SL practitioners preferred a SL central corneal clearance of ~200 μm, and they occasionally encountered SL-related complications in their practice, which they treated similarly to corneal gas permeable CLs.

1. Introduction

With the advent of utilizing highly gas permeable materials in scleral lenses (SL) and improvement in SL designs, SL fitting has increased over the past few years for patients who have corneal irregularities, ocular surface disease, and ametropia [1–6]. While it is true that SL are prescribed for uncomplicated ocular conditions, they are most frequently prescribed to patients who have advanced corneal irregularities because SLs provide a hard refractive surface with an underlying reservoir of tears and preservative free saline solution, which is able to mask corneal irregularity [1]. This masking often dramatically improve a patient's visual experience, even in situations where soft and corneal gas permeable contact lenses (CL) have failed because of factors such as poor lens stability or comfort, while at the same time allowing the eye to be more hydrated and often more comfortable compared to other modalities [2,5,7,8].

The success and generally accepted safety of SLs in challenging and uncomplicated cases have created a renewed interest in this longstanding CL modality [2,6]. Nevertheless, there is a paucity of information related to even the most basic aspects considered by the everyday SL practitioner. One facet is related to SL fitting trends. A SL practitioner typically considers five lens parameters when fitting a SL:

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central corneal clearance (clearance between CL and cornea), lens thickness, limbal clearance, overall lens diameter, and peripheral lens profile [9–11]. Choice of lens material and lens surface properties are also often considered as they may have an impact on lens performance (e.g., lipid deposition) [12]. Evidence suggests that SLs with small lens diameters and minimal corneal clearance result in optimal corneal health because they provide better corneal oxygenation [9–11]. The literature also suggests that scleral shape may affect peripheral SL fit and subsequently have an impact on factors such as bubble formation, fogging, ocular health, and comfort [13]. While each of these ideal parameters likely vary per patient's eye, it is currently unclear what practitioners consider optimal and how they adjust these parameters to obtain ideal outcomes.

There is likewise a lack of evidence related to how frequently practitioners encounter minor, non-emergency SL complications. Of note, SL fogging, a minor complication unique to SLs, has been reported in about one-third of all SL wearers [1]. SL fogging results in progressively blurred vision caused by the buildup of a particulate matter within the tear reservoir that occurs over the course of the day. The origins of this particulate matter have yet to be fully defined, though there is some evidence that it could be a mixture of tear lipids and proteins and/or inflammatory cells [14,15]. SL fogging may be made proportionally worse by fitting SL with a higher central corneal clearance, and it is a problem that can typically only be alleviated by the removing, cleaning, and reapplying of the lens [1,7,15,16]. While the community has begun to characterize SL fogging, there is still a lack of information related to other commonly reported minor CL complications like ocular redness and visual blur [17,18]. Therefore, the purpose of this study was to conduct a survey at an international specialty CL conference. This was done to ensure a sample of SL practitioners who had a range of experience levels, to better understand current SL fitting trends, and to obtain a preliminary estimate of practitioner-reported frequencies of minor SL complications and their treatments of choice for each of these complications.

2. Methods

This study obtained ethics approval from the University of Houston's Institutional Review Board (Protocol Number: IRB00010706). The study complied with the tenets of the Declaration of Helsinki. All specialty CL practitioners who attended the 2017 Global Specialty Lens Symposium (GSLS) were allowed to participate. Subjects were excluded if they were under the age of 18 years, if they had never fit a SL, or if they were unwilling to complete the survey electronically. Study group members consented and enrolled interested participants during the meeting's exhibit hall hours. Subjects also signed a health privacy document. All data were collected in a de-identified manner (no link between consent and questionnaire) with an electronic tablet (iPad, Apple). The survey was administered via a secured web service through www.qualtrics.com (Qualtrics, Provo, UT, USA). All subjects completed an investigator-designed survey that queried practitioners' perception of the SL wearer's wearing experience. The survey questions focused on practitioner experience, lens fitting, frequency of a practitioner ever encountering minor complications such as midday fogging, and the practitioner's preferred methods for treating the minor SL complications (Appendix I). A portion of the survey used the Scleral Lens Fit Scales from the Michigan College of Optometry Vision Research Institute for subjects to grade the amount of central clearance between the cornea and SL (corneal clearance) [19]. Study members assisted subjects with the survey upon request.

All data were analyzed with SAS Version 9.3 or Microsoft Excel. Frequencies were calculated for categorical variables and means and standard deviations were calculated for continuous variables in order to understand the real-world practitioners' fitting preferences and the complications commonly encountered in SL wearers. Correlations were calculated using Pearson's correlation coefficient when both variables were continuous, and Spearman's coefficient when at least one variable was categorical. A p-value of < 0.05 was considered statistically significant.

Table 1
Subject Demographics (n = 164 Subjects).

Practitioner Experience	**Mean ± SD**
Duration of Practicing (years)	16.3 ± 13.4
SL Fitting Experience (years)	5.5 ± 5.0
New SL Fits (fits/month)	7.4 ± 7.1
Lifetime SL Fits	**n (%)**
< 10	20 (12.2)
10-25	31 (18.9)
25-50	34 (20.7)
50-100	23 (14.0)
> 100	57 (34.8)
Mode of Practice	**n (%)**
Co-Management Center	5 (3.0)
Corporate Practice	5 (3.0)
Educational Setting	70 (42.7)
Private Practice	74 (45.1)
Referral Center	10 (6.1)

[*]SL = Scleral Lens.

3. Results

3.1. Subject demographics

This study enrolled 172 SL practitioners of which 164 participants fully completed the survey. Only the subjects who fully completed the survey were included in the analysis. On average SL practitioners had been in practice for 16.3 ± 13.4 years, had been fitting SL for 5.5 ± 5.0 years, and fitted 7.4 ± 7.1 SL per month (Table 1). Furthermore, 12.2% of the practitioners surveyed had fitted fewer than 10 SL in their career, while 34.8% of the practitioners surveyed had fitted more than 100 SL in their career (Table 1). Most practitioners surveyed worked in an educational or private practice setting, though other practice modes were represented (Table 1).

3.2. Scleral lens fitting

Practitioners indicated that their primary reason for selecting a SL design was ability to change parameters (46.4%), familiarity of particular brand or lab (32.7%), availability in the office (9.5%), warrantee/exchange available for the type of lens selected (7.7%), insurance coverage for the lens chosen (1.8%), cost of the lens to the patient (1.2%), and cost of lens to the practice (0.6%). For the initial dispensed SLs and finalized SLs, SL practitioners reported an ideal central corneal clearance of 277.1 ± 56.4 μm and 194.8 ± 51.5 μm, respectively, when asked to complete an open-end response question. When asked to identify the image (multiple choice question) that represented the ideal initial and finalized central corneal clearance, 0.6% and 5.4% chose 50 μm, 11.9% and 65.5% chose 150 μm, 76.8% and 24.4% chose 300 μm, 10.1% and 3.6% chose 500 μm, and 0.6% and 1.2% chose 600 μm, respectively (Fig. 1). Practitioner experience as measured by years of fitting SL was not associated with the subject's selected ideal initial ($r = -0.06$; $p = 0.41$) or finalized ($r = -0.12$; $p = 0.12$) central corneal clearance. However, there was a significant correlation between the average initial central corneal clearance reported by practitioners and the initial central corneal clearance image selected (Spearman correlation coefficient = 0.21, p-value = 0.006). There was also a significant correlation between the ideal final central corneal clearance reported by practitioners and the final central corneal clearance image selected (Spearman correlation coefficient = 0.41, p-value < 0.0001).

When questioned about the starting SL diameter that practitioners selected, 68% of respondents indicated that they started with lens

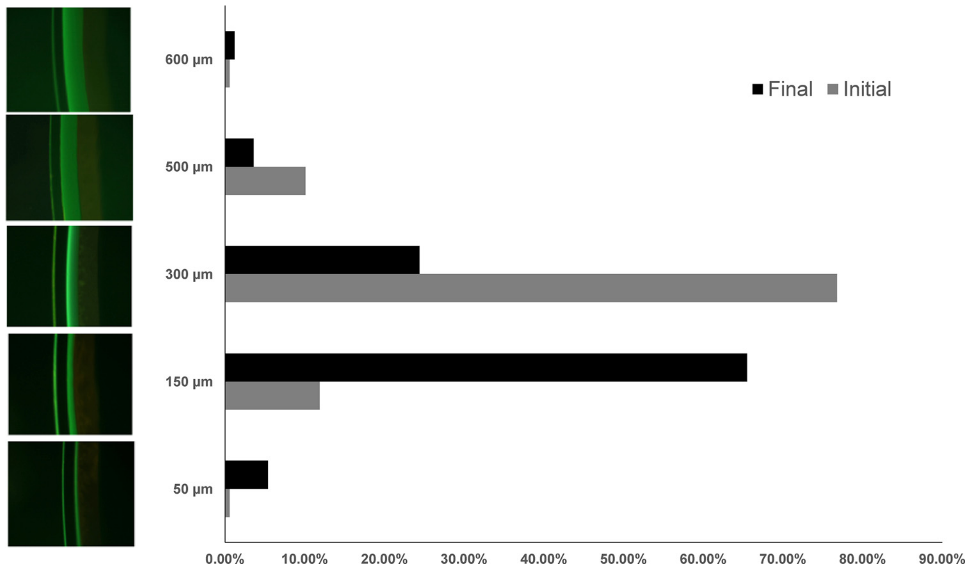

Fig. 1. Distribution of Practitioner's Ideal Initial and Finalized Clearance Between the Cornea and Scleral Lens.

diameters between 15.1 mm–16.5 mm. However, 17% went larger by starting with lens diameters between 16.6 mm–17.5 mm lenses, and 12% went smaller by starting with lenses smaller than 15.1 mm. Only 3% of practitioners start with lens diameters between 17.6 mm–18.5 mm and one subject indicated that they started with a lens diameter > 18.5. Larger initial and final lens diameter were significantly associated with larger initial ($p = 0.17$; $r = 0.03$) and final ($p = 0.02$; $r = 0.81$) ideal central corneal clearance values, respectively.

3.3. Minor scleral lens complications

This study found that 90.8% and 84.8% of practitioners at least occasionally noticed patients with poorly wetting SL and patients with SL fogging, respectively (Table 2). Of the practitioners who indicated that their patients experienced poor SL wetting, the practitioners most frequently noted that their patients complained of visual fluctuations and constant blur, and they thought that the poor SL wetting was likely caused by deposits on the front surface of the lens and debris in the tear film. Of the practitioners who indicated that their patients experienced SL fogging, the practitioners most frequently reported that the fogging occurred within 3 to 5 h after applying the SLs. The practitioners also most frequently indicated that they felt like the SL fogging occurred from debris in the tear film. A large percentage of practitioners also, at least occasionally, encountered SL patients who had blurred central vision (40.2%), ocular redness (34.8%), ocular dryness (24.4%), ocular pain/discomfort (20.7%), and blurred side (peripheral) vision/halos (12.8%) (Table 2). Practitioner-reported SL fogging ($r = 0.26$; $p < 0.001$), patient-reported blurring ($r = 0.18$, $p = 0.02$), and ocular dryness ($r = 0.19$, $p = 0.02$) were all associated with more years of fitting scleral lenses. Encountering all other conditions was independent of duration of years in practice, years of fitting SLs, and number of SLs

Table 2
Practitioner Reported Minor Scleral Lens Complications.

Complication	Frequency (%)
Poor Lens Wetting	90.8
Lens Fogging	84.8
Blurred Central Vision	40.2
Ocular Redness	34.8
Ocular Dryness	24.4
Ocular Pain/Discomfort	20.7
Blurred Side Vision/Halos	12.8

Table 3
Top Treatments for Minor Scleral Lens (SL) Compilations.

Condition with Methods	n	Mean Frequency (%)
Poor Wetting		
Remove, Clean, and Reapply SL	120	45.8 ± 25.9
Remove, Clean, Soak, and Reapply SL	76	44.3 ± 29.0
Artificial Tears	89	32.1 ± 23.2
Rub SL with a Plunger	71	26.8 ± 21.5
Other	40	44.5 ± 28.3
Fogging		
Remove, Clean, and Reapply SL	105	55.1 ± 28.7
Remove, Clean, Soak, and Reapply SL	48	42.4 ± 29.9
Artificial Tears	64	36.9 ± 28.2
Rub SL with a Plunger	25	21.2 ± 27.0
Change SL Fit	12	73.1 ± 24.9
Other	28	55.2 ± 27.0
Ocular Redness		
Change Peripheral SL Curve	45	68.3 ± 25.6
Artificial Tears	21	35.1 ± 32.0
Change SL Diameter	22	21.1 ± 20.1
Change SL Sagittal Height	13	31.7 ± 29.8
Ocular Discomfort		
Change Peripheral SL Curve	28	59.1 ± 29.5
Remove, Clean, and Reapply SL	9	32.8 ± 25.9
Artificial Tears	12	27.3 ± 17.6
Change Base Curve	9	23.3 ± 12.0
Shadowing, Doubling, or Blurry Vision		
Change SL Refractive Power	36	53.6 ± 29.1
Remove, Clean, and Reapply SL	19	51.1 ± 30.4
Change SL Diameter	9	44.4 ± 40.3
Change SL Sagittal Height	27	39.1 ± 30.4
Side Vision Distortion/Halos		
Change SL Diameter	6	58.3 ± 45.9
Change SL Refractive Power	8	50.0 ± 26.7
Change SL Sagittal Height	5	40.0 ± 28.5
Other	5	90.0 ± 22.4
Ocular Surface Dryness		
Artificial Tears	35	60.9 ± 22.3
Agent to treat ocular surface disease	18	38.3 ± 27.2
Remove, Clean, Soak, and Reapply SL	6	36.7 ± 20.7
Other	6	55.0 ± 36.1

Values stated in Table 3 are for practitioners who reported encountering the above condition. Subjects were allowed to select more than one treatment per condition. Individual subject values were required to equal 100% for each condition.

fit per month (All $p > 0.06$).

3.4. Treatment of minor scleral lens complications

Survey participants were polled to determine their top treatments for commonly reported minor SL complications (Table 3). Respondents rated how often they used the treatments, for the ones that they used. Removing, cleaning, and reapplying the SL was the practitioner top choice for patients who were experiencing poor SL wetting and SL fogging (Table 3). Changing the peripheral SL curves was the top treatment of choice for patients who had ocular redness and ocular discomfort. Changing the refractive power of the SL was the top treatment of choice for patients who had blurry central while changing the diameter of the SL was the top treatment of choice for patients who had side vision distortion/halos (Table 3). Artificial tears were the top treatment of choice for patients who were experiencing ocular dryness (Table 3).

4. Discussion

This study administered an electronic survey at an international specialty contact lens meeting to query practitioners' SL fitting trends, complications, and troubleshooting methods. This study specifically found that the average practitioner's preferred final fit had a central corneal clearance of ~200 μm and had a diameter between 15.1 mm–16.5 mm. This study likewise found that most practitioners had encountered patients who experienced midday fogging or poor lens wetting, and the majority of practitioners treated both of these conditions by removing, cleaning, and reapplying the SL.

The average practitioner surveyed in this study indicated in an open-ended response question that their ideal starting SL had an initial corneal clearance of ~280 μm with an overall diameter between 15.1 mm to 16.5 mm. Interestingly, the average practitioner reported in a similarly phrased question that their ideal finalized SL fit should have ~200 μm of central corneal clearance, which is in line with suggestions from Barnett and Johns [6]. The difference between initial and final SLs is likely due to lens settling [20]. Additionally, a practitioner's years of SL experience was not associated with ideal initial or final central corneal clearance suggesting that the majority of the community is fitting SLs in a similar, likely clinically ideal, manner and that general educational resources (e.g., online SL education websites, peer reviewed materials, continuing education lectures) rather than clinical experience or location of optometric practice or training may be shaping fitting trends. With that said, the variance among practitioners with regards to ideal initial and final central corneal clearances may be related to the mean severity of disease that a practitioner is treating since larger lenses with greater central corneal clearances are typically selected for patients who have increasing severities of corneal irregularity [21]. Furthermore, a weak ($r = 0.21$) significant correlation was found between a SL practitioners' initial open-ended response central corneal clearance and SL images selected and a moderate ($r = 0.41$) significant correlation was found between a SL practitioners' final open-ended response central corneal clearance and SL images selected. This suggests that SL practitioners are able to relatively accurately assess initial and final central corneal clearance, which is important when fitting and troubleshooting SL.

Practitioners selecting an ideal final central corneal clearance of ~200 μm likely represents a clinically acceptable balance between fully vaulting the cornea and avoiding negative health consequences [9]. While the fitting results of this study are indicative of current clinical practice, data from modern theoretical and clinical studies of SLs suggest that the practitioner's preferred SL (central corneal clearance of ~200 μm) is likely putting the cornea under minor unavoidable hypoxic stress [9,10]. The literature specifically suggests that the oxygen permeability of the tears rather than the SL itself is the major limiting factor with regards to oxygen delivering to the cornea, and under typical SL fit conditions this translates to the cornea being under a level of hypoxia comparable to the closed eye state [9]. Data also suggests that excess cornea vault may translate into worse visual experience. [21]. Therefore, additional research is needed to determine if the cornea is getting enough oxygen long-term to avoid compromise or if these preferred SL characteristics are providing an ideal balance between corneal oxygen transmission and a SL shape that promotes the best overall safety, comfort, and vision.

While SL are generally considered safe [2,3,22], the majority of SL practitioners at least occasionally detected SL-related complications in their practice such as poor lens wetting (90.3%), which could translate into decreased or variable vision and midday fogging (84.8%), which may be a sign of low grade ocular inflammation [15]. While SL practitioners' experience level was independent of encountering the majority of the tested conditions, SL fogging and ocular pain/discomfort were associated with a SL practitioners' experience level with the more experienced practitioners reporting more fogging and ocular pain/discomfort. It is possible that these associations may be due to an experienced SL practitioners' enhanced ability to detect or elicit SL fogging and/or symptoms of ocular pain and discomfort from their patients. Although these data are preliminary in nature since they only asked practitioners if they had ever encountered the above condition, this study does provide evidence for the need for a SL surveillance study aimed at fully understanding the prevalence of SL complications.

In addition to asking practitioners about the complications that they have encountered in their practice, this study queried what the practitioners' preferred treatment method was to alleviate them. This study found that overall practitioners seemed to follow an intuitive formula for changes based upon treating complications associated with corneal gas permeable CLs [23]. The study specifically found that practitioners prescribed an artificial tear, made a CL parameter change, made a power change, or had their patients remove, clean, and reapply their CL to treat dryness, redness, poor vision, and poor lens wetting, respectively, much like how gas permeable CL practitioners treat these conditions [23]. The main difference with SLs is that these patients often experience midday fogging [1], which the practitioners most commonly treated by having the patients remove, clean, and reapply their SL. Unfortunately, this and past studies have failed to provide information about the effectiveness of these treatments, which suggests the need for follow up studies comparing the effectiveness of the top methods used by practitioners for the conditions analyzed in this study. This work also suggests the need for studies related to understanding the etiology of conditions like midday fogging, which could also aid in the development of new treatment methods.

While this study had a number of strengths such as recruiting practitioners who had a range of experience levels with fitting SLs (mean of 5.5 ± 5.0 years of SL fitting experience), recruiting a sample enriched with SL experts (34% of sample had done over 100 fits), and collecting data from 164 practitioners in only three days, this study did have some limitations (Table 1). One issue is that this survey relied on practitioner recall instead of collecting data from a more reliable source such as clinical charts. Practitioners may have also discussed the study questions with colleagues introducing additional bias. Practitioners who attended this meeting also hailed from around the world, which provided this study with good generalizability, though it likely also led to a greater variability in responses and a sample size of 164 subjects may not have been enough to fully capture international SL fitting trends. While it is true that there may be some bias in our results, the SL research world is still in its infancy, and the data collected during this study can serve as an initial starting point for future, more rigorous studies of SL fitting and complications. An additional limitation may be that the subjects were only polled at an advanced specialty contact lens conference, which may not truly represent the day-to-day practitioner who is fitting SLs or the outcomes of a SL practitioners who relies on an outside consultant or laboratory to improve their patients' results. Nevertheless, this study did include a range of experience levels, so a similar result would likely have been found if practitioners were polled in a more controlled manner.

This study, overall, found that the average SL practitioner selects a 15.1 mm to 16.5 mm diameter SL with a final central corneal clearance of ~200 μm. This study also found that the majority of SL practitioners have encountered patients who have midday fogging and poor lens wetting, which they treat by having their patients remove, clean, and reapplying their SL. While the community has identified a number of means for combating minor SL complications, the methods tend to be similar to those used to correct negative outcomes associated with corneal gas permeable CLs [23]. Regardless of these similarities, more research is needed, which could come from a retrospective chart review, a registry study, or a study surveying SL patients to understand their wearing experience, so the community can fully understand the ideal way to fit and manage patients who wear SLs.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.clae.2018.11.003.

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