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Efficacy of Corneo-Scleral Lenses in Keratoconus Across Severity Grades: A Retrospective Cohort from South India

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Abstract

Aims: To evaluate the improvement in visual acuity provided by corneo-scleral contact lenses (CSLs) in patients with keratoconus as compared to spectacle correction, and to assess the effectiveness of CSLs across varying severities of keratoconus based on the Amsler-Krumeich classification.

Methods: This retrospective study included 19 eyes diagnosed with keratoconus that were fitted with corneo-scleral contact lenses (CSLs). Spectacle-corrected and CSL-corrected visual acuities were recorded and compared after converting to log MAR values. Contact lens fitting was performed using the trial lens method, based on sagittal height and fluorescein staining patterns to ensure optimal fit. The effectiveness of CSLs was further evaluated in relation to the severity of keratoconus, classified according to the Amsler-Krumeich staging system.

Results: A total of 19 eyes from patients with keratoconus were included in the study, of which 14 eyes (73.7%) had undergone prior corneal collagen cross-linking (CXL). The cohort consisted of 16 males and 3 females, with a mean age of 19.74 years. The mean spectacle-corrected visual acuity was 0.68 ± 0.40 log MAR, while the mean CSL-corrected visual acuity significantly improved to 0.06 ± 0.09 log MAR ($p < 0.001$).

Conclusion: Corneo-scleral contact lenses (CSLs) demonstrated significant improvement in visual acuity compared to spectacle correction in patients with keratoconus. Given their non-invasive nature, excellent visual outcomes, and suitability even in advanced stages of the disease, CSLs represent an effective alternative to surgical interventions. Their use may reduce the need for corneal transplantation in select patients while maintaining high visual quality and patient comfort.

Keywords: Corneo-Scleral Lens, Keratoconus, Rigid Gas Permeable

Introduction

Keratoconus (KCN) is a progressive, non-inflammatory ectatic disorder of the cornea characterized by localized thinning and conical protrusion. This leads to irregular astigmatism and higher-order aberrations, resulting in significant visual impairment, particularly among adolescents and young adults [1,2]. The condition typically presents bilaterally with asymmetrical severity between eyes [2,3]. Initial visual rehabilitation in keratoconus often begins with spectacle correction, which may be adequate

in early stages. However, as the disease advances, spectacles fail to correct the increasing irregular astigmatism, necessitating the use of contact lenses (CLs). The choice of contact lens depends on the location, steepness, and morphology of the corneal cone [1].

Soft contact lenses offer limited benefit in moderate to advanced KCN due to inadequate masking of corneal irregularity. Rigid gas permeable (RGP) lenses, considered the standard for mild to moderate KCN, provide better optical correction. However, in severe cases, RGP lenses are often poorly tolerated due to discomfort, decentration, or excessive movement on the steep, irregular cornea.

Scleral lenses, with their large diameters, vault over the cornea and rest entirely on the sclera, thereby avoiding direct contact with the compromised corneal surface. This design offers improved centration, optical quality, and patient comfort, particularly in advanced keratoconus where RGP lenses fall short [2].

Scleral lenses are typically classified into three categories based on their diameter and point of support [4]:

1. **Corneo-scleral lenses (CSLs):** rest partly on the limbus
2. **Mini-scleral lenses:** rest entirely on the anterior sclera
3. **Full scleral lenses:** have the largest diameter, extending further onto the sclera

Among these, corneo-scleral lenses offer a practical balance between ease of fitting and visual improvement, especially in resource-limited settings. In this study, we aim to evaluate the visual performance of corneo-scleral contact lenses in patients with keratoconus, including their efficacy across varying disease severities.

Aims

a. To compare visual acuity outcomes achieved with spectacle correction versus corneo-scleral contact lenses (CSLs) in patients with keratoconus.

b. To assess the efficacy of CSLs across different severities of keratoconus based on the Amsler-Krumeich classification.

Materials and Methods

This retrospective study was conducted at our contact lens clinic and included patients who were prescribed corneo-scleral lenses between January 2022 and June 2023.

Inclusion Criteria

- Patients aged 11 to 25 years diagnosed with keratoconus
- Patients with or without prior corneal collagen cross-linking (CXL)
- Patients who had not undergone keratoplasty

Exclusion Criteria

- Patients outside the specified age range
- History of ocular surgeries other than CXL

A total of 19 eyes meeting the above criteria were included in the study. Institutional scientific and ethical committee approvals were obtained prior to data collection.

Grading of Keratoconus:

Severity of keratoconus was classified using the Amsler-Krumeich (AK) grading system.

Contact Lens Details

All patients were fitted with McAsfeer™ corneo-scleral lenses manufactured by Silver Line Laboratories, composed of Boston XO2® material (a high Dk gas-permeable polymer developed by Bausch + Lomb™).

Contact Lens Fitting Protocol

Lens fitting was performed using the trial lens method, following a structured protocol:

1. **Sagittal Height Determination**

   A trial lens with sagittal height 0.2 mm greater than the steepest keratometry (K) value was selected and inserted.

2. **Initial Fluorescein Evaluation**

   Fluorescein dye was applied to the superior conjunctiva. Apical corneal clearance was confirmed.

3. **Assessment of Lens Landing Zone**

   Limbus and conjunctival vessels were inspected to ensure there was no compression or impingement. Lens centration and mobility were evaluated.

4. **Settling Phase**

   After approximately 30 minutes of wear, fluorescein staining was reassessed. Minimal apical feather touch was acceptable; apical staining was not tolerated.

5. **Over-Refraction**

   Performed to assess visual improvement.

6. **Reassessment After Extended Wear**

   If initial fit and refraction were acceptable, the patient was asked to wear the lens for an additional 4 hours, after which the fit, staining pattern, and refraction were rechecked.

7. **Lens Ordering**

   Upon meeting all criteria, a custom lens was ordered based on trial lens parameters.

8. **Final Evaluation and Training**

   On delivery, the new lens was reassessed after 4 hours of wear. If comfortable, patients were trained in lens insertion, removal, and hygiene.

9. **Wear Schedule**

   Patients were instructed to increase wear time gradually by 1 hour per day.

10. **Follow-up**

    After one week, lens fit, comfort, and visual acuity were reassessed. If satisfactory, the lens was formally prescribed.

Data Analysis

Statistical analysis was performed using STATA software. Visual acuities were converted from Snellen values to log MAR units for uniformity in comparison. Paired data from 19 eyes with keratoconus, including those with prior corneal collagen cross-linking (CXL), were analyzed.

Spectacle-corrected and corneo-scleral lens (CSL)-corrected visual acuities were compared using the Wilcoxon signed-rank test, a non-parametric method suitable for small sample sizes and non-normally distributed data. A p-value of <0.001 was considered statistically significant.

Additionally, subgroup analysis was conducted to evaluate the correlation between visual improvement with CSLs and the severity of keratoconus, as classified by the Amsler-Krumeich grading system.

Results

Demographic Profile

A total of 19 eyes from patients aged 14 to 28 years were included in the study. The mean age was 19.74 years. The cohort comprised 16 males (68%) and 3 females (32%). Of the 19 eyes, 14 (73.7%) had previously undergone corneal collagen cross-linking (CXL) (Table 1).

Visual Acuity Outcomes

Spectacle-corrected and corneo-scleral lens (CSL)-corrected visual acuities were recorded for each eye. Corresponding mean keratometry (K) values were also noted. These values are detailed in Table 2.

Statistical Analysis

Comparison of spectacle-corrected and CSL-corrected visual acuities showed a statistically significant improvement following lens use, with a mean logMAR visual acuity improving from 0.68 ± 0.40 (glasses) to

0.06 ± 0.09 (CSLs). The difference was statistically significant ($p < 0.001$) as shown in Table 3.

Among patients with advanced keratoconus (AK stages 3 and 4), 64% achieved 6/6 visual acuity, while 100% attained 6/9 or better with CSLs.

Discussion

Keratoconus is a progressive, visually debilitating corneal disorder that primarily affects school-aged children and young adults. The resultant irregular astigmatism and higher-order aberrations often lead to significant visual impairment, which is challenging to correct with conventional optical methods. Approximately 10% of patients eventually require keratoplasty due to disease progression, corneal scarring, or inadequate visual rehabilitation with spectacles or rigid gas permeable (RGP) lenses[5].

Scleral contact lenses have transformed the management of keratoconus and other conditions associated with irregular corneas. These lenses offer a non-invasive means of optical correction and provide substantial improvement in visual acuity, particularly in patients who do not tolerate or achieve satisfactory results with RGP lenses. By vaulting the corneal surface and resting on the sclera, they help maintain tear film stability and minimize mechanical trauma, making them especially suitable in advanced disease stages.

Our findings are consistent with existing literature, demonstrating that corneo-scleral lenses (CSLs) offer superior visual outcomes compared to spectacles and RGP lenses [2,6]. In addition to enhanced vision, CSLs offer improved patient comfort, better lens centration, prolonged wear time, and reduced risk of corneal complications [2,6,7].

Although some studies, such as that by Montalt et al., suggest CSLs as an option primarily for mild to moderate keratoconus [2], our study shows notable improvement in patients with advanced disease (AK stages 3 and 4). In these patients, where the only alternative may be surgical intervention, CSLs serve as an effective and non-invasive solution, significantly delaying or potentially eliminating the need for corneal transplantation.

However, the use of CSLs, especially in rural or resource-limited settings like ours, is not without challenges. Barriers include higher costs, a steeper learning curve for lens insertion and maintenance, lack of awareness among patients and practitioners, and limited availability of trained personnel for fitting and follow-up [7].

Despite these challenges, our study supports the adoption of CSLs as a primary visual rehabilitation tool in advanced keratoconus. With proper patient education and infrastructure support, CSLs can bridge the gap between poor optical correction and invasive surgical solutions in keratoconus management.

Conclusion

Corneo-scleral contact lenses offer a safe, effective, and non-invasive solution for visual rehabilitation in patients with keratoconus, including those with advanced disease. Our study demonstrates a statistically and clinically significant improvement in visual acuity with CSLs compared to spectacle correction. The lenses were well tolerated and effective across different severities of keratoconus, including post-CXL eyes. Given their ability to delay or potentially avoid surgical intervention, CSLs should be considered a valuable tool in the comprehensive management of keratoconus, especially in young patients and resource-limited settings.

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Legend Tables and Graphs

Table 1: Demographic and Clinical Characteristics of the Study Population

Parameter	Category	n (%)
Sex	Male	16 (68%)
	Female	3 (32%)
Age (Mean = 19.74 years)	≤ 19 years	12 (63%)
	> 19 years	7 (37%)
CXL Status	CXL Done	14 (74%)
	CXL Not Done	5 (26%)
AK Stage	Stage 1	0 (0%)
	Stage 2	8 (42%)
	Stage 3	2 (11%)
	Stage 4	9 (47%)

Abbreviations: CXL – Corneal Collagen Crosslinking; AK – Amsler-Krumeich

Table 2: Visual Acuity Outcomes and Corneal Parameters

Parameter	Mean log MAR VA (SD)	Snellen Equivalent	Range (log MAR)
UCVA (Uncorrected)	1.18 (0.46)	4/60	0.48 – 2.30
GPVA (With Glasses)	0.68 (0.40)	6/36	0.18 – 1.78
CLVA (With CSLs)	0.06 (0.09)	6/6	0.00 – 0.18
Mean K (Diopters)	54.77 (4.55)	–	48.3 – 67.5

Abbreviations: UCVA – Uncorrected Visual Acuity; GPVA – Glasses-Corrected VA; CLVA – Contact Lens-Corrected VA; K – Keratometry

Table 3: Comparison of Visual Acuity by Mode of Correction

Mode of Correction	Mean log MAR VA (SD)	Snellen Equivalent	Range (log MAR)	p-value
Glasses	0.68 (0.40)	6/36	0.18 – 1.78	
Contact Lenses (CSL)	0.06 (0.09)	6/6	0.00 – 0.18	< 0.001

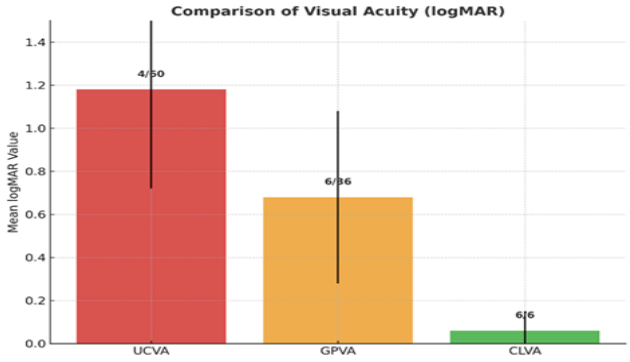

Figure 1: Comparison of Visual Acuity across Different Modes of Correction

Description: This bar chart illustrates the mean logMAR visual acuity achieved in patients with keratoconus under three conditions: uncorrected visual acuity (UCVA), spectacle-corrected visual acuity (GPVA), and corneo-scleral lens–corrected visual acuity (CLVA). A significant reduction in logMAR values was observed with CSL use, indicating substantial improvement in visual acuity. Snellen equivalents are annotated above each bar for clinical interpretation.

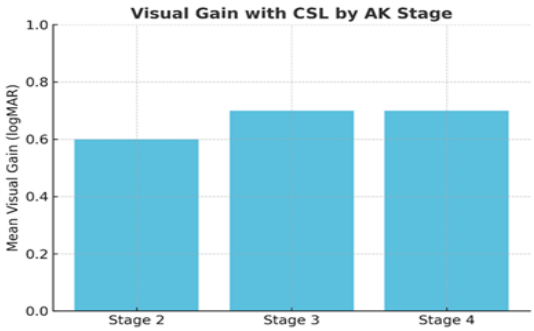

Figure 2: Mean Visual Gain Achieved with Corneo-Scleral Lenses Across Amsler-Krumeich Stages

This bar chart shows the average improvement in visual acuity (logMAR) from glasses to CSL correction across different severities of keratoconus as graded by the Amsler-Krumeich (AK) classification. Patients in Stage 2, 3, and 4 all experienced substantial visual gain, with advanced stages benefiting equally.

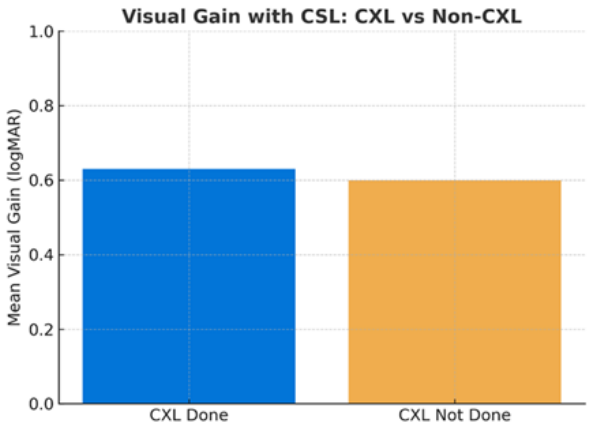

Figure 3: Visual Gain with CSL: CXL vs Non-CXL

Description: This graph compares mean visual improvement between eyes that had undergone **corneal collagen cross-linking (CXL)** and those that had not. Both groups showed significant visual gain with CSLs, indicating lens effectiveness regardless of prior CXL treatment.