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A one-year prospective study on scleral lens wear success

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ABSTRACT

Purpose: To report the success rate of scleral lens wear and the lens handling learning curve from the wearers perspective.
Methods: Ninety-five participants were consecutively screened for enrollment in a prospective study. Participants were divided into two groups: ICGroup (71 participants with irregular corneas) and RCGroup (24 participants with regular corneas). Participants attended several visits: Baseline, Lens Dispense Visit (LDV), 1-month, 3-month, 6-month and 12-month follow-ups. The number and causes of scleral lens discontinuation and the time to correctly apply the lens for the first time at the LDV were evaluated. During follow-ups, participants answered a questionnaire regarding scleral lens wear (mean number of hours/day and days/week of lens wear, methods used for handling, number of attempts to correctly apply and remove the lenses).
Results: Sixty-nine participants (73 %) successfully completed the 12-month period. Twenty-six participants (27 %) discontinued scleral lens wear. None of the discontinuations were due to adverse events. The success rate (number of participants that wore the lenses for the 12 months) was 77 % in ICGroup and 58 % in RCGroup. The main reasons for scleral lens discontinuation were handling issues (35 %) and discomfort (19 %). 36 % of participants required < 15 min to correctly apply the lens at the LDV, however 13 % required > 60 min (participants that wore spectacles, soft lenses or had no correction method at Baseline). The mean wearing time (hours/day and days/week) increased significantly from 1-month to 12-month appointments: from 9.8–11.1 h and 5.1–5.6 days in new scleral lens wearers, while the number of attempts to correctly apply and remove the lenses decreased significantly.
Conclusions: The success rate was 73 % during this prospective 12-month follow-up study. The main reasons for drop-out were handling issues and discomfort. Participants who continued scleral lens demonstrated increased handling skills.

1. Introduction

There is a growing body of evidence in the literature with regard to the indications for modern scleral lens wear [1–3] as well as potential contraindications to their use [3]. However, there is a lack of peer-reviewed prospective studies that evaluate the scleral lens fitting process including lens handling and drop out over the long term. Prospective studies over a short-time period have investigated lens settling [4–9] and the potential hypoxic stress induced by scleral lens wear [10–13]. In addition to the short term nature of these studies, the majority have been conducted on patients with normal corneas, which is not the primary indication for scleral lens wear. Other studies have reported success rates of scleral lens wear that range from 62 % to 89 % [14–21]. However, all of these retrospective analyses differ with regard to scleral lens indications, sample size, scleral lens design, mean follow-up time, study design, and definition of success.

Handling has been reported to be one of the main difficulties that scleral lens wearers face during the fitting process [16,18,20,22]. Along with the larger diameter of these lenses, patients also need to balance a fluid-filled device on a plunger or fingers while maintaining a “face down” posture, which are additional challenges, compared to other contact lens modalities [18].

The main purpose of this study was to determine the success rate of scleral lens wear (the percentage of subjects who wore the lenses for 12 months) over a 1-year follow-up period and the reasons for scleral lens wear failure. In addition, the learning curve in handling these devices (from a wearers’ perspective) as well as the wearing time were analyzed during all follow-up visits.

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2. Methods

2.1. Study design and participants

This was a prospective study involving participants with primary corneal ectasia, penetrating keratoplasty, post-surgical ectasia and regular corneas with high refractive errors. Ninety-five (95) consecutive participants were recruited between December 2015 and March 2017. The participants were divided into two groups according to their corneal condition: an irregular cornea group (IC Group) comprised of corneas with irregularities of different etiologies (134 eyes of 71 participants) and a second group comprised of participants with regular and healthy corneas (RC Group) with high refractive errors (myopia ≥ 6.00 D; astigmatism ≥ 2.00D, hyperopia ≥ 4.00D) that had failed with or rejected other forms of vision correction with contact lenses (46 eyes of 24 participants).

Following the recommendations of the declaration of Helsinki, all participants received information about the study before they agreed to participate and signed a consent form. The protocol of the study was reviewed and approved by the Ethics Subcommittee for Life and Health Sciences of University of Minho (Portugal).

2.2. Scleral lenses used and fitting procedure

All participants attended several appointments during the follow-up period: a baseline assessment, a lens dispensing visit, at which measurements were performed 10 min after lens application and after more than 90 min of lens wear, and follow-up visits at 1 month, 3 months, 6 months and 12 months, all performed after a minimum of 90 min of lens wear prior to the exam. All participants underwent a full optometric examination (baseline), which included the measurement of visual acuity with habitual correction (HC) and best spectacle correction (BSC), anterior eye biomicroscopy and corneal topographic analysis with a Medmont E300. Visual acuity (VA) was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) vision chart in high and low contrast, recorded in logMAR. Comfort was assessed with the Ocular Surface Disease Index (OSDI), a questionnaire graded from 0 to 100, with higher scores representing greater functional impairment/more symptoms. Other questionnaires specific for contact lens wearers, such as Contact Lens Dry Eye questionnaire (CLDEQ-8), were considered. However, the main point of evaluating comfort was to compare the baseline symptomatology (with habitual correction) with the symptoms during scleral lens wear. As some participants did not wear contact lenses as their habitual correction prior to enrolling in the study, the OSDI was selected. Although the OSDI was not specifically designed to assess symptoms in contact lens wearers, it shows good agreement with the CLDEQ-8 [23] and has been previously used in studies evaluating scleral lens fittings and dry-eye related symptoms in scleral lens wearers [24,25]. In the present study, Baseline OSDI scores (with habitual correction) were only presented to distinguish the comfort ratings of subjects that discontinued scleral lens wear to those that continued. The participants that completed the 12-months of follow-up had a significant reduction in their symptomatology, reported elsewhere [26]. During all follow-up appointments, careful inspection of the anterior segment was undertaken with a slit-lamp in order to assess on-eye lens fitting and to quantify hyperemia and staining. No severe adverse events (inflammation or infection) were recorded during the entire follow-up period [26]. All assessments, including scleral lens fittings and handling training sessions, were carried out by the same practitioner (RMA).

All participants were fitted with scleral lenses from Procornea (Eerbeek, The Netherlands) in hexafocon A material (Dk 100 ISO/Fatt). At the baseline visit, the trial lenses were fitted according to the manufacturer's recommendations. By default, participants were trialed (by a trial and error process) with a 16.4 mm diagnostic lens and adjustments were performed accordingly. The final lens diameter was chosen considering the best trial lens fitting and ocular characteristics such as scleral asymmetry and ocular sagittal height. These outcomes were assessed subjectively by evaluating the lens-ocular surface relationship and slit lamp observations, and corneal sagittal height was derived from corneal topography measurements (Medmont E300). The mean number of trial lenses required per eye has been previously described [27]. Fittings were performed with diagnostic fitting sets: one with 16.4 mm lenses (diameters from 15.2–18 mm could be ordered) and other with 20 mm lenses (diameters range from 18 to 24.5 mm could be ordered). Lenses with diameters ranging from 18 to 24.4 mm had toric peripheral curves by default, and lenses with diameters ranging from 15.2–18 mm could have spherical or toric peripheral curves. The back optic zone radius was the same for all of the lenses used (8.20 mm) as recommended by the manufacturer. Other technical characteristics of the lenses used in this study have been described in previous publications [28,29]. Trial lenses were applied with preservative-free saline solution and sodium fluorescein (Fluo Strips, Contacare, India). The lens fit was evaluated with a slit lamp 5–10 minutes after lens application. Tear reservoir thickness was evaluated by comparing the known lens central thickness provided by the manufacturer with the post lens tear layer thickness. The lens should align evenly with the conjunctival surface and vault the entire corneal surface and limbus with a tear fluid reservoir thickness of 300 μm after insertion. If the fit was not satisfactory, another trial lens was applied. When the best trial lens fitting was achieved, participants were asked to continue with the trial lens for another 90 min and then to return for new assessment and to perform over-refraction. After the final assessment, minor adjustments were made and the final lenses were ordered.

2.3. Handling learning curve from the wearers' perspective

The practitioner learning curve for fitting scleral lenses, involving the same participants, has been described previously [27]. In the present study, the learning curve of the participants in handling these devices was evaluated. Only participants who completed the 1 year of follow-up were included in the analysis of handling. In addition to the clinical examination, the time required to correctly apply the scleral lens for the first time at the lens dispensing visit was allocated into one of the following groups: ≤ 15 min, between 15–30 minutes, between 30–60 minutes and > 60 min. A successful application of the lens on eye was considered when the patient was able to apply the lens smoothly to the ocular surface, with the lens perfectly centered and without any air bubbles entrapped in the tear film reservoir underneath the scleral lens. Any lens application that appeared to have been by chance using an inappropriate procedure was not considered successful, even if no air bubbles were observed. At follow-up visits, participants were asked to complete a questionnaire regarding the number of days per week and the number of hours per day of scleral lens wear, and the methods preferred to apply and remove the lenses. The degree of 'ease of handling' with the devices was evaluated based on the reported number of attempts that each participant required to correctly apply and remove the lenses (as reported at each follow-up visit).

All handling-training sessions were performed at the end of the lens dispensing visit by the same practitioner. Prior to this visit the lenses were always applied and removed by the same practitioner (diagnostic lens fitting and lens dispense visit assessments with the ordered lenses). At this time, participants were aware of the sensation of having a scleral lens on eye and some tips and tricks to correctly apply them (facing down and looking to the center of the lens). Before starting the training session, participants watched an instructional video which demonstrated the application methods and received detailed verbal instructions: positioning of the head, how to hold both eyelids, and the two main methods to apply the lens (fingers and plunger). Participants were asked which method they preferred to try first and were instructed accordingly. If the participant had difficulties with the method selected, the other method was tried. The duration of this training session was

dependent on the participants' abilities. If a number of attempts were required to apply the lens, causing the eye to become inflamed, another training session was scheduled. In this training session, participants were also instructed on how to remove the lenses, however, the time to correctly remove the lenses was not recorded. Participants were not dispensed with their lenses until they were able handle the lenses properly. By the end of the final training session, participants were given written instructions for lens handling and some links to videos. Other instructions and training regarding lens disinfecting process and storage were also provided. Participants were also advised about some SL-related events that can occur, with special emphasis on possible oxygen deprivation and consequent corneal oedema. Participants were advised to wear the lenses for a maximum of 12 h, and were also recommended not to wear SL when no visual demand tasks were performed (non-working days, for instance).

2.4. Statistics

Statistical analysis was conducted using SPSS v.25.0 (SPSS, Inc, Chicago, Illinois, USA) to compare the different variables between groups and over time within the same group. Normality of data distribution was assessed using the Kolmogorov-Smirnoff or Shapiro-Wilk test in different groups of participants analyzed, according to the sample size of each group. Pairwise comparisons between groups (IC Group vs. RC Group or drop-outs vs participants who continued scleral lens wear) were done using Independent Sample T-tests for normally distributed data and Mann-Whitney tests for non-normally distributed data. Comparisons over time within the same group were done with one-way ANOVA or Friedman tests with Bonferroni corrections for pairwise comparisons. The level of statistical significance was set at $p < 0.05$.

3. Results

3.1. Dropouts

Tables 1 and 2 summarize the number of participants who were recruited and discontinued scleral lens wear during the follow-up period, as well as the characteristics of both samples and the respective reasons that led to SL discontinuation. Ninety-five participants (175 eyes) were recruited to participate in this prospective study. Fifteen participants were fitted in one eye only, while the remaining were fitted bilaterally. During the follow-up period, a total of 26 participants (27.4 %) of the total sample dropped out – 16 participants (22.5 %) from the IC Group and 10 (41.7 %) from the RC Group. Table 1 also highlights the main reasons for drop-out. Nine participants dropped out the study because of handling issues and 5 participants because of discomfort. Only 2 participants complained about poor wettability of the anterior surface of the lens, which led to visual complaints and drop-out before modifying the lens care system. None of the other participants indicated visual issues as a main reason for dropout and none of them discontinued scleral lens wear due to severe adverse events (inflammation or infection). A total of 69 participants (126 eyes) completed the 1-year follow-up period: 55 (99 eyes) from the IC Group and 14 (27 eyes) from the RC Group.

Of the 16 participants from the IC Group who discontinued scleral lens wear, 11 wore spectacles prior to enrolling in the study, 2 wore corneal rigid gas permeable lenses, and 3 did not use a refractive correction. Of the 10 participants from the RC Group who discontinued, 6 wore spectacles and 4 wore soft lenses prior to enrolling into the study. From the participants of the IC Group that completed the 12 months of follow-up, 82 % wore SL with toric haptics. Regarding lens diameter, 85 % wore 16.4 mm lenses, 5 % wore 16 mm lenses, 2 % wore 15.6 mm lenses, 3 % wore 15.2 mm lenses and 4 % required lenses larger than 18 mm. Participants that required a SL larger than 18 mm were previous scleral lens wearers. From the participants of the RC Group that completed the 12 months of follow-up, 74 % wore SL with toric haptics and regarding lens diameter, the majority were fitted with 16.4 mm lenses and one patient (2 eyes) was fitted with 15.2 mm lenses [28].

Fig. 1 shows the wearing success rate. It indicates all participants who discontinued from the RC Group did so prior to the 3-month follow-up appointment. In the IC Group, 83 % completed the 3-month visit but then a further 6 % discontinued; one reported handling as the main issue causing this late dropout, another was due to discomfort, one reported visual concerns because of poor wettability of the anterior lens surface, and one abandoned the study to undergo corneal cross-linking. In the RC group, the majority of dropouts occurred between the 1- and 3-month appointments (60 %). In the IC Group, the discontinuation was more gradual over the initial 6 months of lens wear.

Table 2 summarizes some of the characteristics of the participants who discontinued scleral lens wear and those who continued. There were no differences between both groups with respect to age, sex or symptomatology with the habitual correction at baseline ($p > 0.05$). Regarding baseline symptomatology, in the RC group the participants who discontinued scleral lens wear had less severe symptoms than those who continued (average OSDI Scores: 14.17 ± 11.38 vs. 26.96 ± 15.48, respectively) although this difference was not statistically significant because of the large variability of the data. Differences

Table 1
Number of participants that enrolled the study and number of subjects that discontinue scleral lens wear.

		Total Sample No. Subjects (No. Eyes)	IC Group No. Subjects (No. Eyes)	RC Group No. Subjects (No. Eyes)
Number of initial subjects		*95 (175 eyes)*	71 (129 eyes)	24 (46 eyes)
Number of dropouts		*26 (49 eyes)*	16 (30 eyes)	10 (19 eyes)
Percentage of dropouts		*27.37% (28%)*	22.54% (23.26%)	41.67% (41.34%)
Reason for drop-out	Never dispensed Δ	*4 (7 eyes)*	2 (3 eyes)	2 (4 eyes)
	Discomfort	*5 (10 eyes)*	4 (8 eyes)	1 (2 eyes)
	Handling Issues	*9 (18 eyes)*	5 (10 eyes)	4 (8 eyes)
	Underwent Surgery	*3 (5 eyes)*	3 (5 eyes)	–
	Poor wettability*	*2 (4 eyes)*	2 (4 eyes)	–
	Lost to follow-up	*3 (5 eyes)*	–	3 (5 eyes)
Number of participants that concluded 1-year follow-up		*69 (126 eyes)*	55 (99 eyes)	14 (27 eyes)

*vision complaints due to poor wettability of the anterior lens surface.
IC – Irregular cornea; RC – Regular cornea.
Δ These are drop outs from the study, but technically are not consider scleral lens drop outs.

in high contrast visual acuity and low contrast visual acuity were found between participants who continued and those who discontinued scleral lens wear. Participants from the RC Group who discontinued scleral lens wear had better high and low contrast visual acuity with their habitual correction (+0.08 ± 0.14 and +0.26 ± 0.16 logMAR, respectively) than those who continued the study (+0.15 ± 0.20 and +0.31 ± 0.23 logMAR, respectively), but this difference was not statistically significant. There were statistically significant differences regarding high and low contrast visual acuity with scleral lenses in the RC Group, with the participants who discontinued scleral lens wear having a better high contrast visual acuity (+0.08 ± 0.13 vs. -0.02 ± 0.09 logMAR, p = 0.013, Mann-Whitney) and low contrast visual acuity (+0.28 ± 0.15 vs. + 0.17 ± 0.07 logMAR, p = 0.020, Mann-Whitney). There were no significant differences in the IC Group regarding the same outcomes. With respect to the time to correctly apply the lens, the vast majority of participants in the IC Group who continued the study applied the lens in less than 30 min at the LDV compared to those who discontinued scleral lens wear (71 % vs. 53 %), and the same was found in the RC Group (64 % vs. 50 %).

3.2. Handling learning curve from the wearer perspective

Table 3 shows the ability to correctly apply the lens for the first time at the lens dispensing visit. Regarding the total sample, 36.2 % of the participants needed less than 15 min to correctly apply the lens for the first time (34.5 % in the IC Group and 42.9 % in the RC Group), 33.3 % needed between 15 and 30 min (36.4 % in the IC Group and 21.4 % in the RC Group), 17.4 % needed between 30–60 minutes (20.0 % in the IC Group and 7.1 % in the RC Group), and 13.0 % required more than 60 min to correctly apply the lens for the first time at the lens dispensing visit (9.1 % IC Group and 28.6 % RC Group).

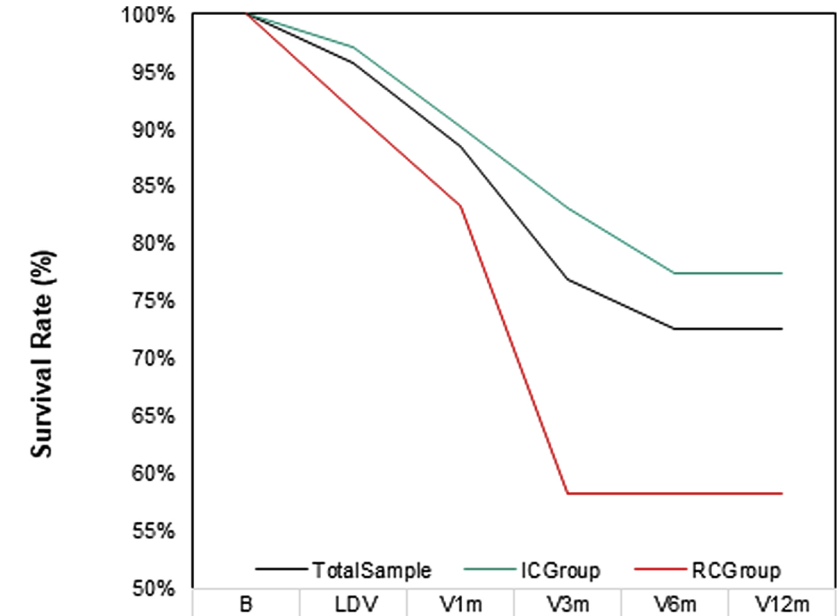
Fig. 2 A, B and C shows the ability to correctly apply the lens for the first time with regard to the habitual correction used prior to entering the present study, for the total sample, the IC group and the RC group, respectively. Eleven participants from the IC group had no correction method before enrolling into the study, 28 wore spectacles (13 from the RC group), 7 wore soft contact lenses (1 from the IC group), 10 wore corneal rigid gas permeable lenses, 6 wore hybrid contact lenses and 7 participants already wore scleral lenses prior to entering the study. Those who wore spectacles, soft contact lenses, or had no refractive correction required more time to correctly apply the lens for the first time at the LDV. As expected, participants already wearing scleral lenses prior to enrolling in the study needed less time to correctly apply the lens.

Table 4 shows the average number of days per week and hours per day of lens wear as well as the number of attempts to correctly apply and remove the lenses during the first month (reported at the 1-month visit), between 1 and 3 months of lens wear (reported at the 3-month visit), between 3 and 6 months of lens wear (reported at the 6-month visit) and between 6 and 12 months of lens wear (reported at the 12-month visit). These results only include the new scleral lens wearers. On average, participants at the 1-month appointment reported wearing the lenses for 9.8 h per day, 5.1 days per week. Both groups underwent an increase in wearing time during the follow-up visits, and at the 12-month appointment participants reported wearing the lenses for an average 11.1 h per day, 5.6 days per week (p < 0.001). Participants from the IC Group reported wearing the lenses for more hours and for more days per week at all follow-up visits (p ≤ 0.015). After 12 months wearing the lenses, the majority (64 %) of the IC group reported lens wear for more than 12 h per day, compared to 33 % from the RC group. Regarding the number of attempts that each participant needed to correctly apply the lens, it decreased from an average of 2.4 ± 1.7 attempts at the 1-month visit to 1.6 ± 1.0 at the 3-month visit (p < 0.001, mean decrease of 0.6 in the IC Group and 1.4 in the RC Group). There was also a decrease between the 3- and 12-month appointment from 1.5 ± 1.0–1.1 ± 0.4 attempts (p = 0.006, mean decrease of 0.5 in the IC Group and 0.6 in the RC Group). Regarding the number of attempts to correctly remove the lens, there was also a decrease over time in both groups (p < 0.001). There were no differences between groups regarding the mean number of attempts to correctly apply and remove the lenses (p > 0.05). Table 5 presents the same outcomes for the 7 participants from the IC Group that wore SL prior to

Table 2
Characteristics of the participants that continued the study and those who discontinued the study.

	Group	Study Subjects (n = 69)	Dropouts (n = 26)	p
Number of Subjects	IC	55 (99 eyes)	16 (30 eyes)	
	RC	14 (27 eyes)	10 (19 eyes)	
Age	IC	36.65 ± 10.14	35.29 ± 13.98	*0.454* ■
	RC	30.00 ± 10.04	32.90 ± 8.14	*0.285* †
	p	***0.019*** †	*0.941* †	
Gender	IC	26 F / 28 M	8 F / 9 M	
	RC	10 F / 4 M	8 F / 2 M	
Condition (% of eyes)	IC	KC (77%)	KC (80%)	
		PK (11%)	PK (10%)	
		SE (8%)	SE (7%)	
		Other (4%)	Other (3%)	
	RC	HM (22%)	HM (32%)	
		HA (78%)	HA (68%)	
Habitual Correction (n subjects)	IC	No Prescr.: 12	No Prescr.: 3	
		Glasses: 16	Glasses: 11	
		Soft CL: 6	–	
		RGP: 10	RGP: 2	
		Hybrid: 4	–	
		Scleral Lens: 7	–	
	RC	Glasses: 13	Glasses: 6	
		Soft CL: 1	Soft CL: 4	
Diameter of the SL fitted (n subjects)	IC	16.4mm: 46	16.4mm: 9	
		16mm: 3	16mm: 3	
		15.6mm: 1	–	
		15.2mm: 2	15.2mm: 2	
		> 18mm: 3	–	
		–	Never dispensed: 2	
	RC	16.4mm: 13	16.4mm: 6	
		–	16mm: 1	
		–	15.6mm: 1	
		15.2mm: 1	–	
		–	Never dispensed: 2	
SL with toric landing zone (% eyes)	IC	Toric: 82%	Toric: 87%	
		Spheric: 16%	Spheric: 13%	
	RC	Toric: 74%	Toric: 79%	
		Spheric: 26%	Spheric: 21%	
Baseline OSDI Score	IC	46.99 ± 22.52	45.22 ± 21.72	*0.797* ■
	RC	26.96 ± 15.48	14.17 ± 11.38	*0.070* †
	p	***0.02*** †	***0.002*** †	–
Habitual Correction HCVA	IC	+0.34 ± 0.35	+0.34 ± 0.33	*0.828* †
	RC	+0.15 ± 0.20	+0.08 ± 0.14	*0.353* †
	p	***0.008*** †	***0.002*** †	–
Habitual Correction LCVA	IC	+0.59 ± 0.35	+0.53 ± 0.27	*0.509* †
	RC	+0.31 ± 0.23	+0.26 ± 0.16	*0.633* †
	p	< ***0.001*** †	< ***0.001*** †	–
HCVA (with lens at LDV)*	IC	+0.08 ± 0.14	+0.09 ± 0.17	*0.871* †
	RC	+0.08 ± 0.13	−0.02 ± 0.09	***0.013*** †
	p	*0.825* †	***0.030*** †	–
LCVA (with lens at LDV)*	IC	+0.34 ± 0.17	+0.37 ± 0.19	*0.481* ■
	RC	+0.28 ± 0.15	+0.17 ± 0.07	***0.020*** †
	p	***0.036*** †	< ***0.001*** †	–
Time to correctly apply the lens at LDV*	IC	< 30 min (71%)	< 30 min (53%)	–
		> 30 min (29%)	> 30 min (47%)	
	RC	< 30 min (64%)	< 30 min (50%)	–
		> 30 min (36%)	> 30 min (50%)	

IC – Irregular cornea; RC – Regular cornea; KC – Keratoconus; PK – penetrating keratoplasty; SE – secondary ectasia; other – cases of corneal injuries that led to irregular corneal surfaces, and post-lasik with visual complaints but without ectasia; HM – High Myopia (≥6D); HA – high astigmatism (≥2D); HCVA – High contrast visual acuity; LCVA – Low contrast visual acuity; LDV – lens dispense visit; *data available only for those who were dispensed. (■) Unpaired Sample T-test; (†) Mann-Whitney.



	B	LDV	V1m	V3m	V6m	V12m
TotalSample	100%	96%	88%	77%	73%	73%
ICGroup	100%	97%	90%	83%	77%	77%
RCGroup	100%	92%	83%	58%	58%	58%

Fig. 1. Wearing success rate for the participants wearing scleral lenses over a 12-month follow-up period. B, Baseline; LDV, Lens Dispensing Visit; V1m – 1-month visit; V3m – 3-month visit; V6m – 6-month visit; V12 m – 12-month visit.

enrolling in the study, presenting higher wearing times (both number of days per week and hours per day) and decreased number of attempts to correctly apply and remove the lenses than new scleral lens wearers (Table 4). 73 % of previous scleral lens wearers reported to wear the lenses for more than 12 h on a daily basis, and none reported to wear the lenses for less than 8 h per day (Table 5).

Regarding the preferred methods for scleral lens application, 77 % of the total sample reported to use a plunger and 20 % used the finger method at 1-month visit, with no difference in the preference between groups. Three percent of participants from the IC group applied the lens with a plunger stand system. Some participants changed from the plunger method to the finger method with time, as at 12-month visit 71 % reported to use plunger and 26 % reported to use the finger method. Regarding the methods preferred for scleral lens removal, the majority (83 %) preferred the plunger at the 1-month visit and, as seen for the application method, some participants changed the preference towards the finger method through time and at 12-month visit 27 % preferred the finger method and 73 % preferred to remove the lens with a plunger.

4. Discussion

The success rate of scleral lens wear is an important clinical outcome that has already been reported in the literature. However, the vast majority of the reports are retrospective analyses. In the present study, the average success rate (participants that completed the 12- month follow-up period) was 72.6 %, which was greater in the IC Group (77.4 %) compared to the RC Group (58.3 %). The IC Group was comprised of participants with corneal abnormalities of different etiologies: keratoconus (77 % of those who continued and 80 % who failed), penetrating keratoplasty (11 % of those who continued and 10 % who failed), secondary corneal ectasia (8 % of those who continued and 7 % who failed) or other irregularities (4 % of those who continued and 3 % who failed). From previous reports, it is known that these lenses are indicated for these kinds of cases, with primary corneal ectasia as the most common indication [14,16,19,30,31]. However, because of their advantage in promoting improved optical quality, comfort and on-eye stability, scleral lenses are increasingly also being fitted in eyes with normal corneas. In the current study, the success rate of scleral lens fitting in eyes with normal corneas was significantly lower than for eyes with corneal irregularities. None of the participants directly attributed poor visual acuity as the main reason for drop out. In fact, both high and low contrast visual acuity with habitual correction were similar or even better in the participants who dropped out of scleral lens wear compared to those who continued the study ($p > 0.05$, Table 2), suggesting that better visual acuity at baseline (with habitual correction) may result in decreased motivation to wear the lenses (namely the RC group). The majority of participants who discontinued scleral lens wear wore spectacles as their habitual correction prior to enrolling into the study (11 from the IC Group and 6 from the RC Group). So, although the vision with scleral lenses was good, the benefit/convenience ratio was not favorable enough for subjects to stop wearing spectacles and instead wear scleral lenses as the primary visual correction option – mainly because of handling issues and comfort. Those participants who had poor VA with their habitual correction may face the same handling challenges/issues, but the visual benefit that scleral lenses provide might have led to a greater effort on the part of these participants to correctly apply and remove their lenses. Apart from VA in the RC Group, there were no statistically significant differences between participants who continued to wear scleral lenses and those who ceased

Table 3
Time required to correctly apply the scleral lens for the first time at lens dispense visit. Results regarding the 69 participants that completed the 1-year of follow up.

	TOTAL SAMPLE n (%)	IC Group n (%)	RC Group n (%)
< 15 min	25 (36.2%)	19 * (34.5%)	6 (42.9%)
15 – 30 min	23 (33.3%)	20 (36.4%)	3 (21.4%)
30 – 60 min	12 (17.4%)	11 (20.0%)	1 (7.1%)
> 60 min	9 (13.0%)	5 (9.1%)	4 (28.6%)
	69 (100.0%)	*55 (100.0%)*	*14 (100.0%)*

IC – Irregular cornea; RC – Regular cornea.
*7 of them were previous scleral lens wearers.

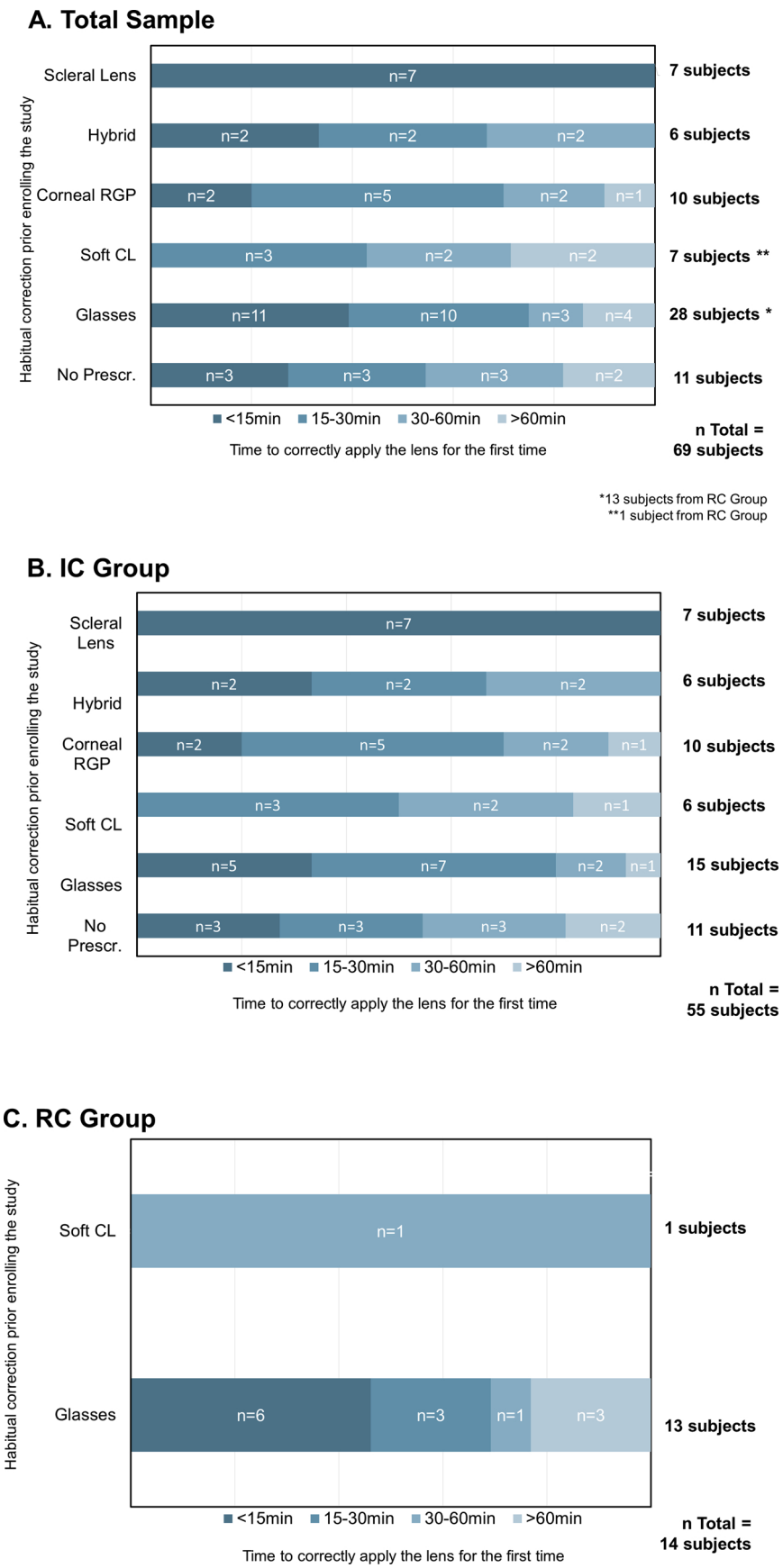


Fig. 2. Ability to correctly apply a scleral lens for the first time at lens dispensing visit with respect to the habitual correction of the participants prior entering the study. (A) Total Sample; (B) IC Group; (C) RC Group.

Table 4
Number (mean ± SD), median and range regarding the number of days per week, hours per day of lens wear and the number of attempts to correctly apply and remove the lenses of new scleral lens wearers. Results regarding 62 participants: 69 participants that completed the 1-year of follow up and excluding previous scleral lens wearers (7 participants).

		1 month Mean ± SD Median [Range]	3 months Mean ± SD Median [Range]	6 months Mean ± SD Median [Range]	12 months Mean ± SD Median [Range]	p † (visits that showed statistically significant differences) #
Number of "days per week" of lens wear	**Total Sample**	**5.1 ± 1.6** **5 [2 to 7]**	**5.2 ± 1.5** **5 [3 to 7]**	**5.3 ± 1.6** **5 [3 to 7]**	**5.6 ± 1.4** **5 [3 to 7]**	**< 0.001** (12 vs 1 & 3 months, p ≤ 0.047)
	IC Group	5.4 ± 1.6 6 [2 to 7]	5.5 ± 1.5 6 [3 to 7]	5.7 ± 1.5 6 [3 to 7]	5.8 ± 1.3 6 [3 to 7]	**0.021**
	RC Group	3.9 ± 1.3 3 [3 to 7]	4.1 ± 1.3 4 [3 to 7]	4.2 ± 1.2 4 [3 to 7]	5.0 ± 1.4 5 [3 to 7]	**< 0.001** (1 vs 12 months, p = 0.002)
	p *	**< 0.001**	**< 0.001**	**< 0.001**	**0.015**	
Number of "hours per day" of lens wear	**Total Sample**	**9.8 ± 3.2** **9 [4 to 16]**	**10.5 ± 3.3** **10 [4 to 15]**	**10.8 ± 3.2** **10 [4 to 16]**	**11.1 ± 3.0** **12 [6 to 16]**	**< 0.001** (1 vs 3 & 6 & 12 months; 3 vs 12 months, p ≤ 0.044)
	IC Group	10.4 ± 3.2 10 [4 to 16]	11.1 ± 3.2 12 [4 to 15]	11.4 ± 3.2 12 [4 to 16]	11.6 ± 2.9 12 [6 to 16]	**< 0.001** (1 vs 6 & 12 months, p ≤ 0.001)
	RC Group	7.7 ± 2.3 7 [5 to 15]	8.3 ± 2.9 8 [4 to 15]	8.9 ± 2.4 10 [6 to 14]	9.6 ± 2.8 10 [6 to 16]	**< 0.001** (1 vs 6 &12 months; 3 vs 12 months, p ≤ 0.043)
	p *	**< 0.001**	**< 0.001**	**< 0.001**	**0.003**	
Time of lens wear:	*< 8 hours*	*11%*	*8%*	*9%*	*7%*	–
IC Group	*8 to 11 hours*	*44%*	*36%*	*30%*	*30%*	
	≥ 12 hours	*44%*	*56%*	*64%*	*64%*	
Time of lens wear:	*< 8 hours*	*52%*	*44%*	*30%*	*22%*	
RC Group	*8 to 11 hours*	*44%*	*44%*	*59%*	*44%*	
	≥ 12 hours	*4%*	*11%*	*11%*	*33%*	
Number of "attempts to insert" the lens	**Total Sample**	**2.4 ± 1.7** **2 [1 to 10]**	**1.6 ± 1.0** **1 [1 to 5]**	**1.2 ± 0.6** **1 [1 to 4]**	**1.1 ± 0.4** **1 [1 to 5]**	**< 0.001** (1 vs 3 & 6 & 12 months; 3 vs 6 & 12 months, p ≤ 0.006)
	IC Group	2.2 ± 1.5 2 [1 to 10]	1.6 ± 1.1 1 [1 to 5]	1.3 ± 0.6 1 [1 to 4]	1.1 ± 0.5 1 [1 to 5]	**< 0.001** (1 vs 3 & 6 & 12 months, p < 0.001)
	RC Group	3.1 ± 2.1 3 [1 to 7]	1.7 ± 0.8 2 [1 to 3]	1.1 ± 0.4 1 [1 to 2]	1.1 ± 0.3 1 [1 to 2]	**< 0.001** (1 vs 6 & 12 months, p < 0.001)
	p *	0.077	0.054	0.709	0.572	
Number of "attempts to remove" the lens	**Total Sample**	**1.9 ± 1.1** **1 [1 to 4]**	**1.5 ± 0.8** **1 [1 to 4]**	**1.3 ± 0.6** **1 [1 to 4]**	**1.1 ± 0.3** **1 [1 to 3]**	**< 0.001** (1 vs 6 & 12 months; 3 vs 12 months, p ≤ 0.003)
	IC Group	1.9 ± 1.1 2 [1 to 4]	1.5 ± 0.8 1 [1 to 4]	1.4 ± 0.7 1 [1 to 4]	1.1 ± 0.3 1 [1 to 2]	**< 0.001** (1 vs 6 & 12 months; 3 vs 12 months, p ≤ 0.025)
	RC Group	1.9 ± 1.2 1 [1 to 4]	1.6 ± 0.9 1 [1 to 4]	1.1 ± 0.4 1 [1 to 2]	1.1 ± 0.4 1 [1 to 3]	**< 0.001**
	p *	0.769	0.466	0.144	0.394	

IC – Irregular cornea; RC – Regular cornea.
(*) Mann-Whitney *U* test (differences between IC & RC groups); (†) Friedman test; (#) Bonferroni-adjusted pairwise comparisons.

Table 5
Number (mean ± SD), median and range regarding the number of days per week, hours per day of lens wear and the number of attempts to correctly apply and remove the lenses of habitual scleral lens wearers that were readapted with a new scleral lens design (7 subjects, IC Group).

	1 month Mean ± SD Median [Range]	3 months Mean ± SD Median [Range]	6 months Mean ± SD Median [Range]	12 months Mean ± SD Median [Range]	p †
Number of "days per week" of lens wear	6.7 ± 0.5 7 [6 to 7]	6.7 ± 0.5 7 [6 to 7]	7.0 ± 0.0 7 [7 to 7]	7.0 ± 0.0 7 [7 to 7]	–
Number of "hours per day" of lens wear	11.6 ± 2.8 10 [8 to 16]	12.1 ± 2.9 12 [8 to 16]	12.7 ± 2.8 14 [8 to 16]	13.6 ± 2.9 14 [8 to 16]	–
< 8 h	0%	0%	0%	0%	
8 to 11 h	64%	64%	45%	27%	
≥ 12 h	36%	36%	55%	73%	
Number of "attempts to insert" the lens	1.2 ± 0.4 1 [1 to 2]	1.0 ± 0.0 1 [1 to 1]	1.0 ± 0.0 1 [1 to 1]	1.0 ± 0.0 1 [1 to 1]	–
Number of "attempts to remove" the lens	1.2 ± 0.4 1 [1 to 2]	1.0 ± 0.0 1 [1 to 1]	1.0 ± 0.0 1 [1 to 1]	1.0 ± 0.0 1 [1 to 1]	–

(†) Friedman test;

lens wear (Table 2). Other authors have not found statistically significant differences between dropouts and scleral lens wearers with regard to topographic data (Sim K and Δ K) and visual acuity [21] or for age, scleral lens diameter or gender [20].

Other studies have reported a success rate similar to that of the present study. Ortenberg et al. [15] reported a success rate of 73 % in their retrospective analysis of 97 consecutive patients with irregular corneas of different etiologies over a mean follow-up time of 34.9 ± 18.5 months. In the present study, a success rate of 77 % was found over the 12-month follow-up period in a group of participants with similar characteristics (IC Group). In the current study, all discontinuations occurred before the 6-month follow-up appointment, and none were due to lens-induced ocular complications. It is important to note that in the present study participants had to attend several periodic appointments which could have led to fewer ocular complications than those reported in retrospective analyses. In addition to the report by Ortenberg et al, [15] other studies have retrospectively reported scleral lens success rates over shorter follow-up times, specifically an 88 % retention rate at 6 months [21] and a retention rate of 77 % at 3 months [20]. Similarly, in 1997 Pullum and Buckley [16] reported a discontinuation rate of 22 %. More recently, other retrospective studies showed similar failure rates: Severinsky et al. [17] presented a failure rate of 21 %, Schornack et al. [18] reported that 38 % of their keratoconus patients chose not to proceed with the fitting process after the initial evaluation, and Segal et al. [19] mentioned a failure rate of 10.4 % in their study.

Several reasons to discontinue scleral lens wear have been proposed, ranging from a lack of visual benefit [15,18,20,21], handling issues [18,19,21] and discomfort [20,21], to adverse events related to ocular complications (intolerance, graft rejection, neovascularization, corneal epithelial defects, hyperemia and corneal edema) [15,22,32] or abandoning scleral lens wear to undergo surgery (penetrating keratoplasty, cataract surgery) [17,18]. In the present study, the main reasons for scleral lens discontinuation were handling issues (35 % of the participants: 31 % in the IC Group and 40 % in the RC Group) and discomfort (19 % of the participants: 25 % in the IC Group and 10 % in the RC Group). Discomfort is a multifactorial condition and could be influenced by several factors. Visser et al. [33] compared the performance of spherical and toric scleral lens designs and concluded that toric designs offered a higher comfort rate and increasing wearing times. Previous work [27] has shown that there is a practitioner learning curve in fitting scleral lenses with toric haptics, suggesting an improvement in fitting skills with the experience of the fitter. This means that any discomfort-related dropout (due to poor peripheral lens alignment) that may have happened during the initial fittings undertaken in this study, could have been avoided if done by a more experienced practitioner. However, in the present study the percentage of participants wearing toric landing zone lenses was very similar in the group of those that discontinued scleral lens wear and those that continued in the study. Lens diameter did not appear to influence discomfort-related dropouts, since the majority of participants (those who dropped out and continued lens wear) were fitted with 16.4 mm lenses. Although statistically insignificant, the only outcome that appeared to differ between participants who dropped out and continued lens wear was the OSDI score at baseline (i.e. symptoms with the habitual correction). The baseline OSDI scores were less (meaning less symptoms) in the participants that discontinued scleral lens wear (namely in the RC Group). This means that scleral lenses may have exacerbated those baseline symptoms. The OSDI was only completed after 1 month of lens wear and some participants dropped out before this appointment, so it was not possible to compare baseline OSDI scores with the 1 month scores in all participants that discontinued scleral lens wear.

This is the first prospective study reporting on the handling and learning curve from the wearers perspective, over a 12-month follow-up period. Table 3 shows that 36 % took less than 15 min to apply the lens for the first time at the LDV, but there was a significant proportion (13 %: 9 % from the IC Group and 27 % from the RC Group) who needed more than 60 min and who, consequently, required additional training appointments. Regarding the habitual correction prior enrolling into the study (Fig. 2), a significant percentage of participants who wore soft lenses or spectacles or who used no refractive correction prior to entering the study, needed more than 60 min to correctly apply the lens for the first time (more visits for handling instructions).

The handling of scleral lenses can be an initial obstacle for some new scleral lens wearers. In the present study, handling difficulties were indicated as the reason for dropout in 35 % of the participants who discontinued scleral lens wear. In addition to the initial difficulty in correctly applying the lens for the first time, wearers also face a learning process in how to correctly handle these devices (Table 4). Handling issues could also be related to the unsatisfactory vision of the participants (without correction), especially in the IC Group. Even if visual acuity improved with the scleral lens, poor unaided vision will negatively impact upon the ability to insert the first lens. Participants were encouraged to firstly insert the lens of the eye with poorer visual outcomes. Although none of the participants mentioned poor visual quality (with scleral lenses) as the main reason to dropout, some of the reported handling-related dropouts could be linked to poor unaided vision. This may have also affected the time to correctly apply the lens for the first time and the handling learning curve of the participants that completed the 12-months of follow-up. Lens handling could be more of an issue in larger diameter SL, however, as seen in Table 2, the dropouts occurred in participants wearing lenses ≤ 16.4 mm in diameter. This is due to the fact that the 3 participants that were fitted with a SL ≥ 18 mm were all previous SL wearers, which made them less likely to discontinue SL wear because of handling issues. Another important point to consider is that none of the participants of this study incurred any costs other than travel expenses for appointments since the scleral lenses and conditioning solutions were provided free of charge. This may have been an additional motivation for participants to enroll into the study and could possibly be related to some of the handling-related dropouts. That is, participants were perhaps more motivated by cost savings than a potential improvement in vision and the time needed to apply SL in their daily lives led them to drop out of the study. Possibly, the number of handling-related dropouts in a clinical practice may be less, as patients may be highly motivated if they have sought out and paid for clinical care.

Several studies refer to the average wearing time as a measure of success of scleral lens fittings. In early studies, the wearing time was reported to compare the success of the fitting between polymethylmethacrylate (PMMA) and rigid gas permeable scleral lenses. Several studies [14,16,34] reported an increase in wearing time after switching PMMA scleral lenses to gas permeable materials. Mean scleral lens wearing times were reported to be between 8 and 16 h [35], 13.7 h (range: 4–18 hours) [22], ≥10 h in 59 % of the 538 patients [36], and 16.2 h (range 3–18 h) [19]. A more recent report from 2010 [15] defined “success” as the ability to wear the lenses for at least 10 h per day. The authors reported a mean wearing time of 10.5 h/day (range: 2–18 hours) and that 65 % of patients wore the lenses successfully (≥10 h per day). In the present study, the mean self-reported wearing times after 12 months of lens wear were 11.6 ± 2.9 h in participants with corneal irregularities and 9.6 ± 2.8 h in participants with regular corneas. Wearing time increased significantly from the 1- to the 12-month appointments ($p < 0.001$). Some of the participants choose to not wear scleral lenses on a daily basis (7 days per week). In the RC group, this could be related to the fact that almost all the participants that completed the follow-up have also spectacles (with very similar visual outcomes) which makes them less dependent on scleral lenses on their daily activities. Regarding the IC group, participants were encouraged and advised to wear the lenses when performing visual-demanding tasks and remove them as soon as possible to avoid potential hypoxic problems.

Many studies refer to the need to take brief breaks from scleral lens wear during the day to enhance vision and comfort, [14,15,19,22,30,37] mainly because of tear debris that could be trapped in the liquid reservoir

between the lens and the cornea, decreasing the quality of vision over time (midday fogging) [37]. In the present study, only two participants from the IC Group frequently reported this problem (3–5 days per week), though others were affected less often (< 2 days per week). Contrary to these results, other studies report that 62 % of patients wearing PMMA lenses needed to take wearing breaks (because of debris-related or oxygen-related problems), but only 46 % of patients wearing rigid gas permeable scleral lenses required such breaks. [14,30]. Others reported that almost half of the patients needed to take breaks during lens wear (49 %) [37]. Recently Ortenberg et al [15] reported that 71 % of their patients needed to take brief wearing breaks during the day – they were instructed to do this to replenish the liquid reservoir behing the lenses. Although symptoms of midday fogging are usually reported to occur in 20–33% of scleral lens wearers [34,35], this issue was reported in only 2 participants (2.1 %) of the 95 who were recruited in the present study. None of the 69 participants who completed this 1-year follow-up study subjectively complained about decreasing vision during lens wear, which may explain the decreased number of participants who reported the need to take brief breaks during the day to enhance vision. The authors hypothesize that the high percentage of fittings with toric haptic zones may have led to the non-existence of midday fogging complaints [26].

5. Conclusions

There was an overall 73 % success rate (participants that completed the follow-up) in scleral lens fitting during this prospective 12-month follow-up study. The success rate was 77 % in participants with corneal irregularities of different etiologies, and 58 % in participants with healthy corneas. The main reasons for drop-out were handling issues and discomfort. Those who continued through the 12-month follow-up period significantly improved their lens handling skills.

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References

[1] E. van der Worp, D. Bornman, D.L. Ferreira, M. Faria-Ribeiro, N. Garcia-Porta, J.M. González-Meijome, Modern scleral contact lenses: a review, Contact Lens Anterior Eye 37 (2014) 240–250, https://doi.org/10.1016/j.clae.2014.02.002.
[2] M.M. Schornack, Scleral lenses: a literature review, Eye Contact Lens 41 (2015) 3–11, https://doi.org/10.1097/ICL.0000000000000083.
[3] D. Fadel, E. Kramer, Indications and potential contraindications to scleral lens wear, Cont Lens Anterior Eye 42 (2018) 92–103, https://doi.org/10.1016/j.clae.2018.10.024.
[4] M.J. Kauffman, C.A. Gilmartin, E.S. Bennett, C.J. Bassi, A comparison of the short-term settling of three scleral lens designs, Optom Vis Sci 91 (2014) 1462–1466, https://doi.org/10.1097/OPX.0000000000000409.
[5] V.M. Rathi, P.S. Mandathara, S. Dumpati, V.S. Sangwan, Change in vault during scleral lens trials assessed with anterior segment optical coherence tomography, Contact Lens Anterior Eye 40 (2017) 157–161, https://doi.org/10.1016/j.clae.2017.03.008.
[6] H. Otchere, L.W. Jones, L. Sorbara, Effect of time on scleral Lens Settling and change in corneal clearance, Optom Vis Sci 94 (2017) 908–913, https://doi.org/10.1097/OPX.0000000000001111.
[7] F. Esen, E. Toker, Influence of apical clearance on mini-scleral Lens settling, clinical performance, and corneal thickness changes, Eye Contact Lens 43 (2017) 230–235, https://doi.org/10.1097/ICL.0000000000000266.
[8] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, The temporal dynamics of miniscleral contact lenses: central corneal clearance and centration, Cont Lens Anterior Eye 41 (2018) 162–168, https://doi.org/10.1016/j.clae.2017.07.002.
[9] C. Courey, L. Michaud, Variation of clearance considering viscosity of the solution used in the reservoir and following scleral lens wear over time, Cont Lens Anterior Eye 40 (2017) 260–266, https://doi.org/10.1016/j.clae.2017.03.003.
[10] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, Corneal changes following short-term miniscleral contact lens wear, Cont Lens Anterior Eye 37 (2014) 461–468, https://doi.org/10.1016/j.clae.2014.08.002.
[11] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, A. Beanland, L. Lam, C.C. Lim, et al., Hypoxic corneal changes following eight hours of scleral contact Lens Wear, Optom Vis Sci 93 (2016) 293–299, https://doi.org/10.1097/OPX.0000000000000803.
[12] V. Compañ, C. Oliveira, M. Aguilella-Arzo, S. Molla, S.C. Peixoto-de-Matos, J.M. González-Méijome, Oxygen diffusion and edema with modern scleral rigid gas permeable contact lenses, Investig Ophthalmol Vis Sci 55 (2014) 6421–6429, https://doi.org/10.1167/iovs.14-14038.
[13] S.J. Vincent, D. Alonso-Caneiro, M.J. Collins, The time course and nature of corneal oedema during sealed miniscleral contact lens wear, Contact Lens Anterior Eye 55 (2018) 6421–6429, https://doi.org/10.1016/j.clae.2018.03.001.
[14] D.T. Tan, K.W. Pullum, R.J. Buckley, Medical applications of scleral contact lenses: 2. Gas-permeable scleral contact lenses, Cornea 14 (1995) 130–137.
[15] I. Ortenberg, S. Behrman, W. Geraisy, I.S. Barequet, Wearing time as a measure of success of scleral lenses for patients with irregular astigmatism, Eye Contact Lens 39 (2013) 381–384, https://doi.org/10.1097/ICL.0b013e31829e8faa.
[16] K.W. Pullum, R.J. Buckley, A study of 530 patients referred for rigid gas permeable scleral contact lens assessment, Cornea 16 (1997) 612–622, https://doi.org/10.1097/00003226-199711000-00003.
[17] B. Severinsky, M. Millodot, Current applications and efficacy of scleral contact lenses - A retrospective study, J Optom 3 (2010) 158–163, https://doi.org/10.1016/S1888-4296(10)70022-4.
[18] M.M. Schornack, S.V. Patel, Scleral lenses in the management of Keratoconus, Eye Contact Lens 36 (2010) 39–44, https://doi.org/10.1097/ICL.0b013e3181c786a6.
[19] O. Segal, Y. Barkana, D. Hourovitz, S. Behrman, Y. Kamun, I. Avni, et al., Scleral contact lenses may help where other modalities fail, Cornea 22 (2003) 308–310, https://doi.org/10.1097/00003226-200305000-00006.
[20] M. Pecego, M. Barnett, M.J. Mannis, B. Durbin-Johnson, Jupiter scleral lenses: the uc davis eye center experience, Eye Contact Lens 38 (2012) 179–182, https://doi.org/10.1097/ICL.0b013e31824daa5e.
[21] I. Baran, J.A. Bradley, F. Alipour, P. Rosenthal, H.-G. Le, D.S. Jacobs, PROSE treatment of corneal ectasia, Cont Lens Anterior Eye 35 (2012) 222–227, https://doi.org/10.1016/j.clae.2012.04.003.
[22] T. Romero-Rangel, P. Stavrou, J. Cotter, P. Rosenthal, S. Baltatzis, C.S. Foster, Gas-permeable scleral contact lens therapy in ocular surface disease, Am J Ophthalmol 130 (2000) 25–32, https://doi.org/10.1016/S0002-9394(00)00378-0.
[23] W. Alghamdi, M. Markoulli, E. Papas, Responses of contact lens wearers to OSDI and CLDEQ-8 questionnaires, Contact Lens Anterior Eye 41 (2018) S89.
[24] M. Serramito-Blanco, A. Privado-Aroco, L. Batres, G. Carracedo, Corneal surface wettability and tear film stability before and after scleral lens wear, Contact Lens Anterior Eye 42 (2019) 520–525.
[25] J.C. Lee, G.B. Chiu, D. Bach, S.R. Bababeygy, J. Irvine, M. Heur, Functional and visual improvement with prosthetic replacement of the ocular surface ecosystem scleral lenses for irregular corneas, Cornea 32 (2013) 3, https://doi.org/10.1097/ICO.0b013e3182a73802.
[26] R.J. Macedo-de-Araújo, A. Amorim-de-Sousa, E. van der Worp, J.M. González-méijome, Clinical findings and ocular surface symptoms over 1 year in a sample of scleral lens wearers, Eye Contact Lens (2019) (in press).
[27] R.J. Macedo-de-Araújo, E. van der Worp, J.M. González-Méijome, Practitioner learning curve in fitting mini-scleral contact lenses in irregular and regular corneas using a fitting trial, Biomed Res Int 2019 (2019) 11, https://doi.org/10.1155/2019/5737124 pages.
[28] R.J. Macedo-de-Araújo, E. van der Worp, J.M. González-Méijome, On-eye breakage and recovery of mini-scleral contact lens without compromise for the ocular surface, Contact Lens Anterior Eye 41 (2018) 311–314, https://doi.org/10.1016/j.clae.2017.12.009.
[29] R.J. Macedo-de-Araújo, A. Amorim-de-Sousa, A. Queirós, E. van der Worp, J.M. González-Méijome, Relationship of placido corneal topography data with scleral lens fitting parameters, Contact Lens Anterior Eye 42 (2019) 20–27, https://doi.org/10.1016/j.clae.2018.07.005.
[30] D.T. Tan, K.W. Pullum, R.J. Buckley, Medical applications of scleral contact lenses: 1. A retrospective analysis of 343 cases, Cornea 14 (1995) 121–129, https://doi.org/10.1097/00003226-199503000-00001.
[31] K. Pullum, R. Buckley, Therapeutic and ocular surface indications for scleral contact lenses, Ocul Surf 5 (2007) 40–49, https://doi.org/10.1016/S1542-0124(12)70051-4.
[32] P. Rosenthal, A. Croteau, Fluid-ventilated, gas-permeable scleral contact lens is an effective option for managing severe ocular surface disease and many corneal disorders that would otherwise require penetrating keratoplasty, Eye Contact Lens 31 (2005) 130–134, https://doi.org/10.1097/01.ICL.0000152492.98553.8D.
[33] E. Visser, R. Visser, H.J.J. Van Lier, Advantages of toric scleral lenses, Optom Vis Sci 83 (2006) 233–236, https://doi.org/10.1097/01.opx.0000214297.38421.15.
[34] J.H.C. Kok, R. Visser, Treatment of ocular surface disorders and dry eyes with high gas-permeable scleral lenses, Cornea 11 (1992) 518–522, https://doi.org/10.1097/00003226-199211000-00006.
[35] O.D. Schein, P. Rosenthal, C. Ducharme, A gas-permeable scleral contact lens for visual rehabilitation, Am J Ophthalmol 109 (1990) 318–322, https://doi.org/10.1016/S0002-9394(14)74558-1.
[36] K.W. Pullum, M.A. Whiting, R.J. Buckley, Scleral contact lenses: the expanding role, Cornea 24 (2005) 269–277, https://doi.org/10.1097/01.ico.0000148311.94180.6b.
[37] E.-S. Visser, R. Visser, H.J.J. van Lier, H.M. Otten, Modern scleral lenses part II: patient satisfaction, Eye Contact Lens 33 (2007) 21–25, https://doi.org/10.1097/01.icl.0000228964.74647.25.