The effects on visual functions and vision-related quality-of-life after fitting of scleral lenses in keratoconus

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Abstract

The purpose of this study was to explore the effects of fitting scleral lenses on visual acuity (VA), contrast sensitivity (CS) and vision-related quality-of-life (VR-QoL) in persons with keratoconus.

An intervention study was undertaken, with a clinical experimental, uncontrolled, single-arm intervention design. The intervention was fitting of scleral lenses to optically correct keratoconus. The outcome measures were monocular and binocular VA at distance and near, CS, and patient-reported VR-QoL using the novel Keratoconus Outcomes Research Questionnaire (KORQ) and National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25).

Twenty-nine participants (54 eyes) were fitted with scleral lenses. Statistically significant improvements were evident between habitual correction and scleral lens correction for all measures including monocular and binocular VA at distance and near ($p < 0.001$), CS ($p < 0.001$), KORQ activity limitations subscale ($p < 0.001$), KORQ symptoms subscale ($p < 0.001$) and NEI VFQ-25 composite score ($p < 0.001$). Additionally, asymmetry in VA between eyes improved significantly with scleral lenses ($p < 0.001$). Spearman correlations showed moderate correlations between improvements in KORQ activity limitations score, VA and CS, improvements in KORQ symptoms score and distance VA, and improvements in the NEI-VFQ-25 near subscale score and near VA.

Fitting scleral lenses significantly improved VR-QoL and visual function in individuals with keratoconus. Although the correlation between improvements in VR-QoL and VA and CS was modest, the findings suggest that individuals with keratoconus should be offered the opportunity to explore scleral lenses as a treatment option to optimise both visual function and VR-QoL. However, as the study used an uncontrolled single-arm intervention design, the results should be interpreted with caution. Future studies including a comparison group are needed to confirm these findings.

Keywords: scleral lenses, keratoconus, visual acuity, contrast sensitivity, vision-related quality-of-life

Introduction

Keratoconus is a chronic eye disease characterised by thinning and steepening of the cornea due to the degradation of corneal collagen, resulting in an irregular cornea (Garcia-Ferrer et al., 2019; Nilagiri et al., 2018). In Norway, the prevalence of keratoconus is 192 per 100,000 with an annual incidence of 19.8 per 100,000 (Kristianslund et al., 2021). Keratoconus usually develops in puberty and progresses until about the age of 40, but the onset can occur earlier, and progression can continue for longer (Garcia-Ferrer et al., 2019). Clinical findings include variable refractive endpoints, steep keratometry readings, irregular astigmatism, and reduced VA, as well as corneal stromal thinning, Fleischer's ring, Vogt's striae, corneal scarring and prominent corneal nerves (Downie & Lindsay, 2015; Garcia-Ferrer et al., 2019). Patients' symptoms vary from little or no reduction of best corrected VA in the early stage to significant loss of visual function in the later stage. Other common symptoms include reduced night vision, photophobia, and eye strain (Garcia-Ferrer et al., 2019; Khadka et al., 2017). Higher-order aberrations due to corneal irregularities impact vision and cause symptoms such as halos, glare, starburst, and/or multiple or ghosting images, especially under dim light conditions (Macedo-de-Araújo, Faria-Ribeiro, et al., 2020). Management of keratoconus includes surgical treatment and optical rehabilitation. Corneal cross-linking can reduce or stop the progression of keratoconus, which prevents vision loss and reduces problems with contact lens fitting and wear (Garcia-Ferrer et al., 2019).

Optical correction with spectacles provides adequate visual quality in early stages of the disease but does not correct irregular astigmatism and higher-order aberrations (Downie & Lindsay, 2015). Consequently, corneal rigid gas-permeable (RGP) lenses are more suitable to optically correct keratoconus (Downie & Lindsay, 2015). Due to irregularities on the back surface of the cornea, the tear lens between the RGP lens and the anterior cornea corrects the irregularities on the anterior corneal surface, but not all the higher-order aberrations (Negishi et al., 2007). Moreover, corneal RGP lenses touch the sensitive corneal apex and may cause epithelial abrasion and corneal scarring (Barnett & Mannis, 2011). Therefore, scleral lenses are currently more frequently used to correct keratoconus (van der Worp, n.d.). Scleral lenses vault over the cornea, which avoids corneal abrasion. Additionally, as scleral lenses rest on sclera, which is less sensitive than cornea, they provide better comfort than corneal RGP lenses in most cases (Barnett et al., 2021). Scleral lenses are suitable for the correction of various corneal surface irregularities, provide a large optical zone, are stable on the eye and have less chance of falling out compared to corneal RGP lenses (Yan et al., 2017).

Patient-reported outcome measures and quality of life provide important information for clinical judgement and shared-decision-making. Some patients suffer from reduced self-esteem when they have trouble performing visual tasks that require high visual function (Garcia-Ferrer et al., 2019). Studies have shown that keratoconus negatively impacts the VR-QoL and that optical correction with RGP lenses can improve VR-QoL (Kymes et al., 2008; Ortiz-Toquero et al., 2016). Further, a recent study found that patients with keratoconus were more satisfied with their overall vision when corrected with scleral lenses than with corneal RGP lenses (Shorter et al., 2020). More knowledge about the impact of modern scleral lenses on visual function and VR-QoL in patients with keratoconus is required. This study aims to explore the effects of fitting scleral lenses on visual function and VR-QoL in persons with keratoconus.

Methods

This was an uncontrolled, single-arm intervention study using a before–after design. The intervention was fitting of scleral lenses to optically correct keratoconus. The outcome measures were patient-reported VR-QoL and visual functions.

The target population was individuals with keratoconus in Norway. The sample consisted of persons with keratoconus over 18 years of age examined at Specsavers Strømmen, Norway, between March 2020 and November 2021. Participants were mainly recruited from the Specsavers Strømmen eye clinic, optometrists and ophthalmologists in the Oslo area, the outpatient eye clinic at Ullevål University Hospital, and through social media promotion. Patients with keratoconus who had not previously been fitted with scleral lenses were eligible. A comprehensive eye examination was performed to rule out other ocular conditions and confirm eligibility. Exclusion criteria included being satisfied with habitual correction, inability to attend follow-up visits, unwillingness to be fitted with scleral lenses, inability to handle contact lenses, unsuitability for lens wear, or inability to provide informed consent. Participants with other eye diseases or systemic conditions affecting vision or VR-QoL were also excluded. Participants who were uncorrected at baseline were fitted with scleral lenses and used these as their habitual correction throughout the study; none switched to spectacles. In unilateral cases, the eye with reduced vision was fitted with a scleral lens, while the fellow eye had normal vision and required no correction. All eligible participants received oral and written information about the study and provided informed consent.

A priori sample size calculation was performed using the G*Power calculator (version 3.1.9.4). The goal was to detect improvements related to VR-QoL and visual function after fitting scleral lenses; an improvement of 20 points for the NEI-VFQ-25 score and a difference of 0.3 log units for VA and CS. The precision level was set at 5%, and the statistical power at 90%. Based on the calculations, a total sample size of 13 patients was required. Considering the potential risk of drop-out from clinical studies, more than double this number of patients were invited to participate.

The data were collected by one optometrist (SMR) at the eye clinic, Specsavers Strømmen. The measurements included self-reported VR-QoL using KORQ and the NEI VFQ-25, habitual and best corrected distance and near VA and CS. This study analyses and reports the VR-QoL and visual function before scleral lens fitting (baseline) and after 6 months of scleral lens wear.

The patients answered KORQ and NEI VFQ-25 questionnaires before the fitting of scleral lenses and after 6 months of scleral lens wear. KORQ is a psychometrically sound, valid, and reliable keratoconus-specific instrument developed for patients with keratoconus (Khadka et al., 2017). The Norwegian validated translation was used (Lundanes et al., 2025). KORQ compromises two subscales. The activity limitations subscale contains 18 questions, and the symptoms subscale contains 11 questions, all with a rating scale from 1 to 4 and a "not applicable" option (Kandel et al., 2020; Khadka et al., 2017; 2022; Lundanes et al., 2025). NEI VFQ-25 is a robust, self-reported vision-target health status questionnaire measuring the influence of visual symptoms and visual disability on generic health domains and daily visual function through one question about general health and 24 vision-targeted questions (Mangione, n.d.; Mangione et al., 2001). The Norwegian-translated and validated version (Jelin et al., 2019) was used.

Distance and near VA and CS were measured monocularly and binocularly with habitual correction and best-corrected spectacles at baseline and after 6 months with scleral lenses. Distance VA was measured using a high contrast Snellen VA chart (Nidek CP-770 projector) at 6 metres and recorded as Logarithm of the Minimum Angle of Resolution (logMAR) VA with one decimal. Near VA was measured with Sloan Early Treatment of Diabetic Retinopathy Study format near vision chart (Precision Vision) at 40 centimetres with the appropriate near correction and recorded as logMAR with one decimal. CS was measured with the Mars letter CS test (Mars Perceptrix Corporation) at 50 centimetres with the appropriate near correction and recorded with two decimals using a log scale.

We defined visual impairment according to International Classification of Diseases, Eleventh Revision (ICD-11) (World Health Organization, 2022) , No vision impairment (logMAR VA ≤ 0.3), Mild vision impairment (0.3 < logMAR VA ≤ 0.5), Moderate vision impairment (0.5 < logMAR VA ≤ 1.0), Severe vision impairment (1.0 < logMAR VA ≤ 1.3), and Blindness (logMAR VA > 1.3). Further, a difference in VA between the eyes by two lines or more, at distance and/or near, was defined as asymmetry in VA. Clinically significant improvement in VA after fitting of scleral lenses was defined as improvement of two lines or more compared to habitual correction (Thiagalingam et al., 2002).

CS was defined according to the Mars CS User manual ("The Mars CS User Manual," 2010), Normal > age 60 (1.52–1.76), Normal middle/young adult (1.72–1.92), Moderate impairment (1.04–1.48), Severe impairment (0.52–1.00) and Profound impairment (< 0.48). We defined an improvement to normal CS after fitting of scleral lenses as a clinically significant improvement in CS.

The data were entered into an Excel spreadsheet by one researcher (SMR) and controlled by visual inspection regarding missing data and outliers. The data were analysed in Excel (version 2108) and IBM SPSS Statistics (Version 31.0.1.0 (49). Outcome variables are reported as arithmetic means with corresponding standard deviations and 95% confidence intervals. Given the paired design and the sample size (n eyes = 54 and n participants = 29), we applied a paired Student's t-test to compare pre- and post-intervention measurements. Normality of the data and the paired differences was assessed using the Shapiro-Wilk test. Minor deviations from normality were considered acceptable because the paired t-test is robust to moderate departures from normality, and the sample size was sufficient for the Central Limit Theorem to apply.

VA at distance and near, as well as CS, were analysed separately for subjects fitted with scleral lenses in both eyes who had unequal habitual VA between the two eyes ($n = 19$). To account for correlation between eyes within the same subject, mixed-effects linear models were used. Each model included treatment (before vs. after) and eye (best vs. worst at baseline) as fixed effects, along with their interaction. Subject was included as a random intercept. Separate models were fitted for each outcome: distance VA, near VA, and CS.

Rasch analysis was performed using RUMM2030+ software to convert KORQ-NO raw scores into a linear logit scale, allowing for interval-level measurement. This analysis estimates person locations (representing each participant's level of activity limitation or symptom severity) and item locations (representing the difficulty or severity of each questionnaire item). Wright maps were generated to visually compare person and item distributions before and after scleral lens fitting, highlighting changes in perceived visual function and symptom burden. The two-sided paired-sample Student t-test was used to analyse differences in outcome measures before fitting of scleral lenses and at the 6-month follow-up. Spearman correlation was used to analyse the correlation between changes is visual function measurements and VR-QoL scores; an R-value of 0–0.25 was considered as no correlation, 0.25–0.5 as a weak correlation, 0.5–0.75 as a moderate correlation and 0.75–1.0 as a strong correlation. A p-value < 0.05 was considered statistically significant.

The study followed the ethical principles of medical research involving human subjects developed (Helsinki declaration) and was approved by the Regional Committee for Medical Research Ethics, REK (953377) Sør-Øst, Norway.

Results

In all, 29 patients, including 54 (93.1%) eyes were fitted with scleral lenses. Twenty-five patients were fitted with scleral lenses in both eyes, and four patients were fitted in only one eye. Twenty-two (75.9%) were males and the median age was 32, ranging from 20 to 68 years. Table 1 provides an overview over patient characteristics, including the type of habitual corrections before fitting of scleral lenses. At the 6-month follow-up, the participants wore the scleral lenses on average more than 5 days a week, ranging from 1 to 7 days a week, as shown in Figure 1. The average daily wearing time was more than 11 hours, ranging from 5 to 16 hours a day.

In general, optical correction with scleral lenses significantly improved self-reported VR-QoL and visual function compared to habitual correction. This is shown in Table 2. The Wright diagrams in Figures 2 and 3 show how most subjects reported improvement both regarding activity limitation and symptoms. The Wright maps displays person locations (left side) and item locations (right side) on a shared logit scale. Each x on the left represents an individual's score, where negative person locations indicate fewer activity limitations or symptoms, and positive values indicate greater limitations or symptoms. On the right, item locations reflect the difficulty or severity of each item: negative values represent more difficult activities or more severe symptoms, while positive values represent easier activities or less troublesome symptoms. The person location means and ±1 and ±2 SDs are marked. The maps show that 6 months after being fitted with scleral lenses, the person location mean shifted toward less impact, indicating improvement in both subscales.

Seeing in the distance (KORQ item AL9) was the hardest item at baseline (item location -1.88 [SD 0.28]) but improved significantly after scleral lens fitting (item location 1.12 [SD 0.34]). Troubled when tired (KORQ item S8) was the worst symptom at baseline and follow-up, whereas distorted vision (S1), trouble wearing rigid lenses (S4), windy days (S7), and smoky environments (S11) were not troublesome to any participants at the 6-month follow-up. The supplementary file at https://doi.org/10.18710/YLLZL5 provides details on person- and item-locations.

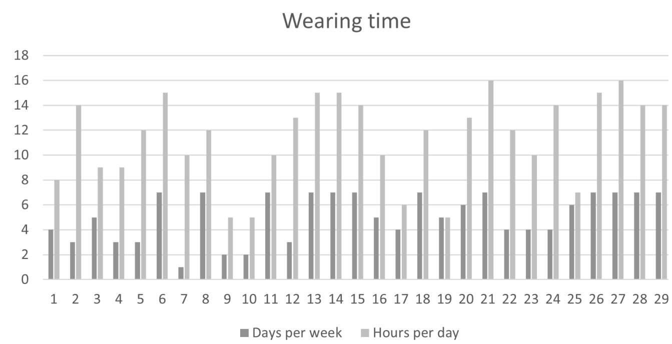

Figure 1: *SCL wearing time at the 6-month follow-up for each subject.*

Table 1: *Patient characteristics and type of habitual correction.*

	Male (n = 22)	Female (n = 7)	Total (n = 29)
Age, median [range]	33 [20–49]	24 [20–68]	32 [20–68]
Duration of keratoconus, years, median [range]	2.5 [0–28]	2 [1–15]	2 [0–28]
History of corneal cross linking, n (%)	6 (27.3)	4 (57.1)	10 (34.5)
Spectacles, n (%)	9 (40.9)	5 (71.4)	14 (48.3)
RGP contact lenses, n (%)	8 (36.6)	0	8 (27.6)
Uncorrected, n (%)	5 (22.7)	0	5 (17.2)
Soft contact lenses, n (%)	0	2 (28.6)	2 (6.9)

Note: Information on VA at baseline is presented separately in Table 3.

Table 2: *Comparison of VR-QoL scores before and after scleral lens fitting.*

	Before SCL	With SCL	Improvement
KORQ activity limitation***	-0,7 (±1.7) [-1.2, -0.2]	-1.9 (±0.9) [-2.3, -1.6]	-1.2 (±1.4) [-1.7, -0.7]
KORQ symptoms***	-0.2 (±1.1) [-0.7, 0.2]	-1.3 (±0.8) [-1.6, -1.02]	-1.1 (±0.9) [-1.4, -0.7]
NEI VQL-25 composite***	77.4 (±11.9) [72.9, 81.9]	89.8 (±9.2) [86.3, 93.3]	12.4 (±9.9) [8.7, 16.2]
NEI VQL-25 distance***	71.2 (±19.9) [63.7, 78.9]	87.4 (±14.9) [81.7, 93.0]	16.1 (±18.2) [9.2, 23.0]
NEI VQL-25 near**	72.9 (±20.1) [65.2, 80.5]	84.6 (±15.9) [78.5, 90.7]	11.8 (±21.3) [3.7, 19.9]
NEI VQL-25 driving***	75.3 (±21.3) [65.4, 81.1]	88.6 (±13.9) [83.1, 94.1]	9.3 (±11.1) [4.7, 13.9]

Note: n = 29. SCL = scleral contact lenses. Mean, SD and 95% CI are shown for each comparison. *$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

For eyes fitted with scleral lenses, the mean (SD) logMAR distance VA was 0.03 (±0.07) at the 6-month follow-up, as seen in Table 3. The distance VA with scleral lenses was significantly improved compared to the habitual distance VA 0.11 (±0.12) (Student's *t*-test, $p < 0{,}001$) and the best spectacle-corrected distance VA 0.13 (± 0.20) (Student's *t*-test, $p < 0.001$). At near, the VA with scleral lenses also significantly improved compared to habitual and best-spectacle correction, 0.02 (±0.07) versus 0.08 (±0.12) and 0.16 (±0.26), respectively (Student's *t*-test, $p < 0.001$).

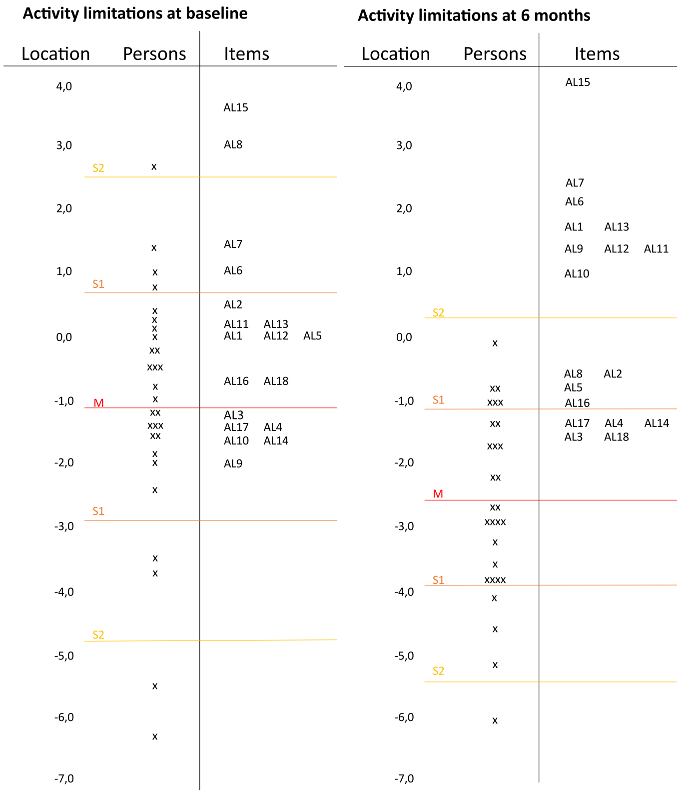

Figure 2: *Wright maps of person and item locations for the KORQ Activity Limitations subscales at baseline and six months after scleral lens fitting. Item content: AL1: using computer, AL2: driving daytime, AL3: driving at night, AL4: reading signs, AL5: watching TV, AL6: walking in steps, AL7: walking onto things, AL8: doing your job, AL9: viewing at distance, AL10: oncoming light. AL11: working near distance, AL12: doing hobbies, AL13: recognising faces, AL14: seeing in poor light, AL15: doing household tasks, AL16: depth perception, AL17: seeing small objects in the distance, AL18: viewing tasks (e.g. using a camera), S1: distorted vision, S2: glare, S3: bright sunny day interfere with ability to see, S4: troubled by wearing rigid gas permeable contact lenses, S5: headaches, S6: dry eyes, S7: windy days, S8: when tired, S9: dry days, S10: dusty days, S11: smokey environments. For complete items, please review KORQ (Khadka et al., 2017).*

In total, 18 (33%) eyes and 19 (35%) eyes had improved distance VA by two lines or more with scleral lenses compared to habitual correction and best-corrected spectacle VA, respectively. For near, improvement in VA of two lines or more compared to habitual near VA and best spectacle near correction was found for 24 (44%) and 28 eyes (52%), respectively. Table 4 presents the interocular differences in VA for distance and near vision before and after scleral lens fitting. A statistically significant reduction in asymmetry was observed, indicating improved balance between the eyes post-fitting. With habitual correction, 14 patients (48%) and 15 patients (57.7%) had a difference of two lines or more in VA between the eyes for distance and near vision, respectively. After scleral lens fitting, this number was reduced to three patients (10.3%) for distance and four patients (15.4%) for near. Furthermore, binocular VA improved by two lines or more with scleral lenses compared to habitual correction in three participants (10%) for distance and 10 participants (34%) for near vision.

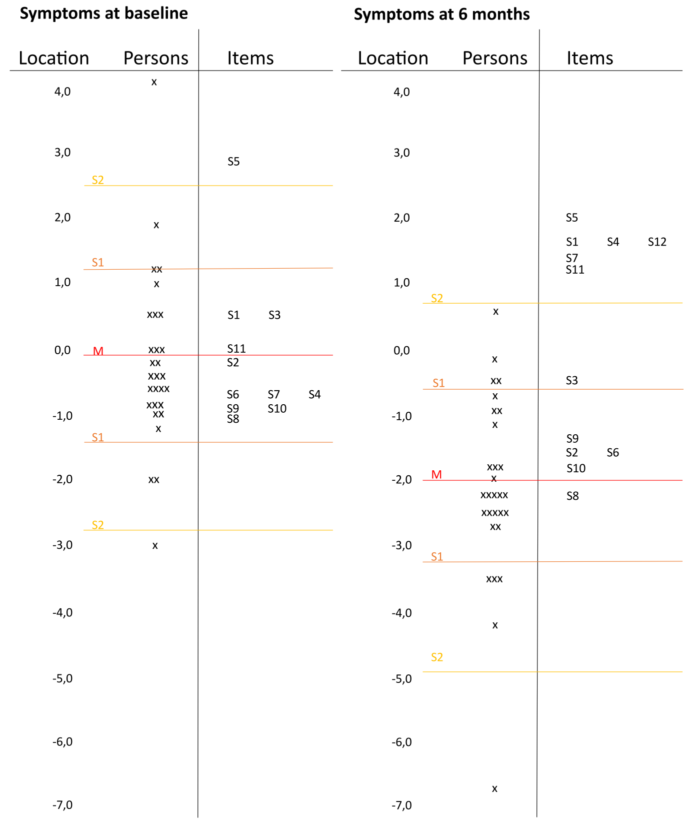

Figure 3: *Wright maps of person and item locations for the KORQ Activity Symptoms subscales at baseline and six months after scleral lens fitting. See Figure 2 for details.*

CS at distance was significantly improved with scleral lenses compared with habitual correction and best-corrected spectacles, log CS 1.76 (±0.08) versus log CS 1.68 (±0.15) (Student's *t*-test, $p < 0.001$) and log CS 1.64 (±0.24) (Student's *t*-test, $p < 0.001$), respectively (see Table 4 and Figure 4). With habitual and best-corrected spectacles, the CS was below normal limits (log CS < 1.48) for 25 (46.3%) and 26 (48.1%) eyes, respectively. Of these 21 (85%) eyes obtained normal CS (log CS ≥ 1.48) with scleral lenses. Moreover, for three (75%) participants with reduced binocular CS with habitual correction, CS improved to normal values (log CS ≥ 1.48) with scleral lenses.

Table 3: *Binocular visual function before and after scleral lens fitting.*

	Habitual correction	Best corrected spectacle Rx	SCL	Improvement with SCL
Distance logMAR VA	0.11 (±0.12) [0.06, 0.15]	0.13 (±0.20) [0.06, 0.21]	0.03 (±0.07) [0.01, 0.06]	-0.07 (±0.11) * [-0.11, -0.03]
Near logMAR VA	0.08 (±0.12) [-0.01, 0.04]	0.16 (±0.26) [0.06, 0.25]	0.02 (±0.07) [-0.01, 0.04]	-0.05 (±0.11) * [-0.11, -0.03]
Log CS	1.68 (±0.15) [1.62, 1.73]	1.64 (±0.24) [1.55, 0.15]	1.76 (±0.08) [1.73, 1.74]	0.07 (±0.12) * [0.03, 0.13]

Note: $n = 29$. SCL = scleral contact lenses. Mean, *SD* and 95% *CI* are shown for each function. $^*p < 0.001$.

Table 4: *Interocular difference in VA for distance and near before and after scleral lens fitting.*

	Habitual correction	Scleral lens correction
Distance VA*	0.28 (±0.34) [0.15, 0.41]	0.07 (±0.10) [0.03, 0.11]
Near VA*	0.29 (±0.30) [0.18, 0.41]	0.07 (±0.10) [0.03, 0.11]

Note: $n = 29$. Mean, *SD* and 95% *CI* are shown for each difference in VA between right and left eyes. $^*p < 0.001$.

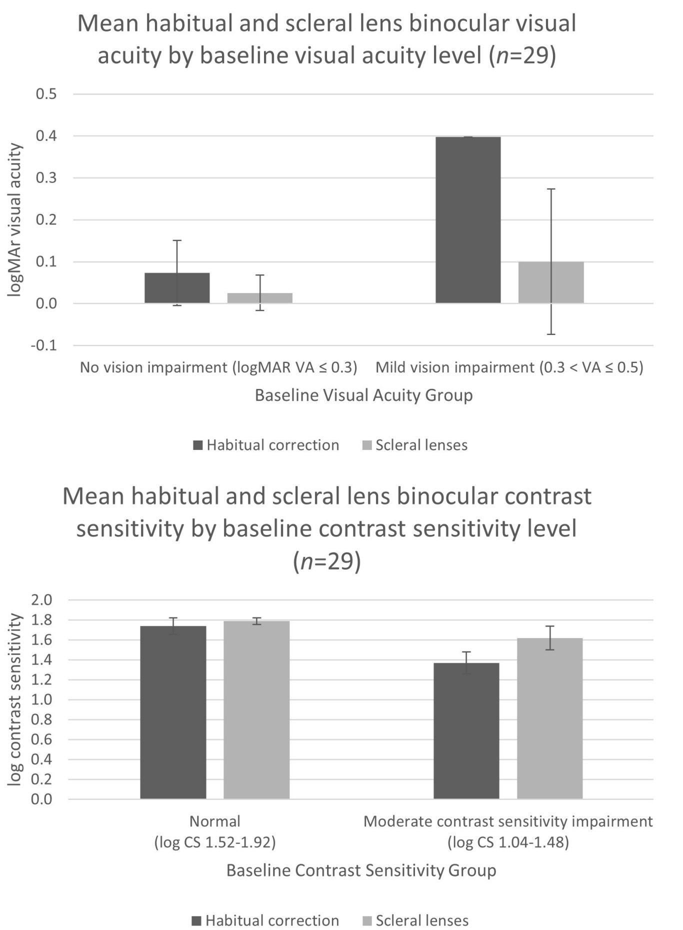

Figure 4: *Binocular VA and CS before and after scleral lens fitting. Binocular distance VA and CS with habitual correction and scleral lenses for all participants. Categories represent ranges of binocular VA (logMAR) and CS (log CS) scores. No individuals fall below the categories shown, meaning all participants achieved values within the displayed ranges.*

Excluding cases of unilateral scleral lens fittings ($n = 4$) did not change the results for distance and near VA or CS. For the 19 for patients fitted with scleral lenses in both eyes who had unequal habitual VA between the two eyes, a mixed model analysis revealed a significant main effect of scleral lens fitting, indicating improved VA with scleral lenses compared to habitual correction ($F(1, 54.00) = 33.58$, $p < 0.001$). On average, the distance VA improved from 0.26 [0.20, 0.32] with habitual correction to 0.06 [0.01, 0.12] with scleral lenses. The was also a significant main effect of eye ($F(1, 54.00) = 18.82$, $p < 0.001$), reflecting that the best eye (defined by habitual VA) had significant better VA than the worst eye, regardless of treatment. Finally, the eye × treatment interaction was significant ($F(1, 54.00) = 9.00$, $p = 0.004$), indicating that the improvement with scleral lenses differed between eyes, with the worst eye showing greater improvement than the best eye. Specifically, the best eye distance VA improved from 0.14 [0.06, 0.21] to 0.04 [-0.03, 0.12], while the worst eye improved from 0.39 [0.3, 0.46] to 0.09 [0.12, 0.16].

Similar patterns were observed for near VA and CS. For near VA, the mixed-effects model showed a significant main effect of treatment ($F(1, 54.00) = 37.21$, $p < 0.001$), with mean values improving from 0.26 [0.21, 0.31] to 0.07 [0.02, 0.12]. The main effect of eye and eye × treatment interaction was also significant ($F(1, 54.00) = 18.61$, $p < 0.001$ and $F(1, 54.00) = 6.71$, $p = 0.012$), indicating that the best eye had better near VA overall and that the worst eye benefited the most from scleral lenses. For CS, the same pattern emerged: overall improvement with scleral lenses, a significant difference between eyes, and a greater gain in the worst eye. Mean CS increased from log CS 1.45 [1.39, 1.55] to log CS 1.67 [1.6 to 1.74], with the worst eye showing the largest improvement.

The correlations between self-reported VR-QoL and visual function were modest to weak. The correlations between improved visual function and improvement in the KORQ activity limitations were moderate (Figure 5). All other correlations between improvements in visual functions and VR-QoL were weak or not significant, Figures 5 and 6.

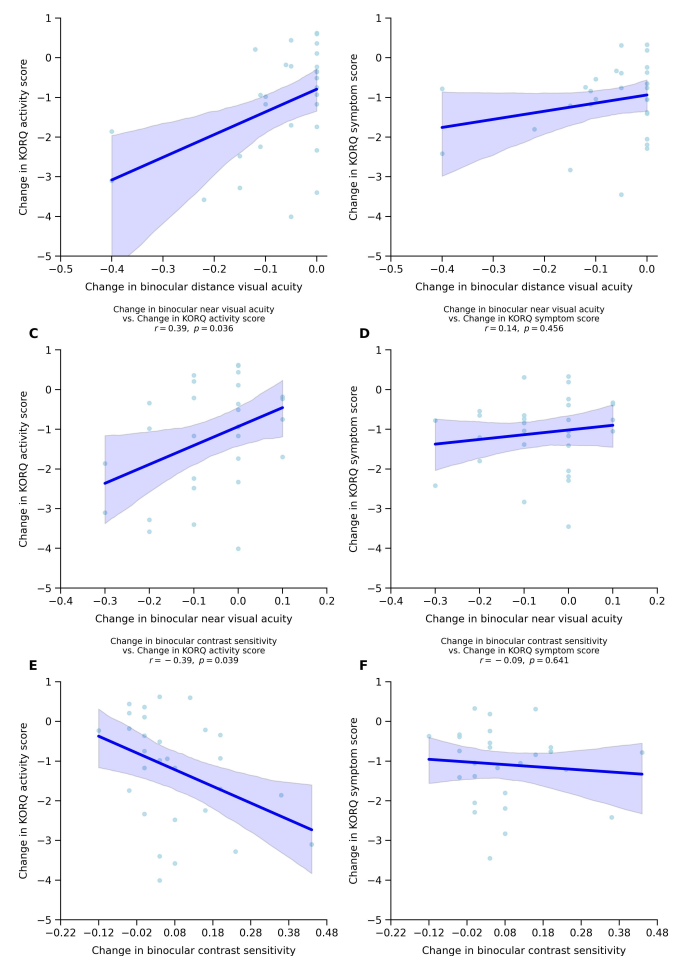

Figure 5: *Correlation between change in visual function measures and change in KORQ scores. Panels show scatter plots with fitted linear regression lines and 95% CIs for the following pairs: Distance VA vs. KORQ Activity, Near VA vs. KORQ Activity, CS vs. KORQ Activity, Distance VA vs. KORQ Symptoms, Near VA vs. KORQ Symptoms, CS vs. KORQ Symptoms. Pearson correlation coefficients (r) and corresponding p-values are displayed in each panel title.*

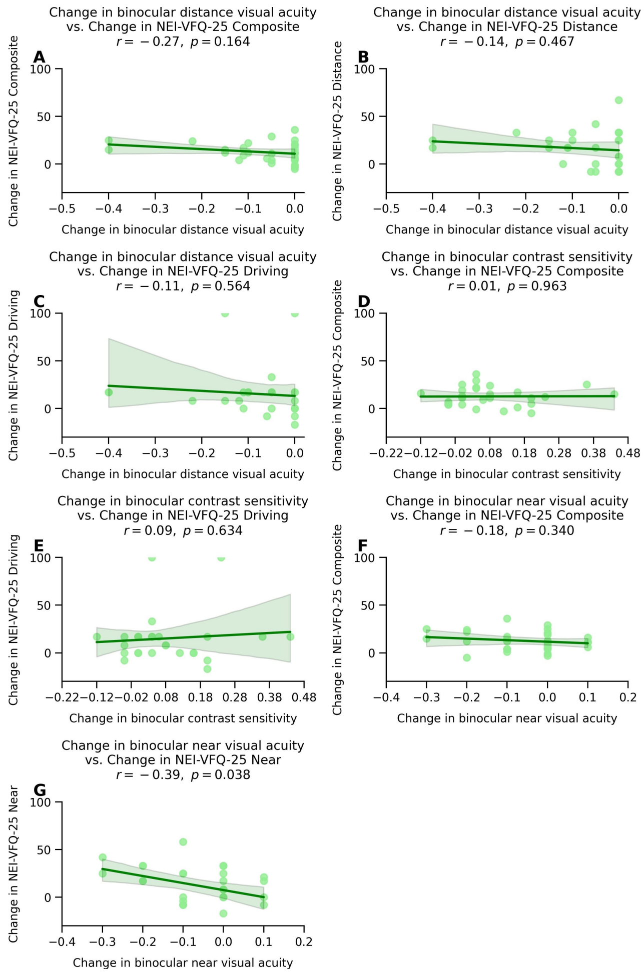

Figure 6: *Correlation between change in visual function measures and change in NEI-VFQ-25. Panels show scatter plots with fitted linear regression lines and 95% CIs for the following pairs: Distance VA and NEI-VFQ-25 Composite, Distance VA and NEI-VFQ-25 Distance, Distance VA and NEI-VFQ-25 Driving, CS and NEI-VFQ-25 Composite, CS and NEI-VFQ-25 Driving, Near VA and NEI-VFQ-25 Composite, Near VA and NEI-VFQ-25 Near. Pearson correlation coefficients (r) and corresponding p-values are displayed in each panel title.*

Discussion

This study demonstrates significant improvement in patient-reported activity limitations and symptoms after optical correction with scleral lenses in patients with keratoconus. Visual function, distance VA, near VA and CS, also significantly improved with scleral lenses. However, the correlation between improvement in VR-QoL and visual function were modest.

To our knowledge, this is the first study to explore the relationship between VR-QoL measured by KORQ and visual function before and after fitting of scleral lenses. When comparing our findings with results of the KORQ validation study (Kandel et al., 2020), the scores for activity limitation and symptoms indicated better visual function and less symptoms than reported by (Kandel et al., 2020), both before and after fitting scleral lenses. Although the Australian population included a larger proportion of females, who tend to report lower VR-QoL than males (Gothwal et al., 2022), this may indicate that the participants in our study had less severe keratoconus. Moreover, the improvement in KORQ scores after fitting of scleral lenses was higher for activity limitation than for symptoms indicating that fitting of scleral lenses may have greater impact on daily activities than on symptom relief in less severe keratoconus, as symptoms may be less severe to start with.

The improvement in VR-QoL was confirmed by significant increases in the NEI VFQ-25 composite score and subscale scores for distance activities, near activities, and driving after fitting scleral lenses. Before lens fitting, these scores were comparable to those reported in previous studies of patients with keratoconus (Kymes et al., 2004; 2008; Saunier et al., 2017). After fitting, the mean composite and subscale scores approached levels reported for healthy controls and individuals with refractive errors (Jelin et al., 2019; Ortiz-Toquero et al., 2016), indicating that scleral lenses can restore perceived visual function to near-normal levels.

However, the correlation between improvements in objective visual function and VR-QoL was modest, reflecting the influence of psychosocial adaptation and coping mechanisms. Adaptation involves factors like self-efficacy, acceptance of disability, and social support, which can significantly enhance perceived QoL even when VA or CS remains limited (Bonsaksen et al., 2019; Jerusalem & Schwarzer, 1992). These findings underscore the fact that VR-QoL captures broader dimensions of living with visual impairments, including resilience and emotional well-being, which objective measures alone cannot explain.

Overall, these results emphasise the substantial impact of scleral lens fitting on patients' daily lives, not only by improving visual function but also by enhancing perceived quality of life. This improvement is supported by reductions in visual impairment and CS impairment, as well as decreased asymmetry of VA between eyes. These outcomes highlight the critical role of contact lens providers in managing keratoconus and the importance of eye care professionals' expertise in specialised lens fitting.

Improvement in distance VA with scleral lenses in the current study corresponds with findings from a study by Macedo-de-Araújo, Fadel, and Barnett (2020) and Baudin et al. (2021) reported that improvements in distance VA increase with the severity of keratoconus. In the current study, monocular distance VA improved by two lines or more in one third of the participants, and binocular distance VA improved by two lines or more in one in ten participants, highlighting the potential of fitting scleral lenses to improve distance vision. Although the number of participants with habitual visual impairment was small, these individual cases illustrate the impact of scleral lenses to restore normal vision and CS.

The study findings indicate that scleral lens fitting produced consistent effects across both eyes, as neither eye laterality nor its interaction with treatment influenced visual outcomes. This suggests clinicians can anticipate similar improvements in each eye when prescribing scleral lenses, streamlining decisions for bilateral fittings. The lack of eye-specific differences reinforces that treatment efficacy depends primarily on lens design and fitting rather than anatomical variations. Moreover, reducing interocular differences in VA after scleral lens fitting may enhance binocularity and potentially improve stereopsis (Levi, 2022). Such improvements could also contribute to better VR-QoL, even though the vision of the better eye typically has a stronger influence on VR-QoL than interocular differences (Jones-Jordan et al., 2013). To our knowledge, previous studies have not assessed the effect of scleral lenses on near VA and CS. One in five had improved near VA by two lines or more with scleral lenses, which was also reflected by the improvement in the activity limitation for near reported by KORQ and NEI VFQ-25. Further, the majority of the participants with impaired CS achieved normal CS with scleral lenses. Therefore, in addition to focusing on distance VA, near VA and CS should be considered by the optometrist and discussed with the patients during the choice, option, and decision talk (Elwyn et al., 2012) to facilitate shared decision-making to meet patients' needs. Moreover, the modest correlation between improvement in visual function and improvement patient reported VR-QoL necessitates a person-centred approach to optical correction and management of patients with keratoconus. To ensure optimal care, patients with keratoconus should be referred to contact lens providers who specialise in keratoconus and advanced contact lens fitting.

This study has several strengths. First, it incorporated patient-reported outcome measures alongside objective visual function assessments to evaluate the impact of fitting scleral lenses in keratoconus. Measuring VR-QoL provides essential insight into symptom relief, care, and rehabilitation (Haraldstad et al., 2019). Two patient-reported outcome measures were used: the NEI VFQ-25, a widely applied instrument for chronic eye disease, and the KORQ, a keratoconus-specific questionnaire. Including both enabled comparison with previous studies while ensuring disease-specific relevance. Second, the achieved sample size exceeded the estimated requirement, and the gender distribution closely reflected that of the Norwegian population (Kristianslund et al., 2021) supporting the reliability of findings. Third, data collection by a single optometrist ensured consistency in measurement procedures. Finally, binocular VA was retained as the primary outcome for VR-QoL analyses because daily visual tasks are typically performed binocularly. This approach reflects real-world functional vision, which depends on combined input from both eyes. Previous research shows that relying solely on monocular VA underestimates the impact of visual impairment on quality of life compared with binocular measures (Kidd Man et al., 2020).

Despite these strengths, some limitations should be acknowledged. Although the sample size exceeded initial estimates, the relatively small number of participants ($n = 29$) and variability in keratoconus severity may limit statistical power and generalisability. Data collection by a single examiner could introduce measurement bias, although standardised protocols were applied to minimise this risk. The study was conducted in Norway, and cultural or healthcare system differences may affect applicability to other populations. Furthermore, the uncontrolled, single-arm before–after design does not account for confounding factors and precludes causal inference.

Future research should include a comparison group, such as patients fitted with RGP lenses, to better evaluate the relative benefits of scleral lenses. Larger studies incorporating detailed participant characteristics — such as corneal curvature, pachymetry, visual function, and VR-QoL — could improve understanding of which patients benefit most from scleral lens fitting. Such evidence would provide valuable guidance for optimising keratoconus management.

Conclusion

In this study, fitting of scleral lenses significantly improved VR-QoL and distance VA, near VA and CS in patients with keratoconus. Despite the modest correlation between improvement in VR-QoL and visual function, the findings imply that patients with keratoconus should be given the opportunity to explore scleral lenses as a treatment option to optimise visual function and VR-QoL.

References

Barnett, M., Courey, C., Fadel, D., Lee, K., Michaud, L., Montani, G., van der Worp, E., Vincent, S. J., Walker, M., Bilkhu, P., & Morgan, P. B. (2021). CLEAR - scleral lenses. *Contact Lens & Anterior Eye*, *44*(2), 270–288. https://doi.org/10.1016/j.clae.2021.02.001

Barnett, M., & Mannis, M. J. (2011). Contact lenses in the management of keratoconus. *Cornea*, *30*(12), 1510–1516. https://doi.org/10.1097/ICO.0b013e318211401f

Baudin, F., Chemaly, A., Arnould, L., Barrénéchea, E., Lestable, L., Bron, A. M., & Creuzot-Garcher, C. (2021). Quality-of-life improvement after scleral lens fitting in patients with Keratoconus. *Eye & Contact Lens*, *47*(9), 520. https://doi.org/10.1097/ICL.0000000000000821

Bonsaksen, T., Lerdal, A., Heir, T., Ekeberg, Ø., Skogstad, L., Grimholt, T. K., & Schou-Bredal, I. (2019). General self-efficacy in the Norwegian population: Differences and similarities between sociodemographic groups. *Scandinavian Journal of Public Health*, *47*(7), 695–704. https://doi.org/10.1177/1403494818756701

Downie, L. E., & Lindsay, R. G. (2015). Contact lens management of keratoconus. *Clinical and Experimental Optometry*, *98*(4), 299–311. https://doi.org/10.1111/cxo.12300

Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P., Cording, E., Tomson, D., Dodd, C., Rollnick, S., Edwards, A., & Barry, M. (2012). Shared decision making: A model for clinical practice. *Journal of General Internal Medicine : JGIM*, *27*(10), 1361–1367. https://doi.org/10.1007/s11606-012-2077-6

Garcia-Ferrer, F. J., Akpek, E. K., Amescua, G., Farid, M., Lin, A., Rhee, M. K., Varu, D. M., Musch, D. C., Mah, F. S., & Dunn, S. P. (2019). Corneal ectasia preferred practice pattern. *Ophthalmology*, *126*(1), 170–215. https://doi.org/10.1016/j.ophtha.2018.10.021

Gothwal, V. K., Gujar, R., Sharma, S., Begum, N., & Pesudovs, K. (2022). Factors affecting quality of life in keratoconus. *Ophthalmic and Physiological Optics*, *42*(5), 986–997. https://doi.org/10.1111/opo.13010

Haraldstad, K., Wahl, A., Andenæs, R., Andersen, J. R., Andersen, M. H., Beisland, E., Borge, C. R., Engebretsen, E., Eisemann, M., Halvorsrud, L., Hanssen, T. A., Haugstvedt, A., Haugland, T., Johansen, V. A., Larsen, M. H., Løvereide, L., Løyland, B., Kvarme, L. G., Moons, P., & Helseth, S. (2019). A systematic review of quality of life research in medicine and health sciences. *Quality of Life Research*, *28*, 2641–2659. https://doi.org/10.1007/s11136-019-02214-9

Jelin, E., Wisløff, T., Moe, M. C., & Heiberg, T. (2019). Psychometric properties of the National Eye Institute Visual Function Questionnaire (NEI-VFQ 25) in a Norwegian population of patients with neovascular age-related macular degeneration compared to a control population. *Health and Quality of Life Outcomes*, *17*(1), 140. https://doi.org/10.1186/s12955-019-1203-0

Jerusalem, M., & Schwarzer, R. (1992). Self-efficacy as a resourse factor in stress appraisal processes. In *Self-Efficacy. Thought Control of Action* (pp. 195–213). Taylor & Francis.

Jones-Jordan, L. A., Walline, J. J., Sinnott, L. T., Kymes, S. M., & Zadnik, K. (2013). Asymmetry in Keratoconus and vision-related quality of life. *Cornea*, *32*, 267. https://doi.org/10.1097/ICO.0b013e31825697c4

Kandel, H., Pesudovs, K., Ferdi, A., Mills, R., Chen, J. Y., Watson, A., Poon, A., Downie, L. E., & Watson, S. L. (2020). Psychometric properties of the Keratoconus Outcomes Research Questionnaire: A Save Sight Keratoconus Registry Study. *Cornea*, *39*(3), 303–310. https://doi.org/10.1097/ICO.0000000000002169

Khadka, J., Schoneveld, P. G., & Pesudovs, K. (2017). Development of a Keratoconus-specific questionnaire using Rasch analysis. *Optometry and Vision Science*, *94*(3), 395–403. https://doi.org/10.1097/OPX.0000000000001035

Khadka, J., Schoneveld, P. G., & Pesudovs, K. (2022). Comparing the measurement properties of visual analogue and verbal rating scales. *Ophthalmic & Physiological Optics*, *42*(1), 205–217. https://doi.org/10.1111/opo.12917

Kidd Man, R. E., Liang Gan, A. T., Fenwick, E. K., Thakur, S., Gupta, P., Teo, Z. L., Cheng, C.-Y., Wong, T. Y., & Lamoureux, E. L. (2020). Using uniocular visual acuity substantially underestimates the impact of visual impairment on quality of life compared with binocular visual acuity. *Ophthalmology*, *127*(9), 1145–1151. https://doi.org/10.1016/j.ophtha.2020.01.056

Kristianslund, O., Hagem, A. M., Thorsrud, A., & Drolsum, L. (2021). Prevalence and incidence of keratoconus in Norway: A nationwide register study. *Acta Ophthalmologica*, *99*(5), e694–e699. https://doi.org/10.1111/aos.14668

Kymes, S. M., Walline, J. J., Zadnik, K., Gordon, M. O., & Collaborative Longitudinal Evaluation of Keratoconus study group. (2004). Quality of life in Keratoconus. *American Journal of Ophthalmology*, *138*(4), 527–535. https://doi.org/10.1016/j.ajo.2004.04.031

Kymes, S. M., Walline, J. J., Zadnik, K., Sterling, J., & Gordon, M. O. (2008). Changes in the quality-of-life of people with Keratoconus. *American Journal of Ophthalmology*, *145*(4), 611–617.e1. https://doi.org/10.1016/j.ajo.2007.11.017

Levi, D. M. (2022). Learning to see in depth. *Vision Research*, *200*, 108082. https://doi.org/10.1016/j.visres.2022.108082

Lundanes, E., Roten, S. M., Falkenberg, H. K., Leren, L., & Sundling, V. (2025). Translation, cross-cultural adaptation, and validation of the Norwegian version of the Keratoconus Outcomes Research Questionnaire. *Journal of Patient-Reported Outcomes*, *9*(1), 57. https://doi.org/10.1186/s41687-025-00896-z

Macedo-de-Araújo, R. J., Fadel, D., & Barnett, M. (2020). How can we best measure the performance of scleral lenses? Current insights. *Clinical Optometry*, *14*, 47–65. https://doi.org/10.2147/OPTO.S284632

Macedo-de-Araújo, R. J., Faria-Ribeiro, M., McAllinden, C., van der Worp, E., & González-Méijome, J. M. (2020). Optical quality and visual performance for one year in a sample of scleral lens wearers. *Optometry and Vision Science*, *97*(9), 775–789. https://doi.org/10.1097/OPX.0000000000001570

Mangione, C. M. (n.d.). Visual Function Questionnaire 25 — National Eye Institute. https://www.nei.nih.gov/learn-about-eye-health/outreach-resources/outreach-materials/visual-function-questionnaire-25
[Online; accessed 2024-06-07].

Mangione, C. M., Lee, P. P., Gutierrez, P. R., Spritzer, K., Berry, S., & Hays, R. D. (2001). Development of the 25-list-item National Eye Institute Visual Function Questionnaire. *JAMA Ophthalmology*, *119*(7). https://escholarship.org/uc/item/3jt571n6
[Online; accessed 2024-04-03].

Negishi, K., Kumanomido, T., Utsumi, Y., & Tsubota, K. (2007). Effect of higher-order aberrations on visual function in keratoconic eyes with a rigid gas permeable contact lens. *American Journal of Ophthalmology*, *144*(6), 924–929.e1. https://doi.org/10.1016/j.ajo.2007.08.004

Nilagiri, V. K., Metlapally, S., Kalaiselvan, P., Schor, C. M., & Bharadwaj, S. R. (2018). LogMAR and stereoacuity in Keratoconus corrected with spectacles and rigid gas-permeable contact lenses. *Optometry and Vision Science*, *95*(4), 391–398. https://doi.org/10.1097/OPX.0000000000001205

Ortiz-Toquero, S., Perez, S., Rodriguez, G., de Juan, V., Mayo-Iscar, A., & Martin, R. (2016). The influence of the refractive correction on the vision-related quality of life in Keratoconus patients. *Quality of Life Research*, *25*(4), 1043–1051.

Saunier, V., Mercier, A.-E., Gaboriau, T., Malet, F., Colin, J., Fournié, P., Malecaze, F., & Touboul, D. (2017). Vision-related quality of life and dependency in French keratoconus patients: Impact study. *Journal of Cataract and Refractive Surgery*, *43*(12), 1582–1590. https://doi.org/10.1016/j.jcrs.2017.08.024

Shorter, E., Schornack, M., Harthan, J., Nau, A., Fogt, J., Cao, D., & Nau, C. (2020). Keratoconus patient satisfaction and care burden with corneal gas-permeable and scleral lenses. *Optometry and Vision Science*, *97*(9), 790–796. https://doi.org/10.1097/OPX.0000000000001565

Thiagalingam, S., Cumming, R. G., & Mitchell, P. (2002). Factors associated with undercorrected refractive errors in an older population: The Blue Mountains Eye Study. *British Journal of Ophthalmology*, *86*(9), 1041–1045. https://doi.org/10.1136/bjo.86.9.1041

van der Worp, E. (n.d.). *A guide to scleral lens fitting (2 ed.)* (2.0). Pacific University Libraries. https://d1arurmukwqrlq.cloudfront.net/production/resources/A_Guide_to_Scleral_Lens_Fitting.pdf

World Health Organization. (2022). ICD-11: International classification of diesases (11th revision). https://icd.who.int/en
[Online; accessed 2024-06-07].

Yan, P., Kapasi, M., Conlon, R., Teichman, J. C., Yeung, S., Yang, Y., Ziai, S., & Baig, K. (2017). Patient comfort and visual outcomes of mini-scleral contact lenses. *Canadian Journal of Ophthalmology*, *52*(1), 69–73. https://doi.org/10.1016/j.jcjo.2016.07.008

Effekter av tilpasning av sklerale linser på synsfunksjon og synsrelatert livskvalitet ved keratokonus

Sammendrag

Formålet med denne studien var å undersøke effekten av tilpasning av sklerale linser på visus, kontrastsensitivitet og synsrelatert livskvalitet hos personer med keratokonus.

Det ble gjennomført en intervensjonsstudie med et klinisk, eksperimentelt, ukontrollert studieoppsett med én intervensjonsarm. Intervensjonen besto av tilpasning av sklerale linser for optisk korreksjon av keratokonus. Utfallsmålene var monokulær og binokulær visus på avstand og nær, kontrastsensitivitet, samt pasientrapportert synsrelatert livskvalitet målt med det nye Keratoconus Outcomes Research Questionnaire (KORQ) og National Eye Institute Visual Funtion Questionnaire-25 (NEI VFQ-25).

Tjueni deltakere (54 øyne) ble tilpasset med sklerale linser. Det ble funnet statistisk signifikante forbedringer mellom habituell korreksjon og sklerallinse-korreksjon for alle mål, inkludert monokulær og binokulær visus på avstand og nær ($p < 0.001$), kontrastsensitivitet ($p < 0.001$), KORQ Synsfunksjon ($p < 0.001$), KORQ Symptomer ($p < 0.001$), og NEI VFQ-25 komposittskår ($p < 0.001$). I tillegg ble asymmetri i visus mellom øynene signifikant redusert med sklerale linser ($p < 0.001$). Spearman-korrelasjoner viste moderate korrelasjoner mellom forbedringer i KORQ Synsfunksjon, visus og kontrastsensitivitet, mellom forbedringer i KORQ Symptomer og visus på avstand, og mellom forbedringer i NEI VFQ-25 nær-delskala og visus på nær.

Tilpasning av sklerale linser ga betydelige forbedringer i synsrelatert livskvalitet og synsfunksjon hos personer med keratokonus. Selv om korrelasjonene mellom forbedringer i synsrelatert livskvalitet, visus og kontrastsensitivitet var moderate, tyder funnene på at personer med keratokonus bør få muligheten til å prøve sklerale linser som behandlingsalternativ for å optimalisere både synsfunksjon og synsrelatert livskvalitet. Siden studien benyttet et ukontrollert studieoppsett med én intervensjonsarm, bør resultatene tolkes med forsiktighet. Fremtidige studier med en kontrollgruppe er nødvendig for å bekrefte funnene.

Nøkkelord: Sklerale linser, keratokonus, visus, kontrastsensitivitet, synsrelatert livskvalitet

Effetti sulle funzioni visive e sulla qualità di vita correlata alla visione dopo l'applicazione di lenti sclerali nel cheratocono

Riassunto

Lo scopo di questo studio era esplorare gli effetti dell'applicazione di lenti sclerali sull'acuità visiva (AV), sulla sensibilità al contrasto (SC) e sulla qualità di vita correlata alla visione (VR-QoL) in soggetti con cheratocono. È stato condotto uno studio con disegno clinico sperimentale non controllato, a braccio singolo. L'intervento consisteva nell'applicazione di lenti sclerali per la correzione ottica del cheratocono. Le misure di outcome includevano l'AV monoculare e binoculare per lontano e vicino, la SC e la VR-QoL riferita dai pazienti, valutata mediante il nuovo questionario Keratoconus Outcomes Research Questionnaire (KORQ) e il National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25).

Ventinove partecipanti (54 occhi) sono stati adattati con lenti sclerali. Sono stati osservati miglioramenti statisticamente significativi tra la correzione abituale e quella con lenti sclerali per tutte le misure, inclusa l'AV monoculare e binoculare per lontano e vicino ($p < 0{,}001$), la SC ($p < 0{,}001$), la sottoscala delle limitazioni nelle attività del KORQ ($p < 0{,}001$), la sottoscala dei sintomi del KORQ ($p < 0{,}001$) e il punteggio composito del NEI VFQ-25 ($p < 0{,}001$). Inoltre, l'asimmetria dell'AV tra gli occhi è migliorata significativamente con le lenti sclerali ($p < 0{,}001$). Le correlazioni di Spearman hanno evidenziato correlazioni moderate tra i miglioramenti nel punteggio delle limitazioni nelle attività del KORQ, l'AV e la SC, tra i miglioramenti nel punteggio dei sintomi del KORQ e l'AV per lontano, e tra i miglioramenti nella sottoscala per vicino del NEI-VFQ-25 e l'AV per vicino.

L'applicazione di lenti sclerali ha migliorato significativamente la VR-QoL e la funzione visiva nei soggetti con cheratocono. Sebbene la correlazione tra i miglioramenti nella VR-QoL e quelli in AV e SC sia risultata modesta, i risultati suggeriscono che ai soggetti con cheratocono dovrebbe essere offerta la possibilità di considerare le lenti sclerali come opzione terapeutica per ottimizzare sia la funzione visiva sia la VR-QoL. Tuttavia, poiché lo studio utilizza un disegno sperimentale a singolo braccio non controllato, i risultati devono essere interpretati con cautela. Studi futuri che includano un gruppo di confronto sono necessari per confermare questi risultati.

Parole chiave: lenti sclerali, cheratocono, acuità visiva, sensibilità al contrasto, qualità di vita correlata alla visione