

An evaluation of 1-day disposable contact lens wear in a population of allergy sufferers

Valérie Y. Hayes^a, Cristina M. Schnider^a, Jane Veys^{b,*}

^a Vistakon®, Division of Johnson & Johnson Vision Care, Inc., Jacksonville, FL, USA

^b Johnson & Johnson Vision Care, Berkshire, UK

Abstract

Purpose: This was a multi-site, 128-subject, bilateral crossover study to evaluate subjective comfort and slit-lamp findings with 1-day disposable contact lenses in a population of allergy sufferers during periods when allergen levels were elevated. **Methods:** The study involved 1-month of single-use daily wear with a 1-day disposable test lens (1·DAY ACUVUE® Brand Contact Lenses, Johnson & Johnson Vision Care) and 1-month of daily wear with subjects' habitual lenses replaced to their usual replacement schedule. Pollen and mould counts were obtained for each site 1 week prior to the study and twice weekly throughout the study period. Subjective comfort and slit-lamp findings were recorded at baseline and after 1-month's wear of each modality. **Results:** Sixty-seven percent of subjects agreed that the 1-day disposable lenses provided improved comfort when compared to the lenses they wore prior to the study, compared with 18% agreeing that the new pair of habitual lenses provided improved comfort. The 1-day disposable lenses showed greater improvement in slit-lamp findings from baseline than new habitual lenses. **Conclusion:** The use of 1-day disposable lenses is an effective strategy for managing allergy-suffering contact lens wearers.

© 2003 British Contact Lens Association. Published by Elsevier Science Ltd. All rights reserved.

Keywords: Soft contact lenses; One day disposable contact lenses; Daily disposable contact lenses; Allergies

1. Introduction

Allergy is widespread and affects approximately one in four of the population in the UK at some time in their lives [1]. Allergy sufferers can exhibit a variety of reactions depending on the allergen and the way it is absorbed into the body [2]. Seasonal allergic rhinitis, also known as hay fever, is caused by an allergy to the pollen of trees, grasses, weeds or to mould spores. Allergic rhinitis is a general term used to apply to anyone who has symptoms of nasal congestion, sneezing and a runny nose due to allergies. This may be a seasonal condition, as with hay fever, or it may be an year-round problem caused by indoor allergens such as dust mite.

More than one in 10 people in Europe (11%) report that they suffer from hay fever and a further one in eight (13%) say they experience other allergies that affect the eyes or cause the eyes to water [3]. In the US, more than 50 million Americans each year suffer from allergic diseases, which include dermatitis, asthma and food allergies, as well as conjunctivitis [4]. Seasonal allergic conjunctivitis is responsible

for about half of all allergic eye diseases, and perennial allergic conjunctivitis, the year-round disease, occurs in about 1% of allergy sufferers [5].

Many contact lens wearers are also allergy sufferers who may experience allergic ocular symptoms such as ocular itching, tearing, redness, as well as seasonal, perennial or contact lens papillary conjunctivitis (CLPC) [4]. Various strategies are used for managing allergic eye disease in contact lens wearers, one of which is to minimise exposure to allergens and irritants that can accumulate with repeated use of a single pair of contact lenses. Although reasons for this approach have not yet been well documented for allergy-suffering contact lens wearers, studies have explored some of the differences between the 1-day disposable modality and conventional replacement modalities with successful contact lens wearers [6–10].

In a 3-year prospective study comparing the clinical performance of 1-day disposable and conventional daily wear contact lenses, the 1-day disposable lens users were more likely to be asymptomatic, reported fewer symptoms of redness, grittiness/dirty sensation and had fewer lens surface deposits than conventional daily wear subjects [6]. Other investigators have reported that 1-day disposables have the lowest rate of overall complications of all contact lens modalities tested [7].

* Present address: Johnson & Johnson Vision Care, The Braccans, London Road, Bracknell, Berkshire RG12 2AT, UK. Tel.: +44-1344-864335; fax: +44-1344-864283.

One day disposable contact lens wearers experience improved comfort, better vision, increased wearing time and fewer unscheduled visits when compared with those using conventional daily wear soft lenses [8–10]. These findings suggest that daily lens replacement may also be an effective strategy for reducing complaints and symptoms among allergy-suffering contact lens wearers.

The purpose of the present study was therefore to evaluate subjective comfort and slit-lamp findings with etafilcon A 1-day disposable lenses among allergy-suffering contact lens wearers, during periods when allergen levels were elevated.

2. Materials and methods

2.1. Study design

The study was designed as a 2-month, 14-site, 120–150 subject, bilateral, crossover, dispensing evaluation. The study involved 1-month of single-use daily wear with a 1-day disposable test lens and 1 month of daily wear with subjects' habitual (control) lenses replaced to their usual replacement schedule. For the control lens phase, subjects were provided with new habitual contact lenses, as well as habitual solutions and fresh lens cases. Subjects and investigators were not masked to either the test or control lenses.

Subjects were surveyed for the presence of signs and symptoms related to allergy at baseline. Specifically, the symptom of ocular itching was included as a recruitment criterion, as it constitutes the hallmark symptom of allergic conjunctivitis [4]. Allergic symptoms were characterised as part of the baseline evaluation, i.e. specific signs and symptoms experienced by the subject, the degree and severity of signs and symptoms, stimuli and/or seasonal factors that influenced those signs and symptoms.

Investigators were selected from geographically diverse practices in the United States from areas representing the potential for medium to high pollen count conditions at the

time of the year the study was conducted (August–October 2001). Each site was to recruit approximately 10 subjects. In order to minimise any variability in assessments, investigators attended a full-day pre-study training meeting where the protocol and all study procedures were reviewed. They were provided with a pictorial grading scale developed by Efron to standardise objective grading of the slit-lamp observations during the study [12].

One week prior to and twice weekly throughout the duration of the study, pollen counts for each investigational site were obtained from <http://www.zyrtec.com> and <http://www.claritin.com>. Mould spore counts from pollen stations were obtained from The National Allergy Bureau [2]. Four stations were selected to represent each region: Pacific Northwest region (OR and WA, four practices), Western Mountain region (UT and CO, five practices), South East (VA, two practices), and South East (FL, three practices). Table 1 shows the scales and ratings for low, medium and high pollen and mould counts and descriptions of related symptoms in allergy sufferers.

2.2. Study population

Subjects were required to be current wearers of reusable spherical soft contact lenses, excluding wearers of 1-day disposable and colour-enhanced lenses. They were not required to be at any particular stage in their lens replacement cycle on enrolment. Recruitment targeted a sample size of 120–150, which allowed for potential discontinuations. To be eligible, subjects were required to respond 'yes' to two screening questions regarding the presence of itchy eyes and problems with contact lens comfort during the allergy season. They also had to be correctable to at least 6/9 with spherical contact lenses in the power range used in the study, and be willing to use lenses on a daily wear basis only during the study. Subjects were excluded if they were deemed by the practitioner not to be suitable for contact lens wear based on ocular findings or systemic conditions, or if they required any prescription or over-the-counter ocular medication.

Table 1
Pollen and mould spore count

Scale	Rating	Description
Pollen (grains/m²)		
0–4.0	Low	Very few individuals among the allergy-suffering public will be affected
4.1–8.0	Medium	Many individuals who suffer from allergies to the predominant pollen types of the season will be affected
8.1–12	High	Most individuals who suffer from allergies to pollen types of the season will experience symptoms, which may become more severe during days with high pollen counts
Mould (spores/m³)		
0–6500	Low	Only individuals extremely sensitive to these moulds will experience symptoms
6501–13000	Medium	Many individuals sensitive to these moulds will experience symptoms
13001–50000	High	Most individuals with any sensitivity to these moulds will experience symptoms
50000+	Very high	Almost all individuals with any sensitivity at all to these moulds will experience symptoms, and extremely sensitive people could have severe symptoms

2.3. Study lenses

The following lens type was used in this study:

Test lens	1-DAY ACUVUE® Brand Contact Lenses (Johnson & Johnson Vision Care)
Material	Etafilcon A, 58% water
Study base curve	8.50 mm
Diameter	14.2 mm
Study power range	−1.00 to −5.00 D (in 0.25 D steps)
Centre thickness	0.084 mm (−3.00 D)
Control lenses	Subjects' habitual spherical contact lenses

2.4. Procedures

All subjects were screened to ensure eligibility and subsequently read and signed a statement of informed consent. Subjects were randomised to an order of wear (test or control lenses first) following confirmation of study eligibility. At the initial visit, subjects completed a questionnaire regarding their signs and symptoms of allergies, as well as answering questions related to contact lens wear with their habitual lenses. Slit-lamp examination (bulbar redness, corneal staining, palpebral redness and lid roughness), refraction and fitting procedures were then carried out. Subjects were instructed to maintain their usual procedures (i.e. solutions, systemic medications, re-wetting drops) consistently throughout the study.

The randomised crossover study design was used to control for differences in the subject population, such as medication usage. The bilateral design also avoided any sympathetic effects that might have occurred with a contralateral design and was chosen to more closely mimic the real-life situation.

At each of the 30-day follow-up visits, prior to the practitioner's examination, the subjects answered a single question to compare the comfort of the study lenses they had worn during the last month (test or control) to that of their habitual lenses. Information regarding the use of medication and re-wetting drops during that month was also collected.

2.5. Statistical analysis

The statistical hypothesis was that the test lenses would have a larger proportion of subjects stating an improvement in comfort compared to the proportion of subjects stating an improvement when provided with new pair of habitual lenses (control). Results of χ^2 analysis with a *P*-value less than 0.05 would be regarded as statistically significant.

A two-group continuity-corrected χ^2 test with a 0.050 one-sided significance level would have 80% power to detect the difference between a Group 1 proportion, π_1 , of 0.650

and a Group 2 proportion, π_2 , of 0.450 (odds ratio of 0.441) when the sample size in each group is 86.

Recruitment therefore targeted a sample size of 120–150, to allow for potential discontinuations.

3. Results

3.1. Study cohort

A total of 134 subjects were enrolled in the study, and the final cohort for statistical analysis comprised 128 subjects. Six of the enrolled subjects did not successfully complete the study: two were discontinued for non-compliance to the visit protocol and two were discontinued because of lens discomfort, one while wearing the new habitual lenses (which was not classified as an adverse response) and one while wearing the test lenses (which was reported as an adverse response, classified as allergic conjunctivitis by the practitioner) necessitating discontinuation of contact lens wear. A further two subjects were lost to follow-up.

A second adverse reaction described as a probable corneal abrasion from a foreign body occurred while wearing the test lens although no clinical signs (e.g. corneal staining) were reported. This resolved upon treatment (irrigation and lubrication) and the subject continued the study without interruption to lens wear.

3.2. Demographic and habitual lens information

The subjects were on average 33.6 years old, and were predominantly females of Caucasian ethnicity (Table 2). The average habitual lens wearing time prior to the study was 14.2 h per day and 6.6 days per week during allergy-free periods, and 10.9 h per day and 5.7 days per week when suffering from allergies (Table 3).

A majority of habitual lenses were replaced on a twice weekly (46%) or monthly (35%) schedule and most (83%)

Table 2
Age, gender and ethnicity of the study population

Variable	All subjects
No. of subjects	128
Age (years)	
Mean	33.6
S.D.	9.0
Min.	18
Max.	57
Sex (<i>n</i> , %)	
Male	32/25
Female	96/75
Ethnicity (<i>n</i> , %)	
Caucasian	121/94.5
African descent	3/2.3
Hispanic	2/1.6
Asian	2/1.6

Table 3

Average contact lens wearing time and replacement schedule reported at baseline

Variable	All subjects
No. of subjects	128
Average wearing time without allergies	
Days per week	
Mean	6.6
S.D.	0.9
Hours per day	
Mean	14.2
S.D.	3.0
Average wearing time with allergies	
Days per week	
Mean	5.7
S.D.	1.8
Hours per day	
Mean	10.9
S.D.	3.6
Replacement schedule (n, %)	
Weekly	1/1
2-weekly	59/46
Monthly	45/35
Other	23/18
Solution type (n, %)	
Preserved	106/83
Non-preserved	22/17

used preserved solutions (Table 3). Over 95% of habitual lenses were manufactured from one of five lens materials or classifications: etafilcon A (45%), HEMA (17%), methafilcon A (12%), vifilcon A (12%), or miscellaneous non-ionic Group 2 materials. The use of preserved multi-purpose versus non-preserved solutions reflected the expected distribution in the current US marketplace [13].

3.3. Biometric findings

Baseline keratometry, refraction and visual acuities are shown in Table 4. Mean keratometry was 44.20 D (7.64 mm) and mean refractive sphere and cylinder powers were -2.90 and 0.40 D, respectively. Almost all subjects (99%) had a best corrected visual acuity of 20/20 (6/6) or better.

3.4. Allergy symptoms

All of the subjects recruited in this study reported that they experienced itchy eyes ('describes me a lot' or 'describes me a little') when suffering from allergies (Table 5). In addition, all 128 subjects reported reduced comfort with their contact lenses while suffering from allergies and 56% of them recognised that wearing contact lenses was difficult when taking allergy medications.

When questioned about the nature of their allergy with respect to chronic symptoms, 80% of subjects said they were affected all year-round ('describes me a lot' or 'describes

Table 4

Baseline keratometry, refraction and visual acuity

Variable	All subjects
Mean keratometry (D and mm)	
No. of eyes	254 ^a
Mean	44.2 (7.64)
S.D.	2.0
Min.	20.7
Max.	47.1
Refractive sphere (D)	
No. of eyes	255 ^a
Mean	-2.9
S.D.	1.3
Min.	-5.8
Max.	-0.3
Refractive cylinder (D)	
No. of eyes	172 ^b
Mean	-0.4
S.D.	0.3
Min.	-1.0
Max.	0.0
Refractive axis ($^{\circ}$)	
No. of eyes	156 ^b
Mean	96.6
S.D.	63.5
Min.	0.0
Max.	180
Best corrected visual acuity (n, %)	
No. of eyes	252 ^c
20/15 (6/4.5)	28/11
20/20 (6/6)	221/88
20/25 (6/7.5)	3/1

^a Practitioner's recording omissions.

^b Represent only patients with astigmatism.

^c Two subjects were corrected in one eye only.

Table 5

Hallmark allergy symptoms and contact lens wear comfort reported at baseline

Variable	All subjects
No. of subjects	128
Itchy (n, %)	
Describes me a lot	108/84
Describes me a little	20/16
Describes me not at all	0/0
Reduced comfort (n, %)	
Describes me a lot	87/68
Describes me a little	41/32
Describes me not at all	0/0
Difficult wear when taking medications (n, %)	
Describes me a lot	25/20
Describes me a little	46/36
Describes me not at all	57/45

Table 6
Nature of the allergy: chronic vs. seasonal reported at baseline

Variable	All subjects
No. of subjects	128
Chronic	
I am affected year-round (n, %)	
Describes me a lot	41/32
Describes me a little	62/48
Describes me not at all	25/20
I respond to allergens not related to the time of the year (n, %)	
Describes me a lot	21/16
Describes me a little	49/38
Describes me not at all	58/45
Seasonal	
My allergies occur at a specific time of the year (n, %)	
Describes me a lot	104/81
Describes me a little	17/13
Describes me not at all	7/5
My allergies are triggered by pollen (n, %)	
Describes me a lot	109/85
Describes me a little	18/14
Describes me not at all	1/1
I suffer from hay fever (n, %)	
Describes me a lot	58/45
Describes me a little	35/27
Describes me not at all	35/27

me a little'), and 54% said they responded to allergies not related to time of year (Table 6). With respect to seasonal symptoms, 94% said their allergies occurred at a specific time of the year, 99% experienced allergies triggered by pollen and 72% reported suffering from hay fever.

While suffering from allergies, subjects reported experiencing upper respiratory manifestations in the following proportions ('describes me a lot' or 'describes me a little'): 96% nasal, 95% sinuses, and 52% lungs (Table 7). With regard to specific eye symptoms, 97% experienced allergy-related redness, 87% watery eyes and 89% burning and stinging. With the exception of symptoms related to the lungs, the severity of symptoms can be considered to be high, as evidenced by the prevalence of responses in the 'describes me a lot' category.

3.5. Habits and practices

At the baseline visit, 55% of subjects were using medications, other than over-the-counter and/or prescription ocular medication, for their allergies and 61% of these subjects reported taking medications on a daily basis when experiencing allergies (Table 8). Additionally, when surveyed about their habits prior to study participation, 60% said they took prescription medications, 73% took over-the-counter medications, and 55% stated they took medications specifically to relieve their ocular symptoms while suffering from allergies. Answers to these three statements were not mutually

Table 7
Upper respiratory and ocular manifestations of allergies reported at baseline

Variable	All subjects
No. of subjects	128
Upper respiratory area affected	
Nose	
Describes me a lot	87/68
Describes me a little	36/28
Describes me not at all	5/4
Sinuses	
Describes me a lot	86/67
Describes me a little	36/28
Describes me not at all	6/5
Lungs	
Describes me a lot	17/13
Describes me a little	50/39
Describes me not at all	61/48
Specific eye symptoms	
Red	
Describes me a lot	74/58
Describes me a little	50/39
Describes me not at all	4/3
Watery	
Describes me a lot	53/41
Describes me a little	59/46
Describes me not at all	16/13
Burning and stinging	
Describes me a lot	69/54
Describes me a little	45/35
Describes me not at all	14/11

Table 8
Allergy medication use

Variable	All subjects
No. of subjects	128
Baseline visit	
Use (n, %)	
Yes	70/55
No	58/45
Prior to study	
How often (n = 73) (n, %)	
Daily	45/61
1–3 times per week	22/30
Weekly	3/4
Other	3/5
Prescription (Rx) (n, %)	
Yes	77/60
No	51/40
Over the counter (n, %)	
Yes	94/73
No	34/27
For eye symptoms (n, %)	
Yes	71/55
No	57/45

Table 9
Re-wetting drops used

Variable	All subjects
No. of subjects	128
Baseline visit, use (n, %)	
Yes	68/53
No	60/47
Prior to study	
How often (n = 76) (n, %)	
Several times per day	26/34
Daily	19/25
1–3 times per week	20/26
Weekly	2/3
Other	9/12

exclusive. The use of medication during the study remained similar at each follow-up visit.

At the baseline visit, 53% of subjects reported using re-wetting drops and most (85%) were using them at intervals ranged from 1–3 times per week to several times per day (Table 9).

3.6. Pollen and mould counts during the study

Pollen and mould counts during the study period for the five regions are shown in Fig. 1a and b. Although the Western Mountain and South East regions hit high pollen levels in the first half of the study (means 8.1 and 7.9 grains/m², respectively), average pollen counts remained in the medium range (4.1–8.0 grains/m²) during the study with a decline to low levels (0–4.0 grains/m²) during the last 2 weeks. In contrast, in the regions where mould was present, the average mould count was mostly high (13,001–50,000 spores/m³) throughout the study with a decline to medium levels (6501–13,000 spores/m³) for about 2 weeks and only low levels (0–6500 spores/m³) for the last few days of the study.

3.7. Comfort comparison

Sixty-seven percent of subjects agreed that the 1-day disposable test lenses provided improved comfort when compared to the lenses they wore prior to the study, compared with 18% agreeing that the new pair of habitual lenses provided improved comfort (Fig. 2). Significantly more subjects agreed that the test lenses provided improved comfort compared to their usual lenses than when compared to a new pair of their habitual lenses (67% versus 18%, $P < 0.0001$).

3.8. Slit-lamp findings

Gradings for bulbar redness, corneal staining, palpebral redness and lid roughness are shown in Fig. 3a–d.

- For bulbar redness (Fig. 3a), 98% of gradings with the test lenses were ‘none’ to ‘trace’, compared to 90% with

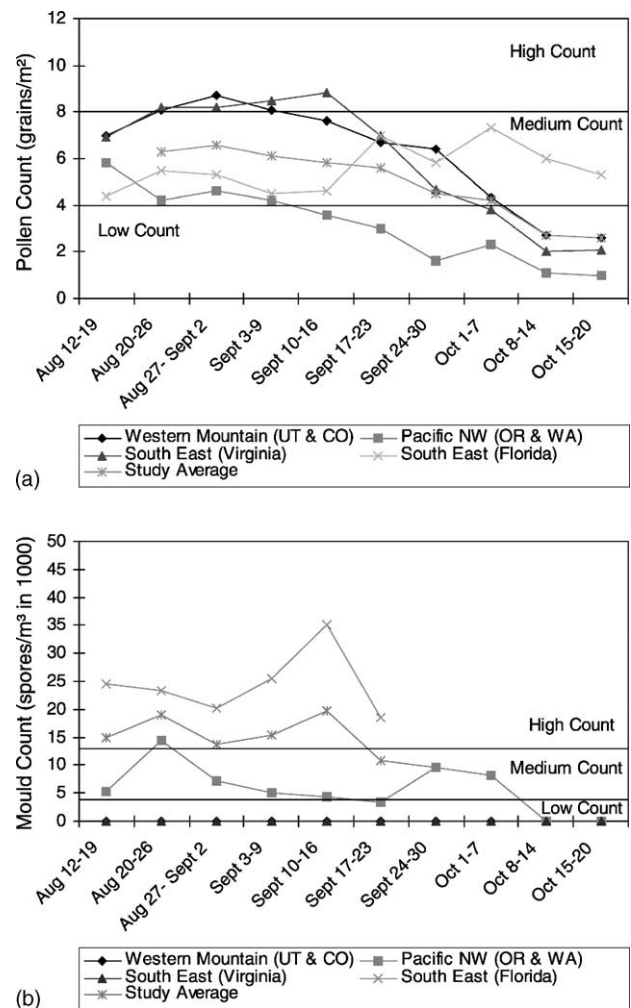


Fig. 1. (a) Pollen counts; (b) mould counts.

new habitual lenses ($P = 0.0011$) and 83% with baseline (BL) habitual lenses ($P < 0.0001$).

- For corneal staining (Fig. 3b), 98% of gradings with the test lenses were ‘none’ to ‘trace’, compared to 94% with new habitual lenses ($P = 0.0019$) and 93% with baseline habitual lenses ($P = 0.0087$).

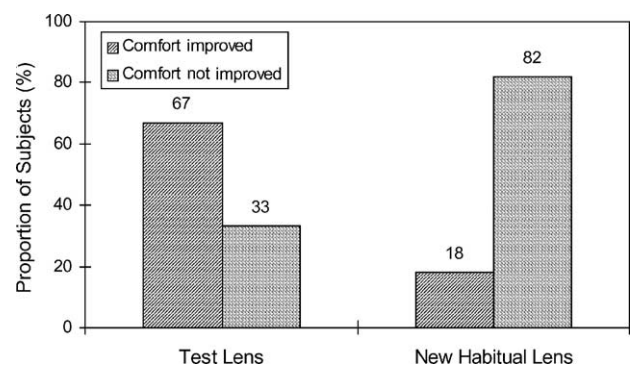


Fig. 2. Comfort improvement of test lenses over habitual lenses.

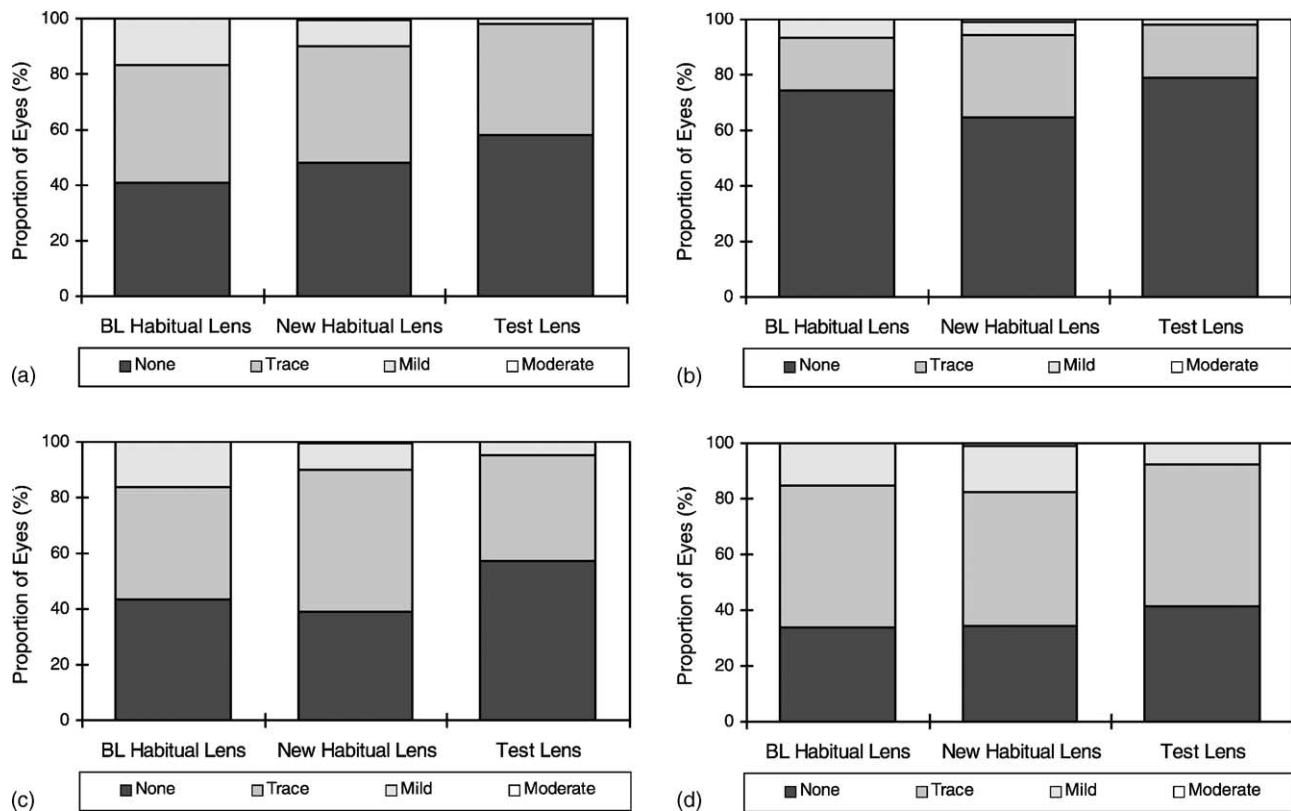


Fig. 3. (a) Bulbar redness gradings; (b) corneal staining gradings; (c) palpebral redness gradings; (d) lid roughness gradings.

- For palpebral redness (Fig. 3c), 95% of gradings with the test lenses were 'none' to 'trace', compared with 90% for new habitual lenses ($P = 0.0004$) and 84% with baseline habitual lenses ($P < 0.0001$).
- For lid roughness (Fig. 3d), 93% of gradings with the test lenses were 'none' to 'trace', compared with 82% for new habitual lenses ($P = 0.0036$) and 85% with baseline habitual lenses ($P = 0.0058$).

4. Discussion

The results of this study show that a majority of allergy-suffering contact lens wearers find that comfort is improved with etafilcon A 1-day disposable lenses when compared to the comfort of their habitual contact lenses replaced to their usual replacement schedule, when allergen levels are elevated. The results also demonstrate that the proportion of subjects for whom comfort is improved is significantly higher than that experienced when using a new pair of their usual lenses.

In addition, objective slit-lamp findings improved during the month of 1-day disposable lens wear to a greater degree than during a month's use of new habitual lenses. The 1-day disposable test lenses provided 93–98% of subjects with statistically significantly improved slit-lamp gradings when compared with new habitual lenses and with baseline

ratings with their habitual lenses. For each variable assessed, fewer 'mild' to 'moderate' findings were recorded in the test lens phase. The findings were particularly noteworthy for lid redness and roughness, both classical signs of allergic eye disease.

The population sampling of this study intended to target allergy-suffering contact lens wearers. This was confirmed by capturing the subjects' self-reported responses to a questionnaire on their allergy symptoms at the baseline visit. All experienced itchy eyes and reduced contact lens comfort while suffering from allergies. A large majority of them also reported symptoms of red, watery, burning and stinging eyes, in addition to nose and sinus manifestations. Detailed assessment of the nature of their allergies indicates that the study population comprised both chronic and seasonal allergy sufferers, therefore the allergic symptoms could have been due to hypersensitivity to year-round or seasonal allergens.

At the time of the study, more than half of the subjects reported using prescription or over-the-counter allergy medications and/or re-wetting drops for relief. Because of the reportedly high incidence of nose and sinus manifestations in the study population, subjects may have taken medications primarily to relieve these manifestations and to a lesser extent to relieve ocular symptoms. Verbatim comments from some subjects indicate that they were able to reduce or stop taking medications when wearing

1-day disposable lenses, even in the early weeks of the study.

According to the scale interpretation of the National Allergy Bureau, the pollen and mould counts in this study indicate that most individuals with any sensitivity to moulds would be expected to experience symptoms throughout the study, and many individuals who suffered from allergies to the predominant pollen types of the season would have been affected during the study period. Some relief may have been experienced during the last 2 weeks of the trial, as both pollen and mould counts declined to lower levels. However, the crossover study design would balance the pollen count variations. Pollen counts are recorded in different ways in Europe from methods used in the US and the types of allergen present and peak seasons also differ [14]. However, the principle behind the categorisation of low, medium and high counts also applies in Europe.

The mechanism responsible for the improved comfort provided by 1-day disposable lenses in allergy-suffering contact lens wearers was not investigated in this study. One hypothesis is that the inherent protein resistance and/or resistance to dehydration of a contact lens material are the key factors in providing improved comfort and reducing symptoms in these patients [15]. However, the association between lens dehydration and subjective comfort and dryness in symptomatic and asymptomatic wearers has been challenged [16].

The results of the present study suggest that the mechanism may not be driven principally by material properties but rather by the age of the lens and the repeated use of a single pair of lenses, enabling the accumulation of allergens and irritants. Furthermore, studies in populations of allergy-suffering contact lens wearers, comparing 1-day disposable and other conventional contact lens regimens ranging from 2-weekly to yearly replacement, support this suggestion [5,15].

The US Food and Drug Administration (FDA) has approved labelling clearance for two 1-day disposable lens types regarding possible relief from some symptoms associated with seasonal allergic conjunctivitis, and improved comfort for many patients who experience mild discomfort and itching associated with allergies during contact lens wear [11,17]. The fact that the two lens types are manufactured from different materials adds weight to the argument that replacement frequency is a more important factor than material properties in relieving symptoms and improving comfort in allergy-suffering contact lens wearers.

Investigators have suggested that the performance benefit is related to material ionicity, in that a non-ionic 1-day disposable lens attracts less protein [5]. Protein in its natural state can aid in lens surface wetting and contribute to a more comfortable lens. Protein deposition on etafilcon A has been shown to be largely lysozyme, a stable molecule which retains its activity and does not become denatured [18]. It is as the lens ages and is exposed to the environment that protein in and on the lens becomes denatured [19]. The body may then react as if the protein were a foreign substance,

causing an allergic reaction such as allergic conjunctivitis or contact lens papillary conjunctivitis [20]. Daily lens replacement limits the amount of denatured protein that could become irritating to the eye and the time the protein is in contact with the eye and lids [19,20]. Further evidence exists to support the performance of etafilcon A in a population of dry and sensitive-eye sufferers [21].

5. Conclusions

This study demonstrates that etafilcon A 1-day disposable lenses can help in the successful management of discomfort experienced by allergy-suffering contact lens wearers during periods when allergen levels are elevated.

Two out of three allergy sufferers agreed that the 1-day disposable lens used in this study provided improved comfort over their habitual lenses. Significantly more allergy sufferers agreed that the 1-day disposable lenses provided improved comfort over their usual lenses compared to a new pair of their habitual lenses. These subjective findings are supported by statistically significantly improved slit-lamp findings with the 1-day disposable lens when compared with subjects' habitual lenses.

The use of 1-day disposable lenses has been shown to be an effective strategy for managing allergy-suffering contact lens wearers.

Acknowledgements

Our thanks to the investigators who took part in the study: Mark Andre, Marisa Atria Kruger, William J Bogus, Kenji Hamada, Daniel R Hock, Janet Mint, Paul Paxman, Joan Ploem-Miller, William K Ramsay, Carol Record, Denise A Remy, David A Rumpf, Frank R Toscano and Susan S Whasey. Thanks also to Visioncare Research for help in the preparation of this paper.

References

- [1] European Allergy White Paper. UCB Institute, London.
- [2] The National Allergy Bureau. American Academy of Allergy, Asthma and Immunology. <http://www.aaaai.org>.
- [3] VisionTrak data, Taylor Nelson Sofres, September 2002.
- [4] The allergy report, vol 1. Overview of allergic diseases. American Academy of Allergy, Asthma and Immunology. <http://www.aaaai.org>.
- [5] Stiegemeier M, Thomas S. Seasonal allergy relief with daily disposable lenses. *Contact Lens Spectrum* 2001;16(4):24–8.
- [6] Solomon OD, Freeman MJ, Boshnick EL, et al. A 3-year prospective study of the clinical performance of daily disposable contact lenses compared with frequent replacement and conventional daily wear contact lenses. *CLAO J* 1996;22:250–7.
- [7] Hamano H, Watanabe K, Hamano T, et al. A study of the complications induced by conventional and disposable contact lenses. *CLAO J* 1994;20:103–8.
- [8] Jones L, Jones D, Langley C, et al. Subjective responses of 100 consecutive patients to daily disposables. *Optician* 1996;211(5536):28–32.

- [9] Nason RJ, Boshnik EL, Cannon WM, et al. Multisite comparison of contact lens modalities. Daily disposable wear versus conventional wear in successful contact lens wearers. *J Am Optom Assoc* 1994;65(11):774–80.
- [10] Sindt C. Daily disposable versus two-week disposable Lenses. *Contact Lens Spectrum* 2000;15(5):33–6.
- [11] Focus Dailies® (nelfilcon A) One-day Contact Lenses. 510(k) number K003586 (FDA document record reference).
- [12] Efron N. Efron grading scales for contact lens complications. In: Efron N, editor. *Contact lens practice*. Oxford: Butterworth-Heinemann; 2001. p. 394–7 and Appendix K.
- [13] Bausch & Lomb. Trends in contact lenses and lens care 2001. *Contact Lens Spectrum* 2001;16(Suppl 12):16.
- [14] Pollen UK. National Pollen Research Unit. <http://www.pollenforecast.co.uk>.
- [15] 1-DAY ACUVUE (etafilcon A) One-Day Contact Lenses. 510(k) number K994324 (FDA document record reference).
- [16] Fonn D, Situ P, Simpson T. Hydrogel lens dehydration and subjective comfort and dryness ratings in symptomatic and asymptomatic contact lens wearers. *Optom Vis Sci* 1999;76(10):700–4.
- [17] 1-DAY ACUVUE (etafilcon A) One-Day Contact Lenses. 510(k) number K013973 (FDA document record reference).
- [18] Mirejovsky D, Bakhit P, Patel AS. Stability of lysozyme adsorbed in high water/ionic lenses. *Optom Vis Sci* 1991;68(12s):110.
- [19] Hart DE. Deposits and coatings hydrogel lens/tear film interactions. In: Bennett E, Weissman B, editors. *Clinical contact lens practice*. Philadelphia: Lippincott-Raven; 1996. p. 3–5, 19–20.
- [20] Jurkus JM. Contact lens-induced giant papillary conjunctivitis. In: Silbert JA, editor. *Anterior segment complications of contact lens wear*. Boston: Butterworth-Heinemann; 2000. p. 138–9.
- [21] Schnider C, Veys J, Hunt C. The use of new 1-DAY ACUVUE in patients claiming dry, sensitive or easily irritated eyes. *CLAE* 2002;25:206.