Fenestrations Enhance Tear Mixing under Silicone-Hydrogel Contact Lenses

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PURPOSE. Extended wear of conventional hydrogel soft contact lenses (SCLs) is associated with adverse ocular responses. Some of these ocular events are thought to result from inadequate tear mixing in the postlens tear film (PoTLF). Therefore, strategies to increase tear mixing may improve the safety of extended-wear SCLs. Recently, it has been suggested that placing fenestrations in soft lenses increases tear mixing. In the present study, hydrodynamic modeling and tear-mixing measurements were used to explore the effects of fenestrations on tear exchange under an SCL.

METHODS. Tear mixing, expressed as the time to deplete 95% of fluorescent dye from the PoTLF ($T_{95}$), was measured in 20 subjects fitted with two pairs of silicone hydrogel SCLs. The lenses were identical except that one pair was fenestrated (F) with 40 holes each 100 μm in diameter. The effect of fenestrations on improving tear mixing is explained and enhancement of tear mixing is predicted, with the use of hydrodynamic modeling.

RESULTS. $T_{95}$ estimates were significantly lower ($P < 0.001$) in the F (mean $T_{95} = 18.3$ minutes) lenses compared with the standard unfenestrated (S-lens) (mean $T_{95} = 22.6$ minutes) lenses ($\Delta T_{95} = 4.3$ minutes, 95% CI = 2.5–6.2) and were in general agreement with the proposed mixing model. Optimization of tear mixing can be achieved by selectively placing fenestrations in the pooling regions before the thinnest regions. The model predictions were sensitive to the distribution of tear-film thickness under the lens.

CONCLUSIONS. Fenestrations improve tear-mixing efficiency. Accurate prediction of the effects of lens parameters on tear mixing, however, demands quantitative measurement of the postlens distribution of tear-film thickness. (Invest Ophtalmol Vis Sci. 2003;44:60–67) DOI:10.1167/iovs.02-0348

Extended wearing of conventional hydrogel soft contact lenses (SCLs) is associated with ocular morbidity and vision impairment. Researchers have attributed many of the more serious complications of extended wear to corneal hypoxia resulting from wearing contact lenses with low oxygen transmissibility (Dk/t). Recently, a lens made of a silicone hydrogel copolymer has been developed with sufficiently high Dk/t to prevent many of the physiological events associated with corneal hypoxia during closed-eye wear (e.g., corneal swelling, increased in vitro bacterial binding, and microcysts). High-Dk/t silicone hydrogel lenses have been approved by the U.S. Food and Drug Administration for up to 30 days of continuous wear. With these lenses, many of the adverse events associated with corneal hypoxia have been eliminated. Nevertheless, there are reports of other complications of extended wear with high Dk/t lenses, including superior epithelial arcuate lesions, superficial punctate keratitis, corneal infiltrates, and mucin balls (spherical postlens debris). It is likely that many of the complications accompanying silicone hydrogel lens wear are caused by the physical interaction between the lens and the eye (i.e., lens performance).

Although several lens characteristics can affect lens performance, one important factor is the time required to restore the normal fluid exchange rate in the postlens tear film (PoTLF) after sleep. A tear exchange rate slower than that observed without a contact lens may allow the metabolic by-products and debris that accumulate between the lens and the cornea during sleep to remain in contact with the epithelium and compromise epithelial integrity.

Design of high-Dk/t soft lenses for improved tear mixing requires a more complete understanding of the physical forces controlling tear exchange. Recently, a hydrodynamic dispersion model has been developed that describes the mixing properties of the PoTLF. This model indicates that tear exchange depends strongly on the periodic, lid-induced vertical (upward–downward) and transverse (inward–outward) lens motions. Although it is possible to increase the vertical motion of the SCL by using small diameters of flatter base curve radius, an increase in vertical travel typically decreases lens comfort. Conversely, increasing transverse lens motion is thought to enhance tear exchange without altering lens comfort; therefore, it is useful to explore alternatives for increasing the anterior–posterior motion of a soft lens.

A recent report suggests a strategy for increasing transverse lens motion. Using a hydrodynamic-lubrication model, Chauhan and Radke demonstrate that fluid resistance in the PoTLF toward transverse motion is reduced with multiple fenestrations in the lens. The fenestrations allow the PoTLF to escape through the holes, rather than only through the lens periphery. Reduction of the hydrodynamic resistance to fluid flow allows for increased transverse motion and a concomitant increase in dispersive tear mixing. We stress that fenestrations do not enhance flushing of the PoTLF simply by allowing fluid to escape through the holes. The reason is that fluid exchange occurs only in a region quite near the holes and does not penetrate to the center of the PoTLF. In this study, we used fenestrated (F) lenses to increase transverse lens motion, thereby improving tear mixing.

Fenestrations have been used previously in both rigid and soft lenses to increase oxygen availability, but with limited success. However, to our knowledge, holes have not been used to increase transverse lens movement to enhance tear mixing. In this study, we employed engineering models to predict the effect of holes on lens movement. We then measured the effects of fenestrations on tear mixing by comparing the tear exchange rate of lenses with multiple holes with that of similarly designed lenses without holes. Using these theoretical arguments and clinical measurements, we present a model that predicts enhanced tear mixing with fenestrations.
Figure 1. A microphotograph of a fenestration in the dehydrated SCL.

and provides a lens-design procedure for optimizing tear exchange under SCLs.

**METHODS**

**Subjects**

Twenty-five experienced SCL wearers, free of ocular disease, 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. After fully describing the procedures, the investigators obtained informed consent from the subjects. Subjects were asked to assess the comfort of the lenses on a 0 to 50 scale (50 represents excellent comfort at all times) after 10 minutes of wear. Only subjects who rated the lens comfort for all lenses at higher than 35 (slight discomfort) were enrolled. Of the 25 recruited subjects who passed the initial survey, only one reported a comfort rating of less than 35 for F lenses and was judged ineligible to proceed. The remaining 24 subjects continued. However, subjects who on either experimental day reported discomfort (<35) were also excluded from the study. Of the 24 enrolled subjects, 4 were excluded (2 for failure to comply with the study protocol, 1 for discomfort with the F lens, and 1 for discomfort with the unfenestrated lens [S-uF]). This study observed the tenets of the Declaration of Helsinki and was approved by the University of California, Berkeley Committee for the Protection of Human Subjects.

**Contact Lenses**

For each subject, tear mixing was measured on experimental silicone hydrogel lenses (designated as lotrafilcon A [exp]; Ciba Vision, Inc., Atlanta, GA). Two lens designs were used: one with fenestrations (F) and the other standard and unfenestrated (S-uF). The F lenses include forty 100-μm diameter through holes. Figure 1 displays a 25× microphotograph of a representative single, cylinder-shaped fenestration in the dehydrated lens matrix. The photograph illustrates that the fenestration walls were smooth; no burring of the edges was observed. Figure 1 also gives evidence of slight crazing near the hole’s periphery (see the damaged region near the left of the fenestration’s edge). Such crazing is likely to disappear when the lens is saturated with water.

Figure 2 illustrates the arrangement of the holes in the lenses. The fenestrations were placed in two radially aligned, concentric rings of 20 holes each. The inner and outer rings were located at 4.15 and 6 mm from the lens center, respectively. Other lens parameters were identical for both lens types (13.8-mm diameter, 4.25-D sphere power, 68-μm center thickness, and 8.6-mm base curve).

**Tear-Mixing Estimate**

We estimated tear mixing with a scanning fluorophotometer to monitor the changes in intensity of a fluorescent dye placed in the tear film behind an SCL 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, T95. In this calculation, only the later fluorescence measurements were included (>5 minutes) to eliminate the influence of reflex tearing. Details of the fluorophotometer and the T95 calculation are described elsewhere. The T95 estimate for each lens type was calculated on separate days. The assigned order of the lenses (F or S-uF) and the experimental eye were randomized. For all parts of the experiment requiring lens wear, subjects wore identical lenses in both eyes, and the subject and the observer were masked to the type of lens assigned to each visit. Each experimental visit began with two measurements of corneal autofluorescence. The subject then inserted the pair of assigned lenses and assessed their comfort. After the baseline fluorescence measurement with the SCL, the subject removed the lens, and the experimenter placed 1 μL of a 4 weight% FITC-dextran (MW = 9.5 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 by means of 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. For the 40 measurements in our 20 subjects, no absorption was measured. At the completion of each tear-mixing measurement, an optometrist performed a slit lamp assessment with fluorescein. In the next section, we outline the underlying theory for improved mixing with fenestrations.

**Modeling**

Creech et al.18 introduced a mechanical-dispersion model for mixing in the tear film under an SCL and showed that tear exchange depends on the lid-induced, periodic motion of the lens. SCL motion causes periodic flow in the PoLTF that enhances radial diffusive transport, thereby increasing mixing in the tear film. This dispersive mixing depends on the amplitudes of the transverse (inward–outward) motion, Δ′, and the vertical (upward–downward) motion, Δ. Using the dispersive-mixing model, we constructed Figure 3 to isolate the dependence of T95 on Δ′. Each line in the figure represents a constant but different PoLTF thickness, b, ranging from 1 to 10 μm. The plot in Figure 3 is based on a constant Δ = 1.0 mm, an FITC-dextran diffusivity of D = 7.5 × 10⁻⁶ cm²/s, and a lens radius of L = 6.9 mm. The figure shows that for small amplitudes of transverse motion (i.e., for Δ′ < 1 μm), T95...
depends primarily on the overall tear-film thickness, but is insensitive to $\Delta'$. Conversely, for large transverse motion (i.e., for $\Delta'$ greater than 1 $\mu$m), $T_{95}$ scales as $1/\Delta'^2$, as illustrated by the asymptotic solid, straight lines. From Figure 3 we learn that to compare the mixing efficiency of two lenses, we must use the absolute value $\Delta'$ to establish the corresponding tear mixing under the PoLTF of each lens.

Figure 3 demonstrates that $T_{95}$ is inversely related to $\Delta'$. However, the large viscous resistance to flow in thin films such as the PoLTF limits the transverse lens motion. To increase the transverse motion, it is necessary to reduce the viscous resistance to fluid flow. This can be accomplished by placing fenestrations in the lens. The fenestrations reduce the amount of liquid that must exit through the lens periphery during a blink, thereby lowering the overall viscous resistance and permitting greater transverse motion.

To understand the effect of fenestrations on transverse motion, it is necessary to quantify the transverse displacement of the contact lens, $\Delta'$. Recently, Chauhan and Radke developed a model to calculate the transverse motion of an SCL. The strategy they used for computing $\Delta'$ applies basic momentum conservation equations in the hydrodynamic-lubrication limit to quantify the resistance to flow under the SCL.

With this information, the transverse lens velocity is computed over the period when the force of the lid acts on the lens. Finally, integrating the velocity over the time of a blink gives the lens displacement in the transverse direction.

We adopted the model of Chauhan and Radke in the current study to estimate the transverse motion of both the fenestrated and unfenestrated lenses. To calculate the resistance to flow, the lens is approximated as a flattened solid plate terminating in the $x$-direction at the lens radius (one half the lens diameter) and extending infinitely in the other direction, $y$. Figure 4 illustrates the simplified configuration of the fenestrated SCL adopted in the model. The holes, aligned to correspond to the actual lens radial configuration shown in Figure 2, are located in two sequential rows at distances $x = L_1$ and $x = L_2$ from the lens center. As illustrated in Figure 4, periodic slices that extend from the center of the lens to the edge divide the lens into regions containing holes and regions without holes, with widths of $w_u$ and $w_ad$, respectively. The tear-film thickness, $h(x)$, can vary in the $x$ direction representing the PoTLF-thickness profile (not shown in the plan view of Fig. 4).

In the slices under the SCL, the lens motion and the pressure distribution drive the flow of fluid. During a blink, the eyelid force causes the lens to move toward the eye with a velocity $U$, building pressure under the lens. Two pressure effects occur in the PoLTF. First, the pressure in each region of the film decreases in the $x$-direction as we approach the edge of the lens. Second, the pressure in the $SuF$ slices, $P_{uF}$, is higher than that in the $F$ slices, $P_F$, because of higher viscous resistance offered to flow in the unfenestrated region. To calculate the amount of inward lens motion, it is necessary to calculate the pressure profiles $P_u(x)$ and $P_F(x)$. For this, we substituted the conservation-of-momentum results into mass-conservation equations in the $x$-direction for the $uF$ and $F$ slices:

$$Q_{uF} = -\frac{1}{12\mu} \frac{\partial p_u}{\partial x} b^3 w_u$$

$$Q_F = -\frac{1}{12\mu} \frac{\partial p_F}{\partial x} b^3 w_F$$

where $Q_{uF}$ and $Q_{F}$ are the volumetric flow rates in the $x$ direction in the fenestrated and unfenestrated regions, respectively. In each equation, the first term on the far right corresponds to the volumetric flow induced by the motion of the lens toward the cornea. In equation 1, the second far-right term is the volumetric flow exiting the unfenestrated region toward the fenestrated region. This term depends on the viscosity of the fluid, $\mu$, the cube of the local tear-film thickness, $b(x)$, and the local pressure difference, $p_u - p_F$, between the unfenestrated and the fenestrated slices.

Equation 2 considers both the fluid volume leaving the unfenestrated region and entering the fenestrated region, and the fluid exiting the PoLTF through each fenestration. In this very last term, the volumetric flow exiting through a single fenestration depends on the contact lens’s thickness, $b$, the liquid pressure at the hole entrance, $p_c$, the hole radius, $R_h$, and the position of the hole, $L$. The factor $u(L_1 - R_h, L_1 + R_h)$ is unity for $x$ between $L_1 - R_h$ and $L_1 + R_h$ (i.e., in the region of the fenestration) and zero otherwise. $N_h$ is the number of rows of fenestrations (i.e., $N_h = 2$, in our case).

These two integrodifferential equations are differentiated once with respect to $x$ to eliminate the integrals and are treated as two coupled, second-order ordinary differential equations for $P_u(x)$ and $P_F(x)$.
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where $W$ is the effective radius of the lens. As illustrated in Figure 4, the configuration of the model lens is a square. Therefore, we chose an effective lens radius so that the area of the square is equal to the area of a circle of radius, $L$. The effective radius is then $W = L \sqrt{\pi/4}$.

Equations 1 through 5 are solved numerically, by using finite differences to determine $F/U$ for a given distribution of tear-film thickness, $d(x)$, and a given lens geometry.

Finally, to calculate the increase in transverse displacement, $\Delta t$, we used a particular force ($F$) applied by the upper lid during a blink ($F = 0.211$ N). We then computed $\Delta t$ numerically by the following integral:

$\Delta t = \int_0^T U(b)dt$. Here $T = 0.1$ second is the blink time; $U(b) = -db/dt$ and is calculated, by using the equations, at time intervals of 0.01 second. The information from Figure 3 was then used to determine the corresponding mixing $T_{mix}$ for any computed transverse motion $\Delta t$.

This procedure allows comparison of the relative mixing efficiency of the lenses under investigation. For this, we introduced a mixing-enhancement factor, $\eta_{mix}$, defined as $\eta_{mix} = T_{mix}(S-uF)/T_{mix}(F)$. Accordingly, the faster the dye depletes from the PoLTf, the larger the enhancement factor.

Figure 6 emphasizes the effect of the PoLTf thickness on the increased tear mixing under the lens. The predicted mixing enhancement is graphed as a function of fenestration radius for 40 equally spaced fenestrations located at $l_1 = 4.15$ mm and at $l_2 = 6$ mm for three uniform PoLTf thicknesses and a constant applied lid force of 0.211 N. The vertical gray line indicates the 50-$\mu$m fenestration radius of the experimental study lenses. Note the strong sensitivity of $\eta_{mix}$ to the PoLTf thickness: For PoLTf thicknesses of 5, 7, and 10 $\mu$m, the corresponding enhancement factors of the 50-$\mu$m radius fenestrations are 1.08, 1.49, and 2.79, respectively. The origin of the increasing mixing enhancement for SCLs with thicker PoLTfs lies in the absolute increase of inward–outward motion, $\Delta t$, and the resultant decrease in $T_{mix}$ per Figure 5. Conversely, from Figure 6, enlarging the size of the fenestrations provides only a modest improvement in tear mixing. The insensitivity to increasing fenestration radius is a combination of lowered fluid resistance through the hole along with a smaller pressure driving force in the PoLTf. The roles of other lens parameters in improving tear mixing are discussed by Chauhan and Radke who also reached the same conclusion, emphasizing the critical importance of the PoLTf thickness.

Distribution of PoLTf

Figure 6 was constructed by using a uniform distribution of tear-film thickness under the lenses. However, to describe transverse lens mo-
Twenty subjects successfully completed the study (15/5, women/men), aged 18 to 25 years (mean ± SD: 20 ± 2). Figure 8 illustrates the measured $T_{95}$ of the FITC-dextran dye from under the SCL for the F and S-uF lenses. A line connects the $T_{95}$ for each subject wearing each of the two lens types. In 16 of the 20 subjects, the fenestrations resulted in an increase in the rate of tear exchange. The average $T_{95}$ (mean ± SD) was 22.6 ± 1.0 and 18.3 ± 1.0 minutes for the S-uF and F lens, respectively, a significant difference (paired $t$-test $= 4.86$, $P < 0.005$).

Using the definition of the enhancement factor, $\eta_{\text{enh}} = T_{95}(\text{S-uF})/T_{95}(\text{F})$, the results correspond to $\eta_{\text{enh}} = 1.28$, or a 28% improvement in tear mixing due to the fenestrations. After the tear-mixing measurement, we assessed vertical lens movement. Both lens types moved approximately 0.5 mm. After we assessed the movement, the lenses were removed, and a slit lamp examination was performed. No corneal staining, redness, or other signs of adverse responses were found with either lens type. Further, the average comfort scores were good: 45.7 ± 3.2, and 46.3 ± 3.3, for the F and S-uF lenses, respectively, and the differences were not significant (paired $t$-test $= 1.5$, $P > 0.1$).

With the PoTLF thickness profile of Figure 7C and the position of the fenestrations illustrated in Figure 4, the predicted mixing enhancement is $\eta_{\text{enh}} = 1.007$. This result is substantially lower than the measured value of 1.28. The discrepancy is due to the sensitivity of the mixing-enhancement calculation to the PoTLT thickness profile, as illustrated in Figure 6. For example, if we rescale linearly the profile in Figure 7C to a central thickness of 7 or 10 μm, then $\eta_{\text{enh}} = 1.064$ and 1.376, respectively. Thus, simply altering the central PoTLT within the error bounds of the measured thickness successfully predicts the measured amount of tear-mixing enhancement. We assert that the proposed mixing model gives

**RESULTS**

**Measured $T_{95}$ clinical results for each subject for both F and S-uF lenses. Lines connect the data points for the S-uF and F lenses worn by each subject.**
an adequate description of the effect of F lenses on tear mixing in the PoLTF.

No attempt was made with the supplied experimental F lenses to preoptimize their performance. It is, however, clinically useful to consider lens-design options that increase tear-mixing efficiency under the F lenses. Figure 9 shows the pressure profile relative to the lens velocity under the SuF SCL for the distribution of PoLTF thickness in Figure 7C. The positions of the thinnest tear film are indicated with arrows. The relative pressure decayed sharply in the regions of thin tear film. This profile was quite different from the smooth-pressure profile in the constant-thickness tear film of the SuF lens in Figure 5, in which the pressure decayed smoothly from the lens center to the edge. The presence of the PoLTF thin-touch regions caused not only the sharp pressure declines in Figure 9, but also raised the pressure in the central area relative to that of the constant-thickness profile of Figure 5. The pressure profile in the non-uniform-thickness PoLTF of Figure 9 suggests that strategic placement of the holes may relieve the large pressure buildup and allow more inward-outward motion of the lens. Therefore, using the above modeling method, we evaluated the role of the location of fenestrations on predicted tear mixing.

To understand the effect of hole location on tear mixing, Figure 10 reports the calculated mixing enhancement for one row of fenestrations (n = 20) in the lens with L₁ lying between 1.0 and 6.0 mm. Again, arrows in Figure 10 locate the two regions of touch in Figure 7C, and the distribution of tear-film thickness underlying Figure 10 corresponds to that in Figure 7C. We found that placing the fenestrations inside the first annulus of touch (i.e., for L₁ < 3.8 mm), where there was extensive pooling of tears, had the greatest effect on T₀S. Conversely, a single row of holes placed at the edge of the lens, corresponding to the thinnest part of the tear film, did not reduce T₀S. The strong resistance to flow in the thin tear film near the edge of the lens was not overcome by placing fenestrations in that region. Therefore, for a single row of holes with L₁ greater than 5.5 mm, fenestrations did not increase transverse motion. Basically, holes located beyond approximately 5.5 mm were ineffective because of the large resistance for liquid to squeeze through the first two touch regions. Conversely, fenestrations placed in pooling regions upstream of a constriction allowed fluid to escape without first draining through a thin-touch region.

Next, we calculated the effects of hole position on η_{mix}, when using two rows of 20 fenestrations in the lens. Figure 11 displays the calculated enhancement in tear mixing as a function of the position of the second row of holes, L₂, for three set locations of the first row, L₁, as shown in the key. Again, the arrows in Figure 11 specify the two regions of touch in Figure 7, and the distribution of tear-film thickness corresponds to that in Figure 7C. In Figure 11, the previous meaning no longer holds of L₁ and L₂, strictly denoting, respectively, the inner and outer annuli of fenestrations. For comparison, the fenestrations in the studied lenses were set at 4.15 and 6 mm, respectively. Thus, the experimental lenses with a calculated mixing efficiency of η_{mix} = 1.007 fell well short of an optimum design. If the holes in the study lenses were instead positioned at L₂ = 2.5 mm and L₁ = 5 mm from the center, the predicted mixing enhancement increased to η_{mix} = 1.14. Of course, even larger improvements would be expected if the central thickness in Figure 7C were raised to 7 or 10 μm.

From Figures 10 and 11, it is apparent that fenestrations are most effective for increasing tear mixing when positioned in the pooling regions somewhat before, but not at, the thinnest film regions. Finally, lenses with a third row of fenestrations positioned at the edge of the third region of pooling, 6.0 mm per Figure 7C, increased the calculated mixing enhancement to η_{mix} = 1.29.

**DISCUSSION**

The experimental FITC-dextran–depletion data clearly demonstrate that placing fenestrations in SCLs enhanced tear mixing. The observed mixing improvement cannot be ascribed simply to the fluid exiting through the fenestrations. The escape of dye through a hole is an edge effect that does not influence mixing throughout the PoLTF. Our proposed explanation for the enhanced mixing with fenestrations is that holes permit increased pumping of the lens, because the PoLTF may exit and re-enter through the holes and not just through the peripheral gap. Increased inward-outward lens motion leads to increased dispersive mixing throughout the PoLTF.¹⁸

Modeling of the increase in transverse motion from the theory section showed that lenses with fenestrations larger than 50 to 75 μm in radius had little effect on further decreasing T₀S. However, according to the model, thicker PoLTFs exhibited significantly improved mixing under the lens. Finally, we learned that strategic fenestration arrangement is important and depends strongly on the distribution of tear-film thickness behind the lens. Specifically, the model demonstrates that placing fenestrations in regions of tear-film pooling inside rings...
of constricted flow, thus relieving the transverse flow resistance under the lens, had the greatest impact on increasing tear mixing.

The observed and predicted $T_{95}$ enhancements both confirm that fenestrations increase tear mixing. However, quantitative agreement was not achieved. The discrepancy between the $T_{95}$ rates is due foremost to the extreme sensitivity to the thickness distribution of the tear film profile. The thickness profile used in our calculations was a rough estimate based on a central tear-film thickness measurement and a photomicrograph of the fluorescence emission pattern under the lens (see Fig. 7). A more accurate representation of the PoTTF thickness profile is needed to predict quantitatively the impact of fenestrations on increasing transverse motion. Also, the model assumes that the eyelid applies a uniformly distributed force over the entire SCL. This may not be the case, and until there is more information on how the eyelid forces are distributed on the lens, the model for transverse motion may be in error quantitatively. In all cases, the $T_{95}$ calculation from the transverse motion assumes a constant and uniform tear-film thickness. For that reason, a $T_{95}$ model that incorporates a variable tear-film thickness is also necessary to establish the impact of fenestrations on tear mixing.

The proposed model predicts an increase transverse motion, with fenestrations leading to increased tear mixing in the PoTTF. Thus, manipulation of critical factors, such as lens motion, may be used to enhance tear mixing under an SCL. For example, a stiff lens may deform less to exhibit greater transverse motion, thereby decreasing $T_{95}$. Because currently there are no techniques available to measure directly the inward-outward motion of a lens, further studies are required to document the effect of increasing of transverse motion. The model also shows that the larger the PoTTF thickness, the greater the transverse motion and that the addition of holes increases this movement further. Therefore, lens designs that maximize tear exchange must provide the thickest possible PoTTF. Moreover, F lenses should have holes placed at strategic locations in regions of tear pooling. It is possible, however, that the fenestration placement must be limited to outside the optic zone to avoid obstructed vision.

Finally, if F lenses are to be clinically applicable, they must be comfortable and the holes must remain unobstructed. For the F lenses we studied, comfort ratings remained high, identical with the companion SuF lenses. Moreover, the lenses were reused multiple times and represented several cumulative hours of lens wear. To determine whether the lenses remained unclogged, after completion of the study, the lenses were inspected under high magnification and were found to be clear of debris. Although the results of this study suggest that fenestrations do not affect comfort and that the holes remain unobstructed, these results are preliminary. Additional clinical studies are necessary to evaluate fully the efficacy and comfort of placing fenestrations in SCLs. We suggest that further studies consider the tear-mixing enhancement of F lenses under extended wear conditions.

In summary, we implemented a hydrodynamic model of the PoTTF to understand some of the factors that control tear mixing under an SCL. The modeling effort predicted that fenestrations augment the inward–outward, or pumping, motion of the lens, thereby improving tear mixing. The amount of mixing enhancement depended dramatically on the distribution of PoTTF thickness under the SCL. We confirmed that fenestrations do indeed enhance tear mixing with human in vivo tear-mixing measurements using a single design of F lenses. From these results, model calculations were used to understand what lens parameters might be adjusted to enhance tear mixing even further. In particular, location of the fenestrations in regions of tear pooling was shown to be important.

References

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