Original Article

Spectrum of Scleral Lens Fit and Patient Compliance: A Single Center Retrospective Study

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Abstract

Objectives: To discuss the results of scleral contact lens fit in patients with difficult corneal and ocular surface pathologies.

Materials and Methods: This single-center, retrospective case-series included 49 eyes of 34 patients who underwent scleral lens fitting for visual acuity improvement from February 2018 to 2023. All patients underwent Orbscan/Pentacam corneal topography before a complete ophthalmological exam. The first trial lens was chosen according to manufacturer guidelines and topographic parameters. Best corrected Snellen visual acuity was assessed with spectacles before fit and over-refraction after fit and converted to logarithm of the minimum angle of resolution (logMAR). The vault was evaluated both at the slit-lamp and with anterior segment optic coherence tomography when possible.

Results: Twenty-one patients (61.8%) were male and the mean age was 37.4±14.8 years (range: 12-71). Twenty-three eyes (46.9%) had keratoconus, 11 eyes (22.4%) had refractive error after penetrating keratoplasty, 7 eyes (14.3%) had irregular astigmatism due to corneal scar, 4 eyes (8.2%) had advanced stage Steven-Johnson syndrome, 2 eyes (4.1%) had corneal perforation repair, and 2 eyes (4.1%) had severe dry eye. The appropriate lens was determined after 3.7±1.9 trials (range: 1-8 trials.) Although five patients refused scleral contact lenses due to cost, lenses were successfully fitted and used in 39 eyes of 29 patients. The mean daily wear time was 9.3±4.5 hours (range: 2-16) and mean follow-up was 52±49 months (range: 12-180). Mean uncorrected logMAR visual acuity and mean spectacle-corrected logMAR visual acuity was 1.09±0.47 and 0.67±0.50, which improved significantly to 0.13±0.20 after scleral contact lens fitting.

Conclusion: Scleral lens fit is a time-consuming practice for the ophthalmologist and an intimidating task for the patient. However, in addition to their good optical results, they provide very good comfort and stability. Although the large diameter may seem like the major disadvantage during scleral lens trial, the cost becomes more of an issue in developing countries.

Keywords: Irregular astigmatism, keratoconus, keratoplasty, scleral contact lens

Introduction

Scleral contact lenses are large-diameter (over 15 mm) rigid gas-permeable (RGP) lenses that are completely supported by the sclera. They do not contact the cornea and limbus and provide a tear film reservoir between the posterior surface of the lens and the anterior surface of the cornea.[1,2] Although scleral lenses have been in ophthalmology practice for over a century, they have been used more frequently over recent years because of newer high-Dk materials that permit better diffusion of oxygen, reducing the complications seen with older generation scleral lenses.[3,4] Scleral lenses play an important role in the treatment of corneal disease, providing hydration of the ocular surface and protecting it from trauma caused by scarred lid margins and lashes.[5,6] They also provide visual rehabilitation by optical neutralization of corneal surface irregularities.

Studies have recognized the benefits of scleral lenses in the management of various ocular surface diseases, including keratoconjunctivitis sicca, cicatrizing conjunctivitis, neurotrophic keratopathy, exposure keratopathy, and limbal stem cell deficiency.[5,6,7,8,9,10,11] Recent studies have also highlighted their effectiveness in managing severe dry eye and ocular surface irregularities.[12,13,14,15]

In this study, we evaluated the results of scleral lens fitting in patients with irregular corneal astigmatism and difficult ocular surface pathologies.

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Materials and Methods

This study was approved by the Dokuz Eylül University Hospital Research Ethics Board before data collection and analysis (decision no: 2024/38-22; date: 13/11/2024). This single-center, retrospective case series included 49 eyes of 34 patients who underwent scleral lens fitting mainly for improvement of visual acuity from February 2018 to 2023. Since the study was a retrospective study, an informed consent form was not used. All patients underwent Orbscan (Bausch & Lomb) or Pentacam (Oculus) corneal topography before a complete ophthalmological exam. The first trial lens was chosen according to the manufacturer's suggestions based on topographic parameters. We started with a base curve of 7.80 mm, diameter of 16 mm, and a vault of 300-350 µm for moderate cones and post-surgical eyes, while we chose larger diameters for severe cones or patients with ocular surface diseases such as Stevens-Johnson syndrome (SJS).

Statistical Analysis

The study data were evaluated using SPSS version 25.0 (IBM Corp., Armonk, NY, USA) software. The Kolmogorov-Smirnov test was used to evaluate whether the data showed normal distribution. Parameters before and after scleral lens wear were compared using Wilcoxon test, with a p value <0.05 considered statistically significant.

Fitting and Evaluation

The lens was mounted on the plunger and filled with saline, which was dyed with a fluorescein strip used for evaluating the ocular surface and the tear film. The patient was then told to sit down and bend their head forward until their face was parallel to the ground. The lens was inserted by one of the researchers (Z.Ö. or C.A.Y.) using the plunger, paying attention not to spill the dyed saline. The upper lid was gently pulled back, the superior edge of the lens was placed under the upper lid first, and then the same technique was repeated for the lower lid. Then the patient was asked to sit up. The position of the lens and the tear reservoir was checked with a blue flashlight. If there was no touch or air bubbles and a nice homogeneous fluorescence was observed underneath the lens, the patient was instructed to wait for 30 minutes for the lens to settle.

Snellen best corrected visual acuity (BCVA) was assessed with spectacles before fit, and over-refraction was performed 30 minutes after fitting. Visual acuity values were converted to logarithm of the minimum angle of resolution (logMAR). Success was defined as at least two lines of increase in BCVA.

The lens and tear reservoir were re-evaluated at the slit-lamp. The thickness of the fluorescent reservoir was simply compared to that of the cornea with slit illumination (Figure 1), and vault was considered appropriate when the thickness of the fluorescence beneath the lens was half the corneal thickness, as an average vault of 200-250 µm was advocated. A steeper base curve was selected when there were air bubbles or conjunctivochalasis at the edge of the lens. The landing zone was also evaluated for blanching. Vault was measured quantitatively by anterior segment optical coherence tomography (AS-OCT; Visante OCT, Zeiss) when available (AS-OCT was out of order in 2020, and some patients were evaluated using a temporary demo AS-OCT [Anterion, Heidelberg Engineering]) (Figure 2). Imaging was difficult in some of our patients, such as those with SJS or

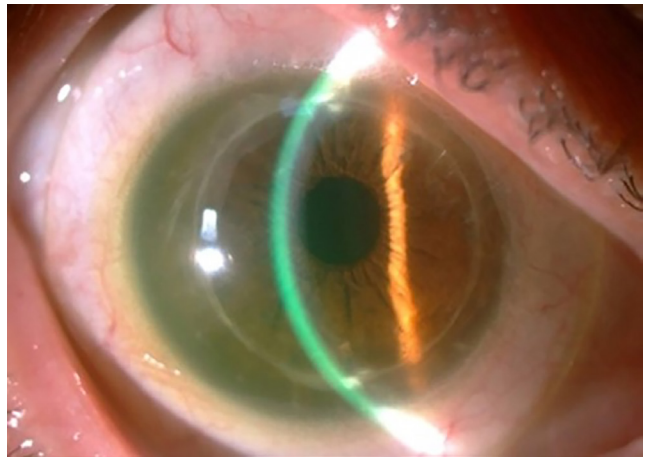

Figure 1. Anterior segment photography of a patient with high astigmatism after penetrating keratoplasty with the scleral lens showing adequate vault

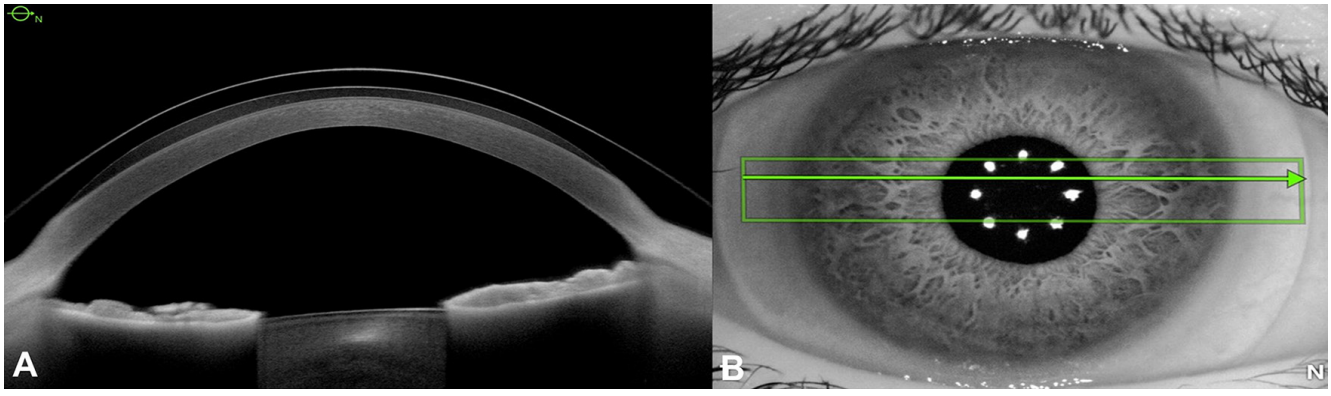

Figure 2. A) Anterior segment optical coherence tomography of a keratoconus patient 30 minutes after fitting scleral lens. B) Infrared image of the same patient 30 minutes after fitting the scleral lens

bilateral corneal perforation (Figure 3). All measurements and examinations were performed by a single researcher (Z.Ö.) to avoid interobserver variability. Vault was increased when touch was observed.

When we decided on the final lens to order, we showed the patient how to put the lens in and take it out and provided an opportunity to practice at the clinic before placing the order. When the lens was delivered, the patient returned to the clinic with the package including the lens, care solution, wetting drops, plunger, and information booklet. After checking the parameters, the package was opened, and we performed the first insertion. We rechecked visual acuity and fit and then taught the patient the insertion and removal once again. Every patient was told to start wearing the lens gradually: for 2 hours on the first day of use, 4 hours on the second, and 6 hours on the third. They were also warned to remove the lens after 4 hours of wear to clean, refill, and reinsert if scleral lens wear was still required, to prevent midday fogging and protein buildup.

Results

Twenty-one patients (61.8%) were male and 13 patients (38.2%) were female. The mean age was 37.4±14.8 years (range: 12-71 years). Twenty-three eyes (46.9%) with keratoconus, 11 eyes (22.4%) with refractive error after penetrating keratoplasty, 7 eyes (14.3%) with irregular astigmatism due to corneal scar, 4 eyes (8.2%) with advanced-stage SJS, 2 eyes (4.1%) with corneal perforation repair, and 2 eyes (4.1%) with severe dry eye were included (Table 1). All patients with keratoconus and grafts had been previously fit with RGP contact lenses but recently were uncomfortable in them. Mean uncorrected logMAR visual acuity and mean spectacle-corrected logMAR visual acuity were 1.09±0.47 and 0.67±0.50, respectively, which improved significantly to 0.13±0.20 after scleral lens fitting ($p<0.05$) (Figure 4). Before ordering the lens, the necessary power adjustment was made considering the vertex distance when over-refraction exceeded 4 diopters. Visual acuity with the scleral lens remained stable without any serious complications during 29.5±14.5 months (range: 12-48 months) of follow-up. All patients reported that they wore their lenses every day for at least 2 hours. Mean duration of wear was 9.3±4.5 hours (range: 2-16 hours) (Table 2). Mean vault height measured by AS-OCT in 23 eyes of 17 patients was 0.21±0.02 mm (range: 0.15-0.26 mm). Twenty-nine patients were successfully fit and all continued wear. Although no scale was used to assess patient comfort, according to information provided by the patients during follow-up visits, all patients stated they were more comfortable with scleral lenses than their previous lenses. However, 5 patients refused to use scleral lenses for financial and practical purposes. Three lenses had to be replaced because one was broken after 3 months of use and the other two patients had changes in refraction while waiting for shipment. Two of our patients continued to use scleral lenses even though they complained of midday fogging. No patient experienced conjunctival blanching, chalasis, or limbal vascularization.

Table 1. Demographic properties

Gender	Male, 21 (61.8%) Female, 13 (38.2%)
Age (years)	37.4±14.8 (range: 12-71)
Indication	**Keratoconus**, 23 eyes (46.9%) **Refractive error after PK**, 11 eyes (22.4%) **Irregular astigmatism (corneal scar)**, 7 eyes (14.3%) **Advanced SJS**, 4 eyes (8.2%) **Corneal perforation repair**, 2 eyes (4.1%) **Severe dry eye**, 2 eyes (4.1%)

PK: Penetrating keratoplasty, SJS: Stevens-Johnson syndrome

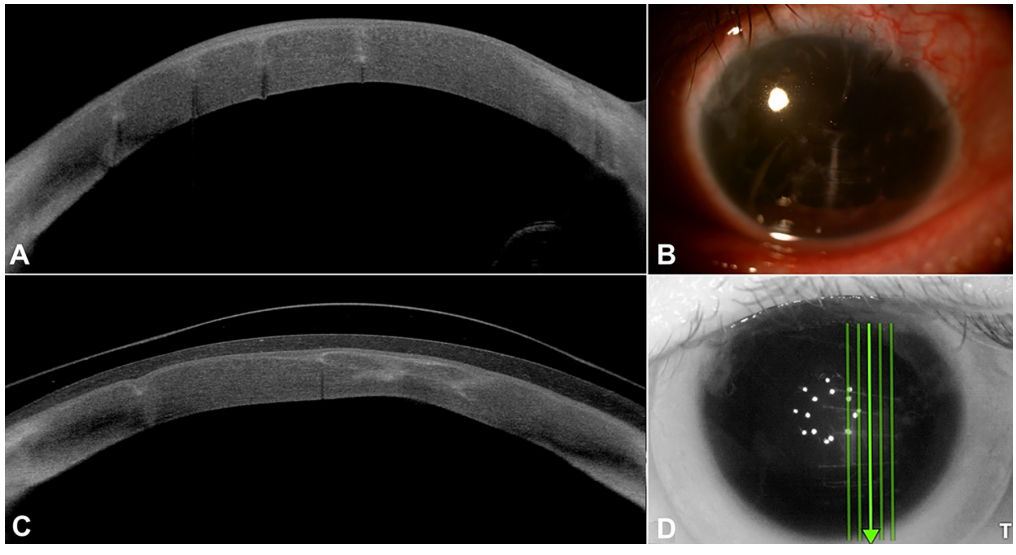

Figure 3. A patient with total aniridia, aphakia, and bilateral corneal perforation repair: A) Anterior segment optical coherence tomography (AS-OCT) before scleral lens fitting. B) Slit-lamp biomicroscopy before fitting. C) AS-OCT 30 minutes after fitting. D) Infrared image 30 minutes after fitting

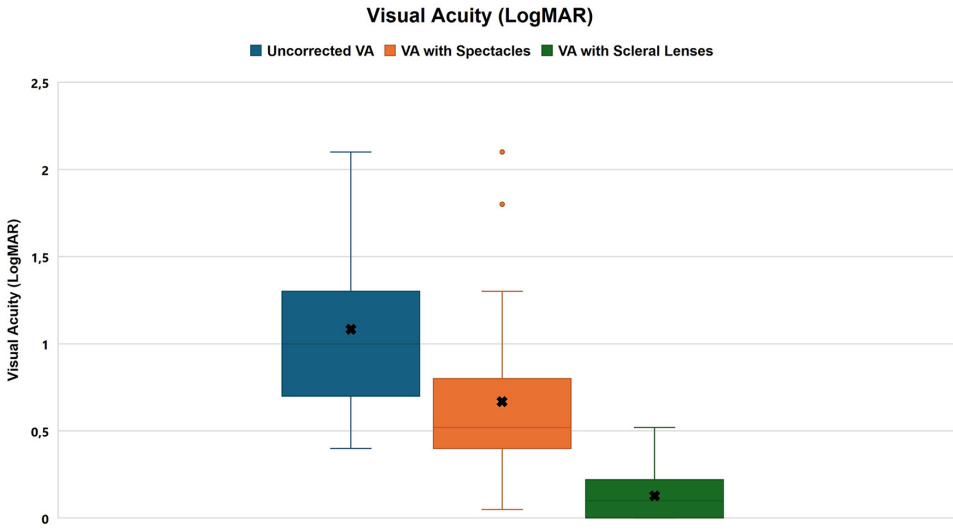

Figure 4. Changes in visual acuity with no correction, spectacles, and scleral lenses
logMAR: Logarithm of the minimum angle of resolution, VA: Visual acuity

Table 2. Characteristics of the patients	
Lens trials (n)	3.65±1.92 (range: 1-8)
Uncorrected VA (logMAR)	1.09*
Spectacle-corrected VA (logMAR)	0.67*
Scleral lens-corrected VA (logMAR)	0.13*
Mean follow-up (months)	52.03±49.04 (range: 12-180)
Mean daily wear time (hours)	9.3±4.5 (range: 2-16)

*p<0.05 (Wilcoxon test), VA: Visual acuity, logMAR: Logarithm of the minimum angle of resolution

Discussion

High and/or irregular astigmatism is the main reason for low vision in patients with keratoconus, pellucid marginal degeneration, keratoglobus, and post-keratoplasty astigmatism. Although soft and RGP lenses may help to improve vision in mild to moderate cases, soft lenses do not work on steeper corneas with advanced disease, and RPG lenses with small diameters simply cannot remain stable on a steep or irregular cornea. They frequently dislocate or bear on the cornea, causing discomfort. Therefore, we may have to offer other alternatives such as piggyback contact lenses, hybrid lenses, and scleral lenses.[11,12,13,14]

Schornack and Patel[12] used Jupiter scleral lenses in the management of keratoconus and reported that median BCVA improved from 20/40 before scleral lens fitting to 20/20 after fitting. They suggested using Jupiter scleral lenses for providing acceptable visual acuity and comfort in patients with keratoconus. Recent studies have also shown the efficacy of scleral lenses in improving vision and quality of life in keratoconus patients. For instance, Marty et al.[13] highlighted the role of scleral lenses in managing irregular corneal conditions, emphasizing their ability to provide superior visual acuity and comfort compared to other contact lens modalities. Our results, show improved visual acuity and better satisfaction with in patients who had previously used RGP and hybrid lenses and were unsatisfied.

Alipour et al.[16] evaluated fitting feasibility, efficacy, and safety of miniscleral contact lenses in correcting vision in patients with corneal grafts. In their study, mean BSCVA before fit was 0.73 logMAR (standard deviation [SD]: 0.50) ranging from 0.09 to 2.00, which improved to 0.17 logMAR (SD: 0.19) with the miniscleral lens. Similarly, Pecego et al.[17] reported positive outcomes using Jupiter scleral lenses in pediatric patients, indicating that scleral lenses can be effectively used across different age groups. In our study, the age of the patients we tested for scleral lenses was between 12 and 71, which supports the literature.

Asena and Altınörs[14] reported the clinical outcomes of scleral Misa lenses for visual rehabilitation in 24 eyes of 12 patients with pellucid marginal degeneration. Mean BCVA improved 3.3 lines with scleral lenses compared to spectacle correction in all patients. Subjective complaints associated with scleral lenses, including discomfort, difficulty with lens insertion and/or removal, and suboptimal quality of vision, were reported by 4 patients (7 eyes, 29%). Rathi et al.[18] discussed recent advancements in scleral lens technology, highlighting improvements in lens materials and designs that enhance patient comfort and visual outcomes.

Parminder and Jacobs[19] evaluated advantages of using scleral lenses for refractive surgery complications in their study and suggested that patients with keratectasia, dry eye syndrome, and corneal neuralgia after refractive surgery benefit from scleral lenses in terms of improved visual acuity and dry eye issues. Additionally, Yuksel et al.[15] successfully fit a patient with corneal exposure secondary to facial nerve palsy with scleral lenses. The spectrum of patients in whom we have tried scleral lenses and had success was diverse; the most common indications

were keratoconus, refractive error after penetrating keratoplasty, irregular astigmatism due to corneal scarring, SJS, dry eye, and postoperative corneal perforation.

Pullum et al.[20] described the current indications for scleral lenses. In their study, 1,560 eyes of 1,003 patients were evaluated, and the total numbers of eyes for each contact lens indication were as follows: primary corneal ectasia, 496 (61.4%); corneal transplant, 150 (18.6%); ocular surface disease, 91 (11.4%); aphakia, 17 (2.1%); myopia, 21 (2.6%); and ptosis, 14 (1.7%). Visser et al.[21] evaluated the subjective performance of modern scleral lenses in 284 eyes of 178 patients. Significantly increased patient scores were noted with the current scleral lens compared to the former correction (78.9% for comfort, 78.2% for visual quality, and 87.7% for overall satisfaction) ($p<0.001$). In the study conducted by Akkaya Turhan et al.[22], the Likert scale was used in patients with keratoconus using mini scleral lenses. A score of 4.69 (range: 4-5) was obtained, which was consistent with the literature. Recent advancements have expanded the indications and improved the outcomes of scleral lens use.[16,18,24,25] Although we did not use any comfort scales, our patients reported satisfaction with their scleral lenses at follow-up visits.

Corneal transplantation (keratoplasty) is widely used for treating corneal diseases such as keratoconus, dystrophy, and corneal scarring. Despite advances in surgical techniques, postoperative astigmatism remains a significant cause of suboptimal visual acuity. Approximately 20% of patients experience high astigmatism after keratoplasty, primarily due to irregularities in the graft-host junction, leading to high-order aberrations.[26,27,28] Suzuki et al.[28] reported that scleral lenses are the most commonly prescribed contact lens type in patients after keratoplasty (61% of 464 eyes studied). Unlike corneal RGP lenses, which rest on the corneal surface, scleral lenses rise above the cornea and rest on the sclera, preventing mechanical pressure at the graft-host junction and reducing the risk of lens-induced trauma.[26,29,30] Scleral lenses provide superior visual rehabilitation after keratoplasty because they mask corneal irregularities. They also provide a protective fluid reservoir that increases ocular surface stability.[28] Studies have reported significant improvement in BCVA with scleral lenses compared with uncorrected visual acuity (UCVA) and conventional BCVA. Barnett et al.[31] reported improved visual acuity from a mean BCVA of 20/50 to 20/25 with scleral lenses compared with spectacles. Kumar et al.[32] reported an improvement from 1.10 logMAR (UCVA) to 0.22 logMAR with scleral lenses. In a study by Penbe et al.[33], visual acuity improved from 1.15±0.26 logMAR (UCVA) and 0.84±0.24 logMAR (with spectacles) to 0.13±0.09 logMAR. Similarly, our postgraft patients had better visual acuity with scleral lenses compared to spectacle correction (0.09±0.10 vs. 0.82±0.64 logMAR).

Subjective comfort levels with scleral lenses were high compared to other types of lenses in postgraft patients. In a study by Lee et al.[34], 82% of patients wore scleral lenses for most or all of their waking hours. Another study found that 75% of patients could wear scleral lenses for more than 10 hours daily.[35] Common complaints of discomfort included difficulty handling the lenses (29%), halos, blurs, or haze (23%), and excessive tear residue in the lens reservoir (23%).[30] In our study, the subjective comfort of postgraft patients was also high, and all of our patients reported better comfort compared other types of lenses.

Some complications were reported in patients wearing scleral lenses after keratoplasty. Corneal graft rejection (5-30%) is a major reported complication.[31,33,35] Although this is a concern, studies suggest that the rejection rate is similar in patients who do not wear contact lenses.[36] Another complication is microbial keratitis (6%).[35,37] Risk factors include overuse, noncompliance with cleaning, and prolonged hypoxia under the lens. The main risk factor for graft edema is low endothelial cell density before lens insertion (6%).[35] However, Penbe et al.[33] found no significant change in endothelial cell density after 6 months of scleral lens use, although caution is advised in patients with preexisting low endothelial cell counts. Our postgraft patients had no complications such as corneal graft rejection or microbial keratitis.

Severe ocular surface disease has been one of the primary indications for large scleral lenses for many years, as they keep the ocular surface moist and protect against dehydration.[16,18,23,24] Alipour et al.[16] reviewed the use of scleral contact lenses in the management of severe ocular surface disease and concluded that they are effective in improving symptoms and ocular surface integrity. The SJS patient in our study reported that in addition to improved visual acuity, she would prefer wearing her scleral lenses just because they significantly alleviated her scratchy and stinging pain complaints due to trichiasis, emphasizing the therapeutic role of scleral lenses in severe ocular surface disease.

Dimit et al.[38] determined the type and distribution of ocular conditions treated in a clinic dedicated to scleral devices and reported the clinical outcomes. The most common reasons for fitting were to relieve symptoms of moderate to severe dry eye syndrome, persistent epithelial corneal defects, SJS, graft-versus-host disease, ocular cicatricial pemphigoid, neurotrophic corneal disease, atopic keratoconjunctivitis, and management of refractive problems with keratoconus.

In our study, the majority of patients experienced significant improvement in visual acuity and comfort with scleral lenses, consistent with findings from recent literature.[14,18,21] The challenges faced by some patients, such as handling difficulties and financial constraints, are also reported in other studies.[14,23] Efforts to improve patient education and reduce costs could enhance the accessibility and acceptance of scleral lenses.

When we review the literature, the follow-up periods of patients who underwent scleral lens trial were reported as 4 to 14 months by Schornack et al.[8], 14.1±3.7 months (range: 8.5-18 months) by Asena and Altınörs[14], 17 months by Schornack and Baratz[9], 22.5 months (range: 3-32 months) by Schornack and Patel[12], and 33.6 months (range: 2-144 months) by Romero-Rangel et al.[11] With a mean follow-up of 29.5±14.5 months (range: 12-48 months), our study has a relatively longer follow-up compared to most of the previous reports, which stands out

as an important aspect.

Two interesting patients in our study group were a woman with SJS and a man who had bilateral corneal perforation after a car accident. He was aphakic and totally aniridic in both eyes. They were both extremely motivated to use scleral lenses despite their poor visual acuity, which caused them extra difficulty in handling. The most striking experience for us was the man who asked if he could have an iris prosthetic aphakic scleral lens. This highlights the potential for customized scleral lenses to address complex ocular conditions, as discussed in recent studies.[25]

Study Limitations

Some limitations of this study are lack of a control group and comfort scale rating for patient feedback, as well as possible selection bias. No control group was included in the study compared to scleral lens users. The study mainly aimed to discuss the results of scleral contact lens fitting in patients with difficult corneal and ocular surface pathologies. At the same time, since it is a single-center study, possible selection bias should not be ignored. In addition, no comfort scale was used to evaluate the comfort results of patients after scleral lenses.

Conclusion

To conclude, scleral lenses are an important option that offer patients comfort and visual rehabilitation. We demonstrated improved vision and better comfort with scleral lenses in patients with keratoconus and grafts as well as patients with severe ocular surface diseases, consistent with recent literature.

Ethics

Ethics Committee Approval: Dokuz Eylül University Hospital Research Ethics Board before data collection and analysis (decision no: 2024/38-22; date: 13/11/2024).

Informed Consent: Retrospective study.

Declarations

Authorship Contributions

Surgical and Medical Practices: Z.Ö., C.A.Y., İ.D., Concept: O.Ö., Z.Ö., Design: O.Ö., Z.Ö., Data Collection or Processing: O.Ö., Analysis or Interpretation: O.Ö., Literature Search: O.Ö., Z.Ö., Writing: O.Ö., Z.Ö.

Conflict of Interest: No conflict of interest was declared by the authors.

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