Prevalence of Ocular Surface Symptoms, Signs, and Uncomfortable Hours of Wear in Contact Lens Wearers: The Effect of Refitting with Daily-Wear Silicone Hydrogel Lenses (Senofilcon A)

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Purpose. Many soft contact lens wearers have symptoms or signs that compromise successful lens wear. This study estimated the prevalence of problems in current wearers of soft contact lenses and tested the effect of refitting patients with senofilcon A silicone hydrogel lenses (ACUVUE Oasys). Methods. Prevalence was estimated from 1,092 current lens wearers for frequent or constant discomfort or dryness, at least 2 hours of uncomfortable wear, at least grade 2 limbal or bulbar hyperemia (0-4), or at least grade 3 corneal staining (0-15). In the second part of the study, 112 of the 564 wearers classified as problem patients were refitted with senofilcon A lenses and reassessed 2 weeks later. Results. Fiftytwo percent (564 of 1,092) had some qualifying criteria, with dryness reported by 23%, discomfort by 13%, and at least 2 hours of uncomfortable wear by 27%. Six percent of subjects had qualifying limbal hyperemia; 10% had bulbar hyperemia; and 12% had corneal staining. After refitting 112 problem patients, 75% had less dryness; 88% had better comfort (P < 0.0001 each); and 76% had fewer uncomfortable hours of wear (P=0.004). Although the average wearing time was unchanged, comfortable wearing time increased significantly (10.4 to 11.6 hours) (P=0.004). All (35 of 35) eyes with qualifying limbal hyperemia before the refit also improved ($P \le 0.0001$), as did 80% (40 of 50) of those with bulbar hyperemia ($P \le 0.0001$) and 76% (26 of 34) of those with corneal staining (P=0.005). Conclusions. Most soft lens wearers encounter clinically significant signs or symptoms with their current contact lenses. Refitting with new-generation silicone hydrogel lenses (senofilcon A) can alleviate some of these common problems.

Key Words: Silicone hydrogel contact lens—Dryness—Discomfort— Symptoms.

Hydrogel contact lens wear is accompanied by many changes to the normal ocular surface, including disruption of the preocular tear film, some degree of corneal hypoxia, and occasionally epithelial disruption seen as corneal fluorescein staining. Although many contact lens wearers do not have significant ocular surface

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signs or symptoms, a substantial proportion of current wearers can be regarded as only marginally successful or even "problem patients," who experience varying degrees of discomfort, reduced wearing time, or compromised ocular physiology. The prevalence of these problems in patients helps to explain why approximately one third of contact lens wearers discontinue.^{1,2}

Soft contact lens wear reduces lipid layer thickness, increases evaporation, and reduces the stability of the tear film.^{3,4} As a result, soft contact lens wear is often associated with symptoms of dryness and discomfort. Dryness is the most common symptom of contact lens wear and its prevalence has been estimated to be between 37% and 73%.^{5,6} Dryness problems vary according to lens material and lens care system, and several studies have suggested that they are reduced with silicone hydrogel lens wear.^{7–9}

Corneal fluorescein staining can be indicative of a wide range of problems in contact lens wearers, including reactions to lens care solutions, lens desiccation, and mechanical disruption. Corneal staining is frequently seen in nonwearers and contact lens wearers and, depending on the severity, may not necessarily require remedial action.^{10,11} However, a greater level of corneal staining may indicate the necessity to refit with an alternative lens type or lens care system to prevent chronic corneal problems.

First-generation silicone hydrogel lenses were developed for extended wear and therefore may have maximized oxygen transmissibility at the expense of other material properties, including modulus and wettability. Later silicone hydrogel lenses have attempted to improve these other lens properties, and one such lens (senofilcon A) is claimed to have superior surface lubricity.¹² The advent of newer silicone hydrogel lenses with improved surface characteristics raises the possibility of using the new lenses as problem solvers.

The primary aim of this study was to estimate the prevalence of specified problems in current soft contact lens wearers. Second, a subset of current wearers who were qualified as problem patients and enrolled in studies that involved refitting with a new silicone hydrogel lens (senofilcon A) were studied to assess the effects of using this lens with problem patients.

MATERIALS AND METHODS

For the prevalence estimate, the symptoms and signs were evaluated for a large sample of existing soft contact lens wearers.

From Johnson & Johnson Vision Care (C.R.), Jacksonville, FL; Visioncare Research Ltd. (G.V.), Farnham, Surrey, UK; and Clinical Trial Consultant (R.C.), Atlanta, GA.

TABLE 1. Qualifying Criteria for Problem Contact Lens Patients

Sign or symptom	Grading or measurement	Qualifying criterion
Reduced comfortable wearing time	Time in hours for average and comfortable wear	Difference of >2 hours between average and comfortable wearing time
Discomfort	4-point descriptive scale ²⁵ (never, infrequent, frequent, or constant)	Frequent or constant
Dryness symptoms	4-point descriptive scale ²⁵ (never, infrequent, frequent, or constant)	Frequent or constant
Limbal hyperemia	0-4 scale	Grade ≥2
Bulbar hyperemia	0–4 scale	Grade ≥2
Corneal staining	0–15 scale ¹³	Grade ≥3

The sample of 1,092 hydrogel contact lens wearers was formed from a number of multisite studies, all of which followed a similar protocol. The studies were conducted at 82 optometry and two ophthalmology practices throughout the United States and Canada. To be eligible for the studies, subjects were required to be existing soft contact lens wearers between 18 and 39 years of age with a refractive error that could be corrected by a spherical lens between -1.00 and -6.00 diopters (D). Subjects were also required to have no evidence of ocular abnormality or disease that would contraindicate contact lens wear, including corneal fluorescein staining of grade 3 or greater in any quadrant.¹³

Subjective and objective refraction, visual acuity, and biomicroscopy, including grading of limbal and bulbar hyperemia and corneal staining, were completed at baseline. Subjects were interviewed about current symptoms, including dryness and discomfort, by using a validated dry eye questionnaire: the Contact Lens Dry Eye Questionnaire.¹⁴ To gauge the extent that subjects were struggling with lens wear, they were asked about their typical average wearing time (AWT) and the typical period of comfortable wearing time (CWT) in hours. The difference between the AWT and CWT was calculated, and a difference of more than 2 hours was considered a significant indication of less-than-successful lens wear. For example, a patient who wore lenses 15 hours per day but reported that they were comfortable for 12 hours would qualify as having a problem based on reduced CWT.

From the baseline examination, subjects were categorized as problem patients or problem-free by using six predetermined criteria (Table 1). These criteria were selected as signs or symptoms that may trigger discontinuation of lens wear by the patient⁵ or prompt the eye care practitioner to consider refitting or taking some remedial action.

The refit phase of the study measured the effect of refitting a subset of the prevalence sample with senofilcon A lenses (ACUVUE Oasys; Johnson & Johnson Vision Care, Jacksonville, FL). A total of 257 of the 1,092 prevalence sample were enrolled in studies that involved refitting with senofilcon A lenses for daily wear and assessed clinical and subjective performance after 2 weeks. One hundred twelve (44%) of those subjects presented at that visit with criteria that qualified them as problem patients. They were then refitted and later returned for the 2-week visit. The balance of the prevalence sample was enrolled in studies involving other lens types and is not the subject of this supplementary analysis. Subjects were masked to the lens type and unaware of the study sponsor, whereas the 22 clinical investigators were masked to the sponsor but not the lens type. All subjects used their habitual lens care system unless advised by the investigator to change to an alternative. The study was conducted in accordance with the Declaration of Helsinki, and subjects provided written informed consent.

The baseline and follow-up results were compared with the paired t test, Wilcoxon rank sum test, or Pearson chi-square test, depending on the nature of the variable under test. A *P* value less than or equal to 0.05 was taken to indicate a significant difference.

RESULTS

Prevalence Study

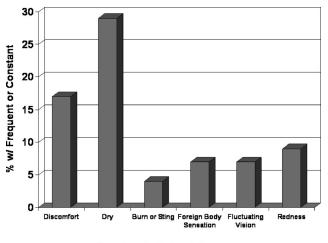
The demographic and biometric data for the 1,092 soft lens wearers in the study are shown in Table 2. Most (54%) subjects were habitual wearers of group IV lenses, whereas fewer subjects were wearing group I (29%) and group II (14%) lenses. The prevalence of ocular surface symptoms in this group is shown in Figure 1. Dryness and discomfort were the symptoms with the highest prevalence.

More than half (52%) of the subjects were classified as only marginally successful or problem patients by presenting with at least one of the criteria in Table 1. The problem patients contained a significantly higher proportion of women than did the problemfree group (75% vs. 64%) (P=0.002). There was no significant difference in age, spherical refraction, visual acuity, or keratometry. The problem group did have a small but significantly higher degree of spectacle cylinder power than did the nonchallenged group (P=0.002).

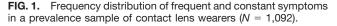
The qualifying criterion most often reported in this cross-section of subjects was reduced CWT (31%), followed by dryness (28%) (Fig. 2). Of the 564 subjects with qualifying criteria, 41% had one; 27% had two; 25% had three; and the rest had four or more. There

 TABLE 2.
 Summary of Subjects' Biometric Data by Challenged Status as Defined in Table 1

Variable	Problem patients	Problem-free patients	<i>P</i> value
No. of subjects	564	528	
Sex			0.002
Male	143 (25%)	188 (36%)	
Female	421 (75%)	340 (64%)	
	Mean (SD)	Mean (SD)	
	Range	Range	
Age (years)	28.0	27.8	0.58
	18–40	18–42	
Spectacle prescription,	-3.22 (1.49)	-3.28 (1.44)	0.41
sphere (D)	-0.25 to -7.25	-0.50 to -7.00	
Spectacle prescription,	-0.29 (0.31)	-0.24 (0.28)	0.002
cylinder (D)	0.00 to -1.00	0.00 to -1.25	
High-contrast visual acuity	-0.03 (0.05)	-0.03 (0.05)	0.79
with spectacle refraction (logMAR)	-0.28 to +0.18		
Mean keratometric	44.09 (1.46)	44.21 (1.31)	0.054
reading (D)	38.50-48.50	40.00-49.38	



Symptom in Order of Appearance



was an average difference between comfortable and total hours of wear of 1.5 ± 2.0 hours. Figure 3 shows the cumulative frequency for subjects' AWT and CWT for the problem patients and the problem-free patients. Eighty-five percent of subjects in the prevalence sample reported an AWT of more than 10 hours per day, although only 63% achieved a CWT of more than 10 hours. Less than half (47%) of patients in the problem group reported achieving a CWT of more than 10 hours, although on average, they wore lenses for approximately 14 hours. By comparison, the median CWT for the problem-free patients was 14 hours. Frequent or constant dryness and discomfort were reported by 23% and 13% of the problem patients, respectively.

Qualifying signs were encountered less often than symptoms in the prevalence sample. Corneal fluorescein staining (12% of subjects) was the most commonly noted qualifying sign, followed by bulbar hyperemia (10%) and limbal hyperemia (6%).

Effect of Refitting With Silicone Hydrogel Lenses

Of the 257 subjects who were enrolled in studies that involved refitting with senofilcon A lenses, 112 (44%) were defined as problem patients. The prevalence of qualifying symptoms or signs

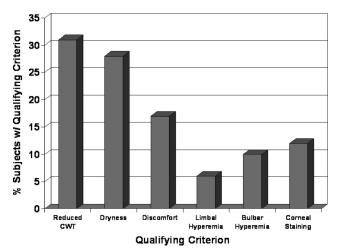


FIG. 2. Prevalence of qualifying signs and symptoms in existing contact lens wearers as defined in Table 1 (N = 1,092).

with habitual lenses was similar to that of the larger prevalence group and is shown in Figure 4. Most (54%) patients who had problems were problem-free at the 2-week follow-up visit. The demographic and biometric data for the 257 subjects who were refitted with senofilcon A lenses is shown in Table 3.

Refitting problematic hydrogel lens wearers with senofilcon A lenses was effective in reducing symptoms of dryness (Fig. 4). Frequent or constant dryness was reduced to infrequent or never in 73% (35 of 59) of the subjects who reported it as frequent or constant before the refit (P < 0.0001), whereas another 16% reported some improvement in dryness. The most responsive symptom was discomfort, for which 88% (29 of 33) (P < 0.0001) of those who had noted it at baseline reported an improvement.

There was a significant reduction in the prevalence of each of the three qualifying slitlamp signs (Fig. 4). Limbal hyperemia was almost eliminated; an improvement (less than grade 2) was recorded for each subject who had presented with at least grade 2 limbal hyperemia before the refit (P < 0.002). Bulbar hyperemia of at least grade 2 was present in 9.7% of the 257 refitted subjects before the refit and in 3.1% of those subjects after refitting (P < 0.0001). The least responsive clinical sign was corneal staining, which reduced to less than grade 2 after refitting in nine (40.8%) of the 22 subjects who had qualifying staining before the refit (P=0.005).

Among the 51 (45%) subjects still experiencing qualifying signs or symptoms after the refit, the most common remaining problem was reduced CWT. Figure 5 shows the AWT and CWT for the 112 subjects before and after the refit with senofilcon A lenses. Seventy-five percent of the subjects who had a reduced CWT before the refit reported an improvement in CWT within 2 weeks of the refit. Although the AWT for the problem patients was unchanged during the 2-week period, their mean CWT increased significantly from 10.4 ± 3.3 hours to 11.6 ± 3.8 hours (P=0.004). Table 4 shows the effect of refitting with senofilcon A on factors relating to wearing time in the 112 problem patients who were refitted.

DISCUSSION

The first part of this study showed that a surprisingly high proportion of existing soft contact lens wearers can be regarded as only marginally successful wearers or even problem patients. Most commonly, these contact lens wearers experience frequent symptoms of dryness and many report several hours of reduced comfort at the end of the day with their habitual lenses. In addition, a smaller proportion show clinically significant slitlamp findings that may warrant consideration of refitting with a more biocompatible lens. Because this study noted some problems in approximately half the soft lens wearers evaluated, the question arises as to whether the sample was biased toward problem patients. Investigators in this study were instructed not to deliberately select problem patients, and in fact, by limiting the upper age to 39 years, this may have biased the sample against older problem patients. It is also possible that patients who stay in closer contact with their practitioner may also be more likely to take part in this type of investigation, which would lead to recruitment of patients more prone to problems. Thus, the sample may not precisely represent the contact lens wearing population as a whole. It does, however, represent a cross-section of wearers presenting for follow-up care and study participation.

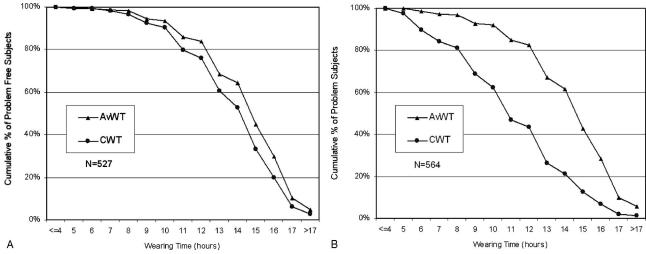


FIG. 3. (A) Cumulative frequency graph of average wearing time (AWT) and comfortable wearing time (CWT) for successful subjects (n = 528). (B) Cumulative frequency graph of AWT and CWT for problem patients (n = 564), as defined in Table 1.

One of the main implications of these findings is that, for many patients, current soft contact lens wear is not optimized. This accounts, in part, for the sustained rate of contact lens dropouts. In the United States, an estimated 2.8 million lens users per year discontinue contact lens wear, which is roughly equal to the number taking up contact lenses.¹⁵ An analysis of the reasons for dropouts in a population of United Kingdom lapsed wearers noted that 36% gave up their lenses for lens-related reasons such as discomfort.¹⁶

Although the problem rates noted in this study may seem high, the prevalence of the various signs and symptoms is consistent with previous work. In the largest survey of dryness in contact lens wearers, Doughty et al.¹⁷ reported dryness symptoms in 50% of wearers, but this estimate included all patients with dryness and not just those with frequent to constant symptoms. Using the same questionnaire and criterion of frequent or constant dryness as in the current study, Begley et al.¹⁸ found a prevalence of dryness symptoms in 29% of contact lens wearers. Likewise, their estimate of the prevalence of discomfort (18%) was similar to that found in this study.

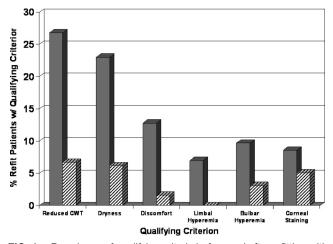


FIG. 4. Prevalence of qualifying criteria before and after refitting with daily-wear silicone hydrogel lenses in problem patients (n = 112). Shaded bars = before refitting; Striped bars = after refitting.

The slitlamp findings in this study were also consistent with previous findings. For example, Nichols et al.¹⁹ reported corneal staining (at least grade 3) in 8% of contact lens wearing eyes compared to 10% in this study. McMonnies and Chapman-Davies²⁰ noted conjunctival hyperemia roughly equivalent to the criterion used in this study in 12% of soft lens wearers. They noted this same sign in only 2% of patients who do not wear lenses.²¹

The second part of the study showed that refitting with a newgeneration silicone hydrogel lens can alleviate some of the common problems of soft lens wear in a high proportion of wearers. Reduction of hyperemia may be the result of the material's relatively high oxygen transmissibility. Previous work has established the link between limbal and bulbar hyperemia and oxygen transmissibility.^{22,23} However, in the case of reduced dryness and other improvements in symptoms, the links are less clear. Several other aspects of the properties of the senofilcon A material may contribute to better clinical performance. Some have suggested that because of their low water content and relatively high bound water content, silicone hydrogel materials may benefit from lower on-

TABLE 3	Summary of Subjects' Biometric Data for Refitting
	Studv

Variable	Problem patients	Problem-free patients	P value
No. of subjects	112	145	
Sex			0.04
Male	30 (27%)	57 (39%)	
Female	82 (73%)	88 (61%)	
	Mean (SD)	Mean (SD)	
	Range	Range	
Age (years)	27.2 (6.2)	27.8 (6.7)	0.52
8 8 9	18–40	18–40	
Spectacle prescription,	-3.37 (1.44)	-3.25 (1.47)	0.29
sphere (D)	-0.75 to -6.50	-1.00 to -6.75	
Spectacle prescription,	-0.25 (0.29)	-0.23 (0.26)	0.44
cylinder (D)	0.00 to -1.00	0.00 to -1.00	
High-contrast visual acuity	-0.03 (0.05)	-0.03 (0.05)	0.51
with spectacle	+0.12 to -0.28	+0.10 to -0.16	
refraction (logMAR)			
Mean keratometric	44.08 (1.38)	44.16 (1.31)	0.49
reading (D)	40.75-47.63	40.00-49.38	

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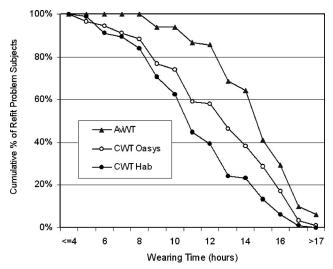


FIG. 5. Cumulative frequency graph of average wearing time (AWT) and comfortable wearing time (CWT) for problem patients before and 2 weeks after the refit with senofilcon A lenses (n = 112).

eye dehydration rates than midlevel water hydrogel lenses.²⁴ The relatively high lubricity (i.e., low coefficient of friction) of senofilcon A may also aid comfort¹² by improving the interaction of the lens at the eye–lens interface through less disruption of the postlens tear film and by reducing lid sensation during blinking.

That many subjects showed signs and symptoms is consistent with previous work that found correlations between signs and symptoms. Begley et al.,²⁵ for instance, noted moderate correlations between symptoms of dryness or discomfort and corneal staining and reported that the best correlations were between signs and late day symptoms. Nomura et al.²⁶ found a correlation between dryness and increased limbal hyperemia and corneal neovascularization. It was also not surprising that many subjects had more than one qualifying criterion with their habitual lenses. For example, subjects who reported dryness also reported reduced CWT. The change in CWT has therefore proved a useful measure of improvement in clinical performance that could easily be incorporated into routine clinical practice.

Obvious criticisms of the study design are that the order of lens use was not randomized and that, in each case, the test lenses were

TABLE 4. Wearing Time and Symptom Results Before and After Refitting Problem Patients With Senofilcon A Lenses

Variable	Before refit	After refit	P value
No. of subjects (eyes)	112 (224)	112 (224)	
	Median Mean (SD) Range	Median Mean (SD) Range	
Average wearing time (hours)	14 13.8 (2.6) 8–19	14 13.6 (2.6) 4–18	0.35
Comfortable wearing time (hours)	10 10.4 (3.3) 2–17	12 11.6 (3.8) 1–18	0.004
Uncomfortable end-of-day hours	3 3.4 (2.7) 0–14	1 1.9 (2.7) 0–15	0.0002
End-of-day comfort rating (1-5)	2.97 (1.0) 1–5	3.41 (1.4) 1–5	0.04

evaluated after the habitual lenses. A masked crossover study would have avoided the risk of subject and investigator bias. That the test lens assessment occurred after baseline measures meant that the procedure more closely followed the typical sequence of events in practice that the study was attempting to simulate.

In summary, this study shows that a high proportion of soft lens wearers encounter clinically significant signs or symptoms with their current contact lenses. The refitting study shows that the use of new-generation silicone hydrogel lenses can alleviate some of the common problems of soft contact lens wear and contribute to longer hours of comfortable wear in patients who experience uncomfortable lenses late in the day.

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