Vision-Related Quality of Life in Keratoconus Patients Rehabilitated with Scleral Lenses

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ABSTRACT

Purpose: To evaluate changes in visual acuity (VA) and vision-related quality of life following fitting with customized scleral lenses in patients with keratoconus.

Materials and Methods: This retrospective study included 59 eyes from 39 patients with keratoconus who were fitted with customized Misa® scleral lenses. Uncorrected VA before fitting and VA with the final scleral lens were recorded in logarithm of the minimum angle of resolution (logMAR) units, and keratometric measurements were expressed in diopters. Complete paired 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) data, collected during routine clinical care before fitting and 6–38 months thereafter, were available for 38 of 39 patients. Per-eye changes in logMAR VA were analyzed using an intercept-only linear model with robust standard errors clustered at the patient level, whereas patient-level NEI VFQ-25 total scores were compared using a paired-samples t test.

Results: The mean age was 27.69 ± 7.73 years, and 72.5% of patients were male. Mean uncorrected VA improved from 0.58 ± 0.30 logMAR before fitting to 0.06 ± 0.07 logMAR with the final scleral lens, corresponding to a mean improvement of 0.52 logMAR (95% confidence interval [CI], 0.44–0.59; $p < 0.001$). The mean NEI VFQ-25 total score increased from 55.4 ± 11.6 to 84.2 ± 5.7, representing a mean increase of 28.8 points (95% CI, 25.5–32.1; $p < 0.001$).

Conclusion: In this retrospective cohort, scleral lens fitting was associated with improved VA and higher NEI VFQ-25 total scores in patients with keratoconus. Prospective controlled studies are needed to confirm these findings.

Keywords: Keratoconus; Scleral Contact Lenses; Vision Rehabilitation; Quality of Life

INTRODUCTION

The cornea provides most of the eye's refractive power, and a regular anterior corneal surface is essential for clear retinal image formation.[1,2] Corneal ectasias comprise a group of disorders characterized by progressive corneal thinning, protrusion, and distortion.[3] Keratoconus, the most common corneal ectasia, causes progressive corneal steepening, irregular astigmatism, and reduced visual acuity (VA).[4] Management options include spectacles, contact lenses, corneal cross-linking, intracorneal ring segments, and keratoplasty.

Progressive myopia and irregular astigmatism can cause substantial visual impairment in patients with keratoconus. Spectacles or soft contact lenses may provide adequate correction in the early stages; however, increasing corneal irregularity often necessitates more advanced optical correction. Soft toric, hybrid, and rigid gas-permeable contact lenses (RGPCLs) are used to compensate for refractive error and corneal irregularity. RGPCL designs include corneal, corneoscleral, and scleral lenses.[5] Scleral lenses vault the cornea and limbus and rest on the sclera, providing visual rehabilitation when conventional optical

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correction is inadequate.[6] The fluid reservoir between the posterior lens surface and the irregular cornea masks irregular astigmatism and reduces higher-order aberrations.[7] These optical and structural properties may also improve lens stability and wearing comfort.

Quality of life is a multidimensional construct that encompasses symptom burden, emotional well-being, social interaction, vision-related concerns, and the ability to perform daily activities.[8,9] Visual impairment is consistently associated with poorer quality of life.[10-12] The 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25), developed by the US National Eye Institute, is a validated and widely used self-report instrument for assessing vision-related quality of life.[13]

Accordingly, this study aimed to evaluate changes in VA and vision-related quality of life following scleral lens fitting in patients with keratoconus.

MATERIALS AND METHODS

Study Design and Ethical Approval

This retrospective study was conducted after approval by the institutional ethics committee (approval no. 2025/6-327). The diagnosis of keratoconus was based on slit-lamp biomicroscopic and Scheimpflug corneal tomographic findings documented in the clinical records. The study included 59 eyes from 39 patients with keratoconus who underwent scleral lens fitting. Because maximum keratometry, minimum pachymetry, corneal scarring, prior corneal hydrops, and formal tomographic stage were not consistently documented, disease severity could not be assigned retrospectively; accordingly, the cohort was not classified as having advanced keratoconus.

All patients underwent a comprehensive ophthalmic examination and contact lens assessment by a single ophthalmologist (B.A.). Refractive data were recorded in diopters (D). Uncorrected VA before fitting and VA with the final scleral lens were measured with an undilated pupil under standardized room conditions and expressed in logarithm of the minimum angle of resolution (logMAR) units. The K1 and K2 corneal curvature radii measured using Pentacam® (Oculus Optikgeräte GmbH, Wetzlar, Germany) were converted to diopters using D = 337.5/r (mm). Mean keratometry (Kavg) was calculated as the average of the dioptric K1 and K2 values.

Each eye was fitted with a customized, large-diameter gas-permeable Misa® scleral lens (Microlens Contactlens Technology BV, Arnhem, the Netherlands). Lens diameter, base-curve radius, and manufacturer-defined nominal sagittal height were selected during diagnostic fitting. The recorded sagittal-height values (3.25–4.25 mm) were lens-design parameters and not in situ measurements of central corneal clearance; accordingly, no settling interval applied to these numerical values. Final lens fit was evaluated with the lens on the eye using slit-lamp biomicroscopy and anterior segment optical coherence tomography. Quantitative central corneal clearance was not included in the analytical dataset.

The validated Turkish version of the NEI VFQ-25 was administered face to face by the same clinician as part of routine clinical care before scleral lens fitting and at a follow-up visit 6–38 months later.[24] Only questionnaires documented during routine care were reviewed; no patient was recontacted or asked to complete an additional questionnaire for research purposes. Complete paired questionnaires were available for 38 of 39 patients and were included in the complete-case analysis.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA), supplemented by a custom Python 3.12 script (NumPy 2.3.5 and SciPy 1.17.0) for the patient-clustered analysis. Categorical variables were summarized as counts and percentages, whereas continuous variables were summarized as means ± standard deviations and ranges. The normality of paired NEI VFQ-25 differences was assessed using the Shapiro–Wilk test. For each eye, change in logMAR VA was calculated as the uncorrected value before fitting minus the value obtained with the final scleral lens. Mean change was estimated using an intercept-only linear model with robust standard errors clustered at the patient level to account for inter-eye correlation; statistical inference was based on the 39 patient clusters (df = 38). Patient-level NEI VFQ-25 total scores were compared using a paired-samples *t* test because the paired differences were normally distributed. Effect estimates are presented

with two-sided 95% confidence intervals (CIs). Complete-case analysis was used for missing data. All tests were two-sided, and $p < 0.05$ was considered statistically significant.

RESULTS

A total of 59 eyes from 39 patients with keratoconus were included. Both eyes were included for 20 patients, and one eye was included for 19 patients. The mean age was 27.69 ± 7.73 years (range, 18–46 years), and 72.5% of patients were male. Of the 59 eyes, 37 (62.7%) were right eyes and 22 (37.3%) were left eyes. Mean K1, K2, and Kavg were 45.15 ± 2.09 D, 47.64 ± 1.98 D, and 46.40 ± 1.84 D, respectively (Table 1).

Spherical refraction data were available for 57 eyes; the mean spherical power was −0.95 ± 2.26 D (range, −6.50 to +4.50 D). Cylindrical correction was documented in nine eyes, with a mean cylindrical power of −0.94 ± 0.37 D (range, −1.25 to −0.25 D).

All eyes were fitted with customized Misa® scleral lenses. Lens diameter was 16.5 mm in 41 eyes (69.5%) and 17.0 mm in 18 eyes (30.5%). The selected base-curve radius was 7.8 mm in 56 eyes (94.9%) and 8.3 mm in three eyes (5.1%). The manufacturer-defined nominal sagittal height was 3.25 mm in two eyes (3.4%), 3.50 mm in 14 eyes (23.7%), 3.75 mm in 26 eyes (44.1%), 4.00 mm in 15 eyes (25.4%), and 4.25 mm in two eyes (3.4%). These values were lens-design parameters and not in situ measurements of central corneal clearance.

Mean uncorrected VA improved from 0.58 ± 0.30 logMAR before fitting to 0.06 ± 0.07 logMAR with the final scleral lens. After accounting for patient-level clustering, the mean improvement was 0.52 logMAR (95% CI, 0.44–0.59; $t(38) = 13.78$; $p < 0.001$) (Table 2).

Complete paired NEI VFQ-25 records were available for 38 of 39 patients (97.4%). In these patients, the mean total score increased from 55.37 ± 11.60 before fitting to 84.18 ± 5.73 after fitting, corresponding to a mean increase of 28.82 points (95% CI, 25.53–32.10; $t(37) = 17.75$; $p < 0.001$) (Table 2). All 38 patients showed an increase in the total score.

Table 1. *Keratometric values of eyes fitted with scleral lenses*

Parameter	n	Minimum	Maximum	Mean ± SD	95% CI
K1 (D)	59	36.41	49.85	45.15 ± 2.09	44.60-45.70
K2 (D)	59	43.60	54.35	47.64 ± 1.98	47.12-48.15
Kavg (D)	59	40.01	51.21	46.40 ± 1.84	45.92-46.88

Values were converted for each eye using D = 337.5/r (mm). Kavg was calculated as the mean of K1 and K2 in diopters. K1, flat keratometry; K2, steep keratometry; Kavg, average keratometry; D, diopters; SD, standard deviation; CI, confidence interval.

Table 2. *Changes in visual acuity and NEI VFQ-25 total score after scleral lens fitting*

Outcome	Analysis unit	Before fitting, mean ± SD (range)	After fitting, mean ± SD (range)	Mean improvement (95% CI)	p value
Visual acuity (logMAR)	59 eyes / 40 patients	0.58 ± 0.30 (0.15-1.30)	0.06 ± 0.07 (0.00-0.30)	0.52 (0.44-0.59)	<0.001
NEI VFQ-25 total score	38 patients	55.37 ± 11.60 (32-78)	84.18 ± 5.73 (70-95)	28.82 (25.53-32.10)	<0.001

Visual acuity change was estimated using a linear model with patient-clustered robust standard errors. NEI VFQ-25 scores were compared using a paired-samples t test. Positive improvement indicates a reduction in logMAR or an increase in NEI VFQ-25 score. NEI VFQ-25, National Eye Institute Visual Function Questionnaire-25; logMAR, logarithm of the minimum angle of resolution; SD, standard deviation; CI, confidence interval.

DISCUSSION

In this retrospective cohort, scleral lens fitting was associated with an improvement in VA, from a mean uncorrected value of 0.58 logMAR before fitting to 0.06 logMAR with the final lens. Scleral lenses can provide effective visual rehabilitation by masking corneal irregularity, creating a more regular refractive surface, and reducing optical aberrations.[16] Yan et al. reported an improvement in mean best-corrected VA from 0.30 to 0.05 logMAR,[17] whereas Fuller and Wang reported an improvement from 0.50 logMAR with spectacles to 0.08 logMAR with scleral lenses.[18] In a post-keratoplasty cohort, Severinsky et al. found that 82% of patients achieved VA of 0.5 logMAR or better with scleral lenses.[19] Although baseline correction conditions differed among these studies, the direction of the visual improvement was consistent.

Beyond its effect on VA, keratoconus can substantially impair vision-related quality of life. Its onset at a young age, progressive course, and symptoms such as impaired night vision, glare, and halos may interfere with daily activities and adversely affect psychological and social functioning. Validated instruments such as the NEI VFQ-25 allow these effects to be quantified.[13] Al Zabadi et al. reported significantly lower NEI VFQ-25 scores among patients with keratoconus than among healthy controls across physical, emotional, and social domains.[20] Al-Dairi et al. reported a mean total score of 58.6 ± 18.0,[21] and Aydin Kurna et al. found lower scores across all NEI VFQ-25 subscales in patients with keratoconus.[22] Consistent with these reports, the mean pre-fitting NEI VFQ-25 total score in our cohort was 55.4 ± 11.6, indicating a substantial baseline burden on vision-related quality of life.

Careful individualized fitting is essential when prescribing scleral lenses. Lens diameter, base-curve radius, and nominal sagittal height should be selected according to corneal and scleral anatomy, and the final lens should be evaluated on the eye for corneal and limbal clearance and haptic alignment. In this cohort, the most frequently selected lens diameter was 16.5 mm, and the most common nominal sagittal-height values were 3.75 and 4.00 mm.

Vision-related quality of life also improved, with the mean NEI VFQ-25 total score increasing from 55.37 ± 11.60 to 84.18 ± 5.73 among the 38 patients with complete paired data. Hadimani et al. reported an increase in the NEI VFQ-25 total score after scleral lens fitting, with particularly notable gains in distance vision, social functioning, and mental health.[14] Baudin et al. likewise observed improved quality-of-life outcomes,[15] and Kreps et al. reported improvements in visual functioning and socioemotional subscales after mini-scleral lens fitting.[23] Taken together, these findings suggest that visual gains after scleral lens fitting may be accompanied by meaningful improvements in patients' daily visual functioning. However, the present result should not be interpreted as evidence of causality because of the retrospective design and absence of a control group.

In Türkiye, Özek et al. evaluated 58 eyes from 40 patients with irregular corneas, including 46 eyes with keratoconus, who were fitted with Misa scleral lenses. They reported that the mean NEI VFQ-25 total score increased from 52.33 to 75.63 after 3 months ($p = 0.02$).[25] Their cohort also included patients with pellucid marginal degeneration and post-keratoplasty astigmatism, whereas the present cohort comprised only patients with keratoconus. Although the findings were directionally similar, differences in cohort composition, follow-up duration, and analytical methods limit direct comparison.

This study has several limitations. First, its retrospective, single-center design, modest sample size, and absence of a control group limit causal inference and generalizability. Second, the lack of consistently recorded maximum keratometry, minimum pachymetry, corneal scarring, prior hydrops, and formal disease staging precluded subgroup analyses according to disease severity. Third, complete paired NEI VFQ-25 data were unavailable for one patient, limiting the questionnaire analysis to 38 patients; face-to-face administration of this self-report instrument may also have introduced interviewer and social desirability bias. Finally, the variable follow-up interval of 6–38 months may have influenced the results. These findings require confirmation in multicenter, prospective, controlled studies with standardized follow-up intervals.

CONCLUSION

In this retrospective cohort, scleral lens fitting was associated with improvements in VA and NEI VFQ-25 total scores in patients with keratoconus. Prospective controlled studies with standardized follow-up are needed to confirm these findings.

Ethical Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the relevant institutional ethics committee (approval no. 2025/6-327). Only existing clinical records and questionnaires completed during routine care were reviewed retrospectively, and no participant was recontacted for research purposes. The requirement for written informed consent was therefore waived by the ethics committee.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

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Author Contributions

All authors contributed equally to the study design, data collection, analysis, interpretation, and manuscript preparation. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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