The Use of the Esclera Scleral Contact Lens in the Treatment of Moderate to Severe Dry Eye Disease

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• PURPOSE: To evaluate the efficacy of the Esclera scleral contact lens (SCL) treatment and its impact on clinical testing for moderate to severe dry eye disease (DED).
• DESIGN: Prospective interventional case series.
• METHODS: A total of 41 eyes from 25 patients with moderate to severe DED were evaluated for the Esclera SCL treatment. Best-corrected visual acuity (BCVA), tear osmolarity, the Schirmer I test, tear film breakup time (TBUT), corneal and conjunctival staining, meibomian grading, and Ocular Surface Disease Index and SF-36v2 questionnaires were assessed before and after the SCL treatment. These values were compared to assess the real benefit of using SCL as a treatment for DED.
• RESULTS: Forty-one eyes from 25 patients were fitted with SCL for management of DED. The underlying diseases were Stevens-Johnson syndrome (22 eyes), Sjogren syndrome (11 eyes), *graft-vs-host disease* (2 eyes), dry eye after keratomileusis in situ (2 eyes), and undifferentiated ocular surface disease (4 eyes). BCVA improved from 0.703 ± 0.55 logMAR with habitual correction to 0.406 ± 0.43 logMAR with SCL ($P < .001$). There was a significant decrease in tear osmolarity values (338.1 ± 27.1 to 314.25 ± 38.8 mOsm/L, $P < .001$) and van Bijsterveld scores (3.63 ± 2.33 to 2.63 ± 2.46 grade, $P = .015$) between the baseline and 12 months after SCL wear. There were also significant improvements in dry eye symptoms and quality of life as assessed by the OSDI and SF-36v2 questionnaires (both with $P < .001$).
• CONCLUSIONS: The Esclera SCL treatment had a positive impact on tear osmolarity and van Bijsterveld score, as well as an improvement in the patients' BCVA, dry eye symptoms, and quality of life. (Am J Ophthalmol 2016;163:167–173. © 2016 by Elsevier Inc. All rights reserved.)

DRY EYE DISEASE (DED) IS DEFINED AS "A MULTIFACtorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability, with potential damage to the ocular surface."[1] DED is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface and is a common disorder that occurs more frequently in women than in men. This disorder affects a significant percentage of the population, especially among adults over 40 years of age. The prevalence is similar across countries worldwide, with rates between 7% and 33%.[2]

Conventional treatments for DED include the application of artificial tears, topical corticosteroids or cyclosporin A, therapeutic soft contact lenses, and surgical procedures such as punctal occlusion and tarsorrhaphy.[3,4] However, despite these therapies, many patients complain of persistent symptoms and continue to show signs associated with ocular surface changes. Additionally, the use of scleral contact lenses (SCLs) has been recognized as an alternative for the treatment of these patients.[5–10]

SCLs are large-diameter, rigid, gas-permeable devices that are completely supported by the sclera and that vault the cornea and limbus. SCLs maintain a fluid reservoir in the space between the posterior surface of the lens and the anterior surface of the cornea. The unique fitting characteristics of SCLs enable the protection of the ocular surface from shear forces generated by eyelid movement over the cornea and provide continuous hydration of the ocular surface.[10,11]

The purpose of this study was to evaluate the impact of wearing the Esclera SCL on dry eye and quality of life in patients with moderate to severe DED.

METHODS

THIS PROSPECTIVE INTERVENTIONAL CASE SERIES WAS approved by the Ethics Committee of Federal University of Sao Paulo (Sao Paulo, Brazil). Informed consent was obtained from all participants after the nature and possible consequences of the study were explained, and the research was carried out according to the tenets of the Declaration of Helsinki.

This study evaluated 41 eyes from 25 patients who were fitted with Esclera SCLs to treat moderate to severe DED. When a patient had an indication for SCL in both eyes,

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we analyzed the values for each eye as independent variables, considering that each eye presents independent anatomic and physiological features. These patients were referred to the Contact Lens Department of Federal University of Sao Paulo (Sao Paulo, Brazil) from February 4, 2013 to November 28, 2014. The mean age was 39.51 ± 12.16 years, and 26 (63.4%) eyes of patients were female. No patients were lost to follow-up.

This study included patients with grades 2, 3, and 4 DED based on the DEWS report, also known as moderate to severe DED, which presents occasionally annoying or constant visual symptoms, changes in conjunctival staining and injection, changes in corneal staining and tear signs, changes in the meibomian glands, a tear film breakup time (TBUT) ≤10 seconds, and a Schirmer score ≤10.1 The patients evaluated had symptoms that could not be controlled by conventional treatments.

Patients with the following conditions were excluded from the study: glaucoma, disorders that affect sensitivity (eg, herpetic disease and diabetes mellitus), corneal decompensation, active ocular infection, anatomic variations of the eyelid and conjunctiva that impair proper SCL fitting, pregnancy, and an inability to correctly handle and care for the SCLs.

For SCL fitting, a trial set with the following parameters was used: scleral design (Esclera; Mediphacos Inc, Belo Horizonte, Brazil); nonfenestrated; diameter, 16-18.2 mm; available sagittal vaults, 4.12-6.27 mm; DK/T, 141 (ISO/Fatt); available powers from −20 to +20 diopters.

All SCL fittings were performed by a practitioner experienced in the field (S.L.P.W.). The 3 parameters that characterize the Esclera SCL are the sagittal depth, base curve, and lens diameter. The initial diagnostic lens was selected based on suggestions in the manufacturer's fitting guide[12] according to the patient's corneal topographic diagnosis, such as moderate cone, advanced cone, pellucid marginal degeneration, or post-penetrating keratoplasty.

The ideal Esclera SCL for fitting had a size at least 2 mm greater than each side of the limbus and a minimum apical clearance of 100 μm. The SCL should not touch the cornea, and the edges of the SCL should not exhibit vascular impingement, conjunctival blanching, or scleral indentation. Those patients with ideal fits were allowed to wear the lenses for 1 hour; then, the apical clearance was reassessed, and spherocylindrical over-refraction was performed.

Follow-up visits occurred at months 0, 1, 3, 6, and 12. Subjective and objective assessments of DED were conducted before the fitting and 6 and 12 months after SCL use. All dry eye tests were performed by the same observer (S.L.P.W.), and the minimum follow-up period was 12 months.

The clinical examinations included assessment of the best-corrected visual acuity (BCVA) using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (CC-100; Topcon Corp, Tokyo, Japan), and this value was recorded as the Snellen equivalent. The corresponding logMAR was then derived from the Snellen equivalent.

At each visit, in order of performance, tear osmolarity, slit-lamp examination, the Schirmer I test, the TBUT, corneal and conjunctival staining, and meibomian grading were assessed for the eyes evaluated. All patients were instructed to discontinue use of the SCLs 1 day prior to dry eye testing.

Osmolarity was measured using a lab-on-a-chip system to simultaneously collect and analyze the electrical impedance of a 50-nL tear sample from the inferior lateral meniscus (TearLab Osmolarity System; OcuSense, San Diego, California, USA).[13,14] We excluded patients with Schirmer I test scores equal to zero from this analysis.

A slit-lamp examination at a magnification of 10-16× was used to detect the presence of active inflammation or structural changes, as evidenced by scarring in the eyelid and conjunctiva, neovascularization, opacities, or thinning of the cornea. The tear meniscus height was classified as present, reduced, or absent.

Tear fluid production was examined with a 5-minute Schirmer I test using a standardized filter strip (Ophthalmos Inc, Sao Paulo, Brazil) without anesthetic. The TBUT was measured by calculating the average of 3 consecutive tear breakup times, which were determined manually using a stopwatch.

Corneal staining was evaluated after fluorescein instillation according to the van Bijsterveld score (VBS)[15] (grades of 0-3 for 3 regions of the ocular surface). Conjunctival and corneal staining with sodium lissamine green dye was assessed using the Oxford score,[16] for which grades of 0-5 are assigned to 3 regions of the ocular surface for a possible total of 15 points.

For meibomian gland evaluation, digital pressure was applied to the upper tarsus, and meibum expression was evaluated semiquantitatively according to the following grades: 0, clear meibum easily expressed; 1, cloudy meibum expressed with mild pressure; 2, cloudy meibum expressed with more than moderate pressure; 3, meibum not expressed even with strong pressure.[17]

Symptoms were assessed at baseline and after 12 months of SCL use using a validated Portuguese version of the Ocular Surface Disease Index (OSDI) (Allergan Inc, Irvine, California, USA). The OSDI scores range from 0 to 100, with higher scores representing greater disability.[18] In addition, the SF-36v2 questionnaire (QualityMetric Inc, Lincoln, Rhode Island, USA)[19] was used to assess patient quality of life (QoL) before and after SCL use. For each domain, a score ranging from 0 (worst health) to 100 (best health) was calculated.

• **STATISTICAL ANALYSIS:** Statistical analyses were performed with the statistical software package SPSS for Windows (version 14.0; SPSS, Inc, Chicago, Illinois, USA). To compare the results obtained at baseline and

at 6 and 12 months after SCL use, we performed the Cochran test, the Friedman test, analysis of variance, and paired *t* tests, depending on the variable analyzed. Normality assumption was evaluated by the Shapiro-Wilk test. In addition, when necessary, Tukey multiple comparisons were performed. Differences were considered statistically significant when the *P* value was less than .05.

RESULTS

THIS STUDY EVALUATED 41 EYES FROM 25 PATIENTS WHO were fitted with SCLs to treat DED. Demographic information on all subjects is summarized in Table 1. The topical dry eye therapy and ocular surgeries attempted before the SCL evaluation are described in Table 2. We noted that most of the patients had previously undergone certain treatment for DED, as suggested by DEWS.[1] Another group of potential subjects (15-20 eyes) attempted to enroll in the study but could not participate because they were unable to handle the contact lens.

TABLE 1. Demographic Data of Dry Eye Disease Patients Evaluated for Esclera Scleral Contact Lens Therapy

Demographic	Value
Eyes/patients (n)	41/25
Laterality of fit (n)	
Right	4
Left	5
Both	16
Age at SCL fitting (y)	
Mean ± SD	39.51 ± 12.158
Range	44
Female/male sex (%)	26 eyes (63.4)/ 15 eyes (36.6)
UDVA (logMAR)	
Mean ± SD	1.047 ± 0.538
Range	1.90
BCVA with habitual correction (logMAR)	
Mean ± SD	0.703 ± 0.555
Range	2.00
Previous spectacle wear (n/%)	
Yes	16/39
No	25/61
Previous contact lens wear (n/%)	
Yes	21/51.2
No	20/48.8
Dry eye grading[a] (%)	
Grade 1	0
Grade 2	37.5
Grade 3	21.9
Grade 4	40.6

BCVA = best-corrected visual acuity; SCL = scleral contact lens; UCVA = uncorrected distance visual acuity.
[a]According to DEWS.[1]

TABLE 2. Topical Dry Eye Disease Therapy and Ocular Surgeries Attempted Before the Esclera Scleral Contact Lens Evaluation

Prior topical therapy, n/% (n = 41 eyes)	
Artificial tears preservative-free	39/95.1
Artificial tears with preservative	7/17.1
Gels/ointments	11/26.8
Topical antibiotic eye drops	10/24.4
Corticosteroid eye drops	24/58.5
Cyclosporine A 0.05% eye drops	4/9.75
Autologous serum tears	1/2.4
Prior ocular surgery, n/%	
Punctal occlusion	14/34.1
Tarsorrhaphy	7/17.1
Penetrating keratoplasty	3/7.3
Eyelid reconstruction	10/24.4
Electrolysis of cilia	11/26.8
Salivary gland autotransplantation	7/17.1
Coating with amniotic membrane	2/4.9

The underlying diseases were Stevens-Johnson syndrome (22 eyes), Sjogren syndrome (11 eyes), graft-vs-host disease (GVHD) (2 eyes), dry eye after in situ keratomileusis (LASIK) (2 eyes), and undifferentiated ocular surface disease (4 eyes).

The BCVA improved from 0.703 ± 0.55 logMAR (mean ± SD; Snellen equivalent, 20/100) with habitual correction to 0.406 ± 0.43 logMAR (Snellen equivalent, 20/50) with the SCL ($P < .001$). All patients who were fitted with SCLs had an improved BCVA, defined as a gain of 2 or more Snellen lines. The mean SCL wear time per day was 11.6 ± 3.0 hours (range, 5-15 hours).

The slit-lamp findings present at baseline were corneal neovascularization (77.8%), corneal opacity (61.1%), corneal thinning (30.6%), and corneal keratinization (16.7%). Eyelid scarring was present in 41.7% of the eyes studied. None of the slit-lamp findings showed changes between the baseline and the 12-month evaluations ($P = 1.000$). The status of the meibomian glands was 2.8% grade 0+, 50% grade 1+, 44.4% grade 2+, and 2.8% grade 3+ (Table 3). The analysis of the tear meniscus height showed that 15 eyes (36.6%) had no meniscus, 22 (53.6%) had a reduced meniscus, and 4 (9.8%) had a present meniscus at baseline. These results showed no changes between the baseline data and those data obtained after 6 and 12 months ($P = 1.000$).

The parameters of the final Esclera SCL fitting were a mean lens sagittal depth of 4.74 ± 0.38 mm and a mean lens base curve of 7.28 ± 0.57 mm. The diameter of the fitted SCL ranged from 16.0 to 17.5 mm, with an average of 16.43 mm.

Table 3 shows the outcomes of the DED testing at baseline and then 6 months and 12 months after SCL wear. We noticed that tear osmolarity and the VBS were significantly different between the analyzed periods ($P < .001$

TABLE 3. Dry Eye Disease Testing Outcomes at Baseline and 6 and 12 Months After Esclera Scleral Contact Lens Wear

	Baseline (n = 41)	6 Months (n = 41)	12 Months (n = 41)	*P* Value
Tear osmolarity (mOsm/L)	338.1 ± 27.1	313.1 ± 44.1	314.25 ± 38.8	<.001[a]
Schirmer I test (mm/5 min)	3.2 ± 3.443	2.85 ± 3.407	2.5 ± 3.204	.372
TBUT value (s)	2.65 ± 1.785	2.9 ± 1.586	2.9 ± 1.518	.555
van Bjisterveld score (grade)	3.63 ± 2.337	3.04 ± 2.458	2.63 ± 2.464	.015[a]
Oxford score (grade)	5.33 ± 3.975	4.5 ± 2.485	4.42 ± 2.376	.209
Meibomian gland status (grade)	2.00 ± 0	2.00 ± 0	2.00 ± 0	1.000

TBUT = tear film breakup time.
Abnormal values: Tear osmolarity ≥316 mOsm/L; Schirmer I test ≤5 mm/5 min; TBUT <10 seconds.
Values expressed as mean ± standard deviation.
[a]Statistically significant correlation ($P < .05$); analysis by repeated-measures analysis of variance test.

and $P = .015$, respectively). Eight eyes were excluded from the tear osmolarity analysis because they presented Schirmer I test scores equal to zero for at least 1 of the measurements.

The tear osmolarity exhibited a statistically significant decrease between different time points: baseline > 6 months ($P < .001$), baseline > 12 months ($P < .001$), and 6 months = 12 months ($P = .929$), as determined using the Tukey test at a 1% level of probability. The statistical significance of the differences in the VBS between different time points were as follows: baseline = 6 months ($P = .194$), baseline > 12 months ($P = .011$), and 6 months = 12 months ($P = .426$), as determined using the Tukey test at a 1% level of probability.

The other DED tests shown in Table 3, such as the Schirmer I test, TBUT assessment, the Oxford score, and assessment of the meibomian gland status, showed no significant difference between baseline and after 6 and 12 months of SCL wear.

Ocular surface symptoms assessed by OSDI score were significantly better after 12 months of SCL wear ($P < .001$) (Table 4). The patient QoL assessed by SF-36v2 questionnaire was also significantly better after 12 months of SCL wear in the 8 domains evaluated ($P < .001$) as described in Table 4.

The mean follow-up period was 16.3 months (range, 12.2-24.5 months). During the follow-up, 1 eye (2.44%) presented with a corneal abrasion during lens insertion, and no patients discontinued SCL wear.

DISCUSSION

THE 2 MAIN MECHANISMS OF DED ARE DRIVEN BY TEAR hyperosmolarity and tear film instability. Tear hyperosmolarity arises as a result of water evaporation from the exposed ocular surface, low aqueous tear flow, or excessive evaporation or owing to a combination of these events. Tear film instability also suggests higher exposure of the ocular surface, resulting in damage to the epithelial surface and the glycocalyx and goblet cell mucin disorders.[1] This process is accompanied by ocular surface inflammation, which causes dysfunction of the lacrimal glands, changing the composition to a state of tear hyperosmolarity, and then completes the vicious circle of tissue damage.[20] The degree of tear film hyperosmolarity has been proven to be the most effective single measure for diagnosing DED,[21–23] and moderate to severe dry eye is characterized by tear osmolarity higher than 316 mOsm/L.[13,23,24]

Over the past decade, several studies have investigated different SCLs for the treatment of DED.[5–8,10,25–33] This interest is due to the introduction of new SCL designs and the improvement of SCL materials and oxygen permeability. The use of SCLs is usually indicated for treating DED in cases of conventional treatment

TABLE 4. Questionnaire Evaluation of Dry Eye Disease Patients Before and 12 Months After Esclera Scleral Contact Lens Wear

Questionnaire	Baseline (n = 25)	After 12 Months (n = 25)	*P* Value[a]
OSDI	30.71 ± 14.13	11.29 ± 11.24	<.001
SF-36v2[b]			
Physical functioning	91.25 ± 3.24	97.47 ± 5.22	<.001
Social functioning	73.38 ± 21.32	84.55 ± 18.96	<.001
Physical problems	54.37 ± 34.14	61.46 ± 40.33	<.001
Bodily pain	66.48 ± 21.94	72.28 ± 23.46	<.001
Emotional problems	55.55 ± 41.14	68.75 ± 43.87	<.001
Mental health	65.55 ± 12.90	74.12 ± 19.02	<.001
Energy and vitality	59.08 ± 10.80	68.76 ± 12.40	<.001
General perception of health	48.55 ± 15.89	62.09 ± 18.33	<.001

OSDI = Ocular Surface Disease Index.
Values expressed as mean ± standard deviation.
[a]Paired *t* test.
[b]1998 US general population norms and norm-based scoring.[17]

failure.[10,29] The SCL acts as a protective covering for the cornea and conjunctivae by controlling evaporation and maintaining direct contact between the fluid and the corneal epithelium. The SCL also protects the cornea from abrasions and mechanical trauma, which commonly result from eyelid scar irregularities and misdirected eyelashes.

The present study evaluated the impact of the Esclera SCL on dry eye and quality of life in patients with moderate to severe DED. Of the 41 eyes assessed in this study, 62.5% were classified as grade 3 or 4 according to DEWS.[1] This percentage explains the severity of the slit-lamp findings and the DED testing outcomes (Table 3) observed during the study. Another group of potential subjects (15-20 eyes) attempted to enroll in the study but could not participate because they were unable to handle the contact lens. The main difficulty was lens placement in the eye by the patients. Given that the SCL is a large-diameter lens and that it should be completely filled with liquid, its placement requires manual skill. Other factors, such as low vision, a lack of previous experience with contact lenses, hand tremors, anatomic abnormalities of the fingers (eg, osteoarthritis), or insecurity due to living alone were decisive for the exclusion of these patients from our study.

Most of the patients evaluated had Stevens-Johnson syndrome (53.7%) or Sjogren syndrome (26.8%). Our study institution is one of the national reference centers for treating these diseases.

We noticed a significant improvement in the BCVA (gain of 2 or more Snellen lines) in all patients who were fitted with SCLs, as also described in previous studies.[5,10,11,29–33] In addition to correcting the refraction of the patient, the SCL promotes the replacement of an irregular ocular surface, with findings such as opacities, scarring, and corneal neovascularization, with a more regular surface. The improvement in the quality of the BCVA could also have been the result of reducing the dry eye symptoms, including irritation, photophobia, and foreign-body sensation, described in the OSDI questionnaire (Table 4), which increases comfort when the eyes are open.

In our study, the diameter of the fitted SCL ranged from 16.0 to 17.5 mm, with an average of 16.43 mm. Previous studies have investigated even larger lenses, with diameters ranging from 15.0 to 23.0 mm.[5,9–11,26–32] We believe that the diameter of the lens used in the present study facilitated successful SCL fittings in patients with eyelid scarring (41.7%).

We observed a statistically significant decrease in the mean tear osmolarity between baseline and after 6 months, and this decrease was maintained after 12 months of SCL wear. The reduction in tissue damage, as assessed based on van Bijsterveld corneal staining, showed a downward trend; this trend was not significant after six months of SCL wear but became significant after 12 months. This finding may suggest that the process of tecidual damage was still active during and after normalization of the tear osmolarity. The SCL reduces tear evaporation, which allows several of the tear properties to be gradually reestablished, regardless of the etiology of the dry eye.

However, several of the measurement parameters related to tear film instability, such as the Schirmer I test results and the TBUT, exhibited no statistically significant changes between periods evaluated, as shown in Table 3. Therefore, the use of the SCL allowed only a partial increase in ocular surface epithelialization because it reverted just 1 of the 2 core mechanisms of damage—namely, the hyperosmolarity—and did not alter the tear film instability.

According to the OSDI, most patients experienced many symptoms associated with dry eye, such as foreign-body sensation, ocular fatigue, and eye redness. However, compared with the value before SCL use, the OSDI showed consistent improvement after SCL use. The average OSDI value ranged from 30.71 to 11.29 after 12 months of SCL use ($P < .001$), with a higher value indicating more severe ocular complaints related to dry eye. Previous studies have shown a significant improvement between pre-SCL and post-SCL OSDI scores, which indicates that the patients experienced improvements in ocular surface comfort and visual function.[21] These results may explain why despite the disadvantages of the lens, such as difficulties in handling and care, patients maintained their use during the follow-up period. In addition, we observed a mean duration of SCL wear per day of 11.6 ± 3.0 hours (range, 5-15 hours), which also demonstrates the adherence to DED treatment with the SCL.

The patient QoL assessed by SF-36v2 questionnaire was also significantly better after 12 months of SCL wear in each of the 8 domains evaluated ($P < .001$). The SF-36 was chosen because it is one of the most widely used measures in health services research and has already been translated into the Portuguese language and validated.[19,34,35] Dry eye disease is clearly associated with poorer QoL, with particular impact on the physical component summary.[36] In our study, the symptoms of moderate to severe dry eye and its primary diseases affected the QoL in general, especially involving the physical problems, bodily pain, emotional problems, mental health, energy and vitality, and the general perception of health (Table 4). This demonstrates that moderate to severe DED has huge impact on the patients' quality of life.

Our study had certain limitations, such as the small sample of eyes evaluated and the lack of a control group. In addition, we analyzed the values for each eye as independent variables, which could lead to some bias. However, despite these limitations, we could demonstrate that Esclera SCL treatment had a positive impact on tear osmolarity and the VBS and also improved BCVA and patients' quality of life. Regardless, more studies with a larger sample size and longer-term follow-up are needed in this field to investigate the impact of SCLs.

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Biosketch

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