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# Use of mini scleral contact lenses in moderate to severe dry eye

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ABSTRACT

*Objective:* To evaluate fitting feasibility and efficacy of mini scleral contact lenses in moderate to severe dry eye patients.
*Methods:* Prospective interventional case series, this study included those patients with grades III and IV dry eye disease, whose symptoms could not be controlled by conventional treatments. Demographic data, UCVA, BSCVA were evaluated before fitting. Mini scleral lens fit was assessed by single experienced practitioner and best corrected vision with mini scleral lens was assessed. After dispensing mini scleral lens, BCVA with mini scleral lens, and possible contact lens related problems were assessed in each visit. Ocular comforts, frequency of artificial tear use, contact lens handling problems were asked in each follow up visit. For those who did not choose to wear lenses, the reason was asked. All data were analyzed using descriptive statistical tests.
*Results:* Twenty eyes of 13 patients were fitted. Mini scleral lens was dispensed for 19 eyes in them assessment of fit was either ideal ($n=9$) or acceptable ($n=10$). Seven patients got their lenses; four patients (seven eyes) of them were satisfied with their lenses based on decrease in discomfort and dry eye symptoms, decrease artificial tear need frequency and improvement in visual acuity during mean follow up period of 18.25 months (range: 15–20). None of them was affected with any contact lens related complication.
*Conclusion:* Mini scleral contact lenses can be considered helpful in management of moderate to severe dry eye.



## 1. Introduction

Dry eye is very common disease [1–3]. Severe dry eye, though less frequent [4], is a challenging disease for ophthalmologists to manage [5]. Despite a brighter horizon that newer medications and ocular surface surgeries provided [6,7], our patients still suffer and have to use frequent non preserved lubricating drops [5,8]. Possible complications also add further concerns [9]. Prevalence of dry eye seems to be increasing [10]. Even ignoring mild dry eye which is very common, moderate to severe cases can arise due to many causes such as Sjogren syndrome, rheumatoid arthritis, Stevens Johnson syndrome, Graft Versus Host Disease (GVHD), mucous membrane pemphigoid, chemical burn, post radiotherapy, frequent use of topical medications [11], viral diseases, post-LASIK dry eye disease and even computer and visual display terminal use.

Various modalities have recently been added to the ophthalmologists' armamentarium to treat moderate to severe dry eye. These include topical cyclosporine A in different concentrations (0.05 [12–14] or 0.1%) [15] and frequencies [16], plasma rich in growth factors (PRGF) [17], combined 0.05% cyclosporine and 1% methylprednisolone [18], CF101 [19], resolvin E1 [20], fatty acid and androgen supplementation and oral antibiotics [21], and ocular iontophoresis of EGP-437 [22]. Besides medical treatments, different surgical interventions from punctual occlusion either with plugs [23,24] or surgical methods [25], to more extensive ocular surface surgeries such as amniotic membrane transplantation [26] or labial salivary gland transplantation [27–29] have been proposed for management of refractory cases of dry eye and other new methods such as reduced submandibular glands [30] or thermodynamic treatments [31] also seem promising.

Another modality that has been used for cases with refractory dry eye is scleral contact lens. Scleral contact lenses have shown to be safe and effective in managing dry eye symptoms [32–37] by providing a fluid cushion for the cornea to rest in and protecting cornea from the rubbing effects of the keratinized lids. This may result in regression of the disease, at least partly, by breaking the vicious circle of inflammation. The regular advantage of any RGP contact lens, which is the ability to mask irregular astigmatism plus providing an optical correction, seems even more exploitable in these patients with corneas suffering from irregularities arising from scars and neovascularization. Unfortunately

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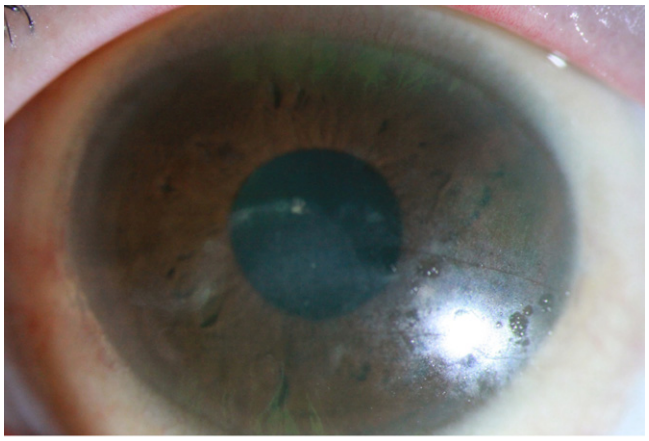
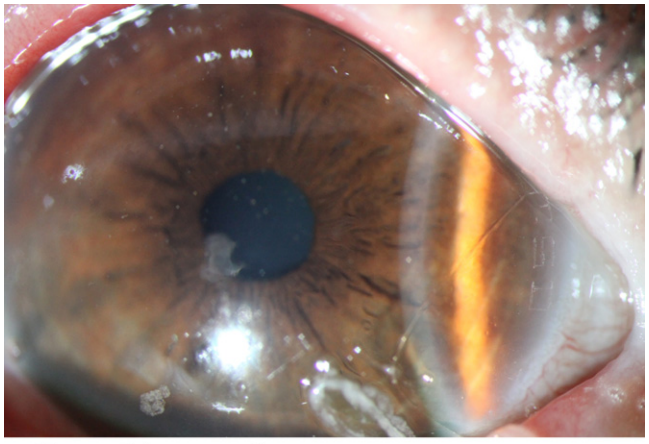


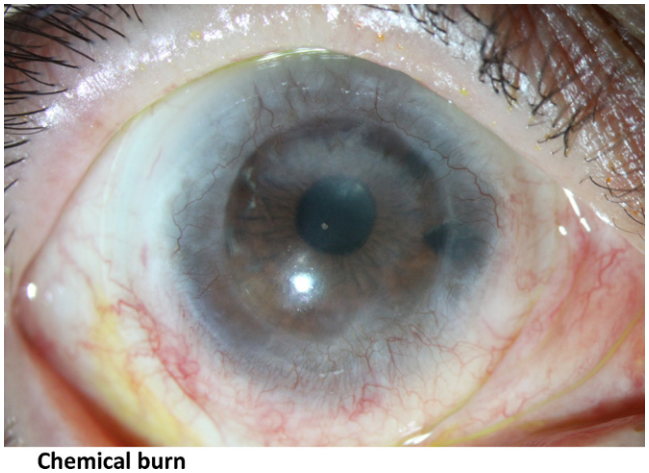
Herpetic neurotrophic keratopathy

**Fig. 1.** Herpetic neurotrophic keratopathy.



Stevens Johnson syndrome

**Fig. 2.** Stevens Johnson syndrome.



Chemical burn

**Fig. 3.** Chemical burn.

though, some disadvantages resulted in under usage of this very helpful modality of treatment in dry eye patients. Scleral contact lenses are large (18–24 mm) and sometimes difficult to fit in patients with ocular surface disease who may have shortened fornices and multiple conjunctival problems such as secondary pterygium and symblepharon. They are also expensive and have to be customized. Difficulty handling is another barrier.

Mini scleral contact lenses are smaller (15–18 mm), and so easier to fit and handle in these patients, more available, less expensive and can be ordered based on a trial set. Although their smaller size results in smaller fluid reservoir, theses advantages motivated us to try these lenses in our patients with severe dry eye. There are a few reports to support our idea [38].

## 2. Materials and methods

In this prospective interventional case series, which was approved in Eye Research Center Ethics Committee (Farabi Eye Hospital, Tehran, Iran); we fitted mini scleral lenses with the below parameters, in patients with moderate to severe dry eye who were referred to the Contact lens Clinic, Farabi Eye Hospital, Tehran, Iran, from February 2010 to November 2011. This study included those with grades III and IV dry eye disease based on DEWS report [39] (with Schirmer test 5 mm or less in grade III and 2 mm or less in grade IV) whose symptoms could not be controlled by conventional treatments including frequent non-preserved artificial tear, permanent occlusion of four puncta and use of autologous serum drops. Patients with the followings were excluded from the study: presence of other ocular disease such as glaucoma, corneal decompensation, active infectious ulcer or persistent epithelial defect.

For fitting mini scleral lens contact lenses, a trial set with following parameters were used:

- Mini scleral design (MSD) (Blanchard Contact Lens Inc., Manchester, Canada)
- Non-fenestrated
- Diameter: 15.8 mm
- Available sagittal vaults: 3.80 mm to 5.60 mm; each in three different profile:
  - D (Decreased)
  - S (Standard)
  - I (Increased)
- DK/T: 100 (ISO/Fatt), 141 (gas to gas)
- Power: Plano, available powers from −20 to +20 diopter.

Fit was assessed with single contact lens practitioner experienced in this field and was evaluated as:

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

Those patients with either ideal or acceptable fit were allowed to wear lenses for more than 1 h and report subjective satisfaction.

Before fitting and in each visit during the follow-up, all patients underwent a complete ophthalmologic examination including measurement of uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) with mini scleral lens and slit lamp examination. Patients were also asked about frequency of artificial tear use with and without mini scleral lenses. At one month after mini scleral lens wear, patient satisfaction was also evaluated based on a subjective measurement of ocular discomfort from 0 (not at all) to 5 (very severe) with and without lens. Moreover, patient's problems in handling mini scleral lens were also asked by 3 different questions:

1. Difficulty handling at the first month

**Table 1**
Demographic and fitting data.

| | Group 1 | Group 2 | *P* value | Overall |
|---|---|---|---|---|
| Age (year) | | | | |
| Mean | 41.57 | 42.7 | 0.82[a] | 42.4 |
| Range | 34–52 | 8–65 | | 8–65 |
| M/F | 2/2 | 3/6 | | 5/8 |
| UCVA (mean, range)logMar | 0.75 (0.15–1.2) | 0.97 (0–3) | 0.67[a] | 0.89 (0–3) |
| CCVA with MSD (mean, range)logMar | 0.18 (0 0.4) | 0.22 (0–1) | 0.94[a] | 0.21 (0–1) |
| Keratometry (mm) | | | | |
| Mean (mean, range) | 7.40 (7.20–8.00) | 7.45 (7.00–7.90) | 0.89[a] | 7.43 (7.00–8.00) |
| Diff (mean, range) | 0.50 (0.0–0.90) | 0.34 (0.0–0.60) | 0.44[a] | 0.38 (0.00–0.90) |
| Too irregular (number of eyes) | 2 | 3 | | 5 |
| MSD sagittal vault | | | | |
| Mode | 4.00 | 4.20, 4.40 | | 4.40 |
| Range | 4.00–4.40 | 3.80–4.60 | | 3.80–4.60 |
| Peripheral profile: D, S, I (number of eyes) | 0, 4, 3 | 1, 4, 8 | | 1, 8, 11 |
| Fit assessment (number of eyes) | | | | |
| Ideal | 3 | 6 | 0.76[b] | 9 |
| Acceptable | 4 | 6 | | 11 |
| Bad | 0 | 1 | | 1 |
| Previous ocular surface surgery (number of eyes) | | | | |
| Yes | 6 | 6 | | 12 |
| No | 1 | 7 | | 8 |

[a] Mann Whitney *U* test.
[b] Fisher's exact test.
(Group 1: patients who continued wearing their lenses. Group 2: patients who did not order or continued wearing lenses. UCVA: uncorrected visual acuity. CCVA: corrected visual acuity).

2. Difficulty handling after one month
3. Needing help for insertion/removal after one month

Overall patient subjective satisfaction was also asked in a scale of 0 (No visual or comfort gain) to 5 (very satisfied).

## 3. Results

Twenty eyes of 13 patients were fitted. The underlying disease was Stevens Johnson syndrome (4 cases), GVHD (2 cases), rheumatoid arthritis, chemical burn, Sjogren's syndrome, herpetic neurotrophic keratopathy, post radiotherapy, lagophthalmous due to seventh cranial nerve palsy and idiopathic each in one case (Figs. 1–3).

Mini scleral lens was dispensed for 19 eyes in them assessment of fit was either ideal ($n = 9$) or acceptable ($n = 10$). The lens was not dispensed for one eye of one patient because of failure to fit. Seven patients (12 eyes) ordered the lenses. The other six patients refused to order the lenses because of the fear/difficulty handling, economic issues, and recommending other modalities such as further surgical interventions by the original physician after considering economic issues and fear of difficulty handling. Although all of these patients were concerned about difficulty handling and economic issues, 4 of them rechecked it with their original physician and not ordering the lenses was their physicians' decision.

Demographic and fitting data are shown in Table 1. These 13 patients included 8 females and 5 males with a mean age of 42.4 years (range, 8–65 years). Mean follow-up period of those patients using their lenses was 18.25 months (range: 15–20 months).

Eleven patients (16 eyes) were emmetropic before initiation of their ocular surface disease and at the time of referral.

Detailed information of those patients who got and wore their lenses is shown in Table 2. Of those seven patients who got their lenses, four patients (seven eyes) of them were satisfied with their lenses based on decrease in discomfort and dry eye symptoms, decrease artificial tear need frequency and improvement in visual acuity. One patient who was suffering from acute SJS and were fitted under tarsorraphy, when got her lenses and wore it after opening her tarsorraphy, found it to be too steep, so the fit was revised and new lenses were ordered. During this waiting period for getting the second pair of mini scleral lenses, the patient's symptom improved significantly and though she felt new lenses comfortable but did not need them too much anymore. One patient who got lenses for both eyes did not come back for follow up.

Reported comfortable daily wearing times were all day long (12–14 h) in 6 eyes and 5–7 h in 2 eyes. Despite 5–7 h comfortable daily wearing time, one patient discontinued lens use after one month because of difficulty handling and not satisfactory visual gain – this patient was the one suffering from GVHD and with inadequate visual gain in that eye (though increasing from finger count at 3 m to 20/70, but still limited because of the corneal scar) and having good vision in the other eye, the patient was scheduled for penetrating keratoplasty by the primary ophthalmologist.

## 4. Discussion

In our study those patients who continued to wear their lenses found it easy to handle after a short period and needed no help for handling their lenses after the initial period. All of them reported significant subjective visual/comfort gain of wearing lenses and 6 eyes out of 7 eyes reported all day long comfortable daily wearing time. Three out of four reported decreased frequency artificial tear use over their lenses. The impact of mini scleral lenses on quality of their life was also significant the most dramatic one was leading to return to work and normal life after 2 years of disability in one engineer patient suffering from depression besides ocular consequences of chemical burn.

The most common reason for avoiding ordering the mini scleral lenses was the original physicians' recommendation after hearing patients' concerns regarding fear/difficulty handling and cost effectiveness. We believe that if the physicians become more optimistic about the safety and efficacy of these lenses more patients will get advantage of this modality of treatment.

Scleral contact lenses have shown to be safe and effective in these patients [32,35–37]. Boston Scleral Lens Prosthetic Device reduces pain, photophobia and increases quality of life in patients suffering from severe dry eye [32]. So scleral contact lenses are now considered as a standard mode of treatment. They have been reported to increase quality of life, visual acuity and ocular comfort [32,35]. Unfortunately there are some drawbacks that results

**Table 2**
Clinical data of patients who got and wore MS lenses.

| | Patient 1 | | Patient 2 | | Patient 3 | | Patient 4 |
|---|---|---|---|---|---|---|---|
| Back ground | SJS | | SJS | | Chemical burn | | Herpetic neuropathy |
| Sex | Male | | Female | | Male | | Female |
| Age | 34 | | 52 | | 38 | | 43 |
| Follow up | 20 | | 20 | | 15 | | 18 |
| | OD | OS | OD | OS | OD | OS | OS |
| Previous ocular surface surgeries | Multiple | Multiple | Multiple | Multiple | Multiple | Multiple | No |
| UCVA[a] | 20/400 | 20/100 | 20/40 | 20/100 | 20/200 | 20/100 | 20/200 |
| BSCVA[b] | 20/400 | 20/100 | 20/30 | 20/63 | 20/200 | 20/100 | 20/200 |
| CVA with MSD[c] | 20/50 | 20/50 | 20/20 | 20/20 | 20/20 | 20/25 | 20/40 |
| Comfortable daily wearing time (h) | 12–14 | 12–14 | 6–8 | 12–14 | 12–14 | 12–14 | 12–14 |
| Discomfort without lens (on a scale of 0–5) | 4 | 4 | 4 | 5 | 4 | 4 | 4 |
| Discomfort with lens (on a scale of 0–5) | 2 | 2 | 1 | 3 | 2 | 2 | 1 |
| Frequency of artificial tear use/without lens (every . . . hour) | 2 | 2 | 1 | 1 | 2 | 2 | 2 |
| Frequency of artificial tear use/with lens (every . . . hour) | 2 | 2 | 3–4 | 2–3 | 4 | 4 | 6 |
| Subjective gain | Good | | Excellent | | Excellent | | Excellent |
| Impact on quality of life | Better functioning at school | | Return to work | | Independence in daily living activities | | Better functioning at work |
| Handling | | | | | | | |
| First month | Difficult | | Easy | | Difficult | | Easy |
| Thereafter | Easy | | Easy | | Easy | | Easy |
| Need to assistance | No | | No | | No | | No |

[a] Uncorrected visual acuity.
[b] Best spectacle corrected visual acuity.
[c] Corrected visual acuity with mini scleral lens.

in under usage of these lenses. These lenses are expensive (almost ten times more expensive than mini scleral lenses), have to be ordered only in a few certified clinics – so not worldwide available. Their fitting process is also more time consuming. Mini scleral lenses are smaller so can provide smaller fluid reservoir but on the other hand are easier to fit and handle and less expensive. So as our study showed they can also be effective in the management of dry eye. The first mechanism that family of scleral contact lenses can help dry eye patients is providing a fluid cushion over the cornea by vaulting all through it, this results in decreased need of lubricating drops and providing an opportunity for the dried cornea to heal. As production of mediators such as matrix metalloproteinase-9, IL-1Ra, IL-6, IL-8/CXCL8, TNF-alpha and EGF is associated with clinical parameters [40–42], the resulting improvement itself may break the vicious circle of inflammation. Another mechanism that is of considerable help in these family of lenses is protecting cornea against rubbing hazards of the keratinized lids and possible trichiasis in these patients suffering from severe ocular surface problems. The only difference regarding these mechanisms is that the fluid reservoir that scleral contact lenses can provide is larger than mini scleral ones, but even this smaller reservoir in our study was shown to be effective in decreasing ocular discomfort and frequency of using lubricating drops. The optical advantage of these lenses was also dramatic, even in those patients who used to be emmetropic before starting of the disease. This can shows us the optical effects of severe dry eye resulting from tear lens instability, and irregularities arising from punctuate epithelial erosions or corneal scars.

The limitation of our study is small number of patients who continued wearing their lenses.

In conclusion our results support the idea that mini scleral lenses can be considered safe and effective in the management of severe dry eye. Although like scleral lenses, difficulty handling and economic issues restrict their usage, even with these smaller, less expensive lenses.

## Financial disclosure

None of the authors has any related financial interests.

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