# **ORIGINAL ARTICLE**

# Scleral Lens Tolerance after Corneal Cross-linking for Keratoconus

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#### ABSTRACT

**Purpose.** Subjective and objective evaluation of scleral lens tolerance and fitting before and after corneal cross-linking (CXL) for progressive keratoconus.

*Methods.* In this prospective cohort, evaluations were made of 18 unilateral eyes in patients who underwent CXL and had been wearing scleral lenses before the procedure. All the patients gave informed consent; they were able to cooperate with the study, were eligible for CXL, had been wearing well-fitting scleral lenses for at least 3 months, and had no other active ocular disease. Data were collected before and 1 year after CXL. Outcome measures were changes in clinical and subjective scleral lens performance. The following components were studied: scleral lens corrected distance visual acuity, scleral lens specifications, scleral lens fit, wearing time, and subjective measures on visual analogue scale questionnaires (1 to 100 mm). *Results.* There was no significant change in scleral lens corrected distance visual acuity (p = 0.632). Sixty-one percent of eyes needed a scleral lens fit and/or power change. Wearing time (median, 16 hours per day) and subjective tolerance were found to be stable.

*Conclusions.* Scleral lens tolerance after CXL appeared to be stable. (Optom Vis Sci 2015;92:318–323)

Key Words: keratoconus, progressive, corneal cross-linking, scleral lens, tolerance

eratoconus is a noninflammatory corneal disease, characterized by cone-shaped changes in the corneal curvature, which usually results in visual loss.<sup>1</sup> Depending on the severity, a spectrum of correction options are available. In the early stages, spectacles, soft lenses, or silicone hydrogel lenses can be prescribed. In more progressive cases, custom-designed soft, piggyback, hybrid, or rigid gas-permeable corneal contact lenses can be applied. Scleral lenses are usually indicated in cases of corneal contact lens intolerance, secondary clinical indications (such as dry eyes), and advanced disease, or to prevent corneal scarring.

Scleral lenses have the unique property of vaulting the cornea and can therefore be fitted to eyes with marked corneal irregularity. The constant precorneal fluid reservoir neutralizes the irregular astigmatism and simultaneously hydrates and protects the corneal surface from exposure and the friction of blinking. Keratoconus is one of the most common indications for scleral lens fitting.  $^{2-6}$ 

The first clinical application of scleral lenses was described by Fick and Muller in the 1880s.<sup>7,8</sup> Since then, scleral lens design and materials have undergone several milestone developments. The availability of trial fitting sets and gas-permeable materials and the development of toric scleral lens designs and, more recently, tangential scleral lenses have improved the fitting process and thus patient comfort and satisfaction.<sup>2,3,6,9–14</sup>

Other available treatment options for keratoconus are corneal ring segments (in cases with stable keratoconus and contact lens intolerance)<sup>15</sup> or corneal transplantation (in cases with severely advanced keratoconus with decreased vision and/or scarring).<sup>16</sup>

In progressive keratoconus, corneal cross-linking (CXL) with epithelial removal can be applied to stabilize the cornea. Corneal cross-linking is a noninvasive medical treatment that uses a combination of ultraviolet A (UV-A) light and riboflavin (vitamin B<sub>2</sub>) eye drops. After CXL, corneal biomechanical stability increases by 70%.<sup>17–19</sup> Corneal flattening and visual improvement have been described after CXL. Furthermore, it is known that after CXL with epithelial removal, corneal sensitivity can be reduced, owing to not only the corneal abrasion but also the use of riboflavin and UV-A.<sup>20</sup>

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Unfortunately, the various CXL studies do not appear to apply a consistent approach in relation to contact lens or scleral lens wear. This makes it difficult to accurately compare lens fitting results after CXL, because refraction and corneal curvature are often influenced by lenses, especially corneal contact lenses.<sup>21</sup> In contrast, scleral lenses vault the cornea and have no mechanical contact with it. Therefore, hypothetically, scleral lens wear should not be affected by corneal curvature changes caused by CXL. To our knowledge, no research has been performed on scleral lens wear after CXL.

This study aims to compare scleral lens tolerance and fitting before and after CXL using clinical and subjective measures. This article forms a backing to provide advice and information for keratoconic patients with scleral lenses who are considering CXL. It is important to guide their future expectations and indicate the potential need to refit the lens post-CXL.

# **METHODS**

In this prospective cohort, a total of 18 eyes of 18 patients with progressive keratoconus who were scheduled for CXL and wore scleral lenses were evaluated.

Prospective data were collected on consecutively planned CXL treatments after approval by the Medical Ethics Committee of the University Medical Center Utrecht (UMCU). Written informed consent was obtained in accordance with the UMCU guidelines, and the study was conducted in compliance with the Declaration of Helsinki.

Data were collected at the baseline visit (meaning  $\leq 6$  weeks before CXL) and at 1 year post-CXL. Inclusion criteria for this study were eligibility for CXL and scleral lens wear for at least 3 months before CXL. We excluded any subjects who were wearing poorly fitted lenses (in case of one or more grade 2 findings, Table 1), or were unable to cooperate, or had other ocular diseases.

Inclusion criteria for CXL were a clear central cornea, documented keratometric progression over 6 to 12 months, a minimum

#### TABLE 1.

Scleral lens fitting characteristics

corneal thickness of 400  $\mu m$  before UV-A irradiation, and no pregnancy or breastfeeding.

All the CXL procedures were performed by the same team at the Department of Ophthalmology of the UMCU using the UV-X system (Peschke Meditrade GmbH) (370 nm and 3 mW/cm<sup>2</sup>) as described previously.<sup>22</sup> Both epithelium-off (n = 15 eyes) and epithelium-on (n = 3 eyes) techniques were applied.

#### **Epithelium-off CXL**

The epithelium was removed using a blunt knife, and isotonic riboflavin 0.1% solution (Medio Cross) was instilled every 3 minutes for 30 minutes. When corneal thickness was less than 400  $\mu$ m after riboflavin instillation, hypo-osmolar riboflavin 0.1% drops were instilled every 20 seconds for 5 minutes. When the required corneal thickness was reached, UV-A irradiation (UV-X 1000, Peschke Meditrade) was performed for 30 minutes, whereas isotonic riboflavin solution was reinstilled every 5 minutes. After the procedure, a balafilcon A bandage lens (Pure Vision, Bausch & Lomb) was placed.

#### **Epithelium-on CXL**

Ricrolin TE eye drops (SOOFT Italia) were instilled every 2 minutes for 15 minutes. Next, an eyelid speculum was placed and a silicone ring was positioned between the eyelids, which was filled with ricrolin TE and refilled when necessary to remain a ricrolin "pool" on the cornea. After 15 minutes, the silicone ring was removed, the cornea was rinsed with balanced salt solution, and pachymetry was measured. With an eyelid speculum in place, UV-A irradiation was performed for 30 minutes, whereas ricrolin TE solution was reapplied to the cornea every 5 minutes.

Patients with epithelium-off CXL received oral analgesics and all patients received antibiotic eye drops. Post-CXL, patients were requested to refrain from wearing their scleral lenses for 1 month. The keratoconus progression was halted at the 1-year follow-up in all our patients, regardless of treatment type.

	Grade -2 unacceptable	Grade -1 acceptable	Grade 0 optimal	Grade +1 acceptable	Grade +2 unacceptable
Central corneal clearance	Corneal contact	≤0.1 mm	0.1 to 0.3 mm	>0.3 to ≤0.5 mm	>0.5 mm
Limbal corneal clearance	Circumcorneal limbal contact	Circumcorneal <0.05 mm	0.05 to 0.2 mm	Circumcorneal >0.2 to ≤0.3 mm	Circumcorneal >0.3 mm
Scleral (haptic) fit	Circumcorneal blanching	Segmented/slight blanching	Scleral alignment	Slightly increased edge clearance	Increased edge clearance, with possible trapped air bubbles
Lens movement (push-up test)	Lens suction	Reduced	Gentle	Increased	Excessive
General lens fit			Optimal	Acceptable	Unacceptable
Front surface lipid deposits			Absent	Slight	Severe
Front surface protein deposits			Absent	Slight	Severe
Scratches			Absent	Slight	Severe

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Fifteen scleral lenses were fitted at the Contact Lens Service and three scleral lenses were fitted at external lens institutions. All the lenses were manufactured from high oxygen-permeable materials at three different laboratories: Procornea (12 bitoric [curveddesigned] scleral lenses) (Eerbeek, the Netherlands), NKL Contactlenzen (3 bitangential designed scleral lenses) (Emmen, the Netherlands), and Microlens (3 bitoric [curved-designed] scleral lenses) (Arnhem, the Netherlands). The materials used in this study were Boston Equalens II (Oprifocon A, Dk 85 [Polarographic ISO/Fatt method]), Boston XO2 (Hexafocon B, Dk 161 [non-edge corrected ISO/Fatt method]) (both manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA), and Tyro-97 (Hofocon A, Dk 97 [ISO/ANSI method]) (manufactured by the Lagado Corporation, Englewood, CO). All scleral lenses evaluated in this study had been fitted diagnostically with trial lenses and were being worn daily.

Our analysis was performed on the first eye of each patient who underwent CXL. Baseline visits took place between July 2010 and October 2012 and the 1-year follow-up took place between August 2011 and November 2013. Sex, date of birth, and lens history were noted. At these two visits, details of the origin of the scleral lens, scleral lens parameters (spherical power, cylindrical power, scleral zone, scleral toricity, sagittal depth, central radius [base curve radius, BCR], total lens diameter), average wearing time, and frequency of breaks from wearing the lens during the day were recorded. The scleral zone was described in either millimeters (radius) or degrees (tangent angle), depending on the type of scleral lens design (curved or tangential). To evaluate and compare these two different parameters, each was assigned a code that varied from -1 (12.25 mm or 47 degrees) to +8 (14.50 mm or 38 degrees), where an increment of 1 was either 0.25 mm or 1 degree. The spherical equivalent (SE) and the required power adjustment in the case of a change in BCR were computed for all the eyes; this is further referred to as the "SE with BCR adjustment." A change in BCR of +0.05 mm resulted in a change in spherical power of +0.25 diopters. In addition, all the patients underwent decimal scleral lens corrected distance visual acuity (CDVA) assessment and slit-lamp biomicroscopy assessment (to grade the lens fitting).

The scleral lens parameters of lenses fitted by external contact lens institutions were obtained from the scleral lens fitter. A previously described classification method was used and adjusted to the present standard to grade the various scleral lens fitting characteristics (Table 1).<sup>2</sup> Grade 0 was considered "optimal"; grade 1, "acceptable"; and grade 2, "unacceptable."

At the end of the baseline visit and follow-up visit, patients were asked to complete a questionnaire on six specific topics: lens comfort, lens dryness, scleral lens visual quality, lens cleanliness, lens handling, and overall satisfaction with the scleral lens. Scores were obtained on a visual analogue scale (VAS) with an axis from 0 mm (unacceptable performance) to 100 mm (excellent performance).

Spectacle CDVA (meaning without the scleral lenses) was evaluated retrospectively by chart review.

#### **Statistics**

After checking all the data, the data file was transferred to SPSS (IBM SPSS Statistics version 20.0 for Windows) for statistical

analysis. The data were tested for normal distribution using the Shapiro-Wilk test for normality. The reported differences were normally distributed and were analyzed with the paired samples t test. A p value of less than 0.05 was considered statistically significant. Variables and series with a normal distribution were characterized by mean and range. If one or more of the variables in a series did not show a normal distribution, they were characterized by nonparametric summary statistics: median and range. Decimal acuity was converted into logMAR (logarithm of the minimum angle of resolution) units with the formula  $-\log$  (decimal acuity). A *post hoc* power analysis for the logMAR scleral lens CDVA was performed for a paired samples t test (sample size of 18 eyes, with  $\alpha = 0.05$  and an effect size of 0.6) and was estimated to be 0.79.

#### RESULTS

All 18 patients (100%) returned for follow-up within the study period. Median follow-up was 12 months (range, 11 to 13 months), which was in accordance with the study protocol.

# Demography

A total of 12 right eyes (67%) and 6 left eyes (33%) were evaluated. Our study group comprised 14 female subjects (78%) and 4 male subjects (22%); mean age was  $28 \pm 10$  years (range, 15 to 48 years). Median total duration of contact lens use and/or scleral lens use was  $66 \pm 105$  months (range, 5 months to 30 years). Median duration with the current scleral lens design was  $9 \pm 24$  months (range, 3 to 88 months).

#### Visual Outcome and Scleral Lens Prescription

Visual acuity at baseline and the outcome at 1-year follow-up are listed in Table 2. No significant change was observed in logMAR scleral lens CDVA (p = 0.632). There was a wide range in outcomes of the scleral lens power units (Table 3). Spherical scleral lens power changed in 11 of the 18 eyes (61%): 8 eyes showed a hyperopic shift and 3 eyes showed a myopic shift. In 5 of the 10 eyes with a cylindrical prescription before CXL, the cylinder changed (50%): an increase occurred in 3 eyes and a decrease occurred in 2 eyes. The SE with BCR adjustment changed in 10 of the 18 eyes (56%).

At 1-year follow-up, spectacle CDVA (i.e., without scleral lenses) had improved by 0.17 logMAR (p = 0.011). Mean duration between the measurements at baseline and at 1-year post-CXL was 13 months (range, 11 to 17 months).

# **Scleral Lens Specifications**

In 12 of the 18 eyes (67%), the scleral lens needed to be replaced during follow-up and the same type of design (same manufacturer) was used. Reasons included routinely scheduled lens replacements with unchanged lens parameters. No replacements were necessary in the remaining six eyes (33%). Outcomes of scleral lens parameters at both visits are listed in Table 4. One year post-CXL, individual lens evaluation showed a change in scleral radius, scleral toricity, sagittal depth, BCR, and total lens diameter

	Baseline visit	1-y follow-up	Difference	р
LogMAR CDVA	0.22 (-0.18 to 0.69)*	0.03 (0.00 to 0.92)*	-0.26 (-0.64 to 0.69)*	0.632†
			-0.03‡	
Decimal CDVA (Snellen CDVA)	0.8 (0.5 to 1.2)* (20/25 (20/40 to 20/16))	1.0 (0.4 to 1.0)* (20/20.5 (20/50 to 20/20))		
	(20/23 (20/40 to 20/16))	(20/20.3 (20/30 to 20/20))		

# **TABLE 2.** Visual outcome with scleral lenses, 1 year after CXL (n = 18 eyes)

\*Median (range).

†Paired samples *t* test. †Mean.

↓iviean.

CDVA, corrected distance visual acuity with scleral lenses.

in 9 (50%), 6 (33%), 7 (39%), 3 (17%), and 3 (17%) eyes, respectively.

#### **Scleral Lens Fitting Results**

All scleral lens fitting components were graded as optimal or acceptable (grade 0 or 1) at the two visits. Most scleral lenses showed grade 0 both times (Table 5). Scleral lens deposits and scratches were also optimal or acceptable. At baseline and at the 1-year follow-up, protein deposits were absent in 11 (61%) lenses and 8 (44%) lenses, respectively. Lipid deposits were absent in 11 (61%) lenses and 15 (83%) lenses, respectively. The remaining lenses had slight (grade 1) protein or lipid deposits. At both visits, 8 (44%) lenses did not show any scratches, whereas 10 (56%) lenses were slightly scratched.

# Wearing Time

Scleral lenses were worn for a median of 16 hours per day at both visits (range, 10 to 17 hours at the baseline visit; range, 10 to 18 hours at 1-year follow-up). The number of patients who needed a break from their scleral lens wear during the day remained approximately identical; the number was 5 (28%) patients at baseline and 4 (22%) patients at 1-year follow-up.

# **Subjective Performance**

The outcomes of the patient questionnaire (VAS 0 to 100 mm) are shown in Table 6. Small decreases were seen in comfort, lens dryness, lens cleanliness, lens handling, and overall satisfaction. Subjective scleral lens visual quality showed a slight increase.

# TABLE 3.

Scleral lens prescription

DISCUSSION
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This study evaluated scleral lens tolerance and fitting before and 1 year after CXL in patients with progressive keratoconus. Our main finding was that CXL did not affect scleral lens tolerance.

To our knowledge, this is the first study on scleral lens wear after CXL. In theory, scleral lens wear should not be affected by corneal curvature changes attributed to CXL, because scleral lenses vault the cornea and therefore do not make any mechanical contact with the cornea (in contrast with corneal contact lenses).

In our patient group, the objective and subjective performance outcomes of the scleral lenses were not affected by variations in scleral lens conditions. Fitting and surface quality (deposits and scratches) of all the scleral lenses were optimal or acceptable at baseline and follow-up. Furthermore, patients did not change to lenses of another type of design (and manufacturer) during the study.

Our study had limitations in terms of a small sample size and the lack of a control group. However, our findings can be considered valuable owing to the prospective study design, which included both analyses and observed results of subjective and objective data before and after CXL. Further research with a larger sample size and a control group is recommended. Although both epithelium-on and epithelium-off CXL procedures were applied, data were analyzed in this case series, because the keratoconus progression was halted at the 1-year follow-up in all our patients, regardless of treatment type.

Individual scleral lens fitting parameters (such as scleral radius, scleral toricity, sagittal depth, BCR, and total lens diameter) changed in 17 to 50% of the cases at 1-year follow-up. In addition, the cylindrical prescription changed in 50% of the eyes, whereas the spherical scleral lens power changed in 61% of the eyes. Variations in scleral lens parameters over time were expected and

	Baseline visit	1-y follow-up
Spherical power (n = 18 eyes)	+1.75 (-4.00 to +6.00)	+2.13 (-2.50 to +6.00)
Cylindrical power (n = 10 eyes)	-1.25 (-2.50 to -0.75)	-1.25 (-2.00 to -0.75)
SE corrected for central radius differences (n = 18 eyes)	+1.50 (-4.00 to +5.38)	1.56 (-3.75 to +5.38)

All values are median (range).

TABLE 4.

Scleral lens specifications (n = 18 eyes)

	Baseline visit	1-y follow-up
Scleral radius, code	2 (-1 to +8)*	2 (-1 to +8)*
Scleral toricity, code	2 (1 to 4)†	2 (0 to 4)†
Sagittal depth, mm	4.14 (3.67 to 4.67)*	4.17 (3.67 to 4.50)*
BCR, mm	8.10 (7.40 to 8.60)†	8.20 (7.40 to 8.60)†
Total lens diameter, mm	20.0 (19.0 to 21.0)†	20.0 (19.0 to 21.5)†
*Mean (range).		

†Median (range).

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TABLE 5.		
Scleral lens	fitting (n =	18 eyes)

		Bas	eline visit, n	(%)			1-у	follow-up, n (	%)	
Grade	-2	-1	0	+1	+2	-2	-1	0	+1	+2
Central corneal clearance	0	2 (11)	14 (78)	2 (11)	0	0	0	16 (89)	2 (11)	0
Limbal corneal clearance	0	2 (11)	16 (89)	0	0	0	2 (11)	15 (83)	1 (6)	0
Scleral (haptic) fit	0	4 (22)	12 (67)	2 (11)	0	0	0	16 (89)	2 (11)	0
Movement	0	4 (22)	13 (72)	1 (6)	0	0	3 (17)	15 (83)	0	0
General lens fit	0	0	14 (78)	4 (22)	0	0	0	18 (100)	0	0

could form a part of these numbers. It is common practice to regularly replace and/or refit scleral lenses in view of potential changes in lens power, corneal or scleral lens fitting, or a decline in scleral lens conditions. Visser et al. found that scleral lens refitting was recommended in 21% of patients who returned for scheduled follow-up. They suggested replacing the lens at intervals of 2 to 3 years.<sup>2</sup> This replacement interval seems to have been reduced over the past few years to 1.5 to 2 years, to guarantee the quality and oxygen permeability of lens materials. Replacement intervals of scleral lenses vary widely from 1 year to several years.<sup>23</sup>

After CXL, patients should be advised to have their scleral lenses checked (and, if necessary, refitted), because some of the lens fitting parameters might have changed. Omitting the application of a necessary increase in the sagittal depth and/or BCR will directly affect the corneal vaulting of the scleral lens and may result in corneal touch. Mechanical stress on the cornea should be avoided.

In the current study, high median visual outcomes were observed before and after CXL, which was consistent with other studies on scleral lens application in patients with keratoconus. Segal et al.<sup>5</sup> reported a scleral lens CDVA of greater than or equal to 20/40 in 91% of the cases in their keratoconus group. Pullum et al.<sup>4</sup> reported that scleral lens CDVA in their primary corneal ectasia group peaked at 20/30, whereas Visser et al.<sup>2</sup> showed that the highest median increase in scleral lens CDVA occurred in eyes with keratoconus, namely, 0.50 decimal acuity. Schornack and Patel<sup>24</sup> reported a median scleral lens CDVA of 20/20 in keratoconic eyes.

Consecutively, the 1-year post-CXL visual results were as follows: scleral lens CDVA remained stable, spectacle CDVA increased significantly, and subjective scleral lens visual quality showed an increasing trend. An explanation for the stable outcome of the scleral lens CDVA might be the small sample size, because the individual scleral lens CDVA outcomes varied widely. Moreover,

#### TABLE 6.

Subjective outcomes (VAS questionnaires 0 to 100 mm) (n = 18 eyes)

	Baseline	1-y follow-up
Comfort	84 (56–100)	79 (65–95)
Lens dryness	79 (45–98)	73 (25–95)
Visual quality	69 (25–96)	75 (24–95)
Lens cleanliness	76 (57–96)	68 (34–96)
Lens handling	85 (56–98)	83 (44–100)
Overall satisfaction	84 (65–98)	81 (57–100)

All values are mean (range).

as scleral lenses correct the total corneal irregularity, CXL effects (such as corneal stabilization and spectacle CDVA improvement) will not necessarily affect scleral lens CDVA. The significant spectacle CDVA improvement in this study is in line with other studies on CXL.<sup>19,25</sup>

Daily wearing time and the need for breaks to clean the lens(es) are indicators of scleral lens performance. In our series, the median wearing time of 16 hours per day was comparable with earlier studies that used a similar method to assess wearing time: Segal et al.<sup>5</sup> reported a mean wearing time of 16.2 hours per day and Visser et al.<sup>12,13</sup> showed a median daily wearing time of 16 hours. The continued good subjective tolerance of scleral lenses after CXL was demonstrated by comparable daily wearing times and the number of breaks during the day, as well as very small differences in comfort, lens dryness, lens handling, and overall satisfaction after 1 year.

In our study, we advised patients to discontinue their scleral lens wear for 1 month after the CXL procedure and to reevaluate the fitting before restarting scleral lens wear. There does not seem to be any consensus in the literature on the (temporary) discontinuation of contact lens wear after CXL.<sup>21</sup> Furthermore, to our knowledge, specific advice on scleral lens wear has not been reported at all. Discontinuation of scleral lens wear during the first month post-CXL did not seem to have any undesirable side effects in our series of patients. Future research into the minimally required discontinuation time would be of value to keratoconic patients who depend on their lenses for adequate daily functioning. Additionally, prospective research into the tolerance and stability of other types of contact lenses is recommended, especially in the case of corneal contact lenses, because of the potential role of decreased corneal sensitivity and corneal flattening after CXL.

In conclusion, objective and subjective scleral lens tolerance remained stable after CXL in this study. However, to maintain optimal and safe lens performance and avoid mechanical stress on the cornea, scleral lens fitting should be reevaluated after CXL, because scleral lens fitting parameters may have changed.

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