

ORIGINAL ARTICLE

Advantages of Toric Scleral Lenses

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ABSTRACT

Purpose. The purpose of this study was to investigate whether back surface toric scleral lenses stabilized (i.e., returned to their original position after rotation) and how long the return times were. Return time was studied in relation with actual wearing time and comfort; moreover, the performance of the spherical scleral lens was compared with the toric scleral lens design.

Methods. Toric scleral lenses were rotated clockwise and counterclockwise over 60°. Return times and the actual wearing time were recorded. Results were transformed into nasal and temporal return times for symmetry reasons. The present and former types of correction were compared for comfort (ranging from 0: very poor to 10: excellent) and regular wearing time. All the subjects attended regular follow-up visits.

Results. Forty-three subjects (43 lenses) entered the study. All the lenses returned to the original position within a median of 4 seconds after nasal rotation and 6 seconds after temporal rotation. A significant correlation was found between mean return times and actual wearing time ($r = 0.63$). Significant increases in median comfort (from 6–8) and median wearing time (from 15–16 hours) were demonstrated when the toric scleral lens designs were compared with the former type of correction (both $p < 0.001$). Median comfort and median wearing time also increased significantly after changing from spherical scleral lenses to the toric design (from 7–8 and from 14–16 hours, both $p < 0.001$, $n = 27$ eyes).

Conclusions. Toric scleral lenses returned rapidly to their original position after rotation. The flattest meridian of the toric scleral lenses stabilized symmetrically. Patient interviews demonstrated differences in comfort and wearing time in favor of the toric design.

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Key Words: scleral lenses, haptic lenses, toric scleral lenses, performance, stabilization

Scleral lenses are indicated for several ocular disorders and can often be fitted successfully when corneal and hydrogel contact lenses fail.^{1–5} They can be used when the cornea is distorted to provide mechanical protection, relief of symptoms, or facilitate healing. The main indication is optical correction of an irregular corneal surface.^{3,6–8} Keratoconus and penetrating keratoplasty are the major group indications, but other forms of irregular astigmatism are also encountered. Mechanical protection and improved function can be achieved in conditions such as entropion, scarred eyelids, and ptosis.⁹ Furthermore, the lenses can relieve symptoms, for example in dry eyes, corneal dystrophies, and facilitate healing of recurrent erosions.^{10–13} The potential value of wearing the lenses overnight has been described for recurrent corneal erosions, corneal exposure, and some ocular surface diseases, but the hypoxic effect can be a limiting factor.^{4,14–16}

The success of scleral lenses lies in the creation of a neutralizing tear lens, corneal clearance, and the retention of a precorneal reservoir, whereas the rigidity of the material affords mechanical protection and optical correction.

High oxygen-permeable materials and preformed fitting techniques have considerably extended the use of the scleral lens.^{7,9–11,17–19} Moreover, technologic innovations in the design and manufacturing of these lenses over the past decade have enabled more precise fitting techniques.⁹ There have also been two important developments in the precise submicron lathing fabrication of the scleral lens. First, a front surface cylinder can be lathed onto the scleral lens to correct any residual astigmatism. Second, a back surface toric scleral part can be lathed onto toric scleras to avoid air bubbles being trapped underneath the lens and to prevent local blanching of the conjunctival scleral vessels, which occur in toric or irregular anterior scleral surfaces, causing tissue changes and discomfort.^{3,13} These fitting problems were described by Bier and Lowther in 1977, who advised the use of spherical oval fitting or toroidal shells in cases with higher scleral toricity.²⁰ To resolve these problems, it is essential that toric scleral lenses (in which the haptic back surface is toric) maintain their position. Moreover, constant stabilization enables correction with a front surface cylinder and other optical corrections such as bifocal, prisms, and aber-

rations, if indicated. We investigated whether toric scleral lenses stabilized (i.e., returned to their original position after rotation) and how long it took. Return time was studied in relation with actual wearing time and comfort. Furthermore, the performance of the spherical scleral lens was compared with the toric designs.

MATERIALS AND METHODS

All the subjects were wearing one or two well-fitted nonfenestrated toric scleral lenses. After receiving informed consent from the subjects (or their legal representatives in the case of minors), data were collected at the first visit in the 2-month study period. Subjects who made an emergency visit or came for (re-)fitting were not admitted to the study. Lenses were being worn on a daily basis.

The study group had been referred to our contact lens clinic by their ophthalmologist, because they had not responded adequately to other contact lens or therapeutic management.

A previously described preformed fitting methodology was followed to fit the lenses.^{1,3,9,10,13} The design was developed in cooperation with Procornea, a rigid lens laboratory (Procornea, Eerbeek, The Netherlands).

The scleral lenses were manufactured at Procornea by precise submicron lathing from Boston Equalens II blanks of 27 mm in diameter and 13-mm thick. They were made of fluorosilicone acrylate copolymer (generic name: itaflufocon B) manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA. The Dk was listed as $85 \times 10^{-11} \text{ cm}^3 \text{ O}_2 \text{ (cm/[(sec) (cm}^2\text{)(mmHg)])}$ at 35° centigrade, ISO/Fatt method. The center thickness of a -3.00 D scleral lens was 0.50 mm.

During the fitting procedure, the first diagnostic lens was selected after on-eye assessment of the corneal and scleral shape. Several parameters needed to be empirically determined by evaluation of the diagnostic lens fitting, namely total diameter (range, 18.0–25.0 mm; 0.5-mm steps), scleral radius (range, 11.75–15.0 mm; 0.25-mm steps), central radius (range, 6.60–9.00 mm; 0.30-mm steps), and sagittal depth (range, 3.57–5.37 mm; 0.10-mm steps). An optional parameter was a blanching offset (range, 0.1–0.6 mm; 0.1-mm steps). In all the scleral lenses, the haptic back surface was toric (toricity of 0.8 mm). Fitting was based on resting the lens on the external sclera and vaulting of the cornea and limbus. 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 with pushup test, approximately 0.25 mm of corneal clearance, and 0.05- to 0.10-mm limbal clearance.

Data were recorded during patient interviews, observation, and examination. We recorded age, gender, former type of correction, comfort (ranging from 0: very poor to 10: very good) and wearing time (hours per day) of the former and current types of correction as well as the duration that the toric scleral lens had been *in situ* at the time of the investigation. Differences were computed between the new and former comfort values and the new and former wearing times. Age was classified in groups of 10 years.

The stabilization axis was established with a slit lamp; a narrow slit was projected parallel to the engravings on the lens (that indicate the flattest meridian) and the axis was read from the protractor. Next, the scleral lens was rotated clockwise over 60°, and the number of seconds it took for the lens to return to its original

position was timed with a stopwatch. Then the lens was rotated counterclockwise in the same manner. Subjects were sitting down during this procedure and they were allowed to blink freely. The results of the right and left lens tests were transformed into nasal and temporal return times for analysis.

Because the data did not show a normal distribution (Shapiro-Wilk test, all p values of < 0.05), the variables were characterized with nonparametric summary statistics: median, range, and quartiles. Spearman rank correlation coefficients were computed. Wilcoxon signed rank test was used to assess the differences in comfort and wearing times within subject and eye groups. Wilcoxon rank sum test was used to test differences between groups. Relative frequency of complete returns was computed with 95% confidence intervals. All the statistical tests were performed in a two-tailed manner and p values of 0.05 or less were considered to be significant. The statistical analysis was applied to one lens per subject. In subjects with two lenses, one lens was selected at random with the SAS procedure RANUNI. The other lens was excluded.

RESULTS

A total of 43 subjects (61 lenses) entered the study, 30 right eyes and 31 left eyes. Eighteen subjects were wearing toric scleral lenses in both eyes, 12 subjects were wearing a right lens only, and 13 subjects were wearing a left lens only. There were 32 males and 11 females; age ranged from 13 to 78 years, with a median of 39 years. The majority of subjects were between 20 and 50 years of age (34 subjects, 79%) (see Table 1). Forty-three lenses were studied after random selection of one lens per subject (23 right eyes and 20 left eyes).

The distribution of the former type of correction is presented in Table 2. Spherical scleral lenses accounted for the former type of correction in 27 eyes (63%), whereas other types of correction or no correction had been worn in 16 eyes (38%).

The median axis of stabilization of the flattest meridian of the lens was 137° (range, 30–180°) in the right eyes and 47° (range, 170–0°) in the left eyes. After correction for symmetry, no differences in stabilization axes could be found between the right and left eyes (p = 0.52). After rotation in both directions, all 43 lenses returned to their original position (95% confidence interval: 93–100%). Median return time was 4 seconds (range, 2–60 seconds) after nasal rotation; 50% of the return times (interquartile range) were between 3 and 9 seconds (total range, 2–60 seconds). After temporal rotation, median return time was 6 seconds (range, 1–17 seconds); 50% of the return times were between 4 and 8 seconds. No differences in clockwise, counterclockwise, nasal, temporal, or

TABLE 1.
Age distribution of the subjects (n = 43 subjects)

	Subjects (n)	Percentage
13–19 yrs	1	2
20–29 yrs	9	21
30–39 yrs	13	30
40–49 yrs	12	28
50–59 yrs	3	7
60–69 yrs	4	9
70–79 yrs	1	2

TABLE 2.

Type of correction before scleral lens fitting (n = 43 subjects)

	Subjects (n)	Percentage
No correction	2	5
Glasses	2	5
Rigid gas-permeable corneal contact lens	7	16
Soft contact lens	2	5
Piggyback	3	7
Spherical scleral lens	27	63

mean return times could be demonstrated between the right and left eyes (all $p > 0.82$).

A moderate and significant correlation was found between the mean return times and the actual wearing time ($r = 0.63$). Longer wearing durations at the time of investigation showed longer mean return times. No significant correlation could be demonstrated between age and mean return time ($r = 0.11$).

Median rating for comfort with the former type of correction was 6 (n = 41; range, 1–9); with the present toric scleral lens, this increased to 8 (n = 43; range, 6–10), which was significant ($p < 0.001$). Median wearing time of the former type of correction was 14 hours a day (n = 41; range, 2–16 hours), whereas median wearing time of the present lens was 16 hours a day (n = 43; range, 8–16 hours). This increase was also significant ($p < 0.001$). The two eyes without former correction were excluded from these comparisons.

No correlation could be demonstrated between the present comfort value or present wearing time per day and the return times.

In 27 eyes whose former correction type had been spherical scleral lenses, median comfort increased significantly by one point after changing to the toric design ($p < 0.001$). Median wearing time showed a significant increase of 2 hours in this group of subjects ($p < 0.001$) (see Table 3).

DISCUSSION

Back surface toric scleral lenses are designed for rotational stabilization. At dispensing and follow-up visits, it is common practice to verify that the lens orientates correctly. One very useful test is to rotate the lens and determine whether it returns to the original orientation. We standardized this test procedure by rotating the lens over 60° and recording the return time in seconds. The 95%

TABLE 3.

Median results of former (spherical) scleral lenses and present (toric) scleral lenses (n = 27 subjects)

	Former: Median (range)	Present: Median (range)
Comfort (scale 1–10)	7 (4–9)	8 (6–10)
Wearing time (hours)	14 (2–16)	16 (8–16)

confidence interval (93–100%) of this intervention indicated that nearly all the lenses will return to the baseline position.

In this study, all the lenses returned relatively rapidly in the nasal or temporal direction after they had been rotated. Moreover, all 18 of the nonselected lenses also returned to their original position. This apparently reliable stabilization of the toric scleral lens therefore makes it possible to apply a front surface cylinder or other types of optical correction to this lens such as bifocal, prism, and aberration.

The moderate correlation of 0.69 between longer return times and longer actual wearing time could be explained by the fit of the scleral lens becoming tighter during the course of the day. As a result of gradual (mucus) deposits and a decrease in the wettability of the lens surface during the day, the lens may settle more closely to the eye. Moreover, the bulbar conjunctiva may swell slightly. To confirm this suggestion of tighter scleral fitting, other investigations will have to be performed such as removing each lens and replacing it before every rotation or measuring the return times in the morning and afternoon.

The flattest meridian of the toric scleral lens stabilized symmetrically. A median axis of 137° in the right eye was almost a mirror image of the median axis of 47° in the left eye. Thus, no difference could be demonstrated between the right and left eyes. Anatomic structure of the eyeball, eye muscles, or eyelid tension was probably responsible for this symmetry.

The interview revealed that the subjects were very satisfied with the toric scleral lenses. Median comfort was 8 (scale 1–10) and median wearing time was 16 hours per day. Various studies on gas-permeable scleral lenses used different methods to assess the wearing time, which makes it difficult to compare the results directly. In the study by Kok and Visser, 83% of the 50 eyes were wearing the lenses for more than 8 hours, which was the longest wearing time that could be given in answer to the question.¹⁰ Tan et al. reported wearing times of between 8 to 11 hours in 15 of 66 eyes and more than 15 hours in 33 eyes.¹⁸ In an ocular surface study, Romero-Rangel et al. observed a mean wearing time of 13.7 hours per day (range, 4–18 hours; n = 75 eyes).¹¹ Segal et al. mentioned a mean wearing time of 16.2 hours (range, 3–18 hours; n = 66 eyes).²¹ In the latest report by Pullum et al., 59% (n = 538 patients) of the patients were wearing their lenses for an average of 10 hours or more per day.⁵ Results can be affected by the diagnoses included in the study groups and may also depend on the definition of wearing time in subjects who wear their lenses all day long.

Several investigators reported prolongation of scleral lens wearing time and improvement in comfort with gas-permeable materials.^{1,7,10,11,17,18,22–24}

In the present study, the advantages of the toric scleral lens design were reflected by the increases in wearing time and comfort. In 27 eyes that had been wearing a spherical scleral lens before the toric scleral lens, comparisons could be made between the two scleral lens designs. The results showed an increase in median comfort by one point and an increase in median wearing time of 2 hours in favor of the toric scleral lenses. Owing to the more balanced distribution of pressure on the sclera, this lens may be less stressful to the eye and more easily tolerated than the spherical designs. In our study, it was not possible to investigate differences between the two designs at the same lens age in the same patient. Further studies on homogenous groups are necessary to reveal dif-

ferences between the lens designs, and it would be worthwhile to collect data after longer wearing durations of the toric scleral lenses.

CONCLUSION

Scleral lenses could be used successfully in the visual rehabilitation and management of subjects with various forms of ocular pathology. The main indication was optical correction of an irregular corneal surface. After rotation, the back surface toric scleral lens returned to its original position. This reliable stabilization means that front surface cylinders can be used and other optical corrections such as bifocal, prism, and aberration correction. The flattest meridian of the toric scleral lenses stabilized symmetrically. Differences in the comfort and wearing times of the spherical and toric designs were demonstrated in patient interviews in favor of the toric scleral lenses. These results should be considered as indicative.

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