Severe Epithelial Edema in Clearkone Synergeyes Contact Lens Wear for Keratoconus

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Objective: The aim was to report three cases of severe bilateral epithelial edema (central corneal clouding [CCC]) in association with ClearKone SynergEyes hybrid contact lenses for the vision rehabilitation of keratoconus.

Methods: Retrospective case series of six eyes of three patients that developed CCC with ClearKone SynergEyes hybrid contact lens wear shortly after beginning to wear those lenses.

Results: Severe CCC was diagnosed on removal of the lenses. Despite attempts to modify the parameters of the lenses to reduce edema, two patients discontinued lens wear entirely, and one patient was able to wear lenses only on a limited basis.

Conclusions: Different degrees of CCC have been reported with the use of polymethyl methacrylate lenses; however, the condition may also occur with the use of ClearKone SynergEyes lenses. Although the lenses may provide good subjective responses, careful observation of the corneal response after 5 hrs of wear is advised.

Key Words: Synergeyes—Clearkone—Keratoconus—Central corneal clouding—Irregular astigmatism—Corneal edema.

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In cases of significant corneal irregularity, rigid gas permeable (RGP) contact lenses are generally believed to provide the clearest possible vision. However, RGPs elicit considerable lens awareness in many patients. Piggyback contact lens systems have been used to attempt to achieve both the clarity offered by RGPs and an increase in comfort but with the burden of a more complicated lens care and handling. SynergEyes lenses[1] (SynergEyes, Inc., Carlsbad, CA), a novel family of hybrid lenses, were introduced in 2001. This family of lenses combines a rigid center with a hydrogel skirt and includes designs to accommodate a wide range of corneal and refractive conditions. Successful management of keratoconus has been reported using SynergEyes lenses.[2] Nau[3] compared SynergEyes with RGP lenses and reported that in 79.5% of patients, comfort was improved when compared with when wearing rigid lenses. But when SynergEyes were compared with soft toric lenses,[4] these were perceived as more comfortable and produced fewer symptoms of dryness and lens awareness than did SynergEyes lenses.

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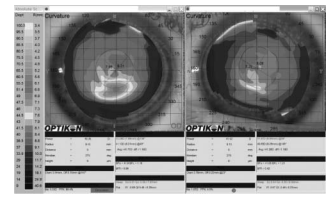
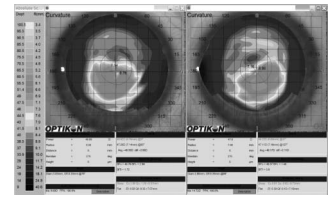
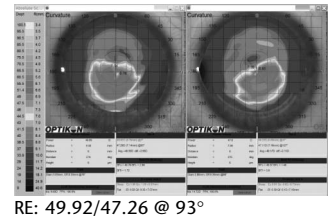
A specific design of SynergEyes lens is the Clearkone, which is intended to fit irregular corneas such as those with keratoconus. The rigid lens component is made of Paragon HDS 100 (Paragon Vision Sciences, Mesa, AZ), with a vault diameter of 7.4 mm and a permeability of 100×10^{-11} (cm^2/sec) [mlO_2/(ml × mmHg)]. The rigid center includes a spherical optic zone and a reversal curve. The soft skirt is nonionic and extends to 14.5 mm and has a water content of 27% and a permeability of 9.3×10^{-11} (cm^2/sec) [mlO_2/(ml × mmHg)]. This lens is fitted[5] using a vaulting method with a goal of minimal clearance over the apex of the cone. ClearKone is available in 11 different vaults in 50-μm steps of which each can be ordered in 3 different skirt curvatures. The fitting process involves individually fitting two different areas of the cornea with trial lenses, high-molecular fluorescein and slitlamp. The goal for the central RGP portion is to find the appropriate vault needed to clear the corneal apex and provide apical clearance. The proper peripheral soft skirt is determined on the basis of the correct curvature that places the proper distribution of the support within the landing zone. As stated in its Clinical fit training guide, ''patient comfort greatly validates fit in ClearKone'' (available through the web page of the company at www.synergeyes.com).

CASES REPORTS

Case 1

A 28-year-old female journalist was examined in our office for fitting contact lenses. Her main complaint was monocular diplopia in her right eye (RE) and difficulty in driving at night because of vision degradation in scotopic conditions. She had been wearing spectacles for several years with a stable refraction until 1 year ago when her refraction changed and the keratoconus diagnosis was performed elsewhere. Several attempts to fit her with RGP lenses were unsuccessful because of intolerance. She was in good general health without a history of allergies or a family history of any ocular disease. Tear break-up time, intraocular pressure, and ocular fundi were within normal limits. Manifest refraction, slitlamp findings, central ultrasonic pachymetry with a DGH 4000 (DGH Technology Inc., Exton, PA), corneal hysteresis, and corneal response factor measured with an ocular response analyzer (Reichert Inc., Depew, NY), and corneal topography data derived from a Keratron Scout (Opticon 2000 S.p.a., Rome, Italy) are enclosed for the three cases in Table 1. In this case, the RE showed a positive cone location and magnitude index[6] for keratoconus detection. After the examination, the diagnosis of mild oval keratoconus in the RE and form fruste in her left eye (LE) was established. Proper management, including intracorneal rings, crosslinking, and contact lens fitting, was

TABLE 1. *Relevant Prefitting Characteristics of the Presented Cases*

	Manifest refraction (VA)		Prefitting biomicroscopy		Corneal topography and Sim-K	Pachimetry (μm)		ORA	
	RE	LE	RE	LE		RE	LE	RE	LE
Case 1 (28-yr-old female)	−1.50 sph./−3.00 × 70° (20/25)	−2.50 sph./−1.00 × 150° (20/22)	(+) FR-p, (+) CN	(+) CN		490	500	CH: 8.0	CH: 6.0
					RE: 42.29/41.13 @49° LE: 41.87/40.69 @149°			CRF: 7.6	CRF: 5.5
Case 2 (39-yr-old male)	−7.00 sph/−1.50 × 180° (20/40)	+1.00 sph./−5.00 × 120° (20/25)	(+) FR-c, (+) LV	(+) FR-c, (+) LV		460	495	CH: 7.3	CH: 7.9
			(+) CN, (+) SW	(+) CN, (+) SW	RE: 51.70/49.92 @ 120°			CRF: 5.2	CRF: 5.4
			(+) CSc	(+) FN	LE: 49.32/46.06 @ 90°				
Case 3 (51-yr-old male)	−18.00 sph/−2.00 × 100° (20/50)	−13.00/−2.00 × 110° (20/40)	(+) FR-c, (+) LV	(+) FR-c, (+) LV		510	500	CH: 8.3	CH: 8.2
			(+) CN	(+) CN	RE: 49.92/47.26 @ 93° LE: 49.22/47.11 @ 127°			CRF: 7.5	CRF: 7.9

CH, corneal hysteresis; CN, thickening of corneal nerves; CRF, corneal response factor; CSc, corneal scarring; FN, fibroplastic nodule; FR-c, complete Fleischer ring; FR-p, partial Fleischer ring; LE, left eye; LV, lines of Vogt; ORA, ocular response analyzer; RE, right eye; SW, swirl staining; VA, visual acuity.

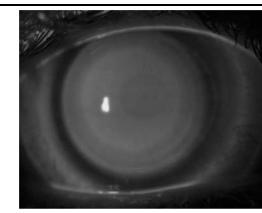
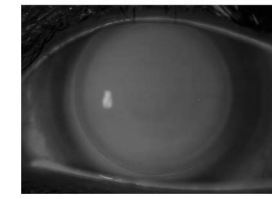
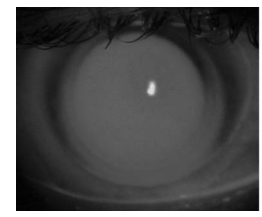
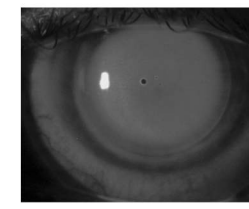
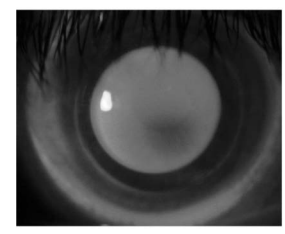
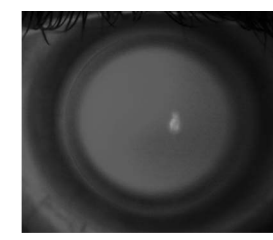
discussed. The patient was not interested in any sort of surgery or in gas permeable lenses because of previous failures.

As a possible contact lens option, ClearKone SynergEyes was suggested. After a trial fitting procedure, the following lenses (Table 2) were finally dispensed:

RE: Clearkone VLT 100, power −2.50 D, overall diameter (OAD) 14.50-mm, skirt medium.
LE: Clearkone VLT 100, power −2.50 D, OAD 14.50-mm, skirt medium.

Visual acuity (VA) with the lens in situ was 20/15 with a plano overrefraction in each eye. High-molecular-weight fluorescein (Fluoresoft, Holles Laboratories, Cohasset, MA) images were recorded after 5 min (Table 2). Comfort was excellent, and the patient was thrilled with the achieved crisp vision. After the patient was instructed about proper manipulation, the lenses were dispensed. A peroxide-based regimen (Aosept, Ciba Vision, Duluth, GA) was prescribed for all the patients in this case report. At the 1-week follow-up, the patient reported good overall comfort with 11 hrs of continuous wear (as the average of the last 3 days of wear time) and vision. But the patient reported of seeing haloes around lights after 6 hrs of wear. VA and overrefraction were unchanged. Lenses were centered with a 2.0-mm interblink movement, and the soft portion showed a correct apposition with the sclera. Because the patient was evaluated in the morning with few hours of wear, I instructed the patient to return after an additional 6 hrs on the same day. When the patient returned, she claimed to see well except for a ''rainbow around lights'' in both eyes. The VA was again 20/15 in each eye. The lenses were similar to those in the previous observation. When the lenses were removed, the anterior segments were evaluated with a slitlamp, and the following images were obtained (Fig. 1). A distinct round cloudy circular area corresponding to the portion of the RGP material (inner landing zone in the SynergEyes terminology) of a light gray color was located in the epithelial layers in both eyes. After finding this, a diagnosis of grade 3 circular corneal clouding (CCC) on the Mandell grading scale[7] in both eyes was recorded (Table 3). No corneal staining was evident with fluorescein. After the lenses were removed, haloes and clinical signs were noticed for an additional 15 min. The CCC was still present after 5 hrs of several attempts at altering the parameters of the skirt configuration. The patient was instructed to discontinue the wear of these lenses and was refitted in a different lens modality.

TABLE 2. *Clinical Information About Fitted Contact Lenses in the Reported Cases*

	Parameters		VA with lenses		Wearing time (hrs)	CCC grade		Fluorescein images	
	RE	LE	RE	LE		RE	LE	RE	LE
Case 1	VLT 100 power −2.50 D Skirt medium	VLT 150 power −3.50 D Skirt medium	20/15	20/15	11	3	3		
Case 2	VLT 200 power −1.00 D Skirt medium	VLT 250 power −1.00 D Skirt medium	20/20	20/20	8	3	1		
Case 3	VLT 300 power −12.75 D Skirt medium	VLT 250 power −9.50 D Skirt medium	20/20	20/20	Inconsistent	3	2		

CCC, central corneal clouding; LE, left eye; RE, right eye; VA, visual acuity.

Case 2

A 39-year-old male electronic technician who was RGP intolerant because of recurrent corneal erosions secondary to a fibrotic nodule was evaluated. His vision with spectacles was regarded as poor with monocular diplopia in his RE. Both topographies were consistent with a central moderate (nipple) keratoconus, with and additional central distortion in the central region of the LE secondary to the nodular elevation. The rest of the examination was within normal limits.

After a trial lens fitting procedure, the following lenses (Table 2) were ordered and consequently dispensed:

RE: Clearkone VLT 250, power −1.00 D, OAD 14.50 mm, skirt standard.
LE: Clearkone VLT 250, power −1.00 D, OAD 14.50 mm, skirt standard.

At the dispensing visit, a VA of 20/20 was achieved in each eye with a plano overrefraction. At the next progress follow-up (1 week), the patient reported that comfort was better than when wearing his previous RGP lenses with an average wearing time of 8 hrs. The patient was happy with the achieved vision and in particular with the ability to move his eyes around without the fear of contact lens dislocation. However, the patient reported hazy vision and haloes around the lights after 5 hrs of wear in his RE. On slitlamp examination, grade 3 CCC in the RE and grade 1 in the fellow eye was recorded. The patient was instructed to quit wearing these lenses. It was not possible to fit a shallower VLT (flatter) lens because of central corneal touch or a different skirt because of lack of comfort. The patient was refitted with a different specialty lens.

Case 3

A 51-year-old male golf player with a long-standing history of RGP intolerance and who was currently wearing soft contact lenses was examined with the purpose to improve his VA. He had a positive history of asthma and psoriasis. A topographic evaluation revealed a symmetric oval moderate keratoconus in both eyes.

After the contact lens fitting procedure, the following lenses were ordered:

RE: Clearkone VLT 300, power −12.75 D, OAD 14.50 mm, skirt standard.
LE: Clearkone VLT 250, power −9.50 D, OAD 14.50 mm, skirt standard.

The vision with the lenses was 20/20 in each eye, and the patient was happy with the crispness of vision. Fluorescein patterns are shown in Table 2.

The patient was ecstatic about his vision during the day and his ability to play sports during the daytime but reported of seeing disturbing "rings around the lights" at night. A CCC grade 3 (Fig. 2) was diagnosed in his RE and grade 2 in the fellow eye after 5 hrs of continuous wear. The patient was recommended to wear ClearKone only for sport-related activities.

DISCUSSION

In this article, the author shows an association between CCC with early wear of ClearKone SynergEyes hybrid contact lenses for the vision rehabilitation of keratoconus. Circular corneal clouding is also known as gross circular edema and was believed to be

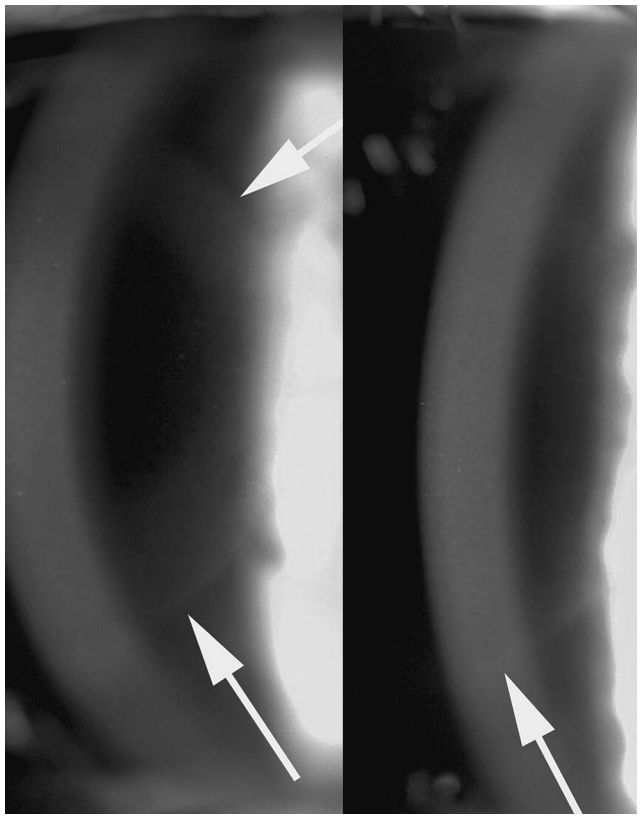


FIG. 1. Anterior segment views immediately after the lenses were removed in both the eyes in case 1. The arrows designated the border of the epithelial edema.

restricted to polymethyl methacrylate contact lens wearers[8] in whom has been an incidence of 76% to 96% in polymethyl methacrylate.[9,10] The higher Dk/*t* values of contemporary contact lens materials and possible better contact lens designs have eradicated this finding from clinical practice. The most obvious symptoms for CCC are spectacle blur (the vision is poor after the lens is removed), haloes around lights, corneal warpage phenomenon, and moderate discomfort.

Pilskalns et al.[11] have studied corneal oxygen uptake and concluded that SynergEyes lens allows significantly more oxygen to reach the cornea during wear than do the SoftPerm lenses in the central cornea. It has been considered that modern lens materials with oxygen permeabilities of 50 to 100 Fatt units or greater should provide reasonable corneal oxygenation under daily wear

TABLE 3. *Grading of CCC*

Grade	Description
0	No CCC
1	Just detectable corneal haze without distinct borders
2	Borders distinct but visible only against pupil background
3	Borders distinct. Area of clouding visible against iris in dimly lit room

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CCC, central corneal clouding.

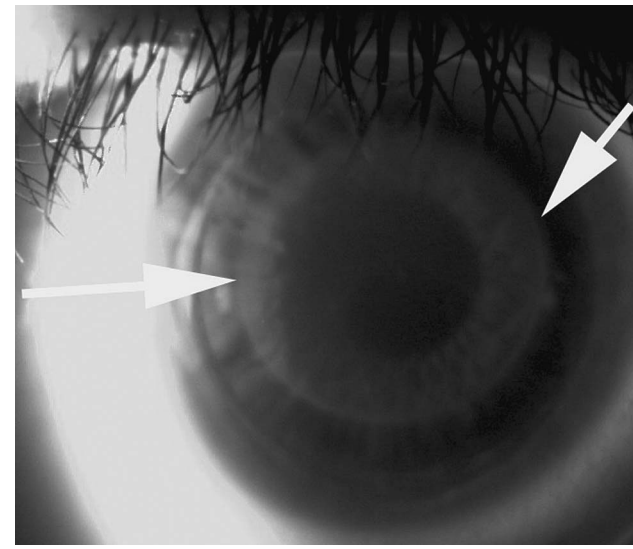

FIG. 2. Central corneal clouding (CCC) in the right eye (RE) of case 2 with the lens in situ.

conditions.[12] It has been also shown[13] that lens movement (tear pumping) offers little oxygenation compared with a lens of 25×10^{-9} oxygen transmissibility. There are several possible causes for the Clearkone lens–induced CCC. The most likely is that because CCC is a hypoxia-associated phenomenon, the RGP portion of the lens does not provide as much oxygen transmissibility as expected. The second is that there is little tear exchange even if there is slight movement of the lens and the vaulted central area contains a stagnant tear layer. The last potential cause is an unusual delayed toxic or hypersensitive reaction of the hybrid lens to hydrogen peroxide disinfecting system. However, all of these suggestions are unlikely, and the reaction that was observed is surprising.

CONCLUSIONS

This report showed evidence of corneal edema (CCC) in a series of patients with keratoconus who wore Clearkone SynergEyes lenses with good VA and comfort. We believe that this is the first case reported about this complication and its association with this particular hybrid contact lens. Although the lenses may provide good subjective responses, careful observation of the corneal response after 5 hrs of wear is advised.

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