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Mini-scleral lenses in the visual rehabilitation of patients after penetrating keratoplasty and deep lamellar anterior keratoplasty



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ABSTRACT

Objective: To evaluate fitting feasibility, efficacy, and safety of mini scleral contact lenses in correcting post corneal graft vision.

Methods: Prospective interventional case series, 56 visually unsatisfied post corneal graft eyes of 45 patients were fitted with miniscleral lenses (15.8 mm).

Keratometric values, UCVA and BSCVA, fit, best corrected vision with the lens, decision to order lens, comfortable daily wearing time (CDWT), contact lens handling issues, and contact lens related complications were documented.

Results: The mean age was 34.6 years (SD: 10.9), ranging from 8 to 63 years. Forty-three eyes had history of full thickness corneal graft, 12 eyes had deep anterior lamellar graft (DALK) and 1 eye had the rotational graft. The mean UCVA was 1.05 logMar (SD: 0.54), ranging from 0.30 to 2.52 logMar. The mean BSCVA was 0.73 logMar (SD: 0.50) ranging from 0.09 to 2.00 which improved to 0.17 logMar (SD: 0.19) with the miniscleral lens. All eyes had ideal (40 eyes) or acceptable (16 eyes) fits. Nineteen patients (23 eyes) ordered their lenses of whom 11 (14 eyes) continued using the lens with a mean follow up time of 21.92 months (SD: 6.8). These patients reported a mean CDWT of 9.62 h/day (SD: 4.5). Five eyes of 4 patients discontinued the lens. Four eyes were lost to follow-up. The main reported barriers for ordering the lenses were economic and handling concerns.

Conclusion: Miniscleral contact lenses can be considered helpful in the visual management of post corneal graft patients. Other factors may influence the acceptance of the lenses.

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1. Introduction

Keratoplasty – either penetrating or lamellar [1–3] – has many indications which are mostly optical. In corneal scars, removing optical barriers is the only way to improve vision [4–7]. Management of highly irregular corneas such as advanced stages of keratoconus or repaired cornea after full thickness laceration is challenging with few options available other than keratoplasty [4,8–11]. Unfortunately, however, the unaided visual result of keratoplasty in a significant percentage of these patients is still far from satisfactory. Up to 4 diopter (and even more) astigmatism, both regular and irregular, is very common [1,12,13]. Although femtosecond laser assisted surgery seems promising [14,15], many post graft patients need some means other than spectacles to improve their vision [16,17]. Re-suturing, astigmatic keratotomy – either

manual or femtosecond laser assisted, corneal inlays, toric IOLs, and keratorefractive surgery are surgical options that can be used for improving vision [16,18–24] but further surgical interventions are neither effective/feasible nor acceptable (at least from patients' point of view) in many cases.

Corneal RGP contact lenses have been used for correcting these refractive errors [17,25] which have proved effective in some patients and ineffective in others due to the high level of irregularity of the cornea or astigmatism; therefore, contact lenses with a special back surface design have been proposed [26,27]. Reverse geometry lenses are the most popular types of these lenses which should be used for flat corneas [28,29]. Considering the fact that the pattern of irregularity is not similar in these patients [25,30], and fitting procedure is time consuming and difficult, these types of contact lenses have not gained wide clinical acceptance.

Miniscleral GP lenses, with their potential to vault the whole cornea, have the ability to correct refractive errors and even many higher order aberrations resulting from the irregularity of the anterior surface of the cornea in challenging situations such as advanced keratoconic patients, post-Intacs patients, and post-penetrating

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keratoplasty patients [31–33]. Fitting of these lenses is relatively easy [32] and because of their large diameter (15–18 mm), they are very well centered in the eye and usually well tolerated. In this manuscript, we reported the results of miniscleral contact lenses for correcting unsatisfactory visual outcomes of post corneal graft patients. Tolerance and safety in those patients who continued to wear the lenses are also reported.

2. Methods

In this prospective interventional case series, 56 post corneal graft eyes of 45 visually unsatisfied patients who were referred to Farabi Eye Hospital Contact lens Clinic for contact lens fitting were fitted with miniscleral lenses.

The parameters of the trial set were as follows:

- Mini scleral design (MSD) (Blanchard Contact Lens Inc., Canada); non-fenestrated; diameter: 15.8 mm.
- Sagittal vault ranging from 3.80 mm to 5.60 mm; each in three different profiles (decreased, standard, and increased).
- Material: Boston XO DK/T: 100 (ISO/Fatt), 141 (gas to gas).

These patients had neither acceptable visual acuity with spectacles, nor could be fitted with corneal RGP lenses (diameter ranging from 9.30 to 11 mm).

The fit was assessed by a single contact lens practitioner experienced in this field after 5 min and then again after at least 30 min of wearing and was evaluated as:

- Ideal: no touch over the entire cornea in the fluorescein pattern viewed under a cobalt light, vaulting between 100–200 μm evaluated by a 30° oblique slit lamp beam (from the midline), no impingement over conjunctival vessels.
- Acceptable: no corneal touch and minimal scleral impingement, i.e. less than 3 h mild conjunctival impingement.
- Bad: corneal touch with maximum available sagittal vault and/or more than 3 h conjunctival impingement.

The patients with either ideal or acceptable fit were allowed to use the lenses for more than 1 h and were then inquired about subjective satisfaction. Then, the lens was prescribed for the patients with either ideal or acceptable fit. The patients who started wearing their lenses were followed regularly for CDWT, contact lens handling issues, visual acuity, and any subjective or objective contact lens related complication.

The recorded data was analyzed using SPSS version 16.0. For analysis, we used Mann Whitney *U* test to compare the average of the variables between DALK and full thickness graft groups. *P*-values less than 0.05 were considered statistically significant.

The study was approved by the Ethics Committee of Eye Research Center, Tehran University of Medical Sciences. As Miniscleral lenses are standard lenses for correcting highly irregular corneas, and we are reporting our routine practice pattern, there were no ethical issues to consider.

3. Results

Fifty-six eyes of 45 visually unsatisfied post corneal graft patients were fitted with miniscleral lenses. Twelve patients (17 eyes) were female and 33 patients (39 eyes) were male. Twenty-eight eyes were right eyes and 28 were left eyes (Fig. 1).

The mean age of the participants was 34.6 years (SD: 10.9), ranging from 8 to 63 years. Demographic and keratometric data are summarized in Table 1.

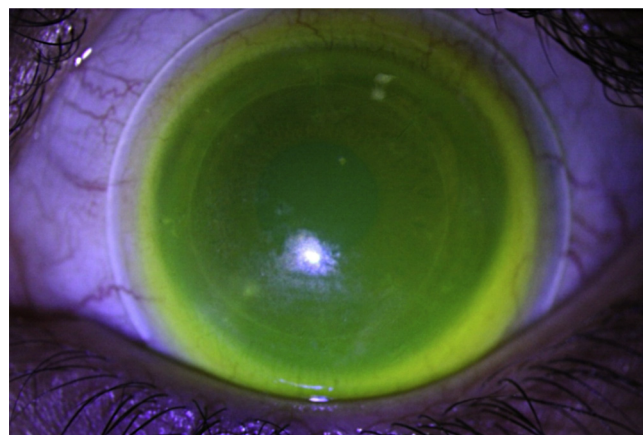


Fig. 1. Ideal miniscleral lens fit.

The background diseases leading to corneal graft were keratoconus in 36 patients (44 eyes), post Lasik ectasia in 4 patients (7 eyes), chemical burn in 2 patients (2 eyes), corneal scar due to repaired sharp penetrating trauma in 2 patients (2 eyes) and pellucid marginal degeneration in one patient (1 eye).

Forty-three eyes received full thickness corneal grafts, 12 eyes underwent deep anterior lamellar grafts (DALK), and one 8-year-old patient had a history of a rotational graft for displacing the dense scar of the visual axis (Fig. 2).

The mean uncorrected visual acuity (UCVA) was 1.05 logMar (SD: 0.54); which improved to 0.17 logMar (SD: 0.19) after MSD fitting (*P* value <0.001). The difference between two subgroups (full-thickness versus deep anterior lamellar graft) regarding in visual acuity improvement was not statistically significant. Table 1 shows more details on visual results. Table 2 summarizes fitting data based on the background.

All eyes had ideal (40 eyes) or acceptable (16 eyes) fits. The lenses were prescribed for all patients but only 19 patients (23 eyes) ordered their lenses. The three main reasons patients mentioned for refusing to order the lens were affordability, fear of difficult handling, and the long waiting period for receiving the ordered lens. The waiting period for receiving the lens is normally 2–3 months, but it raised to more than 6 months sometimes during this study due to economic sanctions. There was no significant difference in visual gain or fit assessment between those who ordered the lenses and those who refused to order.

Fourteen eyes of 11 patients continued wearing their lenses, which means a 25% success rate. The mean follow-up of these patients was 21.92 months (SD: 6.8).

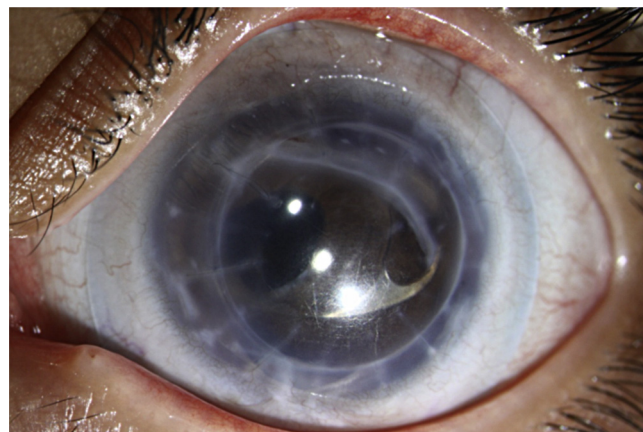


Fig. 2. Miniscleral lens on the eye with rotational graft.

Table 1
Visual and keratometric data.

	Total N=56		Full Thickness graft N=44		Lamellar graft N=12		P value
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	
Age (year)	34.49 (11.90)	8–63	37.07 (11.38)	21–63	28.29 (7.06)	20–41	0.022
Keratometry (mm)							
Mean K	7.45 (0.83)	6.30–10.15	7.58 (0.92)	6.30–10.15	7.07 (0.28)	6.75–7.75	0.158
K1	7.57 (0.89)	6.00–9.90	7.69 (0.98)	6.00–9.90	7.18 (0.40)	6.80–8.00	0.158
K2	7.28 (1.05)	5.80–10.40	7.39 (1.17)	5.80–10.40	6.96 (0.35)	6.45–7.80	0.527
Diff K	0.81 (0.49)	0.00–2.32	0.88 (0.53)	0.00–2.35	0.62 (0.29)	0.26–1.00	0.347
Visual acuity (LogMar)							
UCVA ^a	1.06 (0.59)	0.3–2.5	1.09 (0.63)	0.30–2.52	1.20 (0.58)	0.69–2.52	0.07
BSCVA ^b	0.76 (0.50)	0.09–2.0	0.77 (0.56)	0.09–2.00	0.82 (0.49)	0.15–1.40	0.75
BCVA with MSD ^c	0.17 (0.18)	0.0–1.0	0.17 (0.17)	0.00–1.00	0.13 (0.12)	0.00–0.39	0.28

^a Uncorrected visual acuity.^b Best spectacle visual acuity.^c Best corrected visual acuity with mini scleral design lens.**Table 2**
Fitting data.

	Full thickness graft	Lamellar graft	Total
MSD ^a Sag ^b , number of eye (D, S, I) ^c			
<4.2	2 (1; 0; 1)	0 (0; 0; 0)	2 (1; 0; 1)
4.2–4.8	16 (0; 9; 7)	5 (0; 4; 1)	21 (0; 13; 8)
≥5	9 (0; 1; 8)	3 (0; 0; 3)	12 (0; 1; 11)
MSD power, (Diopter)			
Mean; SD	–6.58; 5.14	–8.12; 3.56	–6.93; 4.82
Range	–21.00 to +2.00	–13.50 to –3.00	–21.00 to +2.00
Fit assessment (number of eyes)			
Ideal	17	4	21
Acceptable	10	2	12
Bad	0	0	0

^a MSD: mini scleral design contact lens.^b Sag: sagittal vault.^c D: decreased; S: standard; I: increased.

These patients reported a mean CDWT of 9.62 h/day (SD: 4.5). Four eyes of three patients were lost to follow-up and no information from them was available after one month. Five eyes of 4 patients discontinued wearing the lenses. The failure reasons were contact lens intolerance in two eyes of one patient, difficult handling in 1 eye of one patient, and economic reasons in 1 eye of 1 patient (the patient broke her lens after 3 months and could not afford to buy another one). Except for asymptomatic conjunctival folds which were observed in some patients in at least one visit, the only contact lens related problems were conjunctival hyperemia and contact lens intolerance after 3 h of wearing the lenses in two eyes of one patient. Other patients did not report any contact lens related complications during the follow-up period. No graft related complications (including rejection or decompensation) were documented or reported in our follow-up visits or from the original corneal surgeon during the follow-up period. All patients had annual specular microscopy and none of them had endothelial cell counts less than 1500 which is considered our alert sign for discontinuation of the lens. Unfortunately, pre fit specular data was not available in none of the cases to analyze.

4. Discussion

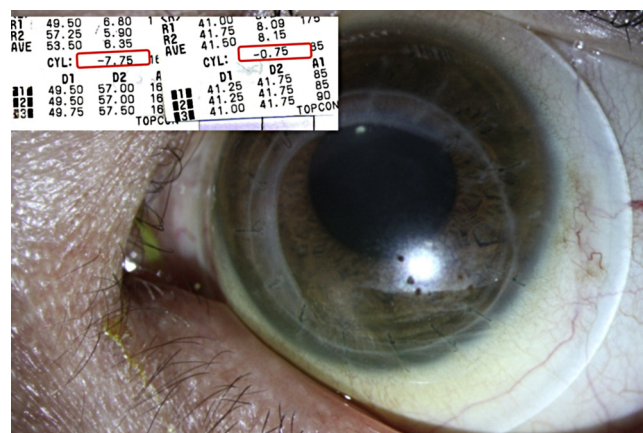
We are reporting feasibility, efficacy, and safety of miniscleral contact lenses in correcting post corneal graft vision which could not be corrected with spectacles or smaller diameter corneal RGP lenses. According to our results, miniscleral lenses could dramatically increase best corrected visual acuity in these patients (Fig. 3).

The indication of the corneal graft was optical in all of our patients, either to remove an optically significant opacity or to reshape the cornea to a more regular shape. Unfortunately, corneal

grafts are still far from excellent unaided visual results in a significant percentage of patients – as in our series.

Fitting of the miniscleral lenses was feasible in all our cases, achieving either an ideal or acceptable fit with subjective comfort after 1 h of trial. All of our patients could be fitted in one session although this session took 3 h in some cases. None of the patients who ordered and received their lenses needed to reorder their lens parameters.

Our patients achieved a significantly better corrected visual acuity with miniscleral lenses when compared to spectacles, which could be due to the fact that significant degrees of irregular astigmatism was present in these cases that could be corrected with miniscleral lenses.

**Fig. 3.** Miniscleral lens on the eye with eccentric graft due to pellucid marginal degeneration.

It was not surprising that less than half of our patients ordered their lenses and even a lower percentage (25%) continued wearing their lenses – which is much less than other reports from other centers [34–36]. Our center is a governmental center and most of our patients are from lower socioeconomic classes of the society. The reasons they mentioned for refusing to order their lenses were economic issues and fear of difficult handling of the lenses in their living and work environments. As there was no difference in the visual gain and fit assessment between those who ordered the lenses and those who refused to, the role of socioeconomic factors – including affording the lens expenses which is not covered by insurance companies for the time being, fear of contamination in their unclean occupational environments, visual needs and self-esteem for handling the lens – becomes obvious. Most of the patients who ordered the lenses used them successfully with nocontact lens related complications. Schornack and Patel also reported that 38% of their patients refused to use scleral lenses and the main reasons in their report were either good uncorrected or best spectacle corrected visual acuity or unremarkable visual gain due to corneal or lens opacity, plus handling concerns. Only one of their patients refused to order the lens due to economic issues (lack of insurance) [36]. As we excluded those with good spectacle corrected acuity from the beginning, our success rate could be considered even lower.

The rate of complications in our series was much less than the rate reported by Severinsky et al. [34] which is most possibly attributable to their longer follow-up period and longer graft age. Although we did not document the exact graft age in our series, most of our patients had a history of graft surgery one to two years before referral. Another less possible factor might be the lens size since full scleral lenses (18.5–19 mm) were dispensed in the above mentioned study which are about 3 mm larger than what we dispensed for our patients. The mean reported comfortable daily wearing time was almost 10 h per day which is pleasing for most activities. This finding is in line with other studies. Handling issues may be dealt with considering extra chair time for training patients. In a series of severe dry eye patients, we showed that handling miniscleral lenses was not an important problem after one month even in patients with a severe ocular surface disease [37].

Achievement of excellent visual results with miniscleral lenses can be promising in managing visually unsatisfied post corneal graft patients. It is especially important since many surgical interventions for correcting post graft astigmatism are designed to correct regular astigmatism [16] and there are few options left for correcting irregular astigmatism.

While conventional corneal RGP lenses cannot mask irregularity arising from peripheral cornea and/or higher amounts of either regular or irregular astigmatism in post graft patients, miniscleral lenses with the ability of vaulting the whole cornea can be very effective in these cases.

The main limitations of our study were its small sample size and not including patients from middle and high socioeconomic classes.

To summarize, although most post penetrating keratoplasty or DALK patients can be fitted successfully with mini-scleral lenses to gain excellent visual results, other factors also affect the patients' decisions to decline this option despite its good impact on visual acuity in the affected eye.

Financial disclosure

None of the authors has any related financial interests.

Conflict of interest

None declared.

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