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ORIGINAL ARTICLE

Scalloped Channels Enhance Tear Mixing Under Hydrogel Contact Lenses

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ABSTRACT

Purpose. Tear exchange under a soft contact lens is directly related to the amount of lateral and transverse lens motion. Hydrodynamic modeling suggests that channels placed on the back surface of a soft lens will reduce fluid resistance and increase transverse lens movement. This study measured the effect of posterior lens surface scalloped channels on tear exchange.

Methods. Tear exchange in the postlens tear film (PoLTF) was estimated using a fluorometer to measure the exponential depletion of high-MW fluorescein under the lens expressed as the time to deplete 95% of dye (T_{95}). A total of 32 subjects wore two pairs of identical lenses except that the experimental lens had 12 scalloped channels placed radially in the midperiphery of the posterior lens surface, whereas lenses without channels served as controls.

Results. The mean ± standard error T_{95} values for the channel lenses was 28 ± 2 minutes compared with 32 ± 2 minutes for the control lenses ($p = 0.107$). There was a marginally significant difference in T95 between two lens groups in Asian eyes ($p = 0.054$).

Conclusion. Placing scallop-shaped channels on high-H_2O content soft lenses improved the postlens tear pumping in Asian eyes.

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Key Words: tear mixing, channels, lens designs, soft lenses, ethnicity

Overnight contact lens wear has been associated with several adverse clinical events. Most clinicians and investigators have assumed that these complications result from contact-lens-induced corneal hypoxia. Although there is no direct evidence linking many of the more worrisome complications (e.g., infection, infiltrative keratitis, peripheral corneal ulcer) to corneal hypoxia, this assumption seems reasonable because there are considerable data showing that corneal hypoxia alters corneal structure and function.[1–6] Therefore, when silicone-hydrogel soft lenses (SHSL) were introduced with oxygen transmissibilities (Dk/t) that provided sufficient oxygen to maintain normal metabolism, clinicians expected that most of the adverse clinical events would be eliminated.[7] Unfortunately, this was not the case. Studies have now documented that the incidence of some of the more serious corneal complications associated with overnight SHSL wear, is similar to that found with conventional hydrogel lens wear.[8–13]

Although the etiology of adverse clinical events associated with SHSL wear is not well understood, most clinicians and investigators agree that corneal hypoxia is not the underlying mechanism. More likely, these complications are related to one or more aspects of the lens material or performance such as lens/lid pressure, lens movement, lens surface properties, postlens tear film (PoLTF), and the rate of tear exchange under the lens. In particular, we believe that efficient tear exchange is necessary to provide for timely removal of the inflammatory cells, metabolic byproducts, and debris that accumulate under the lens during sleep. In previous work, we have shown that overnight wear lowers corneal epithelial barrier function and have suggested that altered epithelial physiology is, in part, as a result of poor tear replenishment after eye opening.[14–16]

Given the possible connection between poor tear exchange and adverse ocular response, we argue that timely removal of debris and restoration of the normal PoTLF after lens wear is a requirement for safe extended wear. Unfortunately, increasing tear mixing rates under a soft lens is not easily achieved. Recently, Creech and coworkers proposed a dispersive tear mixing model that provides information about the physical factors controlling tear exchange under a soft contact lens.[17,18] The model shows that an important factor for tear mixing is the amount of vertical (superior–inferior) and transverse (anterior–posterior) lens movement that occurs during blinking. Because excessive vertical movement of a soft lens usually causes discomfort, the amount of lateral movement is limited. However, transverse movement causes little, if any, discomfort and thus offers a potential strategy to improve tear flow under a soft lens. The tear-mixing model suggests that small increases in transverse movement have a substantial effect on tear exchange.[18,19]

Using hydrodynamic modeling, Chauhan and Radke have shown that transverse lens movement can be increased by either placing multiple holes (fenestrations) in the lens or by incorporating channels into the posterior lens surface.[18] Using either fenestrations or channels reduces the resistance to fluid flow and allows for increased transverse motion during the blink. In a previous study, Miller et al. found a significant increase in tear exchange (i.e., 4 minutes) in fenestrated compared with control lenses of high modulus material.[19] Unfortunately, the placement of fenestrations into soft lenses is technically difficult and will probably not have commercial applicability.

CooperVision Inc. has recently developed a method of placing a series of radial scallop-shaped channels of varying length, depth, and width on the posterior lens surface. These channels are manufactured using a molding technique that provides product consistency and hence commercial application. However, before channels are incorporated in contact lens design, several questions need to be addressed. For example, do channels improve tear exchange? If improved tear mixing is possible using channels, is there an optimum design (e.g., length, width, depth)? Would the placement of channels reduce comfort or cause corneal trauma? These and related questions need to be addressed to determine whether channels provide a safe and effective method to improve tear mixing rates. In this article, we report the effects of a scalloped channel design on tear mixing rates, comfort, and corneal tolerance.

METHODS

Subjects

All subjects were experienced soft contact lens wearers, free of ocular disease, who were recruited from the University of California, Berkeley campus. Subjects taking systemic medications known to affect tear film production and those with seasonal allergies were excluded. All subjects gave informed consent at the beginning of their first visits. This study observed the tenets of the Declaration of Helsinki and was approved by the University of California, Berkeley Committee for Protection of Human Subjects.

Contact Lenses

Tear mixing of fluorescein-labeled dextran (FITC-dextran) was measured using Ocufilcon 55% H_2O content lenses (CooperVision Inc., Pleasanton, CA). Two lens designs were used: one with scalloped channels and the other with no channels serving as the control lens. The remaining lens parameters were consistent, and the specific parameters are listed in Table 1.

The scalloped channel design is illustrated in Figure 1. The central back surface of the lens was spherical and without channels. There were 12 scallop-shaped channels with 30° angular separations on the peripheral back surface as illustrated by the radial fans highlighted by fluorescein dye in Figure 1. The channel length was 2.6 mm and the channel depth increased from zero at the edge of the optical zone to its maximum value of 25 μm. Further information regarding the lens design can be found in two U.S. patent applications.[20,21]

Tear-Mixing Estimate

We estimated tear mixing with scanning fluorometry to monitor the changes in intensity of a FITC-dextran dye placed in the tear film behind a soft contact lens over a 30-minute period. From the fluorescence-intensity data, a composite exponential decay rate was used to calculate the time required to deplete 95% of the dye, T_{95}. In this calculation, only the later fluorescence measurements were included (>5 minutes) to eliminate the influence of reflex tearing. Details of the fluorometer procedures and the T_{95} calculation have been published elsewhere.[19,22]

Study Procedure

For each subject, 2 visit days were required. On one day, the control lens design was worn, and on the other day, the channeled lens was worn. The assigned order of the lens design (control or channel) was randomized as well as the eye (right or left) being measured. Both eyes wore identical lenses (i.e., either control or channel) on the days that tear mixing was measured, and the tear-mixing measurement was taken in one eye only according to the predetermined randomization scheme. The same eye was measured for both visit days. Subjects and observers were masked to the lens type assigned for each visit. Before the first visit, central corneal curvatures and palpebral aperture size (PAS) were measured. Central curvature was measured using a keratometer, and vertical PAS was assessed using a millimeter ruler while subjects were relaxed and looking at straightahead gaze.

Each visit began with corneal autofluorescence measurements. The subject then inserted a pair of assigned lenses. Ten minutes after lens insertion, lens fit was assessed (1 = well centered; 2 = decentration with adequate limbal coverage; 3 = decentration with inadequate limbal coverage) as was postblink lens movement

TABLE 1.
Lens parameters of high H_2O content Ocufilcon lenses (channel and control)

Lens types	BCR (mm)	Optical zone diameter (mm)	Overall diameter (mm)	Power (D)	Elastic modulus (MPa)
Ocufilcon 55	8.6	8.0	14.2	−3.00	0.5

BCR, base curve radius.

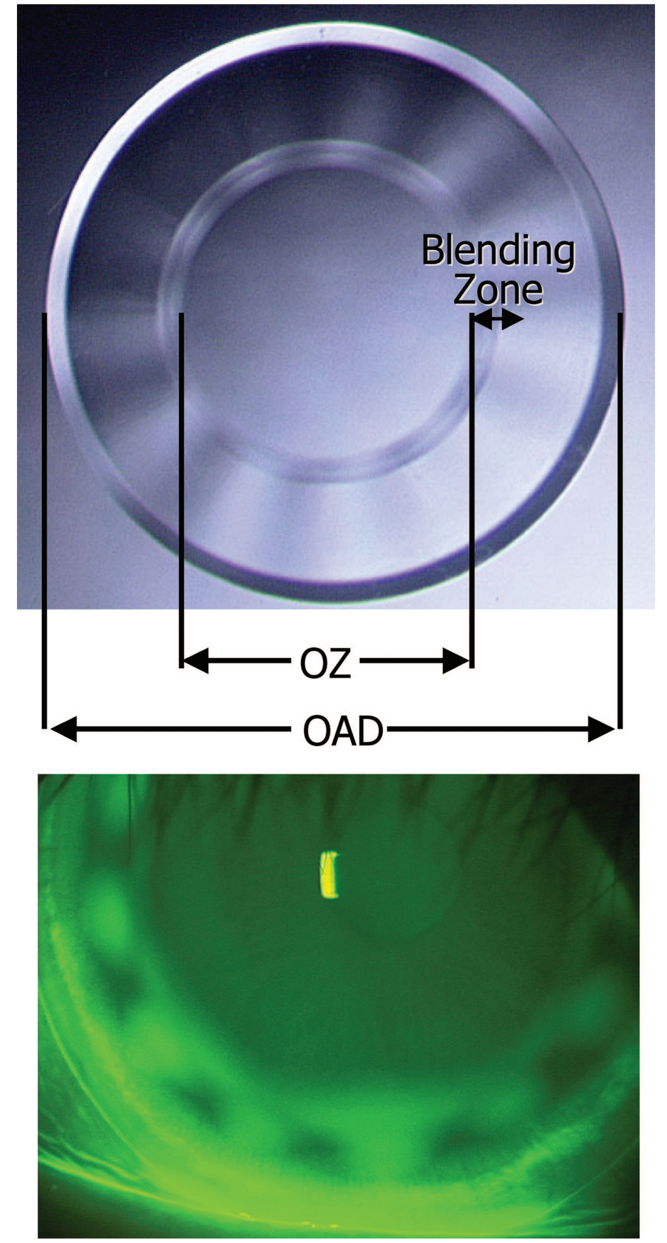

FIGURE 1.

Schematic diagram of a soft lens with scalloped channels illustrated by dark fans (top). On-eye fluorogram of the lens with channels highlighted by fluorescein dye (bottom). OZ, optical zone; OAD, overall diameter.

in the vertical direction at straightahead gaze using a slit lamp calibrated against a magnified millimeter ruler. After lens fit assessment, subjects were asked to rate the lens comfort based on a scale of 0 to 50 (0 = impossible to wear; 50 = very comfortable with no lens sensation). Subjects with comfort ratings of 35 or below or with inadequate lens fit were excluded from the study.

After the lens comfort assessment, the subject removed the lens, and then the observer placed 1 μL of 4 weight % FITC-dextran (MW = 9500 kDa) solution in the lens concavity. The subject reinserted the lens directly onto the cornea, and a fluorescence-intensity reading was taken within 1 minute and repeated at 3-minute intervals for 30 minutes while the blink rate was maintained at 15 blinks per minute with a metronome. After 30 minutes, the lenses were removed, rinsed, and reinserted. Fluorescence measurements were repeated to confirm that FITC-dextran had not penetrated the cornea or the lens matrix. At the completion of each tear-mixing measurement, the corneal surface was examined with using a slit-lamp biomicroscope with fluorescein dye.

The center lens thickness of each lens was determined by taking the average of three measurements from an electronic thickness gauge specifically designed for measuring soft lenses (Model ET-3; Rehder Development Co., Castro Valley, CA).

Statistical Analysis

A paired *t* test was used to assess the mean difference in the T_{95} values between control and channel lenses. According to the results from previous studies, the anatomic differences between Asian and non-Asian eyes can lead to differences in the ocular response to lens wear and the clinical performance of contact lenses.[14,15,23] Therefore, one-way analysis of variance was used to assess the difference in the mean T_{95} and ocular characteristics between Asians and non-Asians.

RESULTS

A total of 32 subjects aged 18 to 38 years (mean ± standard deviation = 22 ± 4 years) participated. Twenty-five of the 32 subjects (14 Asians) completed the protocol, and their data were available for analysis. Data from seven subjects were not available for analysis because three subjects (two Asians) developed extensive corneal staining and four non-Asian subjects yielded tear-depletion data that could not be fitted to an exponential decay curve necessary for obtaining accurate T_{95} estimates.

Lenses were fitted using standard clinical procedures and met the following criteria: well-centered, adequate movement after the blink, and good comfort. The mean ± standard error lens comfort scores were similar between lens groups (control 47 ± 1; channel 46 ± 1; p = 0.728). The mean ± standard error lens movement was 0.25 ± 0.01 mm and 0.24 ± 0.01 mm for the control and channel lens groups, respectively, and the difference was not significant (p = 0.328). There was also no statistically significant difference in the lens center thickness (p = 0.172). The mean ± standard error center thickness was 70 ± 1 μm and 74 ± 2 μm for the control and channel lens groups, respectively. Table 2 provides information on the ocular characteristics of the 25 subjects who completed the study. Asian subjects, compared with non-Asians, had smaller vertical palpebral aperture size, flatter horizontal and vertical corneal curvatures, and higher amounts of corneal toricity. However, the differences in these ocular characteristics between ethnic groups were not significant (all p values were >0.05).

Table 3 lists the tear-mixing rates for control and channel lenses and also provides a comparison of the T_{95} values for Asian and non-Asian eyes. For all participants, the average T_{95} values for the control and experimental lenses were 32 and 28 minutes, respectively (p = 0.107). Stratification of the T_{95} data by ethnicity showed that for the experimental lenses, the Asian subjects showed, on average, a 6-minute faster T_{95} rate than the control lenses (p = 0.054). However, there were no differences in the T_{95} values (31 versus 31 minutes) between control and channel lenses in the non-Asian group (p = 0.898). The difference in T_{95} values between two ethnic groups in control (p = 0.941) and channel (p = 0.145) lens groups was not statistically significant.

TABLE 2.
Ocular characteristics of subjects who wore high H_2O content Ocufilcon lenses

Mean ± Standard deviation	All subjects (n = 25)	Asian (n = 14)	Non-Asian (n = 11)	Analysis of variance F test p values (Asian versus non-Asian)
Ppalpebral aperture size (mm)	10.0 ± 1.4	9.7 ± 0.8	10.3 ± 1.9	0.257
HK (D)	43.16 ± 1.4	42.82 ± 0.79	43.60 ± 1.94	0.184
VK (D)	44.14 ± 1.4	43.91 ± 1.02	44.44 ± 1.86	0.370
ΔK (HK-VK)	−0.98 ± 0.59	−1.09 ± 0.64	−0.84 ± 0.52	0.309

HK, horizontal keratometry reading; VK, vertical keratometry reading.

TABLE 3.
Tear mixing estimates (T_{95}) with high H_2O content Ocufilcon lenses (control versus channel)

High H_2O Ocufilcon lenses	Control mean ± Standard error T_{95} (min)	Channel mean ± Standard error T_{95} (min)	Paired *t* test p value
All subjects (n = 25)	32 ± 2	28 ± 2	0.107
Asian (n = 14)	32 ± 3	26 ± 2	0.054
Non-Asian (n = 11)	31 ± 3	31 ± 2	0.898

DISCUSSION

This is the first clinical evidence that placing scallop-shaped channels on the posterior surface of a soft lens enhances tear mixing without inducing discomfort during lens wear. Although the improvement for all subjects in this study is modest, after data stratification based on ethnic groups, the results provide potential clues for improving PoLTF mixing in Asians. Only Asian eyes had marginally significant difference in tear exchange between lens groups and had a faster tear-mixing rate with channel lenses. This apparent disparity in results between ethnic groups is likely the result of the presumed higher upper-eyelid tension of Asians, which effectively enhances transverse lens motion by exerting more perpendicular pressures on the lens/eye as the lid travels across the lens surface.

The PoLTF thickness is quite small, approximately 10 μm with reported values as low as 2.5 μm.[23–28] It is, therefore, not surprising that rapid exchange of high-molecular-weight fluorescein dye or unwanted substances from behind a soft contact lens is difficult to achieve. Placing channels on the posterior surface of the lens, in our case 25 μm deep, allows escape routes for the tears under the lens, thereby improving tear mixing.[18,26,29] Such a small improvement in tear mixing (i.e., 4 minutes) may be explained by the low modulus of the soft lenses examined in this study, because these low-modulus lenses tend to conform closely to the ocular surface. Therefore, the in-and-out motion induced by the upper eyelid may be diminished because the lens cannot restore its original shape (less recoil) during the interblink, thereby decreasing pumping.

During the course of the study, it was necessary to exclude data from three subjects (9%) as a result of extensive central corneal staining that developed after only 30 minutes of lens wear. We do not know the reason for this reaction, but previous work has shown that soft lenses gradually settle against the cornea.[26,29] It is possible that the presence of channels reduces the fluid flow resistance in the postlens tear film, causing a more rapid lens settling, possibly resulting in mechanical insult to the epithelium in some subjects.[29]

The data from this study agree with dispersive mixing theory, which shows that channels allow for greater in-and-out motion of the lens during the blink, enhancing the fluid flow from under the lens. The dispersive mixing model presumes no fluid exchange of tears—neither through the lens nor through the cornea—only that which occurs at the lens periphery. Exchange of tears through a soft contact lens is obviated by the extremely high hydraulic resistances.[30] Fatt predicts tear supply into the precorneal tear film (PrCTF) driven by an osmotic gradient originating from an assumed hypertonicity of the PrCTF.[31] However, there is no direct evidence for this supply. If the cornea does indeed provide some flow into (or out of) the PoLTF, the amount of that flow must be independent of the presence of channels in a lens provided, of course, that the lens design is otherwise unchanged. Accordingly, the dispersive mixing theory remains a useful guide for understanding tear exchange in the PoLTF.

Finally, we do not know what the optimum tear-flushing rate is to prevent accumulation of debris or other unwanted substances. However, we do know that gas-permeable (GP) lenses have tear-mixing rates that are similar to the physiological tear turnover rate.[32] Clinical studies using GP lenses have shown very few serious complications commonly associated with soft lens extended wear (e.g., superior epithelial arcuate lesion, infiltrative keratitis, and microbial keratitis).[33–37] This observation suggests that it may be important to develop soft lens designs to allow greatly improved tear flushing. It is clear that much work is warranted to optimize the effect of channel design on postlens tear mixing under a soft lens because increased soft lens tear mixing has considerable clinical importance.

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REFERENCES

1. Holden BA, Sweeney DF, Vannas A, Nilsson KT, Efron N. Effects of long-term extended contact lens wear on the human cornea. Invest Ophthalmol Vis Sci 1985;26:1489–501.
2. Mac Rae SM, Matsuda M, Shellans S, Rich LF. The effects of hard

and soft contact lenses on the corneal endothelium. Am J Ophthalmol 1986;102:50–7.
3. Polse KA, Decker M. Oxygen tension under a contact lens. Invest Ophthalmol Vis Sci 1979;18:188–93.
4. Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. Invest Ophthalmol Vis Sci 1984;25:1161–7.
5. Polse KA, Brand RJ, Cohen SR, Guillon M. Hypoxic effects on corneal morphology and function. Invest Ophthalmol Vis Sci 1990; 31:1542–54.
6. Bonanno JA, Polse KA. Corneal acidosis during contact lens wear: effects of hypoxia and CO_2. Invest Ophthalmol Vis Sci 1987;28: 1514–20.
7. Alvord L, Court J, Davis T, Morgan CF, Schindhelm K, Vogt J, Winterton L. Oxygen permeability of a new type of high Dk soft contact lens material. Optom Vis Sci 1998;75:30–6.
8. Lee KY, Lim L. Pseudomonas keratitis associated with continuous wear silicone-hydrogel soft contact lens: a case report. Eye Contact Lens 2003;29:255–7.
9. Lim L, Loughnan MS, Sullivan LJ. Microbial keratitis associated with extended wear of silicone hydrogel contact lenses. Br J Ophthalmol 2002;86:355–7.
10. Sankaridurg PR, Holden BA, Jalbert I. Adverse events and infections: which ones and how many? In: Sweeney DF, ed. Silicone Hydrogels. Oxford: Butterworth-Heinemann; 2003:150–213.
11. Syam P, Hussain B, Hutchinson C. Mixed infection (*Pseudomonas* and coagulase negative staphylococci) microbial keratitis associated with extended wear silicone hydrogel contact lens. Br J Ophthalmol 2004;88:579.
12. Edwards K, Keay L, Naduvilath T, Brian G, Stapleton F. Microbial Keratitis Study Group. Risk factors for contact lens related microbial keratitis in Australia. Invest Ophthalmol Vis Sci 2005;46:E-abstract 926.
13. Stapleton F, Edwards K, Keay L, Naduvilath T, Dart JKG, Brian G, Sweeney D, Holden BA. The incidence of contact lens related microbial keratitis in Australia. Invest Ophthalmol Vis Sci 2005;46: E-abstract 5025.
14. Lin MC, Graham AD, Fusaro RE, Polse KA. Impact of rigid gas-permeable contact lens extended wear on corneal epithelial barrier function. Invest Ophthalmol Vis Sci 2002;43:1019–24.
15. Lin MC, Soliman GN, Song MJ, Smith JP, Lin CT, Chen YQ, Polse KA. Soft contact lens extended wear affects corneal epithelial permeability: hypoxic or mechanical etiology? Cont Lens Anterior Eye 2003;26:11–6.
16. McNamara NA, Fusaro RE, Brand RJ, Polse KA. Epithelial permeability reflects subclinical effects of contact lens wear. Br J Ophthalmol 1998;82:376–81.
17. Creech JL, Chauhan A, Radke CJ. Dispersive mixing in the posterior tear film under a soft contact lens. Indus Eng Chem Res 2001;40:3015–26.
18. Chauhan A, Radke CJ. The role of fenestrations and channels on the transverse motion of a soft contact lens. Optom Vis Sci 2001;78: 732–43.
19. Miller KL, Polse KA, Radke CJ. Fenestrations enhance tear mixing under silicone-hydrogel contact lenses. Invest Ophthalmol Vis Sci 2003;44:60–7.
20. Marmo JC, Dean GA. Contact lenses with blended microchannels. US Patent Application 20030151718. August 14, 2003.
21. Marmo JC. Contact lenses with microchannels. US Patent 06779888. August 24, 2002.
22. McNamara NA, Polse KA, Brand RJ, Graham AD, Chan JS, McKenney CD. Tear mixing under a soft contact lens: effects of lens diameter. Am J Ophthalmol 1999;127:659–65.
23. Lin MC, Chen YQ, Polse KA. The effects of ocular and lens parameters on the postlens tear thickness. Eye Contact Lens 2003;29: S33–6.
24. Petroll WM, Kovoor T, Ladage PM, Cavanagh HD, Jester JV, Robertson DM. Can postlens tear thickness be measured using three-dimensional in vivo confocal microscopy? Eye Contact Lens 2003; 29:S110–4.
25. Lin MC, Graham AD, Polse KA, Mandell RB, McNamara NA. Measurement of post-lens tear thickness. Invest Ophthalmol Vis Sci 1999;40:2833–9.
26. Miller KL, Lin MC, Radke CJ, Polse KA. Tear mixing under soft contact lenses. In: Sweeney DF, ed. Silicone Hydrogels, 2nd ed. Oxford: Butterworth-Heinemann; 2004: 57–89.
27. Nichols JJ, King-Smith PE. Thickness of the pre- and post-contact lens tear film measured in vivo by interferometry. Invest Ophthalmol Vis Sci 2003;44:68–77.
28. Nichols JJ, King-Smith PE. The impact of hydrogel lens settling on the thickness of the tears and contact lens. Invest Ophthalmol Vis Sci 2004;45:2549–54.
29. Chauhan A, Radke CJ. Settling and deformation of a thin elastic shell on a thin fluid layer lying on a solid surface. J Colloid Interface Sci 2002;245:187–97.
30. Monticelli MV, Chauhan A, Radke CJ. The effect of water hydraulic permeability on the settling of a soft contact lens on the eye. Curr Eye Res 2005;30:329–36.
31. Fatt I, Weissman B. Physiology of the Eye: An Introduction to the Vegetative Functions, 2nd ed. Boston: Butterworth-Heinemann; 1992.
32. Kok JH, Boets EP, van Best JA, Kijlstra A. Fluorophotometric assessment of tear turnover under rigid contact lenses. Cornea 1992;11: 515–7.
33. Dumbleton K. Adverse events with silicone hydrogel continuous wear. Cont Lens Anterior Eye 2002;25:137–46.
34. Holden BA, Stephenson A, Stretton S, Sankaridurg PR, O'Hare N, Jalbert I, Sweeney DF. Superior epithelial arcuate lesions with soft contact lens wear. Optom Vis Sci 2001;78:9–12.
35. Sweeney DF, Stern J, Naduvilath T, Holden BA. Inflammatory adverse event rates over 3 years with silicone hydrogel lenses. Invest Ophthalmol Vis Sci 2002;43(suppl):976.
36. Polse KA, Graham AD, Fusaro RE, Gan CM, Rivera RK, Lin MC, Sanders TL, McNamara NA, Chan JS. The Berkeley Contact Lens Extended Wear Study. Part II : clinical results. Ophthalmology 2001; 108:1389–99.
37. Fusaro RE, Polse KA, Graham AD, Gan CM, Rivera RK, Lin MC, Sanders TL, McNamara NA, Chan JS. The Berkeley Contact Lens Extended Wear Study. Part I: study design and conduct. Ophthalmology 2001;108:1381–8.

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