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Modern Scleral Lenses Part I: Clinical Features

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Purpose. To evaluate the indications for modern scleral lenses and their clinical performance in patients who were fitted with scleral lenses at the authors' practices. **Methods.** In this cross-sectional survey, all the necessary data were obtained at the first follow-up visit during the 5-month study period. There were four types of scleral lenses: spherical, front-surface toric, back-surface toric, and bitoric. The preformed scleral lens fitting technique developed at Visser Contact Lens Practice was used in all patients. The lenses were cut by precise Sub Micron Lathing from a Boston Equalens II blank at Procornea. Visual acuity and slitlamp findings were recorded. A specially designed classification for scleral lens fitting was used to investigate clinical performance. **Results.** The largest proportion of the 178 patients (284 eyes) were diagnosed with keratoconus (143 [50.4%] eyes) followed by postpenetrating keratoplasty (56 [19.7%] eyes). The remaining diagnoses were irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses. The ratio of spherical to back-surface toric designs was 1:1.1. Clinical examination showed sharp increases in visual acuity (median increase, 0.45) and safe physiologic responses of the anterior eye. All the patients could continue to wear scleral lenses, with 79.2% with the same lens parameters. **Conclusions.** Several types of corneal abnormality were managed successfully with modern scleral lenses. The main indication was optical correction of an irregular corneal surface. Satisfactory clinical performance meant that all the patients could continue to wear their scleral lenses.

Key Words: Dry eye—Irregular corneal surface—Keratoconus—Scleral lens—Toric scleral lens.

Modern scleral lenses are indicated for several ocular conditions and can nearly always be fitted successfully.[1–5] A scleral lens provides optical correction, mechanical protection, relief of symptoms, and facilitation of healing. It creates a neutralizing tear lens that corrects any corneal irregularities, and it retains a precorneal reservoir. The rigidity of the material affords mechanical protection and optical correction of the corneal surface.

One of the main goals of scleral lens fitting is visual rehabilitation of an irregular corneal surface, such as in primary corneal ectasia (mostly keratoconus), postpenetrating keratoplasty, and other forms of irregular astigmatism.[4–8] Scleral lenses can provide mechanical protection and restore function in conditions such as scarred eyelids, entropion, and ptosis.[9] Furthermore, they can be used to relieve symptoms, as in dry eye and corneal dystrophies, and to facilitate healing, as in cases of recurrent corneal erosion.[10–13] The potential value of wearing scleral lenses overnight has been described for recurrent corneal erosions, corneal exposure, and various ocular surface diseases. Apparently, the hypoxic effect can be a limiting factor.[3,14–16]

The development of materials with high gas permeability, together with various technologic innovations in the design and manufacturing of scleral lenses has opened new perspectives for their use.[7,9,10,17–22] For example, two fairly recent refinements (i.e., a front-surface cylinder and a partial back-surface toric) enabled optimized correction and fitting of the lens. This has resulted in four types of scleral lenses: spherical, front-surface toric, back-surface toric, and bitoric.[5,13]

The aims of this prospective study were to evaluate the indications for modern scleral lenses and their clinical performance. Patient satisfaction is presented in part II.

MATERIALS AND METHODS

Data were gathered for this cross-sectional survey between September 1, 2002 and January 31, 2003. Patients were recruited at the scleral lens clinics of Visser Contact Lens Practice in Nijmegen, Utrecht and 's-Hertogenbosch, The Netherlands. Data were collected from all the patients who fulfilled the selection criteria at their first follow-up visit. They were all of legal age and able to complete the questionnaire, and they all gave written informed consent. Any patients who made an emergency visit or came for a refitting were excluded from the study. All the patients had been referred to the clinic by their ophthalmologist because of one of the indications described earlier, which had not responded to other contact lenses or therapeutic management.

A total of 178 patients (284 eyes) entered the study and included 98 men and 80 women. Age ranged from 18 to 80 years (median, 41.7 years; mean, 45.0 ± 14.8 years). Most patients (96 [53.9%] patients) were between 30 and 50 years of age. Scleral lenses were being worn in both eyes in 106 patients, in the right eye only in 36 patients, and in the left eye only in 36 patients. There were 142 right eyes (50.0%) and 142 left eyes (50.0%), which resulted in a right to left ratio of 1:1.

All the patients had been wearing one or two scleral lenses for at least 3 months that had been fitted according to the standardized fitting methodology developed by Rients Visser.[1,5,9,10,13] The scleral lens design was realized in cooperation with Procornea (Eerbeek, The Netherlands).

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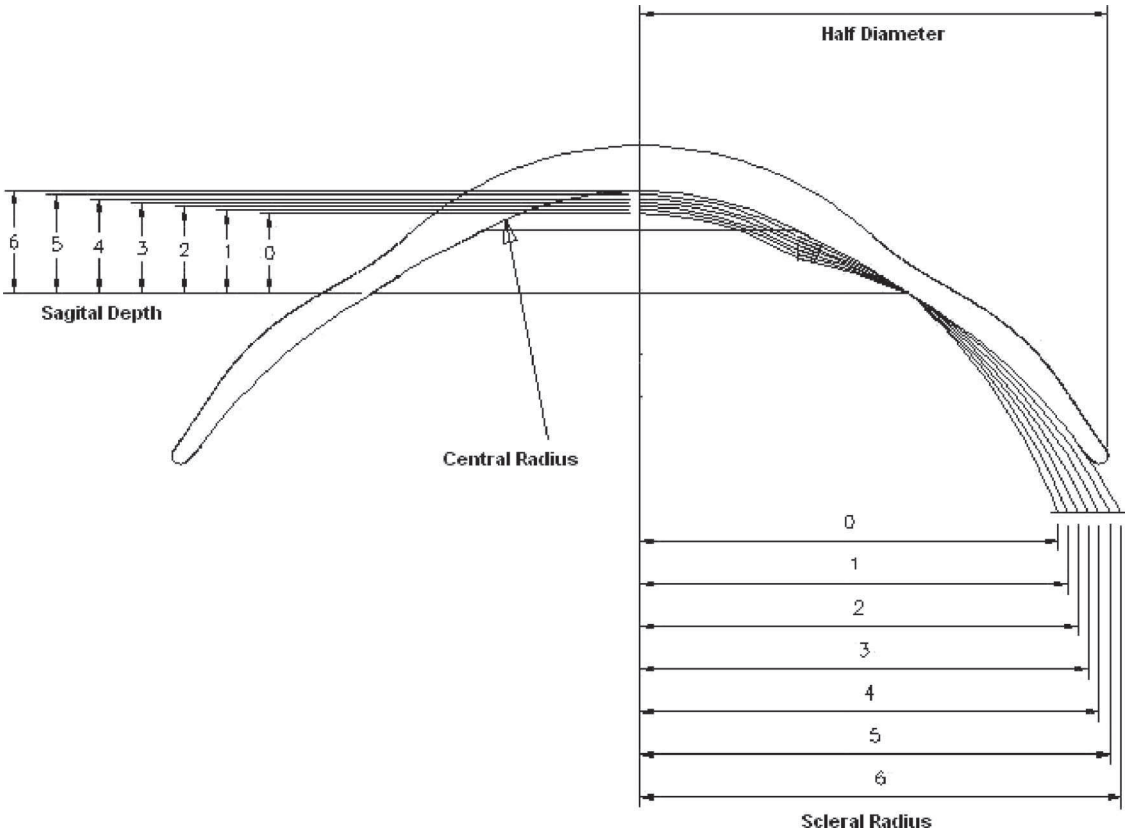

FIG. 1. Schematic design of the scleral lens.

The scleral lenses were manufactured at Procornea by precise Sub Micron Lathing from Boston Equalens II blanks (Polymer Technology, Wilmington, MA) of 27 mm in diameter and 13 mm in thickness. They were made of fluorosilicone acrylate copolymer (itaflurofocon B) manufactured by the Polymer Technology Corporation, Bausch & Lomb. The Dk was listed as 85×10^{-11} cm^3 O_2 (cm/ [(sec)(cm^2)(mm Hg)]) at 35°C (International Organization for Standardization [ISO]/Fatt method). The center thickness of a –3.00 diopter scleral lens was 0.50 mm.

The scleral lens types applied to the patients included 128 spherical scleral lenses (45.1%), five front-surface toric scleral lenses (1.8%), 71 back-surface toric lenses (25.0%), and 80 bitoric scleral lenses (28.2%). This resulted in a 1:1.1 ratio of back-surface spherical designs (spherical and front-surface toric) to back-surface toric designs (back-surface toric and bitoric).

During the empirical fitting procedure, the cornea and sclera were evaluated to select a trial lens. Then, several parameters were determined for the definitive lens on the basis of the trial lens: power, total diameter (range, 18.0–25.0 mm in 0.5-mm steps), scleral radius (range, 11.75–15.0 mm in 0.25-mm steps), central radius (range, 6.60–9.00 mm in 0.30-mm steps), and sagittal depth (range, 3.57–5.37 mm in 0.10-mm steps) (Fig. 1). An optional parameter was a blanching offset (range, 0.1–0.6 mm in 0.1-mm steps). In case of back-surface toric designs, the haptic back surface was toric, with a toricity of 0.8 mm. The fitting was based on resting the lens on the external sclera and vaulting of the cornea and limbus (Fig. 2). To retain normal corneal physiology, a constant tear flow was required. The ideal lens was characterized by a well-balanced haptic bearing, gentle movement of the lens by pushup testing, approximately 0.25 mm of corneal clearance, and 0.05 to 0.10 mm limbal clearance.

The lenses were being worn on a daily basis. Lens care consisted of cleaning, wetting, and disinfecting with standard rigid gas-permeable lens solution systems. Before insertion, the lenses were rinsed and filled with unpreserved saline.

Patient data included date of birth, sex, diagnosis, indication for scleral lenses, scleral lens type, front-surface cylinder, dispensing

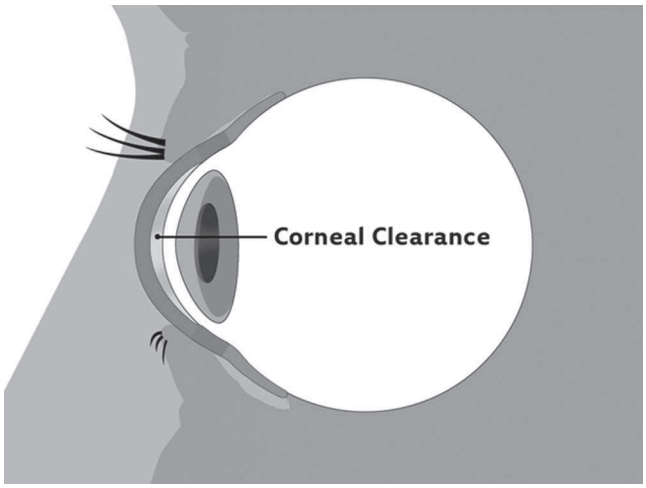

FIG. 2. Resting of the scleral lens on the external sclera and vaulting of the cornea and limbus.

TABLE 1. *Classification of Scleral Lens Fitting*

Fitting feature	–2	–1	0 (optimal)	1	2	3	4
Corneal clearance	<0.1 mm	≥0.1 mm to <0.2 mm	0.2 to 0.3 mm	>0.3 mm to ≤0.5mm	>0.5 mm		
Limbal clearance	Absent	<0.1 mm	Approximately 0.1 mm	0.1 mm to ≤0.2 mm	>0.2 mm		
Scleral fit (in primary position)	Circumcorneal blanching	Segmented blanching	Optimal	Increased edge clearance, acceptable	Increased edge clearance with air bubble, unacceptable		
Lens movement	Reduced, unacceptable	Reduced, acceptable	Optimal	Excessive, acceptable	Excessive, unacceptable		
Trapped air bubbles			Absent	Slight, <2 mm in diameter	Moderate, >2 mm to <4 mm in diameter	Severe, >4 mm in diameter	
Front surface wettability			Smooth uniformly reflecting surface	Coarse hazy surface, resolved with blinking and exacerbated with staring	Stable, dry (nonwetting) area of some magnitude	Nonwettable lens surface	
Front surface deposits			Absent	Very slight, only visible after tear film drying	Slight, visible deposits easily removed	Moderate, deposits adherent and unremovable	Severe, unremovable deposits and comfort affected
Back surface deposits			Absent, clean surface	Very slight, three spots or fewer of moving particles	Slight, as many as 10 spots of moving particles	Moderate, three or fewer nonmoving deposits adherent to lens	Severe, four or more deposits adherent to the lens or corneal indentation

date, starting date of wearing the scleral lens, and starting date of current scleral lens type.

Visual acuity (VA) was measured and noted in decimal form with the scleral lens and with the best-corrected refraction without the scleral lens. The best-corrected refraction was determined by subjective refraction without any contact lens and was performed during the study visit. VA of less than 0.1 was indicated using the following steps: 1/300, 2/300, and 3/300 for hand motions at 1, 2, and 3 m. For finger counting at 1, 2, and 3 m, the VA steps were 1/60, 2/60, and 3/60. To convert Snellen VA to decimal VA, the numerator is divided by the denominator. Thus, the result 20/40 is equivalent to the decimal score of 0.50.

A classification for scleral lens fitting was developed to describe corneal clearance, limbal clearance, scleral fit, lens movement, trapped air bubbles, front surface wettability, front surface deposits, and back surface deposits (Table 1). The 1997 ISO 11980 for Ophthalmic Optics was used as a basis to classify scleral lens fitting and the slitlamp findings.

Slitlamp findings were recorded on the following 10 topics: epithelial edema, stromal edema, corneal infiltrates (epithelial infiltrates and presence of stromal infiltrates at grade 4), corneal vascularization, corneal staining with fluorescein, limbal hyperemia, bulbar conjunctival hyperemia, palpebral signs, anterior blepharitis, and posterior marginal blepharitis. In this study, the ISO standard was extended to include the latter two items. All the topics were classified on a five-point scale, with 0 for none, 1 for trace, 2 for mild, 3 for moderate, and 4 for severe. The investigators used a more detailed explanation to grade each topic. To differentiate scleral lens findings from existing findings before scleral lens wear or findings related to underlying disease, the investigator was asked to indicate whether a sign was related to the scleral lens.

Treatment outcome was recorded as one of the following options: continue, replace current lens, refit with scleral lens, discontinue wearing the scleral lens, and other.

Patient data were recorded on a case report form. The forms were checked for completeness within a few days of the follow-up visit.

Data were stored on a computer with the EPI-INFO package (public domain software). The file was locked after checking all the data and solving any queries. Then the file was transferred to the Statistical Analysis System (SAS) to perform inferences.

Groups were compared using the chi-square test for independence or the Fisher exact test in the case of categorical variables. Because none of the continuous variables turned out to be normally distributed (Shapiro–Wilk test for normality), these were characterized with distribution-free measures of location and dispersion and were analyzed with the Kruskal–Wallis test. When the result was significant, the Wilcoxon test was used to investigate which groups differed from each other.

Comparisons of continuous variables within subgroups (i.e., differences) were performed with the signed rank test. Only groups with more than five observations were entered for statistical testing. This meant that the spherical, the back-surface toric, and the bitoric lenses formed the main three lens types.

Because a considerable number of the points in the figure on VA with and without a scleral lens were equal, (i.e., the x and y variables had the same value in two or more patients or eyes), a small shift was made in the horizontal direction to show how many were equal.

All the tests were performed in a two-tailed manner, and P values of 0.05 or less were considered to be significant.

The study was approved by the Research and Ethical Committee of the City University, London, United Kingdom.

RESULTS

Underlying Scleral Lens Indication

Diagnoses were categorized into six main groups: keratoconus, postpenetrating keratoplasty, primary or secondary irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses

TABLE 2. *Diagnosis Groups, Gender, and Median Age in Years*

Diagnosis group	No. of eyes	Men (%)	Women (%)	Minimum	q1	Median	q3	Maximum
Keratoconus	143	84 (58.7)	59 (41.3)	18.2	31.0	37.5	43.1	67.4
Postpenetrating keratoplasty	56	34 (60.7)	22 (39.3)	23.0	43.5	50.5	68.4	80.2
Irregular astigmatism	36	20 (55.6)	16 (44.4)	21.0	35.8	41.3	55.8	79.9
Keratitis sicca	15	3 (20.0)	12 (80.0)	32.5	40.7	52.4	69.6	78.9
Corneal dystrophy	10	5 (50.0)	5 (50.0)	45.6	59.3	66.2	74.6	76.3
Multiple diagnoses	24	9 (37.5)	15 (62.5)	23.3	34.3	45.1	55.5	67.9
All eyes	284	155 (54.6)	129 (45.4)	18.2	33.8	40.7	54.0	80.2

q1, first quartile; q3, third quartile.

(Table 2). A large proportion of the sample was diagnosed with keratoconus (143 [50.4%] eyes) followed by postpenetrating keratoplasty (56 [19.7%] eyes). Other forms of irregular corneal surface were categorized in the irregular astigmatism group, which included eyes with scars related to herpes simplex keratitis (eight eyes), other forms of keratitis (two eyes), trauma (five eyes), and irradiation (three eyes). The irregular astigmatism group also included six eyes in which the disorder was not further defined, seven eyes with pellucid marginal degeneration, two eyes with pterygium, and one eye with macula corneae. Primary keratitis sicca was seen in four eyes, neurotrophic keratitis in seven eyes, ocular cicatricial pemphigoid in two eyes, and Sjögren syndrome in two eyes. There were four types of corneal dystrophy: map-dot-fingerprint (five eyes), Fuchs endothelial (two eyes), Reis–Bucklers (two eyes), and lattice (one eye).

Table 2 shows a predominance of men in the first three diagnosis groups. Age varied significantly among the diagnosis groups ($P<0.001$, Kruskal–Wallis test). Patients with keratoconus were younger, and patients who underwent penetrating keratoplasty or had keratitis sicca or corneal dystrophy were older than the other patients (Table 2).

Indications could be categorized into six main groups: visual correction alone, corneal protection, visual correction and ptosis neutralization, corneal protection and visual correction, visual correction and corneal vascularization suppression (after a soft contact lens), and visual correction and tear conservation. Visual correction alone (group 1) was by far the most common indication for scleral lens fitting in this sample and accounted for 249 (87.7%) eyes. The combination of corneal protection and visual

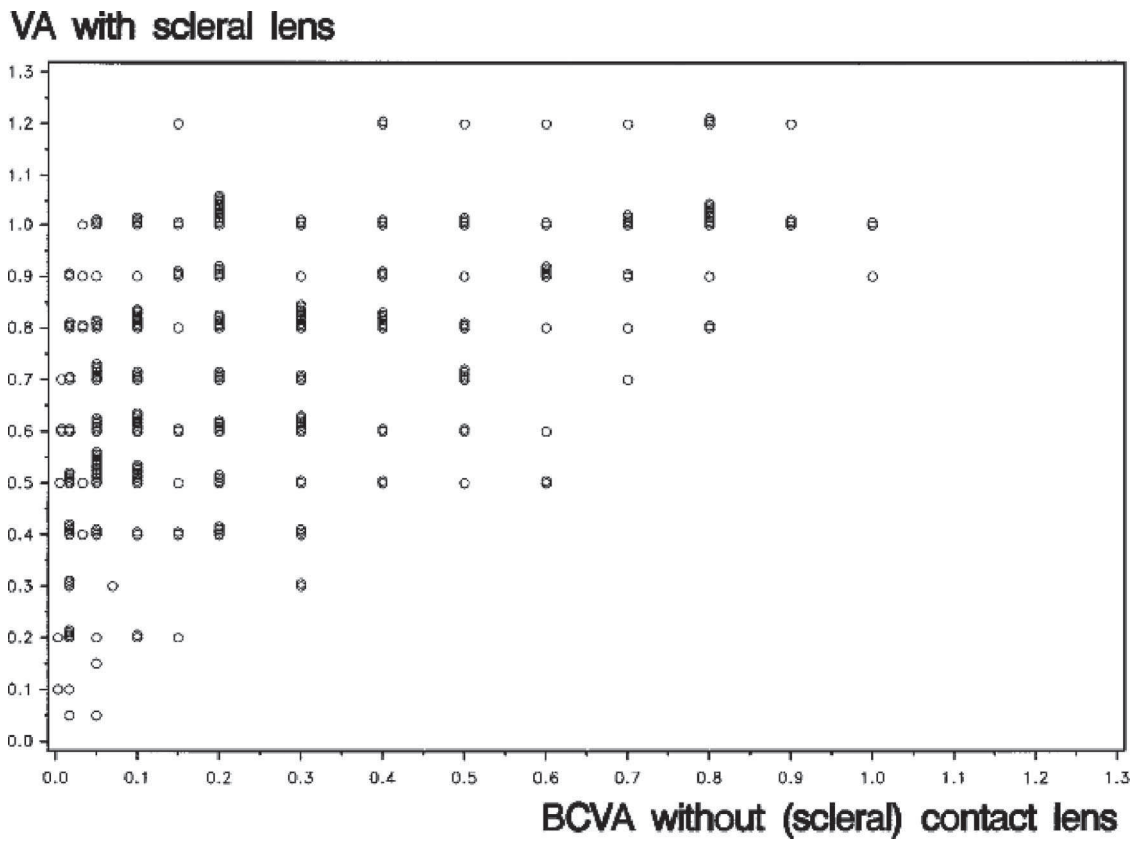

FIG. 3. Relation visual acuity (VA) with scleral lens and best-corrected visual acuity (BCVA) without a (scleral) contact lens.

TABLE 3. *Lens Fitting Features*

Fitting feature	No. of lenses with –2 value (%)	No. of lenses with –1 value (%)	No. of lenses with 0 value (%)	No. of lenses with 1 value (%)	No. of lenses with 2 value (%)	No. of lenses with 3 value (%)	No. of lenses with 4 value (%)
Corneal clearance	14 (4.9%)	58 (20.4%)	163 (57.4%)	48 (16.9%)	1 (0.4%)		
Limbal clearance	7 (2.4%)	67 (23.6%)	173 (60.9%)	37 (13.0%)			
Scleral fit	1 (0.4%)	38 (13.4%)	240 (84.5%)	5 (1.8%)			
Lens movement	6 (2.1%)	59 (20.8%)	206 (72.5%)	13 (4.5%)			
Trapped air bubbles			257 (90.5%)	23 (8.1%)	2 (0.7%)	2 (0.7%)	
Front surface wettability			126 (44.4%)	132 (46.5%)	26 (9.2%)		
Front surface deposits			117 (41.2%)	113 (39.8%)	42 (14.8%)	11 (3.9%)	1 (0.4%)
Back surface deposits			136 (47.9%)	108 (38.0%)	33 (11.6%)	6 (2.1%)	1 (0.4%)

correction applied to 19 (6.7%) eyes, and fitting scleral lenses for other reasons applied to 16 (5.6%) eyes.

Visual Acuity

Median VA with scleral lenses was 0.7 and ranged from 0.05 to 1.2. The median best-corrected VA without a (scleral) contact lens was 0.2 (range, 0.003–1). There was a significant increase in VA with a scleral lens compared to the best-corrected VA without a (scleral) lens ($P<0.001$, signed rank test) (Fig. 3). The median increase in VA with a scleral lens was 0.45 and ranged from a decrease of 0.1 to an increase of 1.05.

The highest median increases were seen in eyes with keratoconus (0.50), postpenetrating keratoplasty (0.48), and irregular astigmatism (0.45). Corneal dystrophies showed a median increase of 0.43, followed by multiple diagnoses (0.35) and keratitis sicca (0.20). The level of VA increase differed significantly among the diagnosis groups ($P=0.006$, Kruskal–Wallis test). Eyes with keratoconus and those that underwent penetrating keratoplasty showed greater increases in VA than expected, whereas eyes with irregular astigmatism showed approximately the expected level. In the three remaining diagnosis groups, the increases were lower than expected.

The front-surface toric lens type showed the highest median VA increase (0.60) followed by the bitoric design (0.47) and the back-surface toric type (0.45). The spherical scleral lenses showed a median increase of 0.40. However, these differences were not significant.

In the 106 patients who were wearing scleral lenses in both eyes, the median binocular VA was 0.9 (range, 0.2–1.2). The median best-corrected VA without a (scleral) contact lens was 0.4 (range, 0.017–1.0). The median increase in binocular VA with scleral lenses was 0.4 and varied from a decrease of 0.1 to an increase of 1.05. These differences were significant ($P<0.001$, signed rank test).

Scleral Lens Fitting Characteristics

Most lenses had the optimal value (0) for corneal clearance, limbal clearance, scleral fit, and lens movement. When these values deviated from 0, more of the features had negative values than positive values (Table 3). Almost all the lenses were free from trapped air bubbles. Front surface wettability, front surface deposits, and back surface deposits were optimal or nearly optimal (with slight deviations) in most eyes.

Side Effects

In 75 (26.4%) eyes, no positive slitlamp findings were identified. This was indicated as "all negative." In 209 (73.6%) eyes, there were one or more positive slitlamp findings during the examination (Table 4). The lowest percentage of positive findings applied to corneal infiltrates (detected in 2.1% of the eyes) and the highest applied to bulbar conjunctival hyperemia (detected in 48.2% of the eyes).

Table 4 also shows the percentages and frequencies of positive lens-related findings. Corneal infiltrates, anterior blepharitis, and posterior marginal blepharitis were never found to be lens-related. Bulbar conjunctival hyperemia was lens-related in 20.8% of the eyes.

Scleral Lens Specifications

A front-surface cylinder had been incorporated into 85 front-surface toric and bitoric scleral lenses. The median power of the cylinder was –1.00 and ranged from –0.50 to –2.50.

The median age of the scleral lenses evaluated in the study was 9.8 months (range, 3.1–53.2 months) (Table 5). The back-surface

TABLE 4. *Slitlamp Findings and Relation to the Scleral Lens*

Slitlamp finding	No. of eyes	No. with grade 0 findings (%)	No. with grade 1–4 findings, lens-related (%)	No. with grade 1–4 findings, non–lens-related (%)
Epithelial edema	284	243 (85.6%)	10 (3.5%)	31 (10.9%)
Stromal edema	284	248 (87.3%)	9 (3.2%)	27 (9.5%)
Corneal infiltrates	284	278 (97.9%)	0 (0.0%)	6 (2.1%)
Corneal vascularization	284	232 (81.7%)	3 (1.1%)	49 (17.2%)
Corneal staining	284	176 (62.0%)	19 (6.7%)	89 (31.3%)
Limbal hyperemia	284	243 (85.6%)	6 (2.1%)	35 (12.3%)
Bulbar conjunctival hyperemia	284	147 (51.8%)	59 (20.8%)	78 (27.5%)
Palpebral signs	284	217 (76.4%)	18 (6.3%)	49 (17.2%)
Anterior blepharitis	284	246 (86.6%)	0 (0.0%)	38 (13.4%)
Posterior marginal blepharitis	284	253 (89.1%)	0 (0.0%)	31 (10.9%)

TABLE 5. *Scleral Lens Age in Months*

Scleral lens type	No. of eyes	Minimum	q1	Median	q3	Maximum
Spherical	128	4.4	13.4	17.7	25.5	53.2
Front-surface toric	5	13.8	13.8	20.8	26.4	26.9
Back-surface toric	71	3.2	4.7	7.8	9.6	23.9
Bitoric	80	3.1	4.7	7.0	8.0	11.6
All types	284	3.1	6.6	9.8	17.6	53.2

q1, first quartile; q3, third quartile.

spherical designs were considerably older than the back-surface toric designs.

Significant differences in age were found among the scleral lenses ($P<0.001$, Kruskal–Wallis test). Spherical scleral lenses were significantly older than back-surface toric and bitoric scleral lenses (both $P<0.001$, Wilcoxon tests). There was a slight difference in age between the latter two groups ($P=0.049$) (Table 5).

Patient Follow-up

After the interview and examinations, the investigator assessed the performance of the scleral lens (i.e., the outcome of the visit) and made recommendations for the future. For 214 (75.4%) eyes, the plan was to continue to wear the same lens (continuation group). The plan for 11 (3.9%) eyes was to replace the existing lens with a lens with the same parameters (replacement group), and for 59 (20.8%) eyes, the plan was to fit a different scleral lens (i.e., to change the parameters [refit group]). No other options were recommended, such as discontinuing scleral lens wear.

The distribution of the outcomes was significantly different among the lens type groups ($P<0.001$, χ^2 test) (Table 6).

Nine of the replacements concerned spherical scleral lenses. In the patients with back-surface spherical designs, the age of the existing lens in the continuation group was significantly different from that in the replacement group ($P=0.002$, Wilcoxon test) (Table 7). This indicated that the scleral lenses that needed to be replaced were older than those in the patients who had been advised to continue wearing their lenses. No other differences could be shown.

There was no difference in the age of the existing lens or the increase in VA between the continuation group and the refit group. With the back-surface spherical designs, VA with the continuation lenses was significantly higher than that with the refit lenses ($P=0.004$, Wilcoxon test) (Table 8).

Separate comparisons of lens fitting features were also made on the spherical and toric designs between the continuation and refit groups. With the back-surface spherical designs, significant differences were found in corneal clearance, limbal clearance, lens movement, and front surface deposits. With the back-surface toric designs, significant differences were found in corneal clearance and back surface deposits. Nonoptimal values of the fitting features resulted more frequently to the recommendation to refit the lens.

TABLE 6. *Outcome for Each Scleral Lens Type*

Scleral lens type	No. of eyes	No. of plans for continuation (%)	No. of plans for replacement (%)	No. of plans for refit (%)
Spherical	128	80 (62.5%)	9 (7.0%)	39 (30.5%)
Front-surface toric	5	3 (60.0%)	0 (0.0%)	2 (40.0%)
Back-surface toric	71	62 (87.3%)	2 (2.8%)	7 (9.9%)
Bitoric	80	69 (86.3%)	0 (0.0%)	11 (13.8%)

TABLE 7. *Lens Age of Back-Surface Spherical Designs*

Outcome	No. of eyes	Minimum	q1	Median	q3	Maximum	*P* value
Continuation	83	4.4	12.1	16.8	23.5	53.2	0.002
Replacement	9	19.4	21.8	27.9	36.4	48.0	

q1, first quartile; q3, third quartile.

DISCUSSION

Outcome

Diagnoses were categorized into six main groups: keratoconus, postpenetrating keratoplasty, primary or secondary irregular astigmatism, keratitis sicca, corneal dystrophy, and multiple diagnoses. Patients with keratoconus formed the largest group (50.4%), followed by penetrating keratoplasty (19.7%), and other forms of irregular astigmatism (12.7%).

A shift from the application of back-surface spherical designs to back-surface toric designs was expressed in the distribution of these designs 1:1.1. This was not surprising because the experience of the authors is that most bulbi are toric. Unfortunately, no topographic measurements of the bulbus were available to investigate this statement.

Significant increases in monocular and binocular VA were found with a scleral lens compared to the best-corrected VA without a (scleral) lens.

The degree of increase in monocular VA was most marked in the eyes with keratoconus (median increase, 0.50) and those that underwent penetrating keratoplasty (median increase, 0.48).

Most scleral lenses showed optimal lens fitting characteristics, whereas the lens surface characteristics were optimal or nearly optimal in most lenses.

To show any side effects of wearing a scleral lens systematically, the slitlamp grading system was used. In 7 of the 10 assessed topics, the frequency of slitlamp signs was less than 20%, and positive findings were nearly always not lens-related. Bulbar conjunctival hyperemia formed an exception, because it was seen more frequently and considered to be lens-related in 20.8% of the eyes.

Nonoptimal values of the lens fitting characteristics and slitlamp grading formed a frequent reason for the recommendation to refit a lens. Refitting a scleral lens was advised in 59 (20.8%) eyes. The experience of the authors is that a proper lens fitting (e.g., a well-balanced haptic bearing, gentle movement of the lens with pushup testing, approximately 0.25 mm of corneal clearance, and 0.05 to 0.10 mm of limbal clearance) is essential to avoid complications.

All patients could continue wearing scleral lenses. Three quarters of the eyes continued to wear their existing scleral lenses. Replacement without any drastic changes in parameters occurred in 11 (3.9%) eyes. The back-surface spherical lenses that needed to be replaced were significantly older than those that could continue to be worn. This was not surprising, because in general, scleral lenses must be replaced after 2 or 3 years, depending on deposits

TABLE 8. *Visual Acuity With Back-Surface Spherical Designs*

Outcome	No. of eyes	Minimum	q1	Median	q3	Maximum	*P* value
Continuation	83	0.05	0.60	0.80	0.90	1.00	0.004
Refit	41	0.10	0.40	0.50	0.80	1.00	

q1, first quartile; q3, third quartile.

and scratches on the lens surface, to guarantee the quality and oxygen permeability of the material. Lens age was a median of 9.8 months and ranged from 3.1 to 53.2 months.

When the underlying corneal topography changed, refitting was usually advised. This was normally the case in progressive anterior eye disorders, such as keratoconus. Many of the back-surface toric and bitoric scleral lenses had been fitted in the past year, which led to relatively new lenses. This was confirmed by the results. Spherical scleral lenses were significantly older than back-surface toric or bitoric scleral lenses.

Comparison With Previous Studies

In the literature, various evaluation methods have led to different results on the performance of scleral lenses. Therefore, it is difficult to make direct comparisons between studies. Since the first successful application of gas-permeable scleral lenses by Ezekiel in 1983, several studies have been published.[17] The current results are compared to the nine most noteworthy and complete studies, when available and applicable. The study designs varied in size, diagnoses, definition of diagnoses, fitting methods, scleral lens types, materials, and so forth. The four largest studies on various diagnosis groups by Tan et al.,[6] Tan et al.,[21] Pullum and Buckley,[7] and Pullum et al.[4] were performed at the Moorfields Eye Hospital, United Kingdom, as was the smaller study by Foss et al.[2] The prospective Dutch study by Kok and Visser,[10] the retrospective Israeli study conducted by Segal et al.,[23] and the retrospective American study by Rosenthal and Croteau[3] also included various diagnosis groups. The study by Romero-Rangel et al.[11] was performed in the United States on one diagnosis group, namely ocular surface disease.

Compared to the other studies, the 178 patients in the current evaluation showed differences in age and sex distributions. There were relatively more women, with a male to female ratio of 1.2:1. Foss et al.[2] reported a ratio of 1.8:1. In the first and second parts of the study by Tan et al.,[6,21] the ratios were 1.6:1 and 1.7:1, respectively. In the two studies by Pullum et al.,[4,7] the ratios were 1.7:1 in both cases. In contrast, Kok and Visser,[10] Romero-Rangel et al.,[11] and Segal et al.[23] reported more female patients, with ratios of 1:1.3, 1:1.7, and 1:1.1, respectively.

The diagnoses included in the aforementioned studies were reflected in the ratios. There were more female patients when a large proportion of the eyes were diagnosed with a form of ocular surface disease, whereas there were more male patients with keratoconus or other forms of primary corneal ectasia and penetrating keratoplasty. Furthermore, Tan et al.[6,21] and Pullum et al.[4,7] reported the highest male-to-female ratios in patients with irregular astigmatism, keratoconus and penetrating keratoplasty; the ratio was lower in their ocular surface disease group. Table 2 shows the sex distribution per diagnosis group in the current study. The results were similar to those described in the earlier studies. Male predominance was seen in keratoconus, penetrating keratoplasty, and irregular astigmatism; female predominance was seen in keratitis sicca and corneal dystrophy.

The median age in this study was 41.7 years (mean, 45.0 years). The inclusion criteria admitted only patients between 18 and 80 years of age. In the previous studies, all ages were included. The mean age was used for comparison purposes, as most of the papers only mentioned this measure of central location. The mean age of 45 years in the current study was slightly higher than that in four other studies with various diagnosis groups: 42.9 years in Kok and Visser,[10] 40.8 and 37.7 years in Tan et al.,[6,21] and 39.6 years in Segal et al.,[23] Pullum et al.[4] showed a peak at approximately 35 years. Romero-Rangel et al.[11] found a mean age of 44.6 in their patients with ocular surface disease. This was expressed in the current series by the significant variation in age between the diagnosis groups; patients with keratoconus were younger, whereas patients with penetrating keratoplasty, keratitis sicca, or corneal dystrophy were older than the other patients. An explanation for these results is that keratoconus occurs at an earlier age than the several forms of keratitis sicca and corneal dystrophy. Moreover, penetrating keratoplasty can be expected in older patients, because in many cases, the surgery was performed on patients with severe progression of keratoconus. This occurs during the course of the disease and thus at an older age.

Except for Foss et al.,[2] all the studies that included various diagnoses showed, in accordance to the current study, a predominance of deviant corneal topography.[3,4,6,7,10,21,23] Not surprisingly, the main indication for scleral lens fitting in these studies was to improve VA. Percentages reported by Tan et al.,[6] by Tan et al.,[21] and in the current study were 85.8%, 80.3%, and 87.7%, respectively. No details will be given on other subgroups, because they were too small.

Contrary to the current study, the British studies also contained aphakia and high myopia as diagnosis groups. The primary corneal ectasia percentage increased, whereas the percentage of aphakes and high myopes decreased over the years.[4,7] It was striking that in comparison with the results of the current study, there were relatively more eyes with ocular surface disease in the reports by Kok and Visser[10] (keratitis sicca 31.9%), Foss et al.[2] (ocular surface disorders 45.5%), and Rosenthal and Croteau[3] (374 eyes with severe ocular surface disease of a total of 875 eyes).

The VA results of the current study were in line with those of other reports. Several studies showed sharp improvements in VA with scleral lenses. This study confirmed the best VA results in the group with deviant topography, in correspondence with other studies.[3,4,6,7,10,21,23] Studies that included indications other than visual correction showed less pronounced improvement in VA in these groups. This was not surprising because this group primarily had a therapeutic indication for scleral lens fitting, namely corneal protection, tear conservation, or pain relief.

The greatest increases in VA were seen in the front-surface toric (median, 0.60) lens designs. The median increase was 0.47 for bitoric, 0.45 for back-surface toric, and 0.40 for spherical scleral lenses.

Other investigators studied their patients for a longer period than the current study did. This enabled them to study failure rates during a longer period. In a retrospective study, Tan et al.[6] found that 71% of the eyes could continue to wear the scleral lens, but the remainder reverted to alternative lens types or progressed to surgery. In another study on oxygen-permeable scleral lenses,[21] the authors found that eventually scleral lenses were unsuccessful in 8.0% of the eyes. Pullum and Buckley[7] described that 22% of their cases failed a scleral trial or stopped wearing their scleral lenses completely. A failure rate of 10.4% was reported by Segal et al.[23] In the most recent report by Pullum et al.,[4] the outcome in a total cohort of 1,003 patients (1,560 eyes) was that 808 eyes could continue to wear the scleral lenses, 56 eyes failed a trial, 42 eyes suspended wearing the lenses temporarily, 145 eyes stopped wearing the lenses, and 508 eyes had lenses in progress or a pending first follow-up visit.

One of the selection criteria in the current study was a minimum scleral lens age of 3 months and patients who came for an emergency visit were excluded from the study. This might have affected the results, in comparison with the other studies that did not use an exclusion criterion of a minimum lens age.

CONCLUSIONS

In conclusion, modern scleral lenses can be used successfully for visual rehabilitation and management of a wide range of corneal disorders that have not responded adequately to other treatment modalities. The main indication was optical correction of an irregular corneal surface, especially those surfaces resulting from keratoconus and penetrating keratoplasty. Furthermore, the scleral lens was of benefit in several forms of ocular surface disease. Clinical examination showed sharp increases in VA and safe physiologic responses of the anterior eye. The satisfactory clinical performance of modern scleral lenses meant that their continued application can be recommended in all cases.

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