



## Long-term effect of corneoscleral contact lenses on refractory ocular surface diseases



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### ABSTRACT

**Purpose:** To report the therapeutic effect of corneoscleral contact lenses (CLs) with a diameter of 14.0 mm on the refractory ocular surface diseases.

**Methods:** Medical records of 13 eyes (of nine patients) attempted for fitting with corneoscleral CLs for the management of the severe refractory ocular surface diseases were retrospectively reviewed including Stevens-Johnson syndrome (SJS; eight eyes) and chronic ocular graft-versus-host disease (GVHD; five eyes). Lenses were fitted to improve refractory punctate epithelial erosions (PEE, ten eyes) and persistent epithelial defect (PED, three eyes with SJS) despite the proper medical management. Short-term (1 month) and long-term (12 months) changes in the best corrected visual acuity (BCVA), corneal fluorescein staining (CFS) score, mean wearing time, and National Eye Institute's Visual Function Questionnaire-25 (VFQ-25) were evaluated.

**Results:** Of the 13 eyes, ten eyes were successfully fitted with the corneoscleral CLs. The fitting was failed in three eyes due to small palpebral fissure and shortened fornices (two eyes) and handling difficulty (one eye). At one-month follow-up after successful fitting in ten eyes, mean wearing time was 12.6 h (6.5–17, all day long) and BCVA improved from  $0.56 \pm 0.59$  to  $0.27 \pm 0.46$  in logMAR ( $P = .018$ ). For the eight well-fitted eyes with refractory PEE, CFS score improved from  $7.38 \pm 2.20$  to  $5.13 \pm 2.48$  ( $P = .024$ ). PED improved in all two eyes which were successfully fitted with corneoscleral CLs (Of the three eyes with PED, one eye failed fitting). At 12-month follow-up, mean wearing time was 11.4 h and the improved BCVA and CFS score were maintained. Furthermore, no adverse events attributable to corneoscleral CLs use occurred.

**Conclusion:** The corneoscleral CLs with a diameter of 14.0 mm were successfully fitted in ten out of 13 eyes with severe refractory ocular surface diseases and demonstrated therapeutic benefits in the well-fitted eyes. The corneoscleral CL can be an option in the management of severe refractory ocular surface diseases.

### 1. Introduction

The rigid contact lenses (CLs) can be divided into 3 categories according to its bearing area and size [1,2]. Most commonly used corneal CLs rests entirely on the cornea and the total diameter is usually smaller than 12.5 mm, the scleral (alternatively called as full scleral) CLs rests on sclera only and the total diameter is usually larger than 15.0 mm, and the corneoscleral (alternatively called as semi-scleral, corneal-limbal, or limbal) CLs rests partly on cornea and partly on sclera and the total diameter usually ranges from 12.5 mm to 15.0 mm [1,3]. Furthermore, as per the scleral lens education society, the scleral CLs can

be divided into two categories according to the size and the length of landing zone: mini-scleral CLs with the total diameter up to 6 mm larger than horizontal visible iris diameter (HVID) and the scleral landing zone up to 1.5 mm and large scleral CLs with size and bearing area more than the dimensions of mini-scleral CLs [2].

Scleral CL is an original design of CL but the usage was limited to 1980s due to the limited oxygen permeability of the materials [4,5]. With the development of the high oxygen permeable rigid CL materials, the usage increased and the indication has expanded [5–7]. Especially for the therapeutic application, the ability to maintain the tear reservoir has received attention from the early times of scleral CL revival [8–11].

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Stevens-Johnson syndrome (SJS), chronic graft-versus-host disease (GVHD), ocular cicatricial pemphigoid (OCP), Sjögren syndrome, persistent epithelial defect (PED), limbal stem cell deficiency, superior limbic keratoconjunctivitis, exposure keratopathy, neurotrophic keratopathy, trichiasis, and entropion are regarded as therapeutic indications for the scleral CLs [1,7–16].

SJS is an acute blistering disease of the skin and mucous membranes [17]. Although relatively rare (reported incidence: 1.2 ~ 6 per million patient-years), the devastating ocular sequelae can follow after prolonged chronic conjunctivitis and cicatricial lid margin abnormalities, which can lead symblepharon formation, PED, and finally corneal scarring [17]. GVHD is a condition when donor-derived immune cells recognize and attack the recipient tissues after allogeneic hematopoietic stem cell transplantation [18]. Although it is a systemic disorder, ocular involvement is relatively common and usually manifests as severe dry eye disease including signs of conjunctival hyperemia, corneal epitheliopathy, meibomian gland dysfunction, conjunctival and corneal scarring, stromal ulceration, and symblepharon [18,19].

Though the scleral CL can be the last resort for severely affected eyes in refractory ocular surface diseases, symblepharon formation and the shortening of the conjunctival cul-de-sac may interfere with the successful fitting of larger CL in some SJS and OCP patients [12,20]. A smaller scleral CLs, including mini-scleral CL and corneoscleral CL, can be helpful in these patients, but there exist only a few studies [20,21]. Recently, there has been a report on the use of a custom designed limbal CL for severe ocular surface diseases with good results [20]. As the customized limbal lenses are not available in Korea, the authors tried to fit commercially available corneoscleral CLs for the treatment of refractory ocular surface diseases. The aim of this article is to report the usefulness of the commercially available corneoscleral CLs in the treatment of refractory ocular surface diseases and to share the clinical experiences on the application of corneoscleral CLs.

## 2. Materials and methods

### 2.1. Patients

The medical records of patients who were attempted for the fitting of the corneoscleral CL for the severe refractory ocular surface diseases were retrospectively reviewed. All the records of the patients who were attempted for the fitting of the corneoscleral CL at Seoul National University Hospital from November 2015 to June 2017 were reviewed and the following conditions were excluded: 1) corneoscleral CL was tried to correct optical problems like keratoconus and irregular astigmatism, and 2) the patients who voluntarily refused fitting during CL fitting procedures. The Institutional Review Board (IRB) of Seoul National University Hospital approved this study (C-1801-087-915) and this study was conducted in accordance with the tenets of the declaration of Helsinki.

Thirteen eyes of nine patients were finally enrolled who was fitted with the corneoscleral CLs for the treatment of the severe refractory ocular surface diseases. Of the 13 eyes, ten eyes were enrolled due to refractory punctate epithelial erosions (PEE) with underlying SJS (5 eyes of 4 patients) and chronic ocular GVHD (5 eyes of 3 patients) (Table 1). Three eyes were enrolled due to the PED with underlying SJS (3 eyes of 2 patients). Of the 8 eyes with SJS, 3 eyes already underwent surgical procedures for ocular surface reconstruction including penetrating keratoplasty (PKP), limbal transplantation, symblepharolysis, and cultivated oral mucosal epithelial transplantation (COMET), resulting in failure (Table 1). All the eyes were treated with multiple topical medications (2–10) and 3 eyes were under treatment with soft bandage CLs when the fitting for corneoscleral CLs was tried. The evaluation of the best corrected visual acuity (BCVA), slit-lamp examination with or without fluorescein staining was performed and the questionnaires for ocular symptoms including National Eye Institute's Visual Function Questionnaire-25 (VFQ-25) were asked before the

beginning of lens fitting [1,20]. The corneal fluorescein staining (CFS) score was assessed as recommended by National Eye Institute [18]. At 1 month follow-up after the order of the final well-fitted CL, the above evaluations were repeated. Patients were followed up every 3–6 months and the BCVA, slit lamp evaluation, fitting status, and the question for the compliance (wearing time) were checked at every visit.

### 2.2. Specification and fitting procedures of corneoscleral Lens

Commercially available SoClear lens (Art Optical Contact Lens, Inc., Grand Rapids, MI, USA, Clean & Bright Cooperation) was used for corneoscleral lens fitting. The lens design has four curves. The total diameter of the lens is 14.0 mm comprising of the 8.5- or 9.0-mm sized optical zone and peripheral zone. The material of the lens is Boston XO2 with oxygen permeability (Dk) value 140 and equivalent oxygen percentage (EOP) 19.5%.

The lens was fitted according to the manufacturer's recommendation with a few modifications. Basic fitting processes were as follows; a base curve of optic zone and peripheral scleral curvature were separately fitted using the standard trial lens sets. First, central base curve radius was chosen. By comparing the post-lens, pre-corneal tear film thickness (clearance) at center and mid-peripheral zone (just inside the limbus and approximately 2 to 4 mm towards the center of the cornea) using fluorescein dye, most appropriate base curve can be chosen which showed mild bearing at mid-periphery and leaves adequate clearance at limbus (Fig. 1, Supplemental Fig. 1). If the mid-peripheral fit has too little clearance, an order adjustment of 1.0 diopter (D) flatter on the base curve will be needed. For the eyes with PED, lighter bearing at the central zone was attempted in consideration of the space in which the epithelium will grow. Thereafter, scleral curve radius was chosen by evaluating the blanching patterns of the limbal vessels, the peripheral edge lift at the limbus, and tear circulation after at least 8 h after the fitting in consideration with settling back effect. Peripheral curvature was selected to allow tear circulation in at least 1/4 of the scleral edge without any compression of the limbal vessels (Supplemental Fig. 1). The peripheral adjustment can be determined by subtract the base curve of the optical zone (in diopter) from the peripheral curvature (in diopter). Finally, the power of the lens was determined by spherical over-refraction.

After the delivery of the ordered lens, the corneoscleral lens was fitted again for at least 8 h, and the central alignment in which post-lens, pre-corneal tear film thickness showed approximately 10–50 μm and the peripheral scleral fit without any compression of the limbal vessels were re-evaluated (Fig. 1, Supplemental Fig. 1). The lens was re-ordered depending on the necessity to modify the fitting.

### 2.3. Statistical analysis

The differences in the parameters before and after the corneoscleral lens fitting were analyzed using Wilcoxon Signed Ranks Test. SPSS statistical software (version 21 for Windows, IBM Corp., Armonk, NY, USA) was used for the statistical analyses presented in this study. Statistical significance was defined as a *P*-value < .05.

## 3. Results

Of the nine patients (13 eyes) enrolled, six patients were female and three patients were male. The mean age of the patients was  $35.7 \pm 15.4$  (15–54) years. Of the 13 eyes, ten eyes were successfully fitted with the corneoscleral CLs. The fitting failed in three eyes due to small palpebral fissure and shortened fornices in two eyes and handling difficulty in one patient (one eye). For the ten successfully fitted eyes, the number of visits until completing the fitting did not exceed twice and the mean number of the ordered lens was 1.4 lenses (1–2). The specifications of the finally fitted corneoscleral CLs in success group are summarized in Supplemental Table 1.

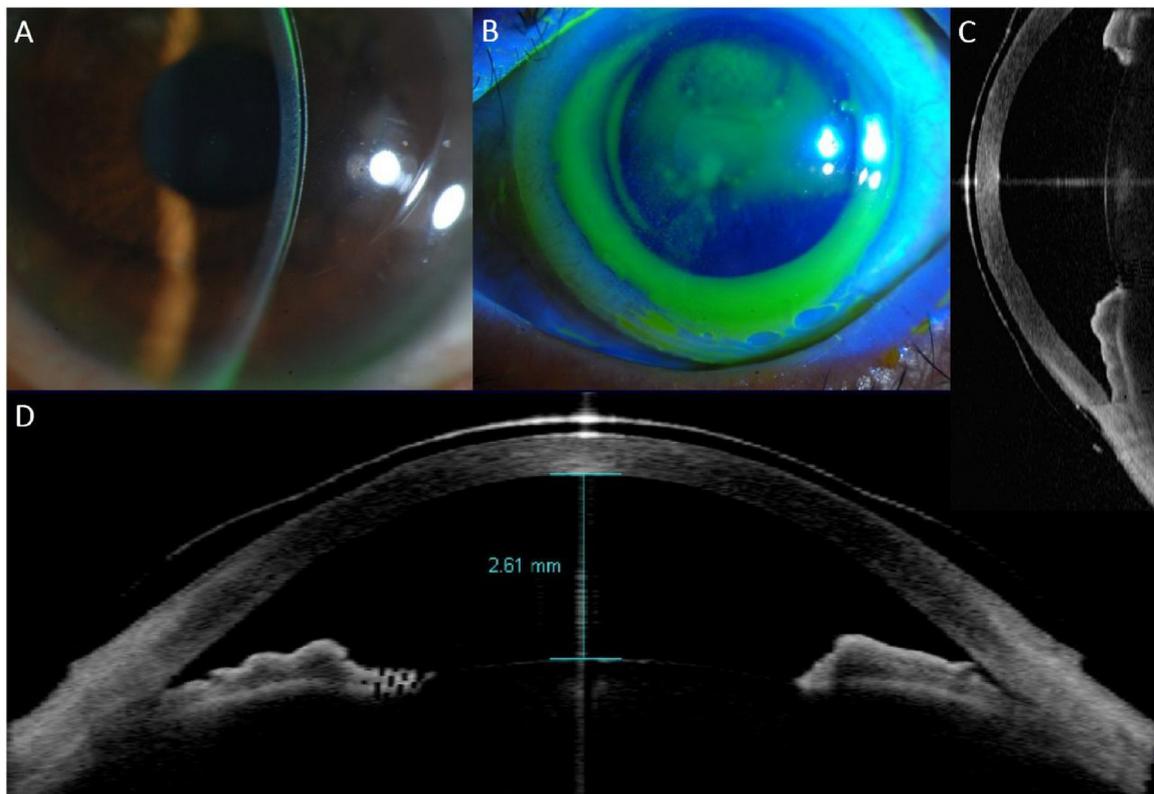
**Table 1**  
Demographics of the patients enrolled in this study.

Age (years)	Sex	Side	Diagnosis	Underlying disease	Past Surgical History	Sym-blepharon	Fitting Outcome
43	F	R	PEE	SJS	None	–	Success
43	F	L	PEE	SJS	None	–	Success
35	M	R	PEE	GVHD	LASIK	–	Success
35	M	L	PEE	GVHD	LASIK	–	Success
53	M	R	PEE	GVHD	None	–	Success
53	M	L	PEE	GVHD	None	–	Success
54	F	R	PEE	SJS	Limbal TPL, symblepharolysis	+	Success
19	F	R	PED	SJS	Symblepharolysis, AMT, PKP, limbal TPL, ECCE/PCL, COMET	+	Success
24	M	R	PED	SJS	None	+	Success
26	F	L	PEE	SJS	None	–	Success
19	F	L	PED	SJS	Symblepharolysis, limbal TPL, AMT, PKP, ECCE/PCL, COMET	+	Failure
52	F	R	PEE	GVHD	None	–	Failure
15	F	L	PEE	SJS	None	+	Failure

PEE: punctate epithelial erosions, PED: persistent epithelial defect, SJS: Stevens-Johnson syndrome, GVHD: graft-versus-host disease, TPL: transplantation, COMET: cultivated oral mucosal epithelial transplantation, PKP: penetrating keratoplasty, AMT: amniotic membrane transplantation, ECCE/PCL: extracapsular cataract extraction with posterior chamber intraocular lens implantation.

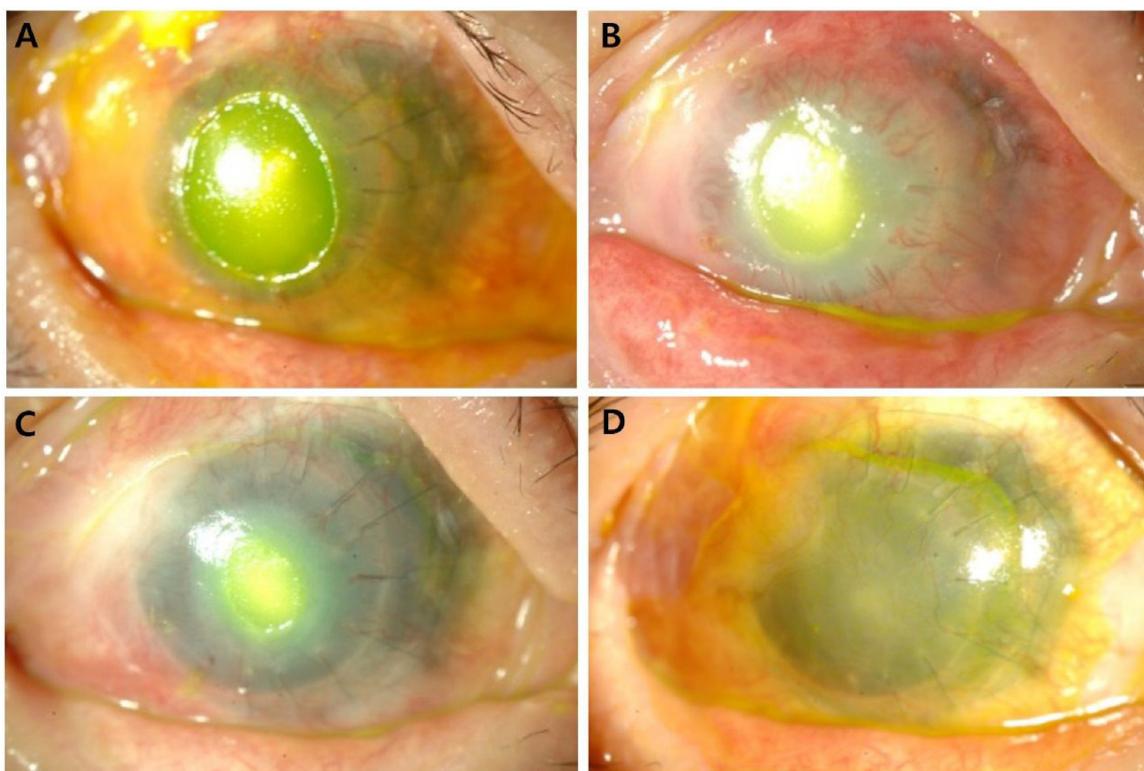
At one month after successful fitting, the mean wearing time of the lens was 12.6 h (6.5–17, all day long) and there was no adverse event. The mean BCVA improved from  $0.56 \pm 0.59$  (logMAR, pre-fitting) to  $0.27 \pm 0.46$  (logMAR, post-fitting) after one month of CL wear ( $P = .018$ , Wilcoxon Signed Ranks Test, Figs. 2A and 3). Improvement in the signs of ocular surface was observed in all the ten eyes. Of the three eyes with PED, two well-fitted eyes, except for one eye that failed fitting due to shortened fornix, were improved (Fig. 4). The mean CFS score improved from  $7.38 \pm 2.20$  (pre-fitting) to  $5.13 \pm 2.48$  (post-fitting) with successful fitting in the eight eyes with refractory PEE ( $P = .024$ , Figs. 2B and 5). Mean number of topical medication decreased from  $4.7 \pm 2.4$  to  $3.5 \pm 1.9$ , though the change was not statistically

significant ( $P = .206$ ). The VFQ-25 score improved from  $54.4 \pm 23.3$  to  $64.6 \pm 21.7$ , however, the change was not statistically significant ( $P = .176$ ). In the long-term follow-up of around 12 months (12.5 months in average, 10.7 ~ 14.8 months), mean wearing time was 11.4 h and BCVA ( $0.40 \pm 0.68$  in logMAR,  $P = .285$  compared with post-fitting) and CFS score ( $5.57 \pm 1.40$ ,  $P = .176$  compared with post-fitting) were maintained. Three patients temporarily stopped CLs during the follow-up period due to epidemic keratoconjunctivitis in one eye and abrupt corneal abrasion in two eyes. Of the two eyes with corneal abrasions, one patient (one eye) remember that it was caused by foreign matter in a dusty environment. Thereafter, none of the patients dropped lens wearing during the 12 months' follow up period.



**Fig. 1.** Fitting result of corneoscleral contact lens. (A, B) An optical section and anterior segment photo with blue filter show the corneoscleral contact lens on eye with a post lens tear film. Central curvature of the lens was selected to allow approximately 10–50  $\mu\text{m}$  of central post-lens tear film thickness with mild bearing at mid-periphery and leaves adequate clearance at limbus. (C, D) Vertical and horizontal optical coherence tomography (OCT) cross-sectional images that show the corneoscleral lens on eye.





**Fig. 4.** The right eye of the 19-year-old female patient was fitted with corneoscleral CL for persistent epithelial defect lasting 2 months after PKP. She was diagnosed with SJS 6 years ago and underwent symblepharolysis, AMT, PKP, limbal transplantation, ECCE/PCL, and COMET. Her right eye had been treated with fortified cefazolin eyedrops (10%) once a day, prednisolone acetate (1%) once daily, autologous serum eyedrops (20%) six times a day, ofloxacin ointment twice a day, and a soft bandage contact lens. A corneoscleral CL was worn for about 12 h a day with proper lens care. (A) Anterior segment photography of the right eye before fitting shows a persistent epithelial defect in the cornea. (B) The area of persistent epithelial defect decreased at two weeks after corneoscleral CL wear. (C) Further improvement was found at one month after corneoscleral CL wear. (D) The epithelial defect was nearly resolved at two months after corneoscleral CL wear.

CL: contact lens, SJS: Stevens-Johnson syndrome, PKP: penetrating keratoplasty, AMT: amniotic membrane transplantation, ECCE/PCL: extracapsular cataract extraction with posterior chamber intraocular lens implantation, COMET: cultivated oral mucosal epithelial transplantation

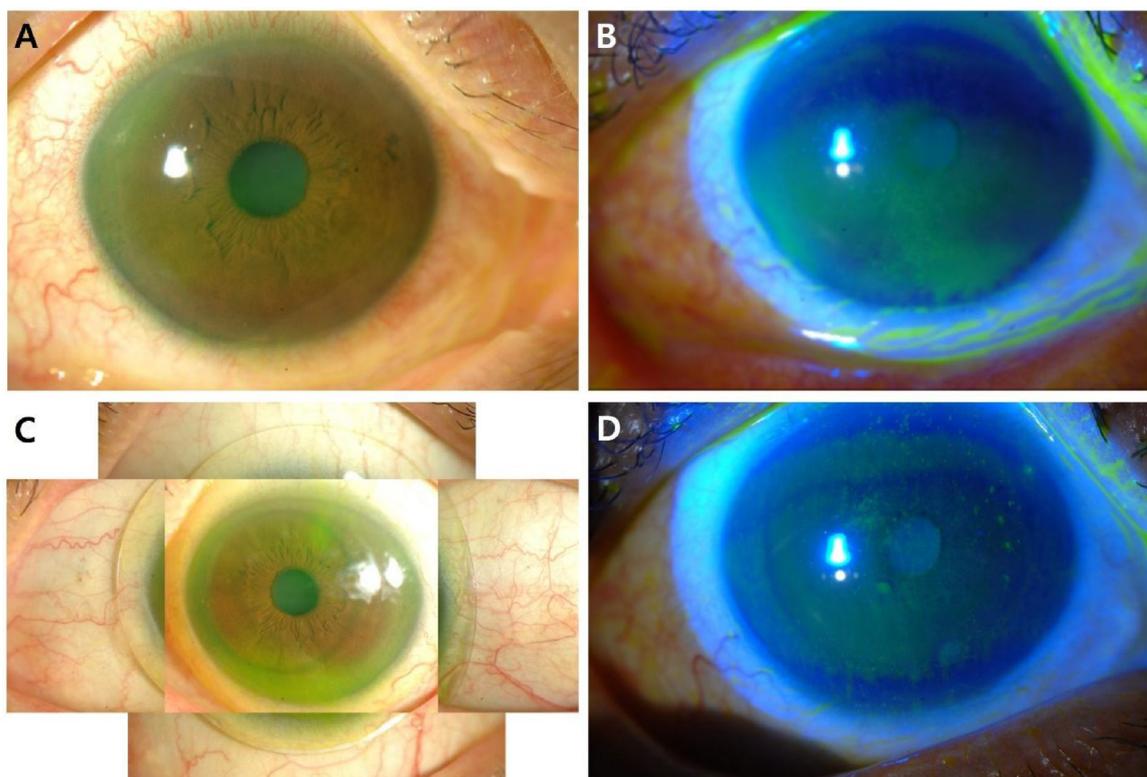
scleral CLs which can be classified as mini-scleral CLs (total diameter: 15.0 mm ~ HVID + 6 mm) and corneoscleral CLs (total diameter: 12.5 mm ~ 15.0 mm) were tried and benefits were reported for severe ocular surface diseases [20,21]. In a report from Iran, mini-scleral CLs with 15.8 mm diameter were tried in grades III and IV dry eye patients with uncontrolled symptoms despite conventional treatments [21]. More than half of them continued wearing their CLs for more than a year. The reasons for discontinuation of mini-scleral CLs were 1) difficulty in handling/dissatisfaction with respect to visual gain, 2) improvement, and 3) loss to follow-up [21]. In another study performed in Japan, 13.0- or 14.0-mm diameter sized rigid CL were tried for SJS or toxic epidermal necrolysis-associated ocular sequelae in 53 eyes of 42 patients [20]. The custom designed CL was named as limbal rigid CL by the authors because of the slightly different design from the usual corneoscleral CLs based on the characteristic projecting edge which enables the inflow of tears under the CL at the time of blinking. Both BCVA and VFQ-25 score improved significantly without the occurrence of any serious adverse events [20]. The present study corresponds well with the above report in terms of demonstrating therapeutic benefit of corneoscleral (limbal) lens with small diameter (14.0 mm).

The effects of small-sized scleral lenses including corneoscleral lens in refractory ocular surface diseases has been reported in previous studies as well as in this study [20,21]. Optical effects of the new optical surfaces by rigid lens materials are well known. However, the mechanism of improvement of the ocular surface pathology in these relatively smaller scleral lenses is not yet fully understood. Reduction of tear evaporation by rigid CLs was suggested in the previous report [19,20]. And clinically, it appears that even though the lens size is smaller than the recommended size, the tear reservoir may still be

remained between diseased cornea and the lens. It is also possible that the mechanical stress on the cornea by cicatrized lid margins and lashes in SJS and GVHD is shielded by the rigid lens [17,19].

Although the total diameter of the lens is not so different, there can be an important difference between the mini-scleral CLs and corneoscleral CLs. With the scleral CL design which is fully supported only by the sclera, the area of the scleral support becomes narrower and the compression of the peri-limbal sclera increases as the total diameter becomes smaller. And sufficient clearance over the limbal area cannot be maintained, which may lead to corneal epithelial bullae on the peripheral cornea [22]. However, corneoscleral CL can reduce excessive compression on the sclera around limbus because it is partly supported by the sclera and partly by the cornea together. The projecting edge reported in the previous article is possible in the corneoscleral CL but not in the mini-scleral CL, which should be fully supported only by the sclera [20]. However, the possibility of corneal abrasion by post-lens foreign bodies can also be possible as with corneal CLs, although it was not reported before. Delayed epithelial healing of PED by mechanical friction with a rigid lens may also be possible. However, the PED healed completely in all two eyes enrolled for PED treatment which are successfully fitted. Despite all the drawbacks mentioned above, corneoscleral CL has advantage for the small eyes and eyes with severely shortened fornices considering that a large rigid CL can be a last resort for the intractable corneal diseases in some cases.

In addition to its advantage in eyes with shortened fornices, the smaller corneoscleral CLs has several additional advantages. Firstly, the fitting procedure is easier compared with full-scleral CL. Because the scleral curvature is not symmetric and the asymmetry increases as it moves away from the limbus, a large scleral CL needs longer fitting time



**Fig. 5.** The right eye of the 53-year-old male patient was fitted with corneoscleral CL. He was diagnosed with GVHD 2 years ago and suffered from severe refractory punctate epithelial erosions and pain despite 3–4 topical medications. (A) Anterior segment photography of the right eye before fitting and the best corrected visual acuity was 20/40. (B) Blue light with fluorescein staining shows severe punctate epithelial erosions in the inter-palpebral and inferior area. (C) Fitting of corneoscleral CL. (D) Blue light with fluorescein staining after 15 months of corneoscleral CL wear shows improved punctate epithelial erosions and the visual acuity improved to 20/20 with corneoscleral CL.

CL: contact lens, GVHD: graft-versus-host disease

and more sophisticated design like toric design and spline-based software as in PROSE scleral CL [14,23–25]. Secondly, smaller size allows the patient to take CLs on and off easily.

Though the fitting failed in three eyes due to small palpebral fissure/shortened fornices and handling difficulty, ten eyes with successful fitting showed improved visual acuity and improved ocular surface status (Fig. 2). The fitting was completed by an average of 1.4 orders (1–2) and none of them dropped until 12 months' follow up period. The wearing time was 12.6 h in 1 month and 11.4 h in long-term follow up, which reflects the subjective usefulness of the corneoscleral CLs for the patients. The small size and light corneal bearing design of the corneoscleral CL allow some degree of tear circulation that is partially consistent with the mechanism of corneal CL [20]. However, with such a long wearing time, tear film debris and subsequent visual changes can be a problem. Patients are instructed to occasionally remove the lens, wash it, and re-wear the CL (lens break during a day) if vision is cloudy or the patient feels discomfort. In general, the use of preservative free artificial tears is recommended to prevent this problem. Though the improvement in subjective symptom scores (VFQ-25) and decrease in the number of topical medications was observed, the values were not statistically significant possibly due to the small number of eyes enrolled in this study. The limitations of this study include the small number of eyes enrolled and retrospective nature of the study. Compared with previous report, this study consisted of smaller number and more heterogeneous patient groups [20]. However, the longer follow up duration (12 months versus 3 months) and the use of more easily available CLs (commercial corneoscleral CL vs custom designed limbal CL) are the advantages of this study [20].

In conclusion, the corneoscleral CLs were successfully fitted in ten out of 13 eyes with severe refractory ocular surface diseases and demonstrated therapeutic benefits in the well-fitted eyes. The

corneoscleral CL can be an option in the management of severe refractory ocular surface diseases especially in the management of severe ocular surface diseases especially in Asians who have a small fissure.

#### Competing interest

None.

The authors have no proprietary or commercial interest in any of the materials discussed in this article.

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#### Appendix A. Supplementary data

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