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# Objective Assessment of Ocular Surface Response to Contact Lens Wear in Presbyopic Contact Lens Wearers of Asian Descent

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Introduction: Contact lens wearers of Asian descent may be predisposed to experience microtrauma of the ocular surface as a result a thinner post-lens tear film and higher eyelid tension, and these effects would be anticipated to be most marked in an older population. The objective of this study was to quantify the mechanical effects of the study contact lenses on the ocular surface in a population of presbyopic contact lens wearers of Asian descent. Methods: Twenty established presbyopic contact lens wearers (hydrogel n=5, none habitual wearers of etafilcon A lenses; silicone hydrogel n=15) of Asian descent were refitted with etafilcon A multifocal daily disposable contact lenses (1-DAY ACUVUE MOIST MULTIFOCAL) for a period of 1 month of daily lens wear. The habitual modalities of wear were 45% daily disposable and 55% planned replacement. Digital photographs of the upper lid margins, nasal and temporal conjunctiva, and superior cornea were taken after 6 hr of wear of the participants' habitual contact lenses, after 1 day without contact lens wear, and after 6 hr of wear of the study contact lenses at the end of the 1-month period. The photographs were masked according to study visit and the staining extent measured using proprietary software.

**Results:** Lid margin staining was significantly lower with the study contact lenses  $(2.0\pm1.0 \text{ mm}^2)$  than with the participants' own contact lenses  $(3.2\pm3.0 \text{ mm}^2)$  after 6 hr of wear, representing a mean staining decrease of 38% (*P*=0.010). Lid margin staining after 6 hr of wear of the study contact lenses was not different from that measured after 1 day without contact lenses (*P*=0.507). Limbal staining was also significantly less with the study contact lenses than with the participants' own contact lenses after 6 hr of wear (*P*=0.009). There was minimal upper corneal staining, and the degree was similar with the study and habitual lenses.

**Conclusions:** Etafilcon A material, worn under a daily disposable modality, was shown to reduce upper lid margin and limbal staining in presbyopic

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OCULAR TECHNOLOGY GROUP–International received support for conducting this study from Johnson & Johnson Vision Care, Inc. T. Karkkainen and K. Moody are employees of Johnson & Johnson Vision Care, Inc. M. Guillon is a consultant for Johnson & Johnson Vision Care, Inc. The remaining authors have no funding or conflicts of interest to disclose.

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Accepted August 22, 2016.

Copyright © 2016 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of CLAO. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. contact lens wearers of Asian descent compared with the wearers' own contact lenses. Because of the high preponderance of dry eye amongst presbyopes, material selection is of importance and consideration should be given to the lens–ocular surface interaction.

Key Words: Asian descent—Multifocal—Contact lens—Lid margin staining—Etafilcon A—Corneal staining—Conjunctival staining—Ocular surface—Daily disposable.

(Eye & Contact Lens 2018;44: 182-189)

t is widely recognized that the eyes, and in particular the upper eyelids, of individuals of East and Southeast Asian descent have anatomical differences from the eyes of whites. Differences in evelid appearance may include the presence of epicanthal folds, an oblique or slanted palpebral fissure, smaller vertical and horizontal palpebral apertures, and significantly more subcutaneous and suborbicularis fat.<sup>1–5</sup> All these features may result in higher eyelid tension in Asians. A number of differences in corneal size and topography have also been published in the literature; however, the results have been conflicting with some studies observing steeper corneas in Asian eves.<sup>6,7</sup> whereas others have reported flatter corneas.<sup>5,8</sup> In the most recently published study, the ocular topography of a large cohort of Chinese, Japanese, and white individuals was examined, and the authors concluded that the corneas of Asians, in particular Chinese Asians, were generally smaller, flatter, and more prolate than those of whites.5

Although it is not surprising that the anatomical differences between Asians and whites have been shown to be important when fitting contact lenses,<sup>6,8–10</sup> it is interesting that Asian eyes have also been reported to respond differently to contact lens wear. Specific differences include a less stable prelens and thinner postlens tear film,<sup>8,11</sup> greater corneal epithelial permeability,<sup>12,13</sup> increased corneal staining,<sup>14</sup> and a significantly higher degree of endothelial bleb formation in response to low oxygen transmissibility lens wear.<sup>15</sup> Asian contact lens wearers have also been reported to have significantly worse comfort<sup>14</sup> and significantly more dryness than non-Asian wearers.<sup>14,16</sup>

It has been proposed that Asian contact lens wearers may be predisposed to experience microtrauma of the ocular surface as a result of the greater shear force that is exerted on the cornea and conjunctiva as a consequence of a thinner postlens tear film and higher eyelid tension which affects the physical fitting relationship between the contact lens and the cornea.<sup>13</sup> This microtrauma may be observed clinically as staining on the cornea and conjunctiva, including the area of the marginal conjunctiva of the eyelids commonly referred to as the lid wiper. The etiology of lid wiper "epitheliopathy" or staining is believed to be inadequate lubrication at the lid wiper–ocular surface,<sup>17</sup> and changes to this area have been shown to be related to contact lens discomfort.<sup>18,19</sup>

Although the frequency of contact lens wear generally decreases with age, many contact lens wearers continue to wear their lenses as they develop presbyopia. A challenge to the success of Asian presbyopic patients with contact lens wear is the greater degree of ocular surface dryness signs and symptoms that this population frequently exhibits.<sup>14,16,20–22</sup> A daily disposable lens modality is becoming increasingly popular among all contact lens wearers and offers many benefits when compared with some reusable contact lenses, including superior comfort and vision and, in some cases, relief from allergies.<sup>23–27</sup> This lens modality has also been shown to be associated with fewer complications.<sup>28–30</sup> For these reasons, a daily disposable lens is a good choice for presbyopic contact lens wearers of Asian descent.

Although clinical observation is the basis of clinical practice, measurement is considered the cornerstone of scientific research. Unfortunately the majority of clinical research studies use simple observation and grading scales for the assessment of the ocular surface,<sup>31,32</sup> despite many limitations including interobserver and intraobserver variability, poor sensitivity and reproducibility, and unequal steps.<sup>33–37</sup> By contrast, objective digital image analysis is able to offer many advantages over grading scales, including greater sensitivity and unbiased assessment and are independent of observer experience and training.<sup>38–42</sup>

### **OBJECTIVE**

The objective of this study was to quantify the mechanical effects of the study contact lenses on the ocular surface in a population of presbyopic contact lens wearers of Asian descent. Eyelid trauma during contact lens wear occurs as the result of friction taking place at each blink. If the contact lens wets well and maintains a stable tear film at its surface at the time of the blink, there is hydrodynamic lubrication of the contact lens and the ocular surface at the lid margin and the friction between the two surfaces is low; however, if there is poor contact lens wettability, there is boundary lubrication and higher friction which can result in micro trauma and lead to lid margin staining.43,44 The rationale for the study was that the study contact lenses (etafilcon A), which have the lowest modulus among current contact lenses,45-47 and a very low lipid uptake due to the high affinity of the lens for lysozymes,48-50 should produce minimal mechanical trauma to both the eyelid and the other ocular surfaces when worn on a daily disposable basis.

## **HYPOTHESES**

The primary hypothesis that was tested was that the staining of the upper eyelid margin measured after approximately 30 days of wear of the study contact lenses would be statistically significantly less than the staining measured at baseline after the wear of the subjects' habitual contact lenses.

Two secondary hypotheses were tested; the first was that the limbal conjunctival staining for the nasal and temporal regions measured after approximately 30 days of wear of the study contact lenses would not be worse than the staining measured at baseline after the wear of

the subjects' habitual contact lenses. The second additional hypothesis was that corneal staining in the region of the upper corneal quadrant measured after approximately 30 days of wear of the study contact lenses would not be worse than the staining measured at baseline after the wear of the subjects' habitual contact lenses.

## MATERIALS AND METHODS

## **Study Design**

The design was a single-arm, open label, bilateral, prospective, interventional refitting study. The International Conference on Harmonization Good Clinical Practice E6 and the tenets of the Declaration of Helsinki 1975, as revised in 2013, were adhered to throughout the study and the experimental protocol was reviewed and approved by an independent review board. All subjects were given written information about the study and signed the consent form at the enrolment visit, before any assessment was carried out.

The experimental routine involved a baseline/enrolment visit, a dispensing visit, a fit verification visit, and a 1-month follow-up visit. At the initial visit, prospective participants were assessed for inclusion in the study. All prospective participants attended this visit having worn their habitual soft contact lenses for at least 6 hr. Eligible participants were subsequently enrolled in the study, and a series of baseline measurements and assessments were made for their habitual lenses. The participants subsequently attended the dispensing visit at any time of the day, not wearing their habitual contact lenses and not having worn contact lenses that day. During this visit, baseline measurements and assessments were recorded before lens wear, and the participants were fitted with study contact lenses, instructed on their use, and dispensed a supply of the study lenses. The participants were instructed to use the study contact lenses as their primary form of vision correction for the duration of the study, wearing the lenses on a daily wear, daily disposable basis for at least 5 days a week, and at least 6 hr per day if possible. All participants attended a fit verification visit, 4  $(\pm 1)$  days after the dispensing visit. At the completion of this visit, the participants either continued with the same contact lens prescription, or with a modified prescription as per the fit optimization findings, for the remainder of the study. The 1-month follow-up visit took place 30 ( $\pm$ 5) days after the dispensing visit, and participants were instructed to have worn the study lenses for at least 6 hr on the day of this visit. Measurements and assessments were made at this visit for the study contact lenses.

#### **Study Products**

The study contact lenses were 1-DAY ACUVUE MOIST Multifocal contact lenses manufactured from etafilcon A material by Johnson & Johnson Vision Care Inc. Specifications for the study lenses are presented in Table 1. All study lenses were fitted according to the manufacturer's fitting guide. The contact lenses were replaced daily, and no lens care system was used; however, all participants were provided with Eye-Cept Rewetting Drops manufactured by OPTICS Laboratory Inc. to use as required during the study.

#### **Study Population**

The study was carried out at a partner site of OCULAR TECHNOLOGY GROUP–International (The Visual Performance Center, Pensacola, FL). Participants had to be currently wearing a presbyopic contact lens correction (e.g., reading spectacles over

TABLE 1. Staining Measured at Each Study Visit

	Visit				
Area of Measurement	Baseline Staining, mm <sup>2</sup> (Habitual Lenses)	Dispense Staining, mm <sup>2</sup> (No Lens Wear)	1-Month Follow-Up Staining, mm <sup>2</sup> (Study Lenses)		
Upper Eyelid					
Margin					
Mean±SD	$3.21 \pm 3.02$	$2.56 \pm 3.06$	$1.96 \pm 1.03$		
Median	2.2	1.91	1.76		
Range	0.51-13.36	0.21–19.07	0.29-4.78		
25%	1.32	1.20	1.21		
75%	3.25	2.91	2.78		
Limbal Overall	5120		200		
Mean±SD	$1.01 \pm 1.60$	$0.84 \pm 4.77$	0.69±0.99		
Median	0.67	0.23	0.32		
Range	0.00-11.2	0.00-42.06	0.01-4.94		
25%	0.28	0.05	0.12		
75%	1.06	0.44	0.80		
Limbal—Nasal					
Mean±SD	1.05±1.43	$0.33 \pm 0.29$	$1.00 \pm 1.66$		
Median	0.69	0.26	0.47		
Range	0.00-7.63	0.00-1.18	0.01-4.94		
25%	0.36	0.07	0.18		
75%	1.11	0.44	1.36		
Limbal—					
Temporal					
Mean±SD	0.96±1.78	1.37±6.79	$0.39 \pm 0.67$		
Median	0.58	0.13	0.18		
Range	0.00-11.2	0.00-42.06	0.00-4.01		
25%	0.14	0.03	0.07		
75%	1.02	0.44	0.43		
Superior					
Cornea					
Mean±SD	0.13±0.46	$0.01 \pm 0.04$	$0.05 \pm 0.12$		
Median	0.00	0.00	0.00		
Range	0.00-2.53	0.00-0.23	0.00-0.58		
25%	0.00	0.00	0.00		
75%	0.04	0.00	0.03		

contact lenses, multifocal or monovision contact lenses) or report symptoms of near vision difficulties with their habitual contact lens correction to be eligible to participate. They had to be of Asian descent, aged 40 and 70 years, and have a spectacle refraction at the corneal plane of +2.00 to -5.75 with  $\leq 0.75$  D cylinder, a reading addition of +0.75 to +2.50 D, and best-corrected visual acuity of 20/20 in each eye. Participants were required to have normal eyes (no abnormality or disease that would contraindicate contact lens wear). Prospective subjects who were currently pregnant or lactating were not eligible to take part in the study. In addition, subjects were ineligible if they had any ocular or systemic allergies or disease, autoimmune disease, medication use, or ocular abnormality or slit lamp findings that may contraindicate or interfere with contact lens wear. Use of any ocular medications was prohibited, with the exception of rewetting drops.

#### **Measurement Procedures**

At the baseline, dispensing, and 1-month follow-up visits, digital images were taken of the appearance of the upper lid margin staining with lissamine green, limbal staining nasally and temporally with lissamine green, and superior corneal staining with sodium fluorescein for both eyes. All images were captured with a Topcon DC3 camera (Topcon Medical Systems, Oakland, NJ) used in conjunction with a Topcon SL-D4 slit lamp. Standard magnifications and preprogrammed software settings were used for each of the image types to ensure optimal and consistent lighting levels across all participants.

## **Post Hoc Analyses**

All analyses were subsequently conducted (post-hoc) at Ocular Technology Group-International (London, UK). The captured images were initially coded in a non-identifiable manner by an unmasked technician (lens type worn, eye, and visit) for subsequent masked analysis. Calibration images were taken under the same magnification and image capture conditions, and from these, it was possible to calculate the number of pixels per millimeter. For all images, the area of interest was first selected manually. Proprietary algorithms were developed in ImageJ (National Institutes of Health, Bethesda, MD), and software was then used to detect the areas of staining; a post detection verification was carried out by a masked technician and subsequent manual adjustments were made when required. For the lid margin images, the amount of lissamine green staining was measured in pixels and then converted to square millimeters. For the conjunctival and corneal images, the total area of staining, as a proportion of the area of interest, was calculated and reported as a percentage (%).

Statistical analysis of the staining data obtained from the digital images was carried out using SPSS 23. The data were first tested for normality and transformed if necessary and possible. For those parameters which were normal either before or after transformation, a mixed linear model was used, and for the parameters that could not be normalized, a generalized linear model was used. For lid margin staining with lissamine green and superior corneal staining, the model included visit, eve, and visit by eve interaction as fixed factors. The model covariance was selected based on the structure that returned the lowest Akaike's information criterion (AICc) value modeling the correlated residuals from the same subject at different times for the two eyes. For the limbal staining, the model included visit, area (nasal or temporal), eye, and all the possible two-way interactions as fixed factors. The selection of the covariance structure was based on the AICc criterion, modeling the residuals from the same subject at different time points, from different areas and different eyes.

## RESULTS

#### Study Population

The overall population comprised 23 subjects (5 male, 18 female), of whom 20 completed the study and formed the cohort population (mean age 50.6±6.85 years, range 40-61 years). All subjects were current soft lens wearers of Asian descent. Fifteen subjects were habitual wearers of silicone hydrogel lenses (five daily disposable and ten 1-month replacement) and five habitually wore hydrogel lenses (three daily disposable and two 1-month replacement); none were using etafilcon A material. The subjects' mean contact lens correction, with the study lens, was  $-3.07\pm1.41$  D for the myopes (range -1.00to -5.75 D) and  $+1.63\pm0.38$  D for the hyperopes (range +1.25to +2.00 D). The wearing times at the time of the visit for both the habitual and the final visit with the study contact lenses were similar (P=0.843), with respective average wearing times on the day of the visit of 7.40±1.17 hr (range 6.00-10 hr) and  $7.31 \pm 1.64$  hr (range 6.00–12.30 hr).

# **Upper Eyelid Margin Staining**

The mean upper eyelid staining observed at each of the study visits is presented in square millimeters in Table 1 and the distribution of the staining at the baseline and follow-up visits are presented in Figure 1. The data were normalized by a log transformation, and the transformed data were compared using a linear mixed model; the results are presented in Table 2. The staining was significantly greater at the baseline visit after wear of the habitual contact lenses than at the follow-up visit (P=0.010). In addition, the distribution of the staining was considerably more skewed to the right at the baseline visit than at the follow-up visit, as evidenced by the differences in maximum values (Fig. 1). This finding is indicative of the presence of a greater prevalence of clinically significant staining at the baseline visit. As a clinical reference, images of lid margin staining at close to the mean value at the follow-up visit and the maximum values recorded at the baseline and follow-up visits are presented in Figure 2A-C, respectively.

The results support the primary hypothesis that the upper lid margin staining after 1 month of daily wear of the study contact lenses is statistically different from the staining after wear of the habitual contact lenses; the statistical difference is associated with a significant clinical difference, with a decrease in mean staining of 39% and a decrease in maximum staining of 64%.

There was no statistically significant difference in staining at the completion of 1 month of wear of the study lenses when compared with the staining measured before contact lens insertion at the dispensing visit (P=0.507). Clinically, the degree of mean staining observed at the two visits was similar, and there was a lower amount of maximum staining measured at the follow-up visit. Both of these findings indicate that wearing the study contact lenses did not induce upper lid margin staining.

## **Limbal Staining**

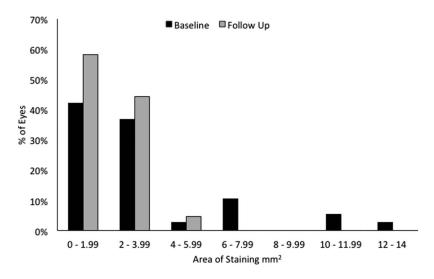
The limbal staining observed at each of the study visits is presented as the percentage of the total surface area of interest in Table 1 and the distribution of the staining at the baseline and follow-up visits are presented in Figure 3. The data were normalized by an inverse transformation, and the transformed data were compared by a linear mixed model; the results are presented in Table 2. The overall limbal staining was significantly less at the follow-up visit than at the baseline visit (P=0.009). The difference between the nasal and temporal regions was significant (P=0.001), and there was a significant interaction between visit and region (P=0.022). Although the average staining observed in the nasal region was very similar at the two visits (P=0.810), the average staining measured in the temporal region was lower at the follow-up visit than at the baseline visit (P=0.001). One subject presented with a pronounced amount of temporal staining in one eye at the dispensing visit; however, the investigator did not determine this to be a contraindication to starting contact lens wear at this visit. In addition, in all cases, the staining distributions were skewed to the right (Fig. 3).

The results for the limbal zone overall, and for the nasal and temporal regions, support the primary hypothesis that the limbal staining after 1 month of wear of the study contact lenses is not worse than the staining after wear of the habitual contact lenses. Furthermore, for the overall limbal zone and for the temporal region, the staining after 1 month of wear of the study contact lenses was significantly less than the staining produced by the habitual contact lenses. The statistical differences were also associated with a significant clinical difference since the decrease in mean staining was 32% for the limbal zone overall and 59% for the temporal region.

The comparison between the follow-up and dispensing visits also revealed a significant difference between the two visits (P=0.001), between the nasal and temporal regions (P<0.001) and for the interaction between visit and region (P=0.006). The difference between visits was, however, inconclusive, as a lower value of mean staining but a greater value of median staining was observed at the follow-up visit; the difference in staining behavior was thought to be associated with a single incidence of very high staining at the dispensing visit.

#### **Corneal Staining**

The superior corneal staining observed at each of the study visits is presented as a percentage of the corneal upper quadrant area of interest in Table 1 and the distribution of the staining at the baseline and follow-up visits are presented in Figure 4. Data normalization was attempted but was not achieved, hence the generalized linear mixed model with gamma as distribution and lLog as a link function was used<sup>51</sup>; the results are presented in Table 2.



**FIG. 1.** Frequency distribution showing the upper lid margin staining at the baseline and follow-up visits.

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TABLE 2.	Statistical Analysis—Linear Mixed Model of Transformed
	Data

		Comparison	
Area of Measurement	Factor/Interaction	Baseline vs. Follow-Up Visit	Dispensing vs. Follow-Up Visit
Upper Eyelid Margin	Visit	0.010	0.507
11 9 9	Eye	0.278	0.580
	Visit/Eye	0.193	0.425
Limbal Overall	Visit	0.009	0.001
	Region	0.001	<0.001
	Eye	0.929	0.978
	Visit/Region	0.022	0.006
	Region/Eye	0.903	0.860
Superior Cornea	Visit	0.260	0.507
•	Eye	0.396	0.580
	Visit/Eye	0.374	0.425

Bold values are statistically significant.

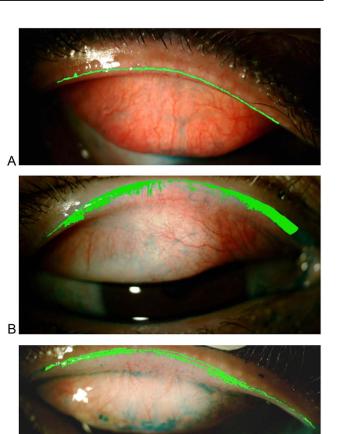
The staining measured at both the baseline visit and follow-up visits was low and not significantly different (P=0.122). The distribution of the staining was highly kurtosed at both visits as indicated by the median values of 0.00% and depicted by the distribution of the individual measurements (Fig. 4). The results support the second secondary hypothesis that the corneal staining after 1-month of wear of the study contact lenses is not worse than the staining after the wear of the habitual contact lenses.

The comparison between the follow-up and dispensing visits also did not reveal any difference in staining between the two visits (P=0.214), confirming that the wear of the study contact lenses for 1 month did not produce any corneal staining.

## DISCUSSION

The higher prevalence of dry eye symptoms and poor tear quality in an older population can create challenges for individuals wearing contact lenses for their correction of presbyopia; inferior lubrication on the contact lens and on the eye can lead to greater friction between the ocular surface and the contact lens. Furthermore, in an Asian population, the higher eyelid tonus could compound the friction, and this may lead to ocular surface damage. Therefore, the rationale for this study was to quantify the effects of daily wear of the study contact lens under a daily disposable modality on the ocular surface.

Although subjective grading is commonly used in clinical practice to categorize the severity and advancement of clinical conditions, as discussed earlier, an ordinal five-point scale is unable to provide the discrimination required for precise quantification and is subject to bias.<sup>31-33,41,52-54</sup> When traditional grading scales are used, a very large population is frequently required to detect small changes, and failure to detect a change may be as a result of lack of discrimination of the methodology used. In the current study, both the primary and secondary endpoints were obtained from the masked, randomized analysis of digital photographs of the ocular surface taken under controlled, preset conditions. Three sets of photographs were taken. The first set comprised the upper eyelid margin, stained with lissamine green to quantify the mechanical effect due to the friction of the front surface of the contact lens, exerted during the blink, on the eyelid tissues. The staining



**FIG. 2.** (A) An example of upper lid margin staining measured to be 1.98 mm<sup>2</sup> in the area of interest. This is similar to the mean staining at the follow-up visit (1.96 mm<sup>2</sup>). (B) An example of upper lid margin staining measured to be 10.92 mm<sup>2</sup> in the area of interest. This is similar to the maximum staining measured at the baseline visit (13.36 mm<sup>2</sup>). (C) An example of upper lid margin staining measured to be 4.78 mm<sup>2</sup> in the area of interest. This is similar to the maximum staining measured at the follow up visit (4.78 mm<sup>2</sup>).

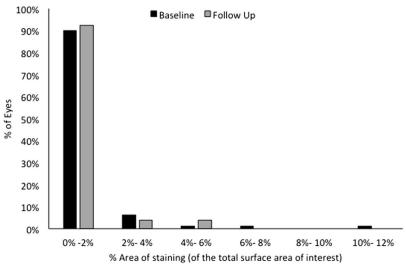
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measured has been described by Korb et al.<sup>18</sup> as lid wiper epitheliopathy and has been shown to be associated with dry eye complaints in contact lens wearers.<sup>18</sup> The second set concentrated on the nasal and temporal limbal area, stained with lissamine green to quantify the mechanical effect of the peripheral area of the contact lens on the conjunctival surface due to a combination of the lens rigidity and design. Finally, the third set of photographs was of the superior cornea, stained, with sodium fluorescein to quantify the mechanical effect of the central area of the contact lens on the corneal surface. The upper region was selected because it is the zone with the greatest severity of mechanically induced staining. The staining in this area typically presents in an arcuate shape and is known as superior epithelial arcuate staining and had a high prevalence with the early generations of high rigidity silicone hydrogel contact lenses.55-57

The general hypothesis that was tested in this study was that, as a result of the low material rigidity or modulus and the low lipid uptake of the etafilcon A study contact lenses used under

FIG. 3. Frequency distribution showing the overall

limbal (nasal and temporal) staining at baseline and



a daily disposable replacement modality—a very high ocular surface tolerance should be achieved and no greater staining, or possibly lesser staining, should occur as compared with the subjects' habitual contact lenses. The results obtained demonstrate this general hypothesis for etafilcon A used under a daily disposable modality. The primary endpoint of less eyelid margin staining occurring than with the subjects' habitual contact lenses was demonstrated, along with the secondary endpoints of not producing greater limbal and corneal staining than with the subjects' habitual contact lenses. With regard to the secondary endpoints, less conjunctival staining with the study contact lenses than with the habitual contact lenses was also demonstrated.

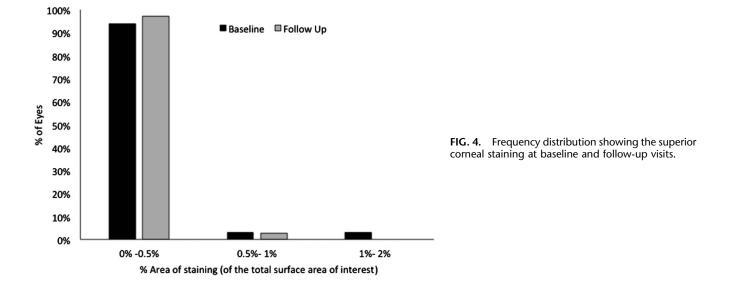
It should be recognized that there are some limitations to the study design. The study population comprised wearers of both daily disposable and monthly replacement lenses, and some degree of the change in staining that is reported may have resulted from a change in replacement modality and/or no longer using a care regimen; however, all the study participants were considered to be -----

successful contact lens wearers and none of them reported that their habitual lenses were uncomfortable.

follow-up visits.

Contact lens interaction with the ocular surface is influenced by many factors. Although this study was not designed to test the effect of rigidity on the interaction with the ocular surface in a controlled manner, the evidence presented would suggest that it is a significant factor since the majority of the habitual contact lenses worn were silicone hydrogel contact lenses, all with a much higher rigidity than the hydrogel study contact lenses. Hence, we propose that using contact lenses with low rigidity under a daily disposable modality when fitting presbyopic contact lens wearers—in particular for those individuals with high eyelid tonus such those of Asian descent—is likely to result in good ocular surface tolerance.

An additional learning from the study is that the measurement of staining in a masked manner achieves a high level of discrimination when quantifying the effects of contact lenses on the ocular surface, even within a relatively small study



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population. The current, clinical methodology used to study contact lens performance throughout the development phase of new contact lenses is based on the rating of observed staining by clinicians using ordinal scales. Although it is accepted that this is necessary in regulatory studies to fulfill the requirements of the FDA and comply with the standards of contact lens clinical trials,<sup>58</sup> the evidence from this study supports the use of more sensitive, objective clinical metrology in the preregulatory phases of contact lens development.

## CONCLUSIONS

The current study compared the effects on the ocular surface of 1-DAY ACUVUE MOIST Multifocal contact lenses over a 1-month period of wear with the effects produced by the habitual contact lenses on a group of presbyopic contact lens wearers of Asian descent, using post hoc, masked measurement of the conjunctival and corneal staining, as recorded by digital slit lamp photography. The results obtained showed that the study contact lenses produced minimal overall staining, which lead to 39% less upper eyelid margin and 32% less limbal staining and a similar degree of upper corneal staining than occurred after lens wear with the subjects' own contact lenses. Differences between the study contact lenses and the habitual contact lenses were a lower material rigidity for the former and a change in wearing modality from planned replacement to daily disposable for half the wearers. Although the study was not designed to test the effect of lens rigidity on the ocular surface in a controlled manner, the evidence collected suggests that using a low rigidity contact lens on a daily disposable modality could be beneficial when fitting patients with presbyopia, in particular patients with high eyelid tonus including those of Asian descent.

#### ACKNOWLEDGMENTS

The authors thank Dr Katie Gilbert-Spear et al. at the Visual Performance Center, Pensacola, FL, for their contributions toward the images captured during the clinical study visits. Partial results from this analysis were reported at the GSLS Conference in Las Vegas, NV, in January 2016.

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