ORIGINAL INVESTIGATION

Clinical Performance of a New Bitangential Mini-scleral Lens

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SIGNIFICANCE: New bitangential mini-scleral lens designs provide a highly precise fit, follow the scleral shape, are comfortable to wear, and can correct residual astigmatism. This new scleral lens design complements the arsenal of medical contact lenses available to eye care practitioners.

PURPOSE: The aim of this study was to evaluate the subjective and objective performance of a new mini-scleral lens design with a bitangential periphery.

METHODS: In this observational study, data were collected for up to 15 months (median, 84 days; interquartile range, 76 days) from the left eyes of 133 patients fitted with this newly designed lens. Data were recorded during regular visits at Visser Contact Lens Practice's scleral lens clinics: diagnosis, clinical indication for scleral lenses, previous contact lens type, subjective performance, horizontal visible iris diameter, corrected distance visual acuity, and scleral lens fitting characteristics.

RESULTS: The most common indication was keratoconus (45%), followed by irregular astigmatism (22%), keratoplasty (16.5%), ocular surface disease (13.5%), and other forms of irregular astigmatism (3%). The majority of patients (79%) scored comfort as either a 4 or 5 (out of 5), and 82% wore their lenses 12 hours or longer a day. Most lenses (81%) had a diameter of 16 mm (median, 16 mm; range, 15.5 to 17 mm) and were composed of Boston XO2 (46%), Menicon Z (44%), Boston XO (9%), or Boston Equalens II (1%). The median corrected distance visual acuity was 0.022 logarithm of the minimal angle of resolution (interquartile range, 0.155). The fitting characteristics revealed optimal values for centration and movement in 91% and 83%, respectively. Finally, the median stabilization axis was 50 degrees.

CONCLUSIONS: New mini-scleral lenses with bitangential peripheral geometry yield satisfactory clinical results and good subjective performance and are therefore an effective option for managing patients who have irregular astigmatism or other corneal pathology.

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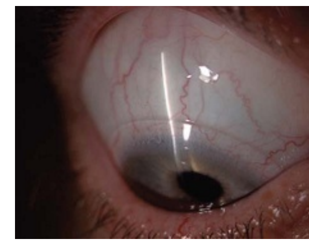

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Scleral lenses are an important tool in medical contact lens practice for managing patients with corneal pathology. Scleral lenses have the unique ability to vault and hydrate[1] the cornea with a fluid reservoir while providing optical correction of the irregular corneal surface. Scleral lenses provide visual benefits in a variety of indications, including corneal ectasia, keratoplasty, and corneal scars, and they provide protection of the corneal surface in ocular surface disease. Since the first scleral lens was produced and described by Fick in 1888,[2] many researchers and eye practitioners have reported on the benefits of scleral lenses. Moreover, the development of gas-permeable materials and innovations in lens design have greatly improved the performance of scleral lenses.[3–7] Visser et al.[8–10] developed a toric scleral lens with a toric periphery in order to produce a more precise fit on the sclera, resulting in considerable improvements in patient satisfaction.

Recently, van der Worp et al.[11] characterized the scleral profile and found that the anterior scleral area is generally more toric than the limbal area. Their analysis also revealed that the majority of eyes have a tangential profile in the anterior sclera, rather than a curved profile.[11,12] Based on these findings, Visser et al.[13] introduced a new large scleral lens design with a bitangential periphery. This lens design is spherical in the center and back-surface toric in the periphery. With different tangential angles in two meridians, this lens design provides a well-balanced landing zone with more precise alignment on a toric sclera, thereby reducing the risk of conjunctival blanching and the passage of bubbles that can form beneath the lens.

Scleral lenses are available as either large scleral lenses or mini-scleral lenses. Based on nomenclature proposed by the Scleral Lens Education Society, the diameter of large scleral lenses and mini-scleral lenses is defined as greater than 6 mm and 6 mm or less, respectively, larger than the horizontal visible iris diameter.[12] However, other studies have used the term "mini-scleral lenses" to describe smaller scleral lenses ranging from 15.1 to 18 mm in total diameter.[14] Several investigators reported on the use of mini-scleral lenses for a variety of indications, including ocular surface disease,[15,16] keratoconus,[16] moderate to severe dry eyes, and penetrating keratoplasty or deep lamellar keratoplasty.[17,18] In studying scleral shape, van der Worp et al.[11] found that many eyes are nonrotationally symmetrical beyond the corneal borders, specifically within the limbal zone. The differences revealed by the study of scleral shape indicate that lenses such as mini-scleral lenses fitted in this limbal zone should have more a toric periphery rather than a rotationally symmetrical periphery. To match the nonrotationally symmetrical scleral surface, a mini-scleral lens should have a peripheral toric back surface.

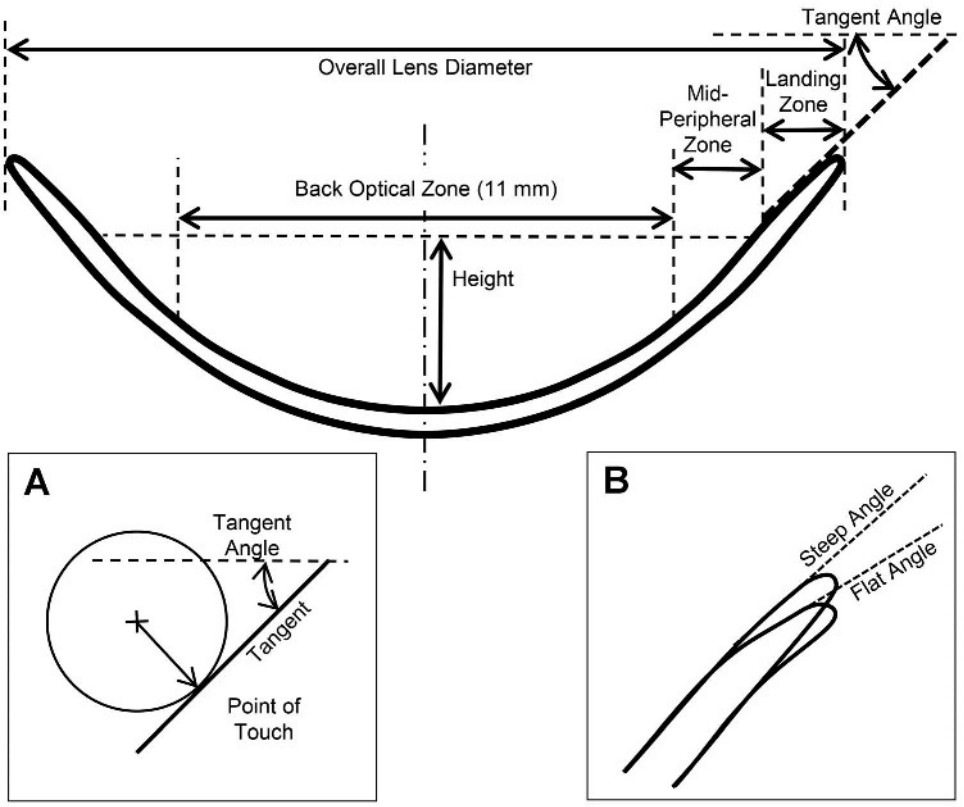

FIGURE 1. Diagram depicting the cross section of a mini-scleral lens design, showing the following zones: a spherical back optical zone, a midperipheral zone, and a linear landing zone near the edge of the lens. This linear landing zone is characterized by an angle that is given relative to a line perpendicular to the optical axis. This angle corresponds to the tangential angle at the assumed point of touch of the linear landing zone (inset A), in which a tangent line touches a curve represented as a circle in this example. In the case of a nonrotationally symmetrical design, the flat meridian and the steep meridian have a different angle than the landing zone (inset B, in which these meridians are superimposed to illustrate the difference in these two angles).

Based on the outcome of these studies regarding scleral shape, a new mini-scleral lens design with a nonrotational peripheral back surface has been developed. Here, we report the results of an observational study to investigate the subjective characteristics and clinical findings of this new lens design.

METHODS

The Bitangential Mini-scleral Lens Design

This new lens (Fig. 1) was designed in collaboration with NKL Contactlenzen (Emmen, The Netherlands), a lens manufacturer for Menicon Co. Ltd. (Nagoya, Japan). This lens consists of a large front optic zone of 10 mm, a spherical back optic zone of 11 mm, and a midperipheral zone to vault the cornea at the limbal area. The midperipheral zone is together with the landing zone 2.5 mm, but can vary depending on the lens's total diameter (which ranges from 14 to 18 mm). The transition at the midperipheral zone is smooth and connects the optical zone with the landing zone (Fig. 2).

The linear landing zone is characterized by an angle relative to a line perpendicular to the optical axis. This angle corresponds to the tangential angle at the assumed point of contact of the lens with the sclera (see the insets in Fig. 1). The linear alignment zone is—in the case of a nonrotationally symmetrical design—manufactured with two different angles in two perpendicular meridians, thereby creating a bitangential periphery. Based on the result of studies regarding scleral shape, the difference between these angles in the fitting set is 6 degrees. The steeper meridian has a larger tangential

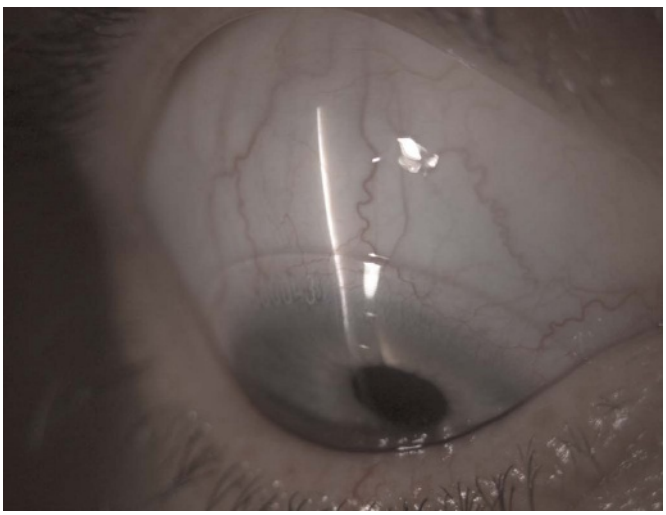

FIGURE 2. Example image of the landing zone and lens edge of a bitangential lens placed on the anterior sclera.

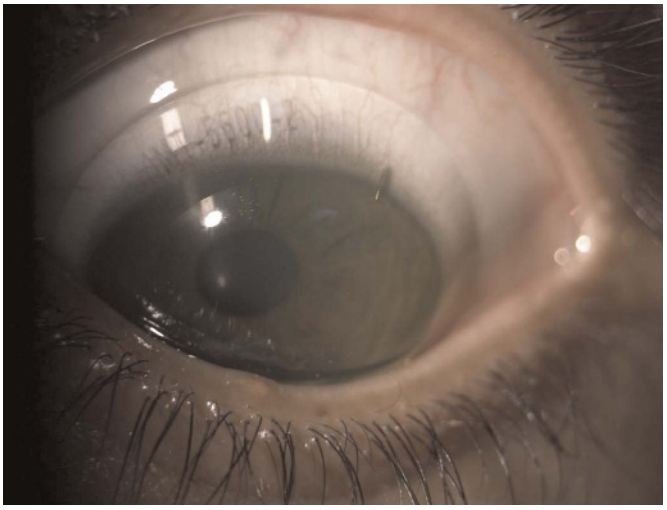

FIGURE 3. Example image of a mini-scleral lens showing the laser-engraved code representing the sagittal height, radius, diameter, and the angle of the flat and steep meridian. A small laser-engraved mark at the edge represents the flattest tangent.

angle, and the shallower meridian has a smaller tangential angle. Because of this difference in angles, the lens is classified as a nonrotationally symmetrical back-surface toric periphery mini-scleral contact lens, which is designed to fit a toric bulbar shape. The difference in tangential angles supports rotational stabilization of the lens and makes it possible to correct any residual astigmatism with a toric front curve.

Each lens is engraved with two laser markings. One marking is at the flattest tangent and is used to indicate the flattest meridian (Fig. 3). In addition, each lens is engraved with a code that represents the total diameter, the sagittal depth, the central radius, the flattest meridian, and the steepest meridian. The standard material used for the lenses in the trial set was Boston XO (Hexafocon-A, Dk 100). The prescribed scleral lenses were available in three additional materials: Boston Equalens II (Oprifocon-A, Dk 85), Boston XO2 (Hexafocon-B, Dk 161), and Menicon Z (Tisilfocon-A, Dk 189). The Boston materials were manufactured by Bausch and Lomb (Wilmington, MA), and the Menicon Z material was manufactured by Menicon Co. Ltd.

Study Design

This observational study was performed in accordance with the tenets of the Declaration of Helsinki. All participating patients were older than 18 years and provided written informed consent prior to enrolling in the study. Both new and existing wearers of scleral lenses were included in the study.

The following eligibility criteria were applied to existing scleral lens wearers: reduced degree of coverage of the anterior sclera was required for their current lenses in the case of a local irregularity in scleral shape (this criterion was also used for wearers of mini-scleral lenses), debris (e.g., mucus or milky particles[12]) formed in the corneal clearance while wearing a large scleral lens, and handling difficulties had been encountered previously with large scleral lenses. New wearers of scleral lenses were included if the patient had not successfully used other lens modalities, including other types of scleral lenses, because of issues with comfort and/or vision. The patients were fitted with the newly designed mini-scleral lens for either unilateral or bilateral treatment, where applicable; for this study, we analyzed only the results of the left eye.

Data Collection

All patients were referred by their ophthalmologist to Visser Contact Lens Practice, where they were fitted in the practice's scleral lens clinic by a team consisting of six eye care practitioners. The data were obtained during regular visits conducted from October 2013 through December 2014, and one data set per patient was used in the analysis. The patients were instructed to wear their lens(es) for at least 4 weeks. For this study, we selected the data from the visit with the longest duration of scleral lens use, which ranged from 4 weeks to 15 months. The scleral lenses were fitted for daily wear, and the patients were instructed to use the prescribed cleaning and disinfection solution and to fill their lenses with unpreserved 0.9% saline solution or unpreserved sodium carboxymethyl cellulose 1.0% (Cellumed; Allergan Pharmaceuticals, Westport, Ireland) before lens insertion.

The patient's date of birth, sex, diagnosis, indication for a mini-sclera lens, horizontal visible iris diameter, wearing duration (in hours per day and days per week), and the number of necessary breaks during the day were recorded. A five-point score ranging from 1 (very poor) to 5 (excellent) was used to rate the patient's comfort while wearing the scleral lens. During each visit, the corrected distance visual acuity while wearing the scleral lens was measured using a Snellen chart and then converted to logarithm of the minimal angle of resolution (logMAR) values for statistical analyses. A fitting set consisting of 16 toric mini-scleral lenses was used in this study (Table 1). All trial lenses had a diameter of 16.00 mm, and the two meridians of the tangential landing zone, which forms an angle perpendicular to the optical axis, had a difference of 6 degrees. Trial lenses were used to perform a diagnostic fit in accordance with our standardized fitting protocol, which starts

TABLE 1. Overview of the diagnostic set of 16 lenses with a base curve radius of 8.4 mm and a diameter of 16 mm

	Tangent				
Height	**32°/38°**	**34°/40°**	**36°/42°**	**38°/44°**	**40°/46°**
3.4 mm	✓	✓	✓	✓	✓
3.6 mm	✓	✓	✓	✓	✓
3.8 mm		✓	✓	✓	
4.0 mm		✓	✓	✓	

All 16 lenses in the set are nonrotationally symmetrical, with a 6-degree difference in between the flat and steep meridian angles. The diagnostic lenses include four height specifications (left column) and five sets of flat and steep tangential angles (top row).

with inserting the first trial lens based on a macroscopic and microscopic evaluation of the scleral and corneal profiles; immediately after lens insertion, the fit was evaluated using a slit lamp. If the trial lens was within the desired limits, the lens was allowed to settle for 30 minutes, after which the following six parameters were assessed using this trial lens: sagittal height, central radius (base curve radius), total diameter, the tangential angles of the flattest and steepest meridian of the landing zone, centration, and stabilization. These lens-fitting characteristics were assessed using a routine slit-lamp examination; corneal clearance was assessed both centrally and near the limbus in four directions (superior, inferior, nasal, and temporal) by comparing the degree of clearance with the central corneal thickness and the thickness of the trial lens (0.35 mm). Fitting of the landing zone was also recorded in these four directions and was graded as steep, desirable, or flat. Movement of the lens was determined using the push-up test and ranged from –2 (no lens movement) to +2 (excessive lens movement), with 0 representing optimal movement.

The centration of the lens was marked as grade 0 (central), grade 1 (acceptable), or grade 2 (undesirable) in the four main directions. The stabilization axis was measured relative to the flattest meridian of the lens and recorded in degrees. The goal was to fit the lens with the desired apical clearance of 0.2 mm, 0.1-mm limbal clearance, and good alignment with the scleral profile upon gentle movement.

Statistical Analysis

The majority of scleral lens wearers in our study (89 of 133 patients) were bilateral scleral lens users; however, in our analysis, we evaluated the left eye only. Patient age was tested for a normal distribution using the Kolmogorov-Smirnov test and the Anderson-Darling test and was the only variable that was normally distributed; this variable is reported as the mean value and range. All other variables were tested with the Anderson-Darling normality test and were not normally distributed; these variables are reported as the median value and range. Statistical analyses were performed using Minitab 17 (Minitab Inc., State College, PA).

RESULTS

All 133 patients returned for follow-up testing, with a median follow-up time of 84 days (range, 4 weeks to 15 months).

Demographics

The left eye was evaluated in a total of 133 patients, with 66 females (49.6%) and 67 males (50.4%); the mean age of the study population was 45 years (range, 18 to 81 years).

Diagnoses

The diagnoses were categorized into five main groups (Table 2). The most common diagnosis was keratoconus (45% of patients), followed by irregular astigmatism (22%), which included patients with corneal scars caused by trauma or keratitis, as well as several other corneal disorders; 16.5% and 13.5% of patients were diagnosed with keratoplasty or ocular surface disease, respectively. The remaining 3% of patients were diagnosed with high refractive error and high astigmatism (>4 diopters [D]).

TABLE 2. Summary of the diagnosis of all 133 eyes included in the study

Diagnoses		No. of eyes (%)
Keratoconus		60 (45)
Irregular astigmatism		29 (20)
Corneal scar	After herpes simplex keratitis	4 (3)
	After infectious keratitis	9 (6.5)
	After trauma	1 (0.5)
	After surgery (pterygium resection)	4 (3.0)
Corneal dystrophy	Fuchs endothelial corneal dystrophy	2 (1.5)
Corneal degeneration	Terrien's marginal degeneration	1 (0.5)
	Congenital scleral cornea	1 (0.5)
Limbal atrophy	Superior limbal keratitis	1 (0.5)
	After adenoviral keratitis	1 (0.5)
Pellucid marginal degeneration		1 (0.5)
Refractive surgery	Post laser-assisted in situ keratomileusis	1 (0.5)
	Post laser epithelial keratomileusis	1 (0.5)
	Radial keratotomy	2 (1.5)
Ocular surface disease	Sjögren syndrome and keratitis sicca	18 (13)
Keratoplasty		22 (19)
Other		4 (3)
Refractive	High refractive error > +/– 10 D	3 (2.5)
	High cylindrical correction >4 D	(0.5)
Total		**133 (100)**

Lens Use History

The majority of patients were existing users of a large scleral lens (49%); 23% wore no lenses previously or were users of a different mini-scleral lens design (9%). The remaining patients were existing users of another contact lens type, including rigid gas-permeable corneal lenses (8%), silicone hydrogel soft lenses (5%), hybrid lenses (4%), piggy-back lenses (1%), or silicone hydrogel bandage lenses (1%) (Table 3).

Primary Clinical Indication for Prescribing the Mini-scleral Lens

The most common reason for fitting patients with the new mini-scleral lens design was to achieve reduced coverage of the anterior sclera (47%) (Table 4). The indications in this group included local anterior scleral irregularities caused by local differences in the sclera such as nodules, pinguecula or other elevations following surgery or trauma, and a small-sized cornea. The second most common indication (in 29% of patients) was the use of large scleral lenses in which debris accumulated in the corneal clearance. The

TABLE 3. Summary of the patients' history with previous lenses

Previous lens	No.	%
Large scleral lens	66	49.62
No lens	31	23.33
Mini-scleral lens	12	9.02
Corneal lens	11	8.27
Hybrid	5	3.75
Soft	6	4.51
Piggyback	1	0.75
Bandage lens	1	0.75
Total	**133**	**100**

group "others" (14% of patients) included patients with comfort-related problems with their existing lens, eyes that require more oxygen, cosmetic differences between the left and right eyes when wearing a large scleral lens, and a small eyelid aperture. The least common indication (10% of patients) was difficulty handling a large scleral lens.

Horizontal Visible Iris Diameter

The median horizontal visible iris diameter of the left eyes in our patient population was 11.5 mm (range, 10.0 to 12.8 mm). Iris diameter was measured using nearby reading chart NL/0149/2013 (Allergan, Dublin, Ireland), which contains a pre-set scale for measuring the iris diameter. Only 7% of patients had a left eye that was considered to contain a microcornea, defined as a horizontal visible iris diameter of less than 10.50 mm. The majority of patients (50%) had a horizontal visible iris diameter of 10.50 to 11.50 mm, followed by patients with a horizontal visible iris diameter of 11.60 to 12.50 mm (40% of patients). The smallest group of patients (3%) had a horizontal visible iris diameter of greater than 12.50 mm.

TABLE 4. Summary of the four main primary clinical indications for the use of the mini-scleral lens design

Primary clinical indication	No. (%)
Less coverage anterior sclera	63 (47)
Local anterior scleral irregularities	45
Horizontal visible iris diameter <10.50 mm	7
Trauma and/or surgery	6
Nodules	4
Pinguecula	1
Debris behind the large scleral lens	38 (28)
Other	19 (15)
Visual and comfort problems with existing lens	14
More oxygen required	3
Cosmetic differences in unilateral lens wear	1
Small eyelid aperture	1
Handling difficulties large scleral lens	13 (10)
Total	**133 (100)**

Subjective Performance

The median score for scleral lens comfort (on a five-point scale) was 4. Twenty percent of patients gave a score of 5, and 59%, 16%, 4%, and 1% of patients gave a score of 4, 3, 2, or 1, respectively. The median daily wearing time was 14 hours (range, 2.5 to 18 hours), and most patients (82%) wore their lenses 12 hours or more a day; 7% and 11% of patients wore their lenses 8 to 12 hours a day or less than 8 hours a day, respectively. The median weekly wearing time was 7 days per week (range, 1 to 7 days per week); 85% of patients wore their lenses 7 days per week. The median number of breaks in daily wearing time was 0 (range, 0 to 10); 80% of patients wore their lenses without interruption, whereas 20% of patients removed their lenses at least once a day in order to refresh the saline solution in the fluid reservoir.

Corrected Distance Visual Acuity

The median corrected distance visual acuity while wearing the scleral lens was 0.022 logMAR (range, –0.097 to 1.301); 55% of patients had a corrected distance visual acuity of 0.0 to 0.05 logMAR (20/20) or better (Table 5). In our study, 47% and 53% of lenses had a spherical correction or spherocylindrical correction, respectively, with a median front surface cylindrical correction of 0.75 D (range, –3.5 to 0.5 D) in order to reach maximum corrected distance visual acuity.

Scleral Lens Characteristics

The diameter of the scleral lenses ranged from 15.5 to 17 mm. For the majority of scleral lenses (81%), the diameter was 16 mm; 15% and 4% had a diameter of 16 to 17 mm or 15.5 to 16 mm, respectively. The lenses were made from the following materials: Boston XO2 (46% of lenses), Menicon Z (44%), Boston XO (9%), or Boston Equalens II (1%). The lenses were fitted with a median tangential angle difference (between the flat and steep meridian) of 6 degrees (corresponding to 100 μm in sagittal depth difference at the edge), with a range of 0 to 14 degrees (corresponding to 0 to 500 μm).

Scleral Lens Fitting Results

Good positioning was observed in 121 eyes (91% of patients); 11 eyes had acceptable decentration of the lens to the inferior position (six eyes, or 4.5%), the temporal position (four eyes, or 3%), or the nasal position (one eye, or 0.80%). Finally, one eye (0.80%) had undesirable decentration in the temporal position (Fig. 4).

TABLE 5. Summary of corrected distance visual acuity (in logMAR units) measured with the bitangential mini-scleral lens

CDVA logMAR	Snellen equivalent	No. (%)
<0	20/15–20/18	11 (8)
0.0–0.05	20/19–20/20	63 (47)
0.06–0.2	20/22–20/31	35 (26)
0.2–0.3	20/32–20/39	17 (13)
>0.3	20/39–20/166	7 (5)
Total		**133 (100)**

CDVA = corrected distance visual acuity; logMAR = logarithm of the minimal angle of resolution.

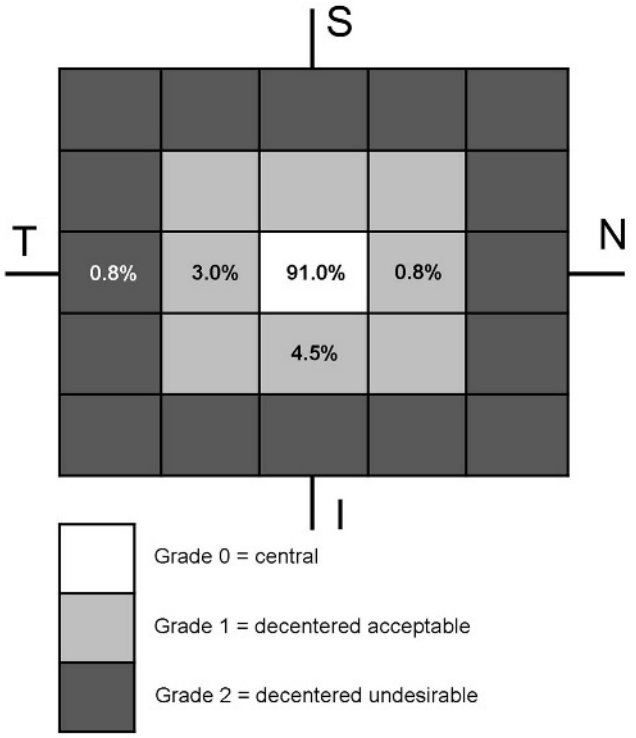

FIGURE 4. Summary of the centration of the 133 bitangential mini-scleral lens; the shading represents the grading scale, which ranges from 0 (central) to 2 (an undesirable degree of decentration). A total of 91% of lenses were centered well, whereas 9.1% had an acceptable degree of decentration (grade 1), with 4.5% and 3% decentered to the inferior or temporal aspect, respectively. I = inferior; N = nasal; S = superior; T = temporal.

With respect to movement of the lens, optimal and acceptable (i.e., slightly reduced or increased) movement of the scleral lens was scored in 110 eyes (83%) and 17 eyes (13%), respectively; no lens movement was scored in six eyes (4%). The stabilization axis ranged from 0 to 90 degrees, with a median stabilization axis of 50 degrees (Table 6).

Corneal Clearance

The median central corneal clearance was 0.26 mm (range, 0.05 to 0.5 mm). Small differences were observed in the limbal clearance; the lowest clearance values were nasal and superior, and the highest clearance values were temporal and inferior (Fig. 5).

TABLE 6. Summary of the stabilization axis of the 133 mini-scleral lenses used in the study

Stabilization axis (degrees)	No. lenses (%)
0–30	33 (25)
30–60	37 (28)
60–90	30 (23)
90–120	5 (4)
120–150	8 (6)
150–180	9 (14)
Other*	1 (1)
Total	**133 (100)**

Median = 50. *This lens was made with a rotationally symmetrical landing zone.

DISCUSSION

Here, we report the objective and subjective performance of a bitangential mini-scleral lens design in 133 patients. This scleral lens was based on the large bitangential scleral lens design that we previously introduced in our practice.[13]

Our study had several considerations that warrant discussion. First, observational design prevented drawing comparisons with other conventional scleral lens designs; however, the aim of this study was to measure the performance of this new mini-scleral lens design in a fairly large group of participants. Future studies should therefore compare this new design with other scleral lens designs. In addition, the follow-up time varied in our study, as the patients began to wear the new lens design at different points in time. Having all patients begin at the same time point would be ideal, but impractical in a daily contact lens practice.

In our patient cohort, the most common diagnosis was keratoconus, followed by irregular astigmatism, penetrating keratoplasty, ocular surface disease, and other diagnoses such as high refractive error. Previous studies reported similar distributions with respect to diagnoses.[6–8,19,20] The most common indication for a scleral lens was visual improvement with an irregular cornea, followed by protecting and hydrating the cornea in ocular surface disease.[15,21–24]

Materials with a high Dk value (e.g., Menicon Z and Boston XO2) were generally preferred, particularly when higher oxygen supply was needed (e.g., in corneas with high oxygen demand)

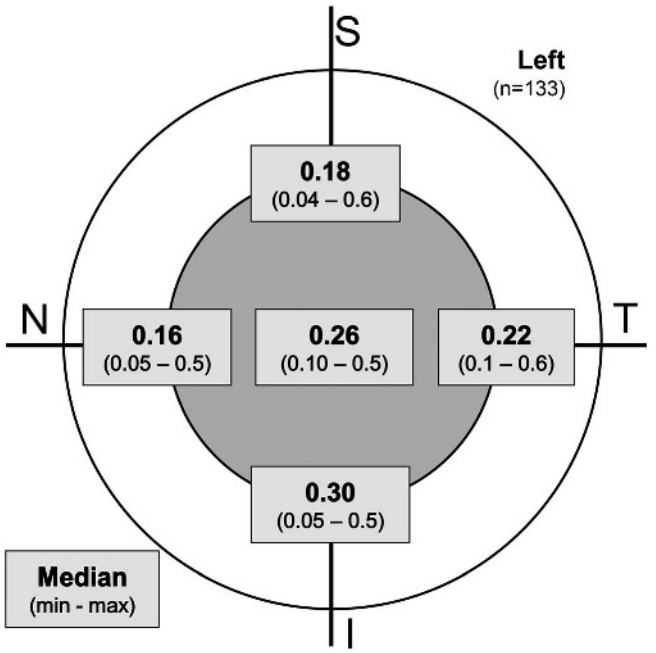

FIGURE 5. Summary of the clearance of 133 lenses; the values are given as the median clearance in millimeters, as well as the range. The median apical clearance was 0.26 mm, and the highest median clearance was 0.30 mm, at the inferior aspect. I = inferior; N = nasal; S = superior; T = temporal.

and in patients with high refractive error with high central thickness of the lens. These high-Dk materials better meet the theoretical estimates of oxygen supply, as discussed by Michaud et al.[25] and Bergmanson et al.[26]

The majority of our patients rated the comfort of their lens as either a 4 or 5 (out of 5), which reflects relatively good performance for this lens design. Both Segal et al.[19] and Ortenberg et al.[27] reported that wearing time can be used as an indication of success. In our study, we found that median wearing time was 14 hours a day, 7 days a week, and 80% of our patients wore their lenses continuously throughout the day. The median corrected distance visual acuity when wearing the scleral lens was 0.022 logMAR, which is consistent with previous reports that scleral lenses can improve visual acuity[15] and can improve quality of life.[28]

Recently, van der Worp et al.[15] discussed the need to have several scleral lens diameters in order to achieve an optimal fit. Mini-scleral lenses are indicated in patients with local scleral elevations, small horizontal visible iris diameter, a predisposition for debris within the corneal clearance, unilateral lens wear, small eyelid aperture, difficulties handling a large scleral lens, and scleral lens decentration. Here, we show that a mini-scleral lens can be fitted successfully in patients with an anterior scleral elevation, including pingueculas, nodules, or elevations caused by surgery or trauma, conditions that can make it difficult to fit a large scleral lens. Scleral elevations can be bridged using a large scleral lens. However, in the case of an advanced elevation, there is a risk of compression; therefore, a mini-scleral lens can accommodate the scleral elevation if it is not located too close to the limbal area. In our study, our new mini-scleral lens design was successfully fitted in several patients with a glaucoma valve implanted in the sclera and in one patient with multiple scleral irregularities due to a fireworks-related injury.

We also found that the mini-scleral lens diameter is determined by horizontal visible iris diameter. Specifically, we found that patients with an extremely small cornea (<10.50 mm in diameter) are ideal candidates for a mini-scleral lens; nevertheless, the horizontal visible iris diameter does not seem to be the most important factor, given that patients with either smaller or larger horizontal visible iris diameter values were successfully fitted with the new mini-scleral lens design. Our median horizontal visible iris diameter value of 11.50 mm was consistent with previous findings; for example, Caroline and Andre[29] reported a mean horizontal visible iris diameter value of 11.8 mm in 100 eyes.

McKinney et al. (*IOVS* 2013;54:ARVO E-abstract 5483) recently concluded that minimal central and limbal corneal clearance with an appropriate lens edge can reduce the amount of debris in the corneal clearance when this so-called "fogging" phenomenon is related to a predisposition for dry eyes. In this respect, patients who have a high rate of debris formation when using a large scleral lens are candidates for a mini-scleral lens, which additionally covers a smaller area of the sclera with less movement and improved centration. Large scleral lenses can become decentered toward the inferotemporal position[13] because of differences in the anterior peripheral sclera.[11,12,15] Centration of a mini-scleral lens is related to the limbal-scleral area, which seems to be more regular.[15] In our study, 91% of patients had good centration of the mini-scleral lens, and decentered lenses were generally decentered toward the inferotemporal position.

The majority of lenses in our study had optimal movement; however, 15% of the lenses had no movement and were therefore fitted more tightly than desired. The median stabilization axis of the mini-scleral lenses was 50 degrees (range, 0 to 180 degrees), which is similar to previous studies using large scleral lenses.[9,13]

Only 1 of our 133 patients was fitted with a rotationally symmetrical lens; the remaining patients were fitted with a nonrotationally symmetrical lens, suggesting that the sclera close to the limbal area is nonrotationally symmetrical more often than that reported by van der Worp et al.[11] A possible explanation for this difference may be that a scleral lens settles in the soft conjunctiva, which may have unequal stiffness around the eyes, leading to a relatively nonsymmetrical shape of the underlying tissue due to the attachment of the muscles to the eye. This notion is supported by this and previous studies.[13]

In conclusion, the bitangential, nonrotational periphery of our new mini-scleral lens design provides stable lens fitting, resulting in favorable fitting characteristics, including good centration, limited movement, and a stable axis, which provide cylindrical correction and high visual acuity. Thus, this new mini-scleral lens design provides good performance and high comfort as shown by extended daily wearing time with few interruptions.

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