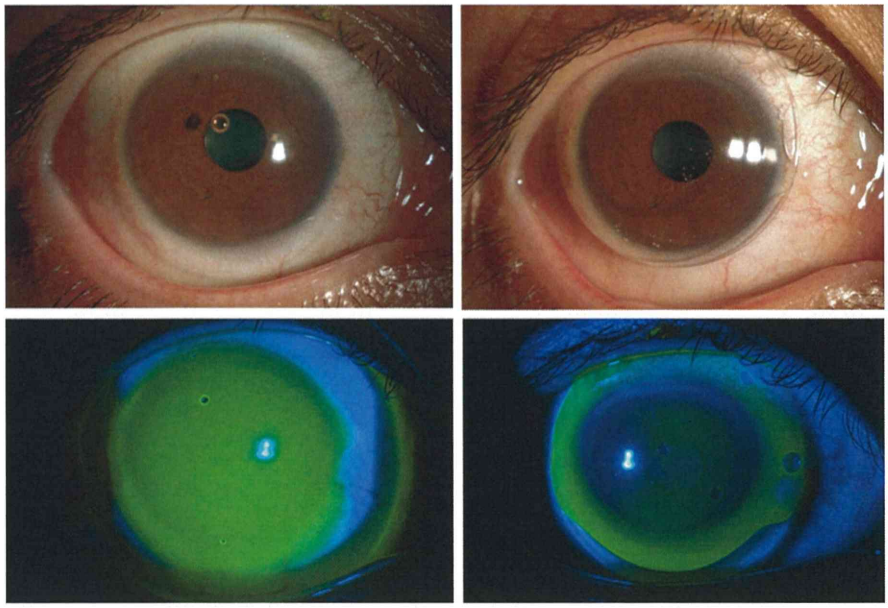

FIGURE 2. Images comparing a scleral contact lens (CL) and the limbal CL designed for Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). (Top left and Bottom left) When using a scleral CL, the lens design causes fluid to be trapped between the lens and the cornea. The thick fluid coverage remains trapped beneath the CL and does not exchange with each blink. (Top right and Bottom right) In contrast, the design of the limbal CL allows for a fluid layer to exist at the peripheral zone of the lens and for the tear beneath the lens to be exchanged at every blink.

TABLE 1. Ocular Surface Grading Score of the Eyes With Ocular Sequelae Resulting From Sevens-Johnson Syndrome or Toxic Epidermal Necrolysis

		BCVA before Limbal Contact Lens Fitting		
	Total	Group 1: BCVA worse than 20/2000 (logMAR > 2), Average Grade	Group 2: BCVA 20/200 to 20/2000 (2 ≥ logMAR >1), Average Grade	Group 3: BCVA 20/200 or Better (1 ≥ logMAR), Average Grade
No. of eyes	53	11	31	11
Ocular surface grading score				
Corneal complications				
Epithelial defect	0.00	0.00	0.00	0.00
Loss of POV	2.89	2.91	2.94	2.73
Conjunctivalization	2.70	2.82	2.71	2.55
Neovascularization	2.02	2.64	1.94	1.64
Opacification	1.42	2.27	1.23	1.09
Keratinization	0.83	1.82	0.77	0.00
Conjunctival complications				
Hyperemia	1.17	1.00	1.16	1.36
Symblepharon formation	1.25	1.73	1.23	0.82
Eyelid complications				
Trichiasis	1.77	2.09	1.90	1.09
Mucocutaneous junction involvement	2.04	2.36	2.00	1.82
Meibomian gland involvement	2.94	3.00	3.00	2.73
Punctal damage	2.51	2.64	2.45	2.55
Total	21.7	25.3	21.5	18.5

BCVA = best-corrected visual acuity; logMAR = logarithm of the minimal angle of resolution; POV = palisades of Vogt.

& Lomb, Inc, Rochester, New York, USA), a special polymer with an oxygen permeability value of 100 Dk. The curvature of the lens was designed with an 8.5- or 9.0-mm diameter optical zone at the center of the lens and a peripheral zone at the peripheral area of the lens (Figure 1). The peripheral zone is designed in the shape of a projecting

edge, for instance, like the brim of a hat, which consists of a quad-curve design that enables the inflow of tears under the CL at the time of blinking. In the use of scleral CLs, the edge of the CL touches the sclera and the thick fluid coverage beneath the CL remains trapped and does not exchange (Figure 2, Top left and Bottom left). In contrast, in the use of limbal CLs, a thin fluid layer exists under the CL with a fluid reservoir at the peripheral zone of the CL (Figure 2, Top right and Bottom right), thus allowing tear exchange beneath the CL at every blink.

Although patients using scleral CLs must remove and clean the CL several times per day, patients using the limbal CL do not need to remove and clean the lens because of the continual tear exchange. The diameter of the lens (13 or 14 mm; larger and smaller diameter sizes also can be made), the base curve (750 to 810 mm), the size of the optical zone (8.5 or 9 mm), and the peripheral-area design (2 available patterns: flat or tight) are selections that are determined by the physician at the time of the patient's trial fitting.

• TEAR EXCHANGE UNDER THE CONTACT LENS: Of the 53 total eyes involved in this study, 4 eyes of 3 patients who wear scleral CLs participated in the preliminary experiment to elucidate tear exchange via fluorescein staining patterns under the CL, that is, between the CL and the cornea. All 3 of those patients used a Boston Scleral Lens Prosthetic Device (The Boston Foundation for Sight, Inc, Needham, Massachusetts, USA) prescribed at other clinics. Those 4 eyes were examined and selected to wear either a scleral CL or the limbal CL. In the experiment, 50 μL of 0.001% sodium fluorescein dye (Fluorescite; Alcon Japan Ltd, Tokyo, Japan) was put into the concave side of the respective CLs before CL wear to elucidate the change in fluorescein pattern and concentration between the CL and the cornea associated with each type of CL. Each type of CL first was filled with fluorescein dye, and then placed on the patient's eye. The patient then was instructed to blink normally for 10 minutes. Artificial tears then were instilled in the eye at between 5 and 10 minutes after insertion of the CL, and the change in fluorescein staining pattern and concentration then was calculated by a fluorophotometer (Anterior Fluorometer FL-500; Kowa Company, Ltd, Nagoya, Japan) at the following 3 time points: (1) immediately after insertion of the CL, (2) after 5 minutes of CL wear, and (3) after 10 minutes of CL wear.

• OCULAR SURFACE GRADING SCORE: All enrolled patients underwent slit-lamp examinations to observe 12 components of the following 3 categories of ocular sequelae: (1) corneal sequelae consisting of epithelial defect, loss of the palisades of Vogt, conjunctivalization, neovascularization, opacification, and keratinization; (2) conjunctival sequelae consisting of hyperemia and symblepharon formation; and (3) eyelid sequelae consisting of trichiasis, mucocutaneous junction involvement, meibomian gland involvement, and punctal damage in accordance with our previously reported grading system.[36] Each component was graded on a scale from 0 to 3, depending on the severity of involvement. The sum of each grading score was defined as the ocular surface grading score (maximum score, 36).

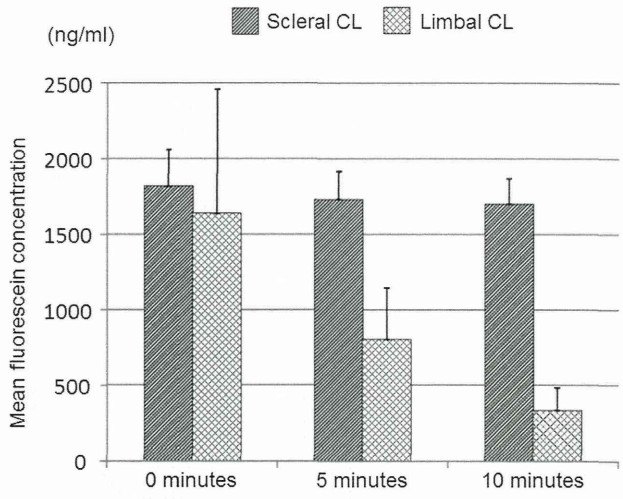

FIGURE 3. Bar graph showing the difference of fluorescein dilution between a scleral contact lens (CL) and the limbal CL. To investigate the difference of fluorescein dilution between a scleral CL and the limbal CL, 50 μL 0.001% sodium fluorescein dye was put on the concave side of each lens, and each lens was then put on a patient's eye. After 10 minutes of lens wear for each lens, no change of fluorescein concentration was observed in the eyes wearing the scleral CL; however, the fluorescein concentration gradually decreased in the eyes wearing the limbal CL (n = 4, mean ± SD). The top lines of each box represent the mean value, and the vertical lines extending from the top of each box represent the SD.

• OUTCOMES: The main outcome measure was the BCVA before CL fitting and after 3 months use of the limbal CL after fitting. The 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) composite score was defined as the secondary outcome. The SJS- or TEN-related ocular surface sequelae were graded on a scale from 0 to 3 according to their severity as described above. The patients were divided into 3 groups according to the BCVA before CL fitting: group 1, VA worse than 20/2000 (the logarithm of the minimal angle of resolution [logMAR] > 2); group 2, VA from 20/200 to 20/2000 (2 ≥ logMAR > 1); and group 3, VA 20/200 or better (1 ≥ logMAR). The ocular surface grading score, the change of VA, and the change of the NEI VFQ-25 composite score then were compared among the 3 groups.

• VISUAL ACUITY: Best-corrected visual acuity was measured at baseline (before fitting of the limbal CL) and after 3 months use of the limbal CL. Best-corrected visual

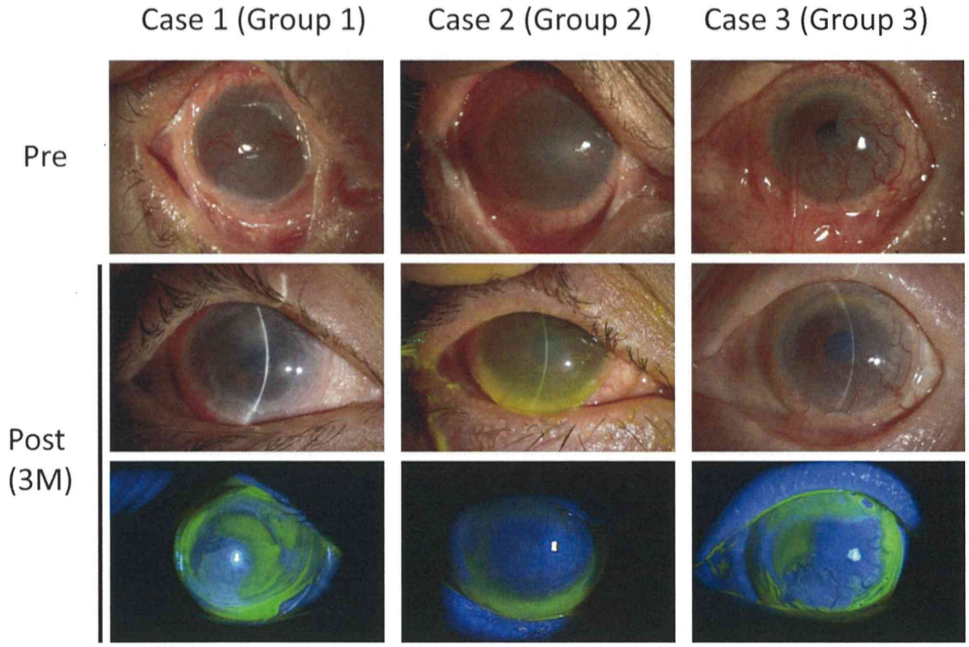

FIGURE 4. Representative appearances of the eyes with ocular sequelae resulting from Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) in each group. (Top row) Corneal appearances before fitting of the limbal CL. All 3 patients had ocular surface scarring, including fornix shortening, conjunctivalization, and neovascularization of the cornea and severe lacrimal dysfunction. (Middle and Bottom rows) Appearances at after 3 months use of the limbal CL. The thin fluid layer beneath the CL (Bottom row) is exchanged at every blink. Patient 1 was a 31-year-old man with SJS or TEN for 24 years. With the use of the limbal CL, his visual acuity (VA) improved from hand movements to 0.04. Patient 2 was a 36-year-old man with SJS or TEN for 19 years whose VA improved from 0.04 to 0.8 as a result of using the limbal CL. Patient 3 was a 59-year-old women with SJS or TEN for 29 years whose VA improved from 0.4 to 0.9 as a result of using the limbal CL.

acuity at baseline was best-corrected spectacle VA, and BCVA at after 3 months of CL use was measured with the CL fitted, and if needed, with spectacles. Improvements in VA were analyzed in relation to changes in logMAR BCVA. Counting fingers, hand movements, and light perception were determined to be 0.004, 0.002, and 0.001, respectively.

• **VISUAL FUNCTION QUESTIONNAIRE:** Each patient completed a Japanese language version of the NEI VFQ-25 at the baseline examination and after 3 months of limbal CL use to evaluate their vision-related quality of life.[37] The questionnaire was administered via a direct interview by a trained interviewer (S.M.) who was otherwise not involved in the patient's care.

• **STATISTICAL ANALYSIS:** The Wilcoxon signed-rank test was used to compare the NEI VFQ-25 data at baseline and after 3 months of limbal CL use. *P* values of less than .05 were considered statistically significant.

• **ADDITIONAL COLLECTED DATA:** For each patient, additional collected data included the diameter and the peripheral design of the CL, the base curve and the size of the optical zone, the length in time of CL wear, patient reports of symptoms, if any, during CL wear, and all adverse events that occurred during the period of CL use.

RESULTS

• **PATIENT CHARACTERISTICS:** This retrospective study involved a total of 53 eyes of 42 SJS or TEN patients (15 men and 27 women) ranging in age from 28 to 78 years (mean age ± standard deviation [SD], 51.8 ± 13.9 years). At disease onset, patient age ranged from 2 to 64 years (mean age ± SD, 22.4 ± 16.7 years), and 23 (53.5%) of the 41 patients were younger than 20 years. The duration of the illness ranged from 2 to 68 years (mean duration ± SD, 29.3 ± 15.7 years), and the mean ± SD patient follow-up period was 25.7 ± 15.7 months. The causative drugs were cold medicines in 13 patients, nonsteroidal anti-inflammatory drugs in 11 patients, antibiotics in 6 patients, anticonvulsants in 2 patients, and others in 6 patients.

Prior ocular surgeries had been performed in 37 (70.0%) of the 53 eyes at Kyoto Prefectural University of Medicine

or at a different medical facility. Corneal reconstruction was performed in 21 eyes: COMET in 9 eyes, cultivated limbal epithelial transplantation in 5 eyes, limbal transplantation or keratoepithelioplasty in 5 eyes, and penetrating keratoplasty or lamellar keratoplasty in 6 eyes. Conjunctival reconstruction was performed in 17 eyes: amniotic membrane transplantation in 11 eyes, COMET in 2 eyes, oral mucosal transplantation in 2 eyes, and other surgeries in 2 eyes. Cataract surgery was performed in 13 eyes. Entropion surgeries were performed in 12 eyes, and ptosis surgeries were performed in 4 eyes. Fitting and use of the limbal CL was initiated only when the ocular surface had been stable for at least 1 month after cataract or eyelid surgery and for at least 3 months after ocular surface reconstruction or keratoplasty.

• OCULAR SURFACE GRADING SCORE: As reported previously, the ocular surface grading score reflects the severity of sequelae caused by SJS or TEN.[36] The loss of the palisades of Vogt and meibomian gland involvement were grade 3 in 50 eyes (94.3%) and 51 eyes (96.2%), respectively. That is, more than 95% of eyes were limbal stem cell deficient and also had severe meibomian gland dysfunction. Mild to moderate neovascularization and opacification of the cornea existed (Supplemental Table, available at AJO.com).

There were 11 eyes in group 1, 31 eyes in group 2, and 11 eyes in group 3. All ocular surface grading scores (except those for hyperemia and punctal damage), as well as the total score, were highest in group 1 and lowest in group 3 (Table 1).

• TEAR EXCHANGE UNDER THE CONTACT LENS: The results of the tear-exchange experiment revealed substantial differences in fluorescein staining patterns and concentrations between the scleral CL and the limbal CL. Fluorescein patterns showed no change of fluorescein concentration over a 10-minute period in the eyes with the scleral CL, but did reveal a gradual decrease of fluorescein concentration in the eyes with the limbal CL (Figure 3).

• LIMBAL CONTACT LENS WEAR IN EYES WITH OCULAR SURFACE SCARRING: The limbal CLs were able to be used for eyes with fornix shortening, conjunctivalization, and neovascularization of the cornea, and there was no need to fill the CL with saline or artificial tears. During limbal CL wear, a thin fluid layer existed beneath the CL (Figure 4) and the precorneal fluid layer exchanged at every blink (Supplemental Video, available at AJO.com).

• VISUAL ACUITY: Best-corrected visual acuity improved from 1.61 to 0.86 logMAR after 3 months of limbal CL use, and in 43 eyes (81.1%), the BCVA improvement was more than 0.2 logMAR (Figure 5). The BCVA

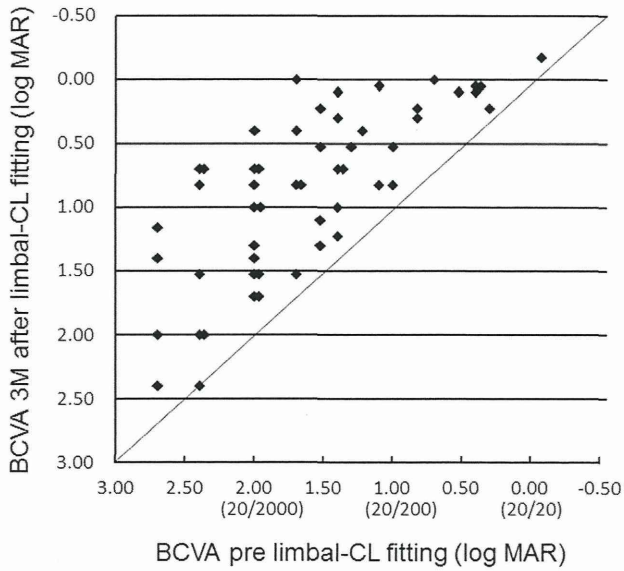

FIGURE 5. Scatterplot showing the change in best-corrected visual acuity (BCVA) measured in logarithm of the minimal angle of resolution (logMAR) units before and at after 3 months use of the limbal contact lens in 42 patients (53 eyes) with ocular sequelae resulting from Stevens-Johnson syndrome or toxic epidermal necrolysis. The diagonal line indicates the values at which the preoperative and postoperative visual acuity values were the same. Counting fingers, hand movements, and light perception were determined to be 0.004, 0.002, and 0.001, respectively.

improvement in groups 1, 2, and 3 was 0.95 logMAR, 0.82 logMAR, and 0.37 logMAR, respectively (Table 2). Mean BCVA after 3 months of CL use was 1.55 logMAR in group 1, the worst among the 3 groups. However, BCVA improvement was best in group 1. Of 29 cases in which the CL was fitted unilaterally, the CL was fitted in the eye with better VA in 26 cases and in the eye with worse VA in 3 cases. At the final examination, the eye fitted with the limbal CL was the eye with better VA in all 29 unilateral cases.

• VISUAL FUNCTION QUESTIONNAIRE: The mean NEI VFQ-25 composite score of the 11 subscores improved from 37.6 ± 16.0 to 58.4 ± 17.4 ($P = .000001$). Significant improvement was found in all 11 subscores, except for the score for driving ability (Table 3). Significant improvement was found not only in the vision-related subscores, but also in the behavioral subscores. It should be emphasized that the subscore for mental health (ie, patient well-being) was very low in group 1, but greatly improved after using the limbal CL.

Comparison of the subscores among the 3 groups revealed that the vision-related subscores most improved in group 3, except for the score for color vision. However, the subscores of general health most improved in group

TABLE 2. Comparison of the Change of Visual Acuity Among the 3 Groups Divided According to Best-Corrected Visual Acuity Before Limbal Contact Lens Fitting

		BCVA Before Limbal CL Fitting		
	Total	Group 1: BCVA Worse Than 20/2000 (logMAR >2), Average Grade	Group 2: BCVA 20/200 to 20/2000 (2 ≥ logMAR > 1), Average Grade	Group 3: BCVA 20/200 or Better (1 ≥ logMAR), Average Grade
No. of eyes	53	11	31	11
BCVA before limbal CL fitting (logMAR)	1.61	2.51	1.67	0.57
BCVA after 3 months of limbal CL use (logMAR)	0.86	1.55	0.85	0.20
BCVA improvement (logMAR)	0.75	0.95	0.82	0.37

BCVA = best-corrected visual acuity; CL = contact lens; logMAR = logarithm of the minimal angle of resolution.

1 (Table 4). Among the behavioral subscores, social functioning and dependence improved almost equally in the 3 groups. Both mental health and role difficulties (ie, role limitations) improved most in group 3, but the improvement of mental health in group 1 also was high.

• LIMBAL CONTACT LENS SIZE, BASE CURVE, AND PERIPHERAL DESIGN: Of the total 53 eyes, the diameter of the limbal CL was 14.0 mm in 45 eyes, 13.0 mm in 6 eyes, 12.5 mm in 1 eye, and 16 mm in 1 eye. The base curve of the lens ranged from 780 to 810 mm in 48 eyes (ie, 750 mm in 1 eye, 760 mm in 1 eye, 770 mm in 3 eyes, 780 mm in 18 eyes, 790 mm in 12 eyes, 800 mm in 7 eyes, and 810 mm in 11 eyes). The size of the optical zone was 8.0 mm in 2 eyes, 8.5 mm in 32 eyes, 9.0 mm in 17 eyes, and 9.5 mm in 2 eyes. The peripheral design was the flat-pattern type in 49 eyes and the tight-pattern type in 4 eyes.

Because of the highly irregular corneal surface in each patient, the corneal shape could not be evaluated by use of topography. To determine the CL size, base curve, and peripheral design, we first tested the CL fitting using the 790/0/14.0-8.5 flat-pattern type. Next, we changed and tested the CL, step by step, by evaluating the fluorescein staining pattern both at rest and during blinking. In the eyes with slight scarring of the ocular surface, the large optical zone CL was well fitted and the peripheral tight-pattern design was preferred.

• LENGTH OF TIME OF CONTACT LENS WEAR AND ADVERSE EVENTS: In 33 eyes, the limbal CL was used from morning into the evening, that is, more than 12 hours per day. In 3 eyes, the CL was used only during the part of the day when the patients left their house to go outside. In 3 eyes, the patients reported eye pain after several hours of CL wear; all 3 eyes had severe scarring of the upper fornix, and the symblepharon was asymmetrical between the upper and lower fornix. In 1 eye, a small epithelial erosion occurred, but healed within several days after the discontinuation of CL wear. No other complications or infections occurred as a result of CL wear. Seven patients lost their CL because of low VA, making it extremely difficult for them to find the CL by themselves.

DISCUSSION

THE OCULAR SEQUELAE RESULTING FROM SJS OR TEN CAN be devastating to a patient's vision, and the associated severe ocular discomfort is extremely serious and lasts throughout the patient's life. The improved VA and quality of life achieved through the use of the tear-exchangeable limbal CL are encouraging, because this CL has the potential of being a new treatment option that can provide better VA, improved ocular comfort, or both for patients with SJS or TEN.

It should be emphasized that before the initial use of this new CL, BCVA in 79% of the eyes (42 of the 53 eyes) was worse than 20/200 (groups 1 and 2). Moreover, BCVA in 21% of the eyes (11 of the 53 eyes) before CL use was worse than 20/2000, hand movements, or counting fingers (group 1). The mean change in BCVA was 0.95 logMAR, the greatest change being in group 1. Visual acuity improved immediately after the CL fitting, and the patients were surprised with the instant improvement. In fact, that improvement of VA allowed some of the patients to see their doctor's face for the first time.

With the use of this new CL, spontaneous exchange of tear fluids or artificial tears occurs during every blink. In contrast, with the use of scleral CLs (diameter, 16 to 23 mm), there is little or no exchange of tear fluids or artificial tears, and the CL must be cleaned every 4 to 6 hours. Our findings show that all-day wear of our new CL is possible, because there is no need to remove and clean the CL during that extended period.

In recent years, semiscleral CLs with a diameter of 15.0 to 18.0 mm were reported to offer the benefit of improving VA in eyes with severe dry eye or an irregular cornea.[38,39]

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• **LENGTH OF TIME OF CONTACT LENS WEAR AND ADVERSE EVENTS:** In 33 eyes, the limbal CL was used from morning into the evening, that is, more than 12 hours per day. In 3 eyes, the CL was used only during the part of the day when the patients left their house to go outside. In 3 eyes, the patients reported eye pain after several hours of CL wear; all 3 eyes had severe scarring of the upper fornix, and the symblepharon was asymmetrical between the upper and lower fornix. In 1 eye, a small epithelial erosion occurred, but healed within several days after the discontinuation of CL wear. No other complications or infections occurred as a result of CL wear. Seven patients lost their CL because of low VA, making it extremely difficult for them to find the CL by themselves.

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In recent years, semiscleral CLs with a diameter of 15.0 to 18.0 mm were reported to offer the benefit of improving VA in eyes with severe dry eye or an irregular cornea.[38,39]

TABLE 3. Twenty-five-Item National Eye Institute Visual Function Questionnaire Results for the Patients With Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis Before and After 3 Months of Limbal Contact Lens Use

	Before CL Fitting	After CL Fitting	Mean Change	*P* Value[a]
Composite score 11				
Mean ± SD	37.6 ± 16.0	58.5 ± 17.4	20.8 ± 15.8	.000001
Median (range)	35.2 (8.4 to 69.4)	58.4 (23.2 to 92.7)	21.6 (–17.2 to 59.7)	
Composite score 7				
Mean ± SD	35.7 ± 16.0	58.4 ± 17.6	22.7 ± 17.6	.000001
Median (range)	35.1 (4.3 to 67)	57.2 (17.0 to 93.9)	20.7 (–17.4 to 67)	
Subscale scores				
General health				
Mean ± SD	47.4 ± 21.2	58.8 ± 15.1	11.4 ± 21.6	.006265
Median (range)	50 (0 to 100)	60 (5 to 85)	0 (–27.5 to 65)	
Vision-related subscales				
General vision				
Mean ± SD	32.6 ± 15.8	65.1 ± 20.3	32.6 ± 22.6	.000001
Median (range)	30 (0 to 75)	70 (0 to 100)	35 (–15 to 75)	
Near vision				
Mean ± SD	31.1 ± 17.0	53.1 ± 21.7	22 ± 19.9	.000007
Median (range)	29.2 (0 to 66.7)	54.2 (8.3 to 100)	22.5 (–16.7 to 66.7)	
Distance vision				
Mean ± SD	29.9 ± 17.2	53.4 ± 18.3	23.5 ± 18.7	.000003
Median (range)	33.3 (0 to 62.5)	50 (12.5 to 95)	25 (–12.5 to 60)	
Color vision				
Mean ± SD	62.9 ± 24.2	77.1 ± 21.0	14.3 ± 24.1	.003496
Median (range)	75 (0 to 100)	75 (0 to 100)	0 (–50 to 75)	
Peripheral vision				
Mean ± SD	33.1 ± 24.0	50.0 ± 23.9	16.9 ± 25.5	.000447
Median (range)	25 (0 to 100)	50 (0 to 100)	25 (–75 to 75)	
Ocular pain				
Mean ± SD	43.9 ± 29.9	65.7 ± 25.9	21.8 ± 24.7	.000061
Median (range)	50 (0 to 100)	75 (12.5 to 100)	12.5 (–25 to 87.5)	
Behavioral subscales				
Mental health				
Mean ± SD	28.9 ± 21.1	52.8 ± 22.8	23.9 ± 21.5	.000003
Median (range)	25 (0 to 80)	55 (10 to 95)	20 (–15 to 75)	
Social function				
Mean ± SD	51.8 ± 16.8	66.9 ± 17.5	15.1 ± 20.9	.000661
Median (range)	50 (25 to 91.7)	66.7 (33.3 to 100)	16.7 (–25.0 to 58.3)	
Role limitation				
Mean ± SD	36.3 ± 22.6	57.4 ± 20.9	21.2 ± 20.6	.000009
Median (range)	37.5 (0 to 81.3)	56.3 (0 to 100)	18.8 (–18.8 to 68.8)	
Dependency				
Mean ± SD	39.5 ± 25.6	60.4 ± 22.4	20.9 ± 21.7	.000009
Median (range)	43.8 (0 to 87.5)	62.5 (12.5 to 100)	18.8 (–18.8 to 93.8)	
Ability to drive				
Driving				
Mean ± SD	6.1 ± 18.7	14.6 ± 29.8	9.9 ± 20.5	.278517
Median (range)	0 (0 to 75)	0 (0 to 100)	0 (0 to 75)	

CL = contact lens; SD = standard deviation.
[a]Wilcoxon signed-rank test.

The limbal CL presented in this study may seem to be similar to a large-diameter rigid gas permeable CL or a semiscleral CL. However, the chief difference between our new CL and a semiscleral or large-diameter CL is the entrapment of the fluid reservoir beneath the flange that extends beyond the limbus when using this CL. To bring the tear under the CL automatically, the CL design includes a multicurve zone at the periphery of the CL, thus

TABLE 4. Comparison of the Change of the 25-Item National Eye Institute Visual Function Questionnaire Scores Before and After 3 Months of Limbal Contact Lens Use among the 3 Groups Divided According to Best-Corrected Visual Acuity before Limbal Contact Lens Fitting

	Total	Group 1: BCVA Worse Than 20/2000 (logMAR > 2), Average Grade	Group 2: BCVA 20/200 to 20/2000 (2 ≥ logMAR > 1), Average Grade	Group 3: BCVA 20/200 or Better (1 ≥ logMAR), Average Grade
No. of cases	35	8	18	9
Composite score 11	20.8	18.1	20.2	24.5
Composite score 7	22.7	20.8	21.5	26.9
Subscale scores				
General health	11.4	13.8	12.6	6.9
Vision-related subscales				
General vision	32.6	26.3	30.8	41.7
Near vision	22.0	19.6	19.5	29.1
Distance vision	23.5	23.8	22.2	25.8
Color vision	14.3	9.4	18.1	11.1
Peripheral vision	16.9	12.5	17.6	19.4
Ocular pain	21.8	21.9	20.1	25.0
Behavioral Subscales				
Mental health	23.9	25.6	19.5	31.1
Social function	15.1	14.6	16.2	13.4
Role limitation	21.2	18.0	20.1	26.2
Dependency	20.9	18.0	22.2	20.8
Ability to drive				
Driving	9.9	0.0	2.1	28.3

BCVA = best-corrected visual acuity; logMAR = logarithm of the minimal angle of resolution.

establishing a thin tear layer on the entire corneal surface that can bring relief to the patients with severe ocular discomfort.

Our new CL comprises an 8.5- or 9.0-mm diameter central zone and a peripheral zone that lies on the corneal and conjunctival limbus. During the lens design process, we found that in the eyes with severe cicatrization of the ocular surface, the shape of the sclera beyond the limbus is flatter than that of normal eyes. Therefore, the peripheral zone in our limbal CL was designed to be flatter than the central optical zone, and it incorporates a projecting multicurve edge design that is like the brim of a hat. Although our limbal CL with an 8.5-mm diameter central zone was well fitted in the severely cicatrized eyes in comparison with the moderately affected eyes, the CL with a 9.0-mm diameter central zone was well fitted in moderately damaged eyes or in the eyes without fornix shortening. The peripheral design with the flat-pattern type was well fitted in the moderate to severe cicatrized eyes. In contrast, the peripheral design with the tight-pattern type was well-fitted in the eyes with slight or no cicatrized eyes.

As reported previously, the quality of life in SJS or TEN patients is worse than that in the patients with Sjögren syndrome.[35,40] Use of our limbal CL not only increased the patients' VA, but also improved their general health and mental health. In fact, even the end-stage blind patients (group 1) experienced improved vision and general health. Moreover, because of the decrease of tear evaporation, eye pain also decreased during CL wear. The use of scleral CLs reportedly reduces symptoms related to severe dry eye,[31,32] and our findings show that using our new limbal CLs also reduces those same symptoms.

It should be noted that COMET is reportedly a reliable option for obtaining improved vision in eyes with end-stage SJS or TEN.[24] However, the damage in the eyes treated by COMET in that study was more severe than in the eyes enrolled in this present study. In this study, 11 cases used this CL after ocular surface reconstruction using the COMET technique. These patients were able to obtain improved vision by COMET alone, yet use of the limbal CL enhanced that improvement of vision. Thus, the use of this CL alone, or the 2-step treatment of COMET and limbal CL use, are safe and reliable treatment methods for ocular sequelae resulting from SJS or TEN. In conclusion, the findings of this study show that our new tear-exchangeable, limbal CL increases VA and also increases general health and mental health in SJS or TEN patients, especially those with end-stage blindness.

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