V I S I O N C A R E R E S E A R C H L T D

FINAL REPORT

VERSION 1

One Month Clinical Evaluation of Eye See Multi-purpose Care System

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CONFIDENTIAL

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One-month clinical evaluation of EYE SEE multi-purpose solution care system

EYEC-2301

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A. INTRODUCTION

The Lapis Lazuli EYE SEE multipurpose solution is indicated for the cleaning and disinfection of soft (hydrophilic) contact lenses. The product is CE-marked and has been marketed in Europe since 1994. The product is CE-marked for use with frequent replacement soft lenses using a rinse but no-rub regimen. The product contains constituents already used in FDA-approved multipurpose solutions. The disinfecting agent is polyheximethylene biguanide (PHMB) which is widely used in other multi-purpose solutions, including AMO COMPLETE MoisturePLUS.[1]

An earlier clinical study confirmed the product's safety and efficacy when used with a rub and rinse step as part of the regimen.[2] The purpose of this study was to gather the necessary clinical data for FDA 510k submission by evaluating the clinical performance of the EYE SEE multipurpose solution in comparison with another PHMB-containing multipurpose solution (COMPLETE MoisturePLUS).

A.1 Study Objectives

The objective of this study was to test whether the EYE SEE multipurpose solution is substantially equivalent to another PHMB-containing multipurpose solution (COMPLETE MoisturePLUS) when used with a no-rub regimen.

A.2 Statement of Compliance

Sixty-five (65) subjects were enrolled in the study. Of these, 43 subjects (66%) used the test solution (EYE SEE) and 22 subjects (34%) used the control solution (COMPLETE MoisturePLUS).

Summary of subject status

	EYE SEE			COMPLETE MoisturePLUS			Total
	Acuvue 2	Acuvue Advance	Sub Total	Acuvue 2	Acuvue Advance	**Sub Total**	
Enrolled	22	22	**44**	10	11	**21**	**65**
Dispensed	22	22	**44**	10	11	**21**	**65**
Completed	20	21	**41**	10	10	**20**	**61**
Discontinued	2	1	**3**	1	0	**1**	**4**

Four subjects discontinued prior to the end of the study. One subject discontinued while using the control solution and three subjects discontinued while using the test solution (A2 Table 8). None of these discontinuations were considered to be related to the care products. Details of the discontinuations are given below.

- Subject 01/16/LJ, a 20 year old female, was dispensed the COMPLETE MoisturePLUS and Acuvue Advance contact lenses. After 15 days in the study, the subject returned for the scheduled 2-week follow-up visit complaining of dry eyes. Both lenses were poorly fitting (too tight) and showed moderate film deposits. Both eyes showed grade 1.5 staining and the investigator discontinued the subject due to unacceptable slit lamp findings. No post-study follow-up visit was required.

- Subject 02/32/JS, a 20 year old male, dispensed Acuvue 2 and EYE SEE, was discontinued following an adverse event. The subject informed the investigator, at an unscheduled visit four days after the 2-week visit, that the right lens had failed to settle two days previously and had then fallen out. Since then the right eye had been watery, a little itchy and with some stickiness on waking. Mild conjunctival injection, some swelling of the bulbar conjunctiva and marked redness and roughness of the palpebral conjunctiva were noted. The investigator diagnosed contact lens papillary conjunctivitis (CLPC) and advised the subject to discontinue lens wear until the next visit. The subject returned 10 days later, at which time the adverse event had been resolved and the subject exited the study.

- Subject 03/54/NS, a 24 year old female, was dispensed EYE SEE and Acuvue Advance. The subject returned for an unscheduled follow-up visit four days after dispensing complaining of discomfort and lens edge awareness in the left eye. The investigator dispensed a new lens. The subject returned 17 days later not wearing lenses wanting to discontinue due to continued lens awareness. This was not felt by the investigator to be related to the care product.

- Subject 03/61/EF, a 35 year old female, was dispensed EYE SEE and Acuvue 2. The subject did not return for any follow-up visits and was deemed lost to follow-up 48 days after enrolment.

There was one missed follow-up visit: Subject 03/58/AQ (control group) missed their 2-week follow-up visit. None of the subjects in the test solution group missed a scheduled visit.

Missing data for vision, lens fit and deposit variables occurred for one test eye at the 2-week visit and one control eye at the 1-month visit. In both cases the subject had presented to the visit only wearing one contact lens.

A.3 Investigational Sites

The study was conducted at three investigational sites. The study was conducted by appropriately qualified and licensed investigators who each had at least three years experience of contact lens practice. They were also given trained in Good Clinical Practice and in the methods and grading systems of the study. The investigator names and addresses are listed in Appendix 1. The numbers of subjects enrolled at each site are given below.

Summary of number of subjects enrolled by site

	EYE SEE	COMPLETE MoisturePLUS
Site 1	15	6
Site 2	14	8
Site 3	15	7

B. MATERIALS AND METHOD

B.1 Study Materials

B.1.1 Lens Care Products

Subjects were instructed to use only the study lens care products. Subjects were not permitted to use rewetting drops, protein removers or separate cleaning solutions.

Test Products:

Lapis Lazuli EYE SEE multi-purpose solution care system used in the same way as the control solution (thoroughly rinse both sides of lens, and soak i.e. no-rub).

Lapis Lazuli FDA-approved lens case (K 991206).

Control Products:

AMO COMPLETE MoisturePLUS multi-purpose solution (0.0001% PHMB) cleaning & disinfection solution used on removal according to the manufacturers instructions (rinse lenses and soak i.e. no-rub).

AMO COMPLETE lens case.

B.1.2 Contact Lenses

The following lens types were used in suitable lens powers.

A.	Brand Name:	Vistakon Acuvue 2
	FDA Group:	IV
	Material	etafilcon A (58%)
	BOZR:	8.70mm, 8.30mm
	TD:	14.0mm
	BVP:	-6.00D to +6.00D (-0.25 steps)
	BVP:	-6.25D to -8.00D (-0.50 steps)
B.	Brand Name:	Vistakon Acuvue Advance
	FDA Group:	I
	Material	galyfilcon A (47%)
	BOZR:	8.30, 8.70mm
	TD:	14.0mm
	BVP:	-6.00D to +4.00D (-0.25 steps)

Subjects wore the lens powers closest to their own sphere requirement. Base curves were chosen by the investigator to provide the best fit. The Acuvue 2 lenses were replaced on a 2-weekly basis. There were no scheduled replacements of the Acuvue Advance lenses during the study.

B.2 Study Design and Population

Sixty-five subjects (130 eyes) were enrolled, all of whom were dispensed lenses. The sample size was selected to allow at least 60 subjects (120 eyes) to successfully complete the study.

This was a one-month, open-label, bilateral, randomised, daily wear, comparative study. Approximately two-thirds (44/65) of the subjects were randomised to use the test solution (EYE SEE) and the remaining subjects (21/65) used the control solution (COMPLETE MoisturePLUS). Within the test and control groups, approximately half of the subjects were randomised to wear Acuvue 2 and the other half to wear Acuvue Advance.

There were up to four visits for each subject: lens issue visit, an optional follow-up assessment after one week, a visit after two weeks wear and a final assessment at one month.

B.2.1 Inclusion/Exclusion Criteria

Subjects were required to be adapted soft contact lens wearer, with a sphere requirement in the range +6.00 to -8.00D, have less than 1.25D of astigmatism in both eyes and be correctable to 6/12 (+0.30 logMAR) in each eye. Subjects were excluded who showed evidence of eye disease or abnormality or who suffered from systemic illness or were taking medication likely to affect contact lens wear.

B.2.2 Randomisation

A random number generator (Microsoft Excel) was used to determine the randomisation of lenses and care products. Enrolment (ID) numbers were, where possible, assigned consecutively to maintain randomisation. In the event of a subject having a sphere power requirement in the range +4.25 to +8.00D or -6.25 to -8.00D, they were enrolled using the next available Group IV lens ID number. The next suitable subject enrolled would then take the skipped ID number.

B.2.3 Visits Schedule

There were four scheduled visits as follows:

Visit No.	Time	Visit Window	Forms Completed
1	Baseline	-	Informed Consent Baseline CRF Dispensing CRF
2 (Optional)	1-week	7 days ± 3 days	Follow-up CRF
3	2-week	14 days ± 3 days	Follow-up CRF
4	1-month	30 days ± 7 days	Patient Evaluation Questionnaire Follow-up CRF Exit CRF

The following variables were collected at each visit.

	Baseline visit	Dispensing visit	Follow-up Visits	Exit Visit
Refraction (spectacle)	X	-	-	-
Spectacle high contrast visual acuity (VA)	X			X
Slit lamp examination	X	-	X	-
Biometry (Keratometry, HVID, Palpebral aperture)	X	-	-	-
Comfort	-	X	X	-
Symptoms, problems and complaints	-	-	X	-
High contrast VA with contact lenses	-	X	X	X
Over refraction (sphero-cyl) and VA	-	X	X	-
Vision quality (with sphero-cyl over-ref)	-	X	X	-
Average wearing time (at visit & on average)	-	-	X	-
No of days worn	-	-	X	-
Non-invasive break-up time	-	X	X	-
Pre-lens tear film quality	-	X	X	-
Lens Fit	-	X	X	-
Lens condition (Modified Rudko)	-	-	X	-

B.3 Data Analysis

Summary tables have been produced in accordance with the FDA guidelines.[3]

Where appropriate, comparisons have been made between the test and control results: Mann-Whitney test for non-normal data, the 2-sample t-test for normal data and Pearson's Chi-square test for nominal data. In all cases a *P*-value less than or equal to 0.050 has been taken to indicate a statistically significant difference.

C. SUBJECTS

C.1 Subject Demographics

The subjects' biometric data are given in A2 Table 2 and A3 Table 1. Subject biometric data were similar for both treatment groups. On average, subjects in the test and control groups had a similar level of refractive sphere (-3.16D vs. -2.90D respectively), refractive astigmatism (0.37DC vs. 0.43DC respectively), horizontal visible iris diameter (11.3mm with both groups), palpebral aperture (9.8mm with both groups) and mean keratometry readings (7.68mm and 7.67mm respectively).

Subjects in the test group were, on average, significantly older than those in the control group (*P*=0.02), mean ages were 33 and 27 years old with test and control groups respectively. Although this difference is statistically significant, the mean difference was not felt to have affected the outcome of the study.

There were some significant differences between groups at the baseline visit with respect to slit lamp findings. Corneal staining was graded significantly higher in the control group (*P*=0.03) and bulbar hyperaemia (*P*=0.002) significantly greater in the test group (A3 Table 5). Mean corneal staining was 0.67 (0-4 scale) in the control group compared to 0.30 in the test group; 67% (28/42) of eyes showed positive corneal staining at the baseline visit in the control group compared to 39% (34/88) in the test lens group (A2 Table 4A-D, A2 Table 9). Mean bulbar hyperaemia was 1.09 (0-4 scale) in the test lens group compared to 0.75 with the control lens group; 100% (88/88) of the control group showed some hyperaemia compared to 90% (38/42) of the control group.

All subjects were current soft contact lens wearers. The most common previously worn lens brands were Acuvue 2 (25%), Focus Dailies (17%) and 1·Day Acuvue (12%) (A4 Table 1).

C.2 Completed and Discontinued Subjects

Of the 65 subjects enrolled, 61 (41 test and 20 control) successfully completed the 1-month study. The remaining four subjects were discontinued (A2 Table 8). All of the four discontinued subjects were dispensed lenses, three were discontinued from the test group and one was discontinued from the control group. A detailed description of each discontinuation is provided in Section A.2.

D. DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE

D.1 Adverse Reactions

There were no adverse reactions directly attributable to either care product during the course of the study, however one adverse event was reported. The definition of adverse reaction/event included, but was not limited to, sight threatening conditions such as: corneal ulcers, anterior uveitis (iritis), other ocular infections or inflammations, corneal scarring, or permanent loss of vision.

Subject 02/32/JS showed contact lens papillary conjunctivitis (CLPC) in the right eye (left eye normal). The subject was problem-free at the 2-week visit but reported for an unscheduled visit four days later having found the lens to be unstable. The investigator judged the event to be mild and non-significant, however, the subject was discontinued at this point as the CLPC necessitated cessation of lens wear. When reviewed one week later, the CLPC had cleared. Given that the subject was problem-free at the 2-week visit and that the problem affected one eye only, this event is not regarded as having been care product-related.

D.2 Slit Lamp Findings

There were no significant differences between the test and control products with respect to any of the physiological variables at either follow-up visit. These findings suggest that the physiological response to the two care systems is substantially equivalent.

'Other' Slit Lamp Findings

All of the slit lamp findings categorized as 'other' were grade 2 or less and most were reports of pre-existing corneal scars, pingueculae or neovascularisation. Full details may be found in the Slit Lamp Findings tables (A2 Table 4A-D).

Slit Lamp Findings Requiring Treatment

Any slit lamp finding requiring temporary or permanent discontinuation from lens wear or medical treatment were recorded. One subject required treatment (i.e. cessation of lens wear) due to slit lamp findings in the EYE SEE group (see Section D1) while no subjects in the COMPLETE MoisturePLUS group required treatment.

D.3 Symptoms, Problems and Complaints

With those subjects that completed the study, the most frequently reported symptoms with the EYE SEE group were dryness, blurred vision and 'lens needs cleaning'. At the 1-month visit these symptoms were noted in 37% (30/82), 24% (20/82) and 18% (15/82) of EYE SEE eyes, respectively. The most frequently reported symptoms with the COMPLETE MoisturePLUS group were dryness, lens needs cleaning, redness and blurred vision; these were noted at the 1-month visit in 50% (20/40) and 23% (9/40), 15% (6/40) and 15% (6/40) respectively.

No statistically significant differences were noted between the two groups when all subjects' (completed and discontinued) symptoms and problems were compared.

In general, the symptoms reported in this study were equivalent for the two care systems and are typical for soft contact lens wearers (Vajdic et al, 1999).

'Other' Symptoms, Problems and Complaints

All of the problems categorized as 'other' were moderate or less. Full details may be found in the Slit Lamp Findings tables (A2 Table 5A-D).

Symptoms, Problems or Complaints Requiring Treatment

No subjects in either group had a symptom, problem or complaint that of itself necessitated temporary or permanent discontinuation from lens wear or medical treatment.

D.4 Visual Acuity

Visual acuity (VA) was measured using high contrast charts and recorded in logMAR at Site 1 and metric Snellen notation (e.g. 6/6) at Sites 2 and 3. The Snellen VA measurements were, where required, converted to logMAR for statistical analysis (A3 Table 4) and the logMAR VA measurements were converted to metric Snellen for the purpose of examining changes through the study (A2 Table 6). VA was also normalised with respect to baseline spectacle VA.

Only one statistically significant difference was noted with respect to visual performance. Normalised VA with over-refraction for the EYE SEE group was, on average (in logMAR notation), significantly better than the COMPLETE MoisturePLUS group at the dispensing visit (+0.02† vs. -0.02 logMAR; P=0.05).

There were no other significant differences in visual acuity between groups. Subjective visual quality was on average greater than 87% for both groups at each visit.

VA with lenses at the final visit was recorded as two or more lines different from baseline VA in 12 eyes (of 10 subjects); of these eight eyes were using the test product and four using the control product. In one of the eight differences with the EYE SEE group, this was actually an increase in VA. With each of the other 11 cases, the apparent decrease in VA was explained by either lens deposits or uncorrected refractive error.

D.5 Average Wearing Time

The mean wearing times were high with each group; these are summarised in A2 Table 7 and A3 Table 3. There were no significant differences in mean wearing time. The mean wearing time was 12 hours/day and mean weekly wearing time was 6 days/week with both groups during the study.

D.6 Discontinued Subjects

There were four discontinuations: three EYE SEE subjects and one from the COMPLETE MoisturePLUS group. These are summarised in A2 Table 8 and a detailed description of each case is provided in Section A.2.

D.7 Lens Surface Characteristics

Lens surface characteristics (deposits, break-up time and pre-lens tear film quality) are summarised in A2 Table 10 and A3 Table 2. There were no significant differences between the test and control groups with respect to any characteristic. The mean tear break-up time

† A positive normalised VA indicates better VA than Baseline spectacle VA.

ranged from 7.5s (control 2-week) to 10.0s (test 2-week). At the 1-month visit, 80% (66/82) of the EYE SEE eyes and 73% (29/40) of the COMPLETE MoisturePLUS eyes were recorded as showing either none or slight film deposits.

D.8 Lens Fit

The lens fit results are summarised in A3 Table 2. Both groups of eyes showed, on average, similar lens fit characteristics. All lenses were judged to give an overall fit acceptance of at least grade 2 at every visit. There were no significant differences with respect to any of the lens fit variables at any visit between the two solution groups. At the 1-month visit, mean tightness on push-up was 52% and 53% with the test and control groups respectively.

D.9 Subjective Responses

Comfort

Comfort was measured on a 10cm visual analogue scale (VAS) at each lens-wearing visit (A3 Table 2). Comfort was rated, on average, to be high with both groups at each visit and no statistical differences were found between groups. The mean comfort score ranged from 8.3 (Control 1-month) to 9.2 (Control Dispensing).

Evaluation Questionnaire

Subjects completed a questionnaire at the end of the study regarding the care system they had used for the study (A4 Table 2). There were no significant differences between responses from the test and control groups. This questionnaire was completed by 82 subjects (42 test and 20 control).

Subjects were asked to rate the study care system with respect to overall performance, overall comfort and cleaning performance and to compare it to their current system. In each case, a majority of subjects rated the care system as ‘Excellent’ or ‘Very good’. A higher proportion of subjects rated it as better (‘Somewhat’ or ‘Much’) than their previous care system than rated it worse. The overall performance of the EYE SEE care system was rated ‘Excellent’ or ‘Very good’ by 62% (26/42) subjects and 29% (12/42) of subjects preferred it to their previous lens care system. This compares to 75% (15/20) of subjects rating COMPLETE MoisturePLUS as ‘Excellent’ or ‘Very good’ and 20% (4/20) of preferring it to their previous lens care system.

Subjects were also asked if they were likely to switch from their previous care system to the study care system. Of the 42 EYE SEE subjects, 11 (26%) said they were ‘Likely’ or ‘Very likely’ to change compared with 30% (6/20) of the COMPLETE MoisturePLUS subjects.

D.10 Unscheduled Visits

There were three unscheduled visits (excluding those for lens or solution replacement) for two subjects, all using EYE SEE. The details of the unscheduled visits are listed below.

Summary of unscheduled visits:

Subject	Date	Visit Details	Outcome
02/32/JS	07-Dec-04	Subject had lost right lens and also reported that the right eye had been watery, slightly red and sticky. Subject had mild injection and roughening of palpebral conjunctiva (See adverse reactions).	Ceased lens wear until next visit (see below)
02/32/JS	14-Dec-04	Follow-up for adverse event. AE in right eye was resolved.	Problem resolved, exited study
03/54/NS	27-Oct-04	Subject complained of lens discomfort in the left eye. A new lens was dispensed which resolved the problem.	Completed study

E. TREND ANALYSIS PROFILE

The Trend Analysis Profiles are shown in A2 Table 9A-B. Trend analysis shows a slight increase in corneal and conjunctival staining for the test group. However, this is in line with the control group.

F. CONCLUSIONS

i. The EYE SEE care system proved to be substantially equivalent to the control care system (COMPLETE MoisturePLUS) over a 1-month period when used with a no-rub regimen.

ii. The EYE SEE care system is a safe and effective solution for soft contact lens care when used with a no-rub regimen.

G. REFERENCES

1. Christie CL and Meyler J. Contemporary contact lens care products. *Contact Lens Ant Eye* 1997;20:S11-S17

2. Research Report by Dr OC Geyer, Institut fur Medizinsche Sehhilfen. 12 Dec. 2003.

3. Guidance for industry - Premarket notification (510k) guidance document for contact lens care products, FDA CDRH. May 1997.

4. Lowther GE, Hammack GG, Wissner S Alvord L. Quantification of visible deposits in hydrogel contact lenses. *ICLC* 1991; 18:219-225.

APPENDIX 1

List of Investigators

Summary of Investigators

Site No.	Investigators	Address	Tel
1	Graeme Young BSc MPhil PhD FCOptom DCLP FAAO * Louise Nicklin BSc MCOptom Mary Ware BSc MCOptom	Visioncare Research Ltd Craven House West Street Farnham Surrey GU9 8UW UK	Tel: +44(0)1252 718719
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* Principle investigator

APPENDIX 2

Informative Summary Reporting Tables

APPENDIX 2

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A2 Table 1
Accountability of Eyes Enrolled and Distribution by Status

Status	Number of Eyes		
	Control	Test	Total
Enrolled Dispensed			
Completed	40	82	122
Total Active	0	0	0
Discontinued	2	6	8
Incomplete	0	0	0
Total Dispensed	42	88	130
Enrolled Not Dispensed	0	0	0
Total Enrolled	**42**	**88**	**130**

A2 Table 2
Demographics

Age of Subjects:	From 16 to 56, Average 31.
Sex:	Female 50, Male 15, ratio 0.30.

A2 Table 3

Adverse Reactions/Events (3A)

Subject	Time in Investigation	Details
02/32/JS (Test)	18 days	Contact lens related conjunctivitis (CLPC) in one eye requiring cessation of lens wear. Subject complained that the right lens failed to settle two days previously (16 days after enrolment) and had then fallen out. Since then the right eye had been watery, a little itchy and with some stickiness on waking. Mild conjunctival injection, some swelling of the bulbar conjunctiva and marked redness and roughness of the palpebral conjunctiva were noted. The investigator diagnosed CLPC and advised the to cease lens wear until further notice. The subject returned 1 week later, the problem was resolved and the subject exited the study.

SLFs Requiring Treatment (3B)

Subject	Time in Investigation	Details
02/32/JS (Test)	18 days	See above.

SPCs Requiring Treatment (3C)

Subject	Time in Investigation	Details
There were no SPCs requiring treatment		

A2 Table 4A
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Completed Control Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Limbal Hyperaemia												
Grade 0	8	20	0	0	3	8	2	5	0	0	13	11
Grade 0.5 or 1	31	78	2	100	27	68	29	73	0	0	89	73
Grade 1.5 or 2	1	3	0	0	6	15	9	23	0	0	16	13
Grade 2.5 or 3	0	0	0	0	2	5	0	0	0	0	2	2
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Bulbar Hyperaemia												
Grade 0	4	10	0	0	0	0	0	0	0	0	4	3
Grade 0.5 or 1	32	80	2	100	25	63	26	65	0	0	85	70
Grade 1.5 or 2	4	10	0	0	12	30	14	35	0	0	30	25
Grade 2.5 or 3	0	0	0	0	1	3	0	0	0	0	1	1
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Hyperaemia												
Grade 0	4	10	0	0	2	5	2	5	0	0	8	7
Grade 0.5 or 1	28	70	2	100	21	53	24	60	0	0	75	61
Grade 1.5 or 2	8	20	0	0	13	33	14	35	0	0	35	29
Grade 2.5 or 3	0	0	0	0	2	5	0	0	0	0	2	2
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Roughness												
Grade 0	6	15	0	0	4	10	4	10	0	0	14	11
Grade 0.5 or 1	23	58	2	100	21	53	20	50	0	0	66	54
Grade 1.5 or 2	10	25	0	0	13	33	16	40	0	0	39	32
Grade 2.5 or 3	1	3	0	0	0	0	0	0	0	0	1	1
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Hyperaemia												
Grade 0	2	5	0	0	2	5	2	5	0	0	6	5
Grade 0.5 or 1	28	70	2	100	20	50	29	73	0	0	79	65
Grade 1.5 or 2	10	25	0	0	16	40	9	23	0	0	35	29
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Roughness												
Grade 0	8	20	0	0	7	18	6	15	0	0	21	17
Grade 0.5 or 1	23	58	2	100	21	53	25	63	0	0	71	58
Grade 1.5 or 2	9	23	0	0	10	25	9	23	0	0	28	23
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0

A2 Table 4A (cont.)
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Completed Control Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Corneal Staining (Extent)												
Grade 0	14	35	0	0	14	35	16	40	0	0	44	36
Grade 0.5 or 1	24	60	2	100	22	55	22	55	0	0	70	57
Grade 1.5 or 2	2	5	0	0	1	3	1	3	0	0	4	3
Grade 2.5 or 3	0	0	0	0	1	3	1	3	0	0	2	2
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Corneal Staining (Depth)												
Grade 0	14	35	0	0	15	38	16	40	0	0	45	37
Grade 0.5 or 1	26	65	2	100	22	55	24	60	0	0	74	61
Grade 1.5 or 2	0	0	0	0	1	3	0	0	0	0	1	1
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Conjunctival Staining												
Grade 0	22	55	0	0	4	10	0	0	0	0	26	21
Grade 0.5 or 1	16	40	2	100	21	53	27	68	0	0	66	54
Grade 1.5 or 2	1	3	0	0	11	28	11	28	0	0	23	19
Grade 2.5 or 3	1	3	0	0	2	5	0	0	0	0	3	2
Grade 3.5 or 4	0	0	0	0	0	0	2	5	0	0	2	2
Other												
Grade 0	36	90	1	50	35	88	37	93	0	0	109	89
Grade 0.5 or 1	4	10	1	50	3	8	3	8	0	0	11	9
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**2**	**5**	**0**	**0**	**0**	**0**	**2**	**2**
Total Eyes	**40**		**2**		**40**		**40**		**0**		**122**	
Positive eyes	40	100	2	100	38	95	40	100	0	0	120	98
Negative eyes	0	0	0	0	0	0	0	0	0	0	0	0
Total Evaluations	**400**		**20**		**380**		**400**		**0**		**1200**	
Positive evaluations	282	71	19	95	294	77	315	79	0	0	910	76
Negative evaluations	118	30	1	5	86	23	85	21	0	0	290	24

A2 Table 4As
Slit Lamp Findings - 'Other' Explanations

Completed Control Eyes

Subject	Eye	Visit	Date	Grade	Description
01/07/LT	Right	FU1	27-Oct	0.5	Scar (Overlooked at baseline)
01/07/LT	Right	FU2	3-Nov	0.5	Scar, as before.
01/07/LT	Right	FU3	16-Nov	0.5	Scar, as before.
01/12/AC	Right	BL	21-Oct	0.5	1 Vacuole (nasal).
01/12/AC	Left	BL	21-Oct	1	1 vacuole (inferior) and trace neovascularisation at 5 o'clock
02/29/DR	Right	BL	28-Oct	1	Scar at 10 o'clock.
02/29/DR	Right	FU2	11-Nov	1	Scar at 10 o'clock.
02/29/DR	Right	FU3	29-Nov	1	Scar at 10 o'clock.
02/39/IA	Right	BL	4-Nov	1	Small corneal opacity, mid periphery 12 o'clock
02/39/IA	Right	FU2	18-Nov	1	Small round corneal opacity as previously seen.
02/39/IA	Right	FU3	2-Dec	0.5	Small round scar as previously seen.

A2 Table 4B
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Completed Test Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Limbal Hyperaemia												
Grade 0	8	10	0	0	9	11	4	5	0	0	21	9
Grade 0.5 or 1	63	77	0	0	48	59	54	66	0	0	165	67
Grade 1.5 or 2	10	12	0	0	23	28	23	28	0	0	56	23
Grade 2.5 or 3	1	1	0	0	2	2	1	1	0	0	4	2
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Bulbar Hyperaemia												
Grade 0	0	0	0	0	5	6	2	2	0	0	7	3
Grade 0.5 or 1	58	71	0	0	33	40	40	49	0	0	131	53
Grade 1.5 or 2	24	29	0	0	44	54	40	49	0	0	108	44
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Hyperaemia												
Grade 0	6	7	0	0	3	4	4	5	0	0	13	5
Grade 0.5 or 1	61	74	0	0	57	70	54	66	0	0	172	70
Grade 1.5 or 2	13	16	0	0	19	23	20	24	0	0	52	21
Grade 2.5 or 3	2	2	0	0	2	2	4	5	0	0	8	3
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Roughness												
Grade 0	8	10	0	0	10	12	6	7	0	0	24	10
Grade 0.5 or 1	57	70	0	0	57	70	56	68	0	0	170	69
Grade 1.5 or 2	15	18	0	0	13	16	18	22	0	0	46	19
Grade 2.5 or 3	2	2	0	0	2	2	2	2	0	0	6	2
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Hyperaemia												
Grade 0	6	7	0	0	6	7	7	9	0	0	19	8
Grade 0.5 or 1	54	66	0	0	39	48	42	51	0	0	135	55
Grade 1.5 or 2	22	27	0	0	36	44	32	39	0	0	90	37
Grade 2.5 or 3	0	0	0	0	0	0	1	1	0	0	1	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Roughness												
Grade 0	13	16	0	0	18	22	13	16	0	0	44	18
Grade 0.5 or 1	46	56	0	0	39	48	45	55	0	0	130	53
Grade 1.5 or 2	21	26	0	0	24	29	23	28	0	0	68	28
Grade 2.5 or 3	2	2	0	0	0	0	0	0	0	0	2	1
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0

A2 Table 4B (cont.)
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Completed Test Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Corneal Staining (Extent)												
Grade 0	50	61	0	0	30	37	29	35	0	0	109	44
Grade 0.5 or 1	30	37	0	0	39	48	41	50	0	0	110	45
Grade 1.5 or 2	2	2	0	0	10	12	12	15	0	0	24	10
Grade 2.5 or 3	0	0	0	0	3	4	0	0	0	0	3	1
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Corneal Staining (Depth)												
Grade 0	49	60	0	0	32	39	29	35	0	0	110	45
Grade 0.5 or 1	32	39	0	0	50	61	53	65	0	0	135	55
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Conjunctival Staining												
Grade 0	42	51	0	0	9	11	8	10	0	0	59	24
Grade 0.5 or 1	33	40	0	0	35	43	38	46	0	0	106	43
Grade 1.5 or 2	7	9	0	0	27	33	28	34	0	0	62	25
Grade 2.5 or 3	0	0	0	0	6	7	8	10	0	0	14	6
Grade 3.5 or 4	0	0	0	0	4	5	0	0	0	0	4	2
Other												
Grade 0	60	73	0	0	62	76	55	67	0	0	177	72
Grade 0.5 or 1	18	22	0	0	16	20	22	27	0	0	56	23
Grade 1.5 or 2	4	5	0	0	4	5	5	6	0	0	13	5
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Total Eyes	**82**		**0**		**82**		**82**		**0**		**246**	
Positive eyes	82	100	0	0	82	100	82	100	0	0	246	100
Negative eyes	0	0	0	0	0	0	0	0	0	0	0	0
Total Evaluations	**819**		**0**		**816**		**819**		**0**		**2454**	
Positive evaluations	577	70	0	0	632	77	662	81	0	0	1871	76
Negative evaluations	242	30	0	0	184	23	157	19	0	0	583	24

A2 Table 4Bs
Slit Lamp Findings - 'Other' Explanations

Completed Test Eyes

Subject	Eye	Visit	Date	Grade	Description
01/01/JR	Right	BL	14-Oct	0.5	0.25mm neovascularisation.
01/01/JR	Right	FU2	28-Oct	0.5	Neovascularisation as before.
01/01/JR	Right	FU3	11-Nov	0.5	Neovascularisation as before.
01/01/JR	Left	BL	14-Oct	0.5	0.5mm neovascularisation (inferior).
01/01/JR	Left	FU2	28-Oct	0.5	Neovascularisation as before.
01/01/JR	Left	FU3	11-Nov	0.5	Neovascularisation as before.
01/03/HJ	Right	BL	15-Oct	1	Pingueculae.
01/03/HJ	Right	FU2	29-Oct	1	Pingueculae.
01/03/HJ	Right	FU3	12-Nov	1	Pingueculae.
01/03/HJ	Left	BL	15-Oct	1	Pingueculae.
01/03/HJ	Left	FU2	29-Oct	1	Pingueculae.
01/03/HJ	Left	FU3	12-Nov	1	Pingueculae.
01/05/SJ	Right	FU3	16-Nov	0.5	3 Mucin ball imprints.
01/05/SJ	Left	FU3	16-Nov	0.5	2 Vacuoles.
01/06/JH	Right	BL	21-Oct	0.5	A few blocked meibomium glands.
01/06/JH	Right	FU3	16-Nov	1	Blocked meibomium glands on lower lid.
01/06/JH	Left	0	21-Oct	0.5	A few blocked meibomium glands.
01/06/JH	Left	2	04-Nov	0.5	2 mucin balls
01/06/JH	Left	3	16-Nov	1.5	blocked meibomium glands upper/lower lids.
01/08/CM	Right	0	21-Oct	1	Pingueculae, nasal
01/08/CM	Right	2	04-Nov	1	Pingueculae as before.
01/08/CM	Right	3	19-Nov	0.5	Pingueculae
01/08/CM	Left	0	21-Oct	2	Pingueculae, calculi, nasal
01/08/CM	Left	2	04-Nov	2	Pingueculae as before with calculi.
01/08/CM	Left	3	19-Nov	2	Pingueculae and calculi
01/11/TA	Right	0	21-Oct	1	Inferior and temporal neovascularization halarisation.
01/11/TA	Left	0	21-Oct	0.5	Inferior and temporal neovascularization halarisation.

A2 Table 4Bs (cont.)
Slit Lamp Findings - 'Other' Explanations

Completed Test Eyes

Subject	Eye	Visit	Date	Grade	Description
01/14/AC	Right	0	22-Oct	0.5	Pingueculae
01/14/AC	Right	2	05-Nov	1	Pingueculae.
01/14/AC	Right	3	22-Nov	1	Pingueculae
01/14/AC	Left	0	22-Oct	1	Pingueculae
01/14/AC	Left	2	05-Nov	1	Pingueculae
01/14/AC	Left	3	22-Nov	1	Pingueculae
01/15/CC	Left	0	22-Oct	1	Corneal scar
01/15/CC	Left	2	05-Nov	1	Corneal scar as before.
01/15/CC	Left	3	22-Nov	1	Corneal scar unchanged.
01/17/EC	Right	0	26-Oct	1	Neovascularisation most 8 o'clock
01/17/EC	Right	2	08-Nov	1	Neovascularisation unchanged
01/17/EC	Right	3	23-Nov	1	Neovascularisation unchanged
01/17/EC	Left	0	26-Oct	1	Neovascularisation inferior and superior.
01/17/EC	Left	2	08-Nov	1	Neovascularisation unchanged
01/17/EC	Left	3	23-Nov	1	Neovascularisation unchanged
01/21/NB	Right	3	09-Dec	2	Crusted upper eye lashes
01/21/NB	Left	3	09-Dec	1.5	Crusted eyelashes
02/23/HW	Right	0	04-Nov	2	Ring of pooling Na-Fl mid peripheral cornea
02/23/HW	Right	2	17-Nov	2	Ring of mid-peripheral pooling Na-Fl (as before)
02/23/HW	Right	3	01-Dec	2	Some dryness on upper lid and skin.
02/23/HW	Left	0	04-Nov	1	Ring of pooling Na-Fl mid peripheral cornea.
02/23/HW	Left	2	17-Nov	1	Ring of mid-peripheral pooling Na-Fl (as before)
02/26/JH	Right	3	25-Nov	0.5	4 mucin balls behind lens causing "indentation" staining.
02/26/JH	Left	3	25-Nov	0.5	Plugged meibomium gland
02/31/CL	Right	0	03-Nov	0.5	Mild limbal bv growth
02/31/CL	Right	3	30-Nov	1	Some neovascularisation
02/31/CL	Left	0	03-Nov	0.5	Mild limbal bv growth
02/31/CL	Left	3	30-Nov	1	Some neovascularisation

A2 Table 4Bs (cont.)
Slit Lamp Findings - 'Other' Explanations

Completed Test Eyes

Subject	Eye	Visit	Date	Grade	Description
02/36/AR	Right	0	03-Nov	1	Scar under R lid
02/36/AR	Right	2	17-Nov	0.5	Scar under R lid
02/36/AR	Right	3	01-Dec	0.5	Scarred tarsal plate
02/38/PC	Left	2	17-Nov	0.5	Blocked meibomium gland, upper lid
02/42/AC	Right	0	04-Nov	2	Corneal neovascularisation.
02/42/AC	Right	2	18-Nov	2	Corneal vascularisation
02/42/AC	Right	3	01-Dec	0.5	Neovascularisation, both eyes (longstanding).
02/42/AC	Left	0	04-Nov	2	Corneal neovascularisation.
02/42/AC	Left	2	18-Nov	2	Corneal vascularisation
02/42/AC	Left	3	01-Dec	0.5	Neovascularisation, both eyes (longstanding).
02/44/VA	Right	2	24-Nov	1	Pigmented limbus.
02/44/VA	Right	3	06-Dec	1	Pigmented limbus.
02/44/VA	Left	2	24-Nov	1	Pigmented limbus.
02/44/VA	Left	3	06-Dec	1	Pigmented limbus.

A2 Table 4C
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Discontinued Control Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Limbal Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	2	100	0	0	2	100	0	0	0	0	4	100
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Bulbar Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	2	100	0	0	2	100	0	0	0	0	4	100
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1.5 or 2	2	100	0	0	2	100	0	0	0	0	4	100
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Roughness												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	0	0	0	0	1	50	0	0	0	0	1	25
Grade 1.5 or 2	2	100	0	0	1	50	0	0	0	0	3	75
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1.5 or 2	2	100	0	0	2	100	0	0	0	0	4	100
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Roughness												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	0	0	0	0	1	50	0	0	0	0	1	25
Grade 1.5 or 2	2	100	0	0	1	50	0	0	0	0	3	75
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0

A2 Table 4C (cont.)
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Discontinued Control Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Corneal Staining (Extent)												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	1	50	0	0	0	0	0	0	0	0	1	25
Grade 1.5 or 2	1	50	0	0	2	100	0	0	0	0	3	75
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Corneal Staining (Depth)												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	2	100	0	0	2	100	0	0	0	0	4	100
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Conjunctival Staining												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	2	100	0	0	2	100	0	0	0	0	4	100
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Other												
Grade 0	2	100	0	0	2	100	0	0	0	0	4	100
Grade 0.5 or 1	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Total Eyes	**2**		**0**		**2**		**0**		**0**		**4**	
Positive eyes	2	100	0	0	2	100	0	0	0	0	4	100
Negative eyes	0	0	0	0	0	0	0	0	0	0	0	0
Total Evaluations	**20**		**0**		**20**		**0**		**0**		**40**	
Positive evaluations	18	90	0	0	18	90	0	0	0	0	36	90
Negative evaluations	2	10	0	0	2	10	0	0	0	0	4	10

A2 Table 4D
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence rates

Discontinued Test Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Limbal Hyperaemia												
Grade 0	0	0	0	0	1	50	0	0	2	33	3	21
Grade 0.5 or 1	6	100	0	0	1	50	0	0	3	50	10	71
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Bulbar Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	2	33	2	14
Grade 0.5 or 1	4	67	0	0	2	100	0	0	3	50	9	64
Grade 1.5 or 2	2	33	0	0	0	0	0	0	0	0	2	14
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	4	67	0	0	2	100	0	0	2	33	8	57
Grade 1.5 or 2	2	33	0	0	0	0	0	0	3	50	5	36
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Upper Palpebral Roughness												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	3	50	0	0	2	100	0	0	1	17	6	43
Grade 1.5 or 2	2	33	0	0	0	0	0	0	3	50	5	36
Grade 2.5 or 3	1	17	0	0	0	0	0	0	1	17	2	14
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Hyperaemia												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	6	100	0	0	2	100	0	0	3	50	11	79
Grade 1.5 or 2	0	0	0	0	0	0	0	0	2	33	2	14
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Lower Palpebral Roughness												
Grade 0	0	0	0	0	0	0	0	0	0	0	0	0
Grade 0.5 or 1	6	100	0	0	2	100	0	0	3	50	11	79
Grade 1.5 or 2	0	0	0	0	0	0	0	0	2	33	2	14
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0

A2 Table 4D (cont.)
Slit Lamp Findings by Visit, Tabulated by Eyes and Incidence Rates

Discontinued Test Eyes

Grade	Baseline		FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Corneal Staining (Extent)												
Grade 0	4	67	0	0	2	100	0	0	3	50	9	64
Grade 0.5 or 1	2	33	0	0	0	0	0	0	2	33	4	29
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Corneal Staining (Depth)												
Grade 0	4	67	0	0	2	100	0	0	3	50	9	64
Grade 0.5 or 1	2	33	0	0	0	0	0	0	2	33	4	29
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Conjunctival Staining												
Grade 0	2	33	0	0	0	0	0	0	5	83	7	50
Grade 0.5 or 1	4	67	0	0	1	50	0	0	0	0	5	36
Grade 1.5 or 2	0	0	0	0	1	50	0	0	0	0	1	7
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Other												
Grade 0	6	100	0	0	2	100	0	0	5	83	13	93
Grade 0.5 or 1	0	0	0	0	0	0	0	0	0	0	0	0
Grade 1.5 or 2	0	0	0	0	0	0	0	0	0	0	0	0
Grade 2.5 or 3	0	0	0	0	0	0	0	0	0	0	0	0
Grade 3.5 or 4	0	0	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**17**	**1**	**7**
Total Eyes	**6**		**0**		**2**		**0**		**6**		**14**	
Positive eyes	6	100	0	0	2	100	0	0	5	83	13	93
Negative eyes	0	0	0	0	0	0	0	0	0	0	0	0
Total Evaluations	**60**		**0**		**20**		**0**		**45**		**125**	
Positive evaluations	44	73	0	0	13	65	0	0	30	67	87	70
Negative evaluations	16	27	0	0	7	35	0	0	20	44	43	34

A2 Table 5A
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Completed Control Eyes

Grade	FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%
Discomfort / Pain										
None	2	100	31	78	35	88	0	0	68	83
Mild	0	0	2	5	4	10	0	0	6	7
Moderate	0	0	5	13	1	3	0	0	6	7
Severe	0	0	0	0	0	0	0	0	0	0
Lens edge awareness										
None	2	100	32	80	36	90	0	0	70	85
Mild	0	0	3	8	2	5	0	0	5	6
Moderate	0	0	3	8	2	5	0	0	5	6
Severe	0	0	0	0	0	0	0	0	0	0
Burning/Stinging										
None	2	100	36	90	39	98	0	0	77	94
Mild	0	0	1	3	1	3	0	0	2	2
Moderate	0	0	1	3	0	0	0	0	1	1
Severe	0	0	0	0	0	0	0	0	0	0
Dryness										
None	2	100	19	48	20	50	0	0	41	50
Mild	0	0	18	45	18	45	0	0	36	44
Moderate	0	0	1	3	0	0	0	0	1	1
Severe	0	0	0	0	2	5	0	0	2	2
Itching										
None	2	100	37	93	32	80	0	0	71	87
Mild	0	0	0	0	6	15	0	0	6	7
Moderate	0	0	1	3	2	5	0	0	3	4
Severe	0	0	0	0	0	0	0	0	0	0
Redness										
None	2	100	31	78	34	85	0	0	67	82
Mild	0	0	7	18	6	15	0	0	13	16
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Blurred vision										
None	2	100	31	78	34	85	0	0	67	82
Mild	0	0	2	5	5	13	0	0	7	9
Moderate	0	0	5	13	1	3	0	0	6	7
Severe	0	0	0	0	0	0	0	0	0	0
Photophobia										
None	2	100	36	90	40	100	0	0	78	95
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	2	5	0	0	0	0	2	2

A2 Table 5A (cont.)
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Completed Control Eyes

Grade	FU1 (Optional) #	FU1 (Optional) %	FU2 #	FU2 %	FU3 #	FU3 %	Unsched. #	Unsched. %	Total #	Total %
Haloes										
None	2	100	34	85	38	95	0	0	74	90
Mild	0	0	4	10	2	5	0	0	6	7
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Tearing										
None	2	100	37	93	38	95	0	0	77	94
Mild	0	0	1	3	2	5	0	0	3	4
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Secretion										
None	2	100	38	95	36	90	0	0	76	93
Mild	0	0	0	0	2	5	0	0	2	2
Moderate	0	0	0	0	2	5	0	0	2	2
Severe	0	0	0	0	0	0	0	0	0	0
Lens needs cleaning										
None	2	100	32	80	31	78	0	0	65	79
Mild	0	0	2	5	5	13	0	0	7	9
Moderate	0	0	2	5	2	5	0	0	4	5
Severe	0	0	2	5	2	5	0	0	4	5
Other										
None	2	100	33	83	38	95	0	0	73	89
Mild	0	0	3	8	2	5	0	0	5	6
Moderate	0	0	2	5	0	0	0	0	2	2
Severe	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**2**	**5**	**0**	**0**	**0**	**0**	**2**	**2**
Total Eyes	**2**		**40**		**40**		**0**		**82**	
Positive eyes	0	0	32	80	25	63	0	0	57	70
Negative eyes	2	100	6	15	15	38	0	0	23	28
Total Evaluations	**26**		**494**		**520**		**0**		**1040**	
Positive evaluations	0	0	67	14	69	13	0	0	136	13
Negative evaluations	26	100	427	86	451	87	0	0	904	87

A2 Table 5As
Symptoms, Problems and Complaints - 'Other' Explanations

Completed Control Eyes

Subject	Eye	Visit	Date	Grade	Description
01/04/HJ	Left	FU2	29-Oct	Mild	Tear in edge of lens.
01/04/HJ	Left	FU3	12-Nov	Mild	Tear in lens.
01/13/SB	Both	FU2	5-Nov	Mild	Lens seems to tighten on eyes in evening.
02/39/IA	Both	FU2	18-Nov	Moderate	Handling difficult - lenses are softer and floppy than used to.
03/66/KY	Right	FU3	10-Dec	Mild	Difficulty removing.

A2 Table 5B
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Completed Test Eyes

Grade	FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%
Discomfort / Pain										
None	0	0	62	76	75	91	0	0	137	84
Mild	0	0	13	16	6	7	0	0	19	12
Moderate	0	0	5	6	1	1	0	0	6	4
Severe	0	0	2	2	0	0	0	0	2	1
Lens edge awareness										
None	0	0	70	85	75	91	0	0	145	88
Mild	0	0	10	12	6	7	0	0	16	10
Moderate	0	0	2	2	1	1	0	0	3	2
Severe	0	0	0	0	0	0	0	0	0	0
Burning/Stinging										
None	0	0	80	98	79	96	0	0	159	97
Mild	0	0	1	1	2	2	0	0	3	2
Moderate	0	0	1	1	1	1	0	0	2	1
Severe	0	0	0	0	0	0	0	0	0	0
Dryness										
None	0	0	52	63	52	63	0	0	104	63
Mild	0	0	16	20	21	26	0	0	37	23
Moderate	0	0	12	15	9	11	0	0	21	13
Severe	0	0	2	2	0	0	0	0	2	1
Itching										
None	0	0	76	93	78	95	0	0	154	94
Mild	0	0	6	7	3	4	0	0	9	5
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	1	1	0	0	1	1
Redness										
None	0	0	75	91	74	90	0	0	149	91
Mild	0	0	4	5	8	10	0	0	12	7
Moderate	0	0	2	2	0	0	0	0	2	1
Severe	0	0	1	1	0	0	0	0	1	1
Blurred vision										
None	0	0	65	79	62	76	0	0	127	77
Mild	0	0	14	17	15	18	0	0	29	18
Moderate	0	0	3	4	5	6	0	0	8	5
Severe	0	0	0	0	0	0	0	0	0	0
Photophobia										
None	0	0	80	98	81	99	0	0	161	98
Mild	0	0	2	2	1	1	0	0	3	2
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0

A2 Table 5B (cont.)
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Completed Test Eyes

Grade	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Haloes										
None	0	0	82	100	82	100	0	0	164	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Tearing										
None	0	0	77	94	78	95	0	0	155	95
Mild	0	0	3	4	3	4	0	0	6	4
Moderate	0	0	1	1	1	1	0	0	2	1
Severe	0	0	1	1	0	0	0	0	1	1
Secretion										
None	0	0	77	94	78	95	0	0	155	95
Mild	0	0	2	2	2	2	0	0	4	2
Moderate	0	0	3	4	2	2	0	0	5	3
Severe	0	0	0	0	0	0	0	0	0	0
Lens needs cleaning										
None	0	0	61	74	67	82	0	0	128	78
Mild	0	0	8	10	11	13	0	0	19	12
Moderate	0	0	13	16	2	2	0	0	15	9
Severe	0	0	0	0	2	2	0	0	2	1
Other										
None	0	0	75	91	78	95	0	0	153	93
Mild	0	0	5	6	4	5	0	0	9	5
Moderate	0	0	2	2	0	0	0	0	2	1
Severe	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Total Eyes	**0**		**82**		**82**		**0**		**164**	
Positive eyes	0	0	50	61	46	56	0	0	96	59
Negative eyes	0	0	32	39	36	44	0	0	68	41
Total Evaluations	**0**		**1066**		**1066**		**0**		**2132**	
Positive evaluations	0	0	134	13	107	10	0	0	241	11
Negative evaluations	0	0	932	87	959	90	0	0	1891	89

A2 Table 5Bs
Symptoms, Problems and Complaints - 'Other' Explanations

Completed Test Eyes

Subject	Eye	Visit	Date	Grade	Description
01/03/HJ	Left	FU2	29-Oct	Mild	Nick in lens edge.
01/18/MH	Right	FU2	19-Nov	Mild	Irritated/gritty last night in outer corner - non lens related
02/30/AM	Left	FU2	12-Nov	Mild	Excessive movement of lens.
03/45/DB	Both	FU2	28-Oct	Mild	Mild stinging on insertion.
03/47/HM	Both	FU3	12-Nov	Mild	Lid soreness.
03/51/LH	Both	FU3	18-Nov	Mild	Dryer towards end of day.
03/64/KL	Both	FU2	23-Nov	Moderate	Storage box is poor.

A2 Table 5C
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Discontinued Control Eyes

Grade	FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%
Discomfort / Pain										
None	0	0	0	0	0	0	0	0	0	0
Mild	0	0	2	100	0	0	0	0	2	100
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Lens edge awareness										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Burning/Stinging										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Dryness										
None	0	0	0	0	0	0	0	0	0	0
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	2	100	0	0	0	0	2	100
Severe	0	0	0	0	0	0	0	0	0	0
Itching										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Redness										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Blurred vision										
None	0	0	0	0	0	0	0	0	0	0
Mild	0	0	2	100	0	0	0	0	2	100
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Photophobia										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0

A2 Table 5C (cont.)
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Discontinued Control Eyes

Grade	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Haloes										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Tearing										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Secretion										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Lens needs cleaning										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Other										
None	0	0	2	100	0	0	0	0	2	100
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Total Eyes		**0**		**2**		**0**		**0**		**2**
Positive eyes		0	0	2	100	0	0	0	0	2 100
Negative eyes	0	0	0	0	0	0	0	0	0	0
Total Evaluations	**0**		**26**		**0**		**0**		**26**	
Positive evaluations	0	0	6	23	0	0	0	0	6	23
Negative evaluations	0	0	20	77	0	0	0	0	20	77

A2 Table 5D
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Discontinued Test Eyes

Grade	FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%
Discomfort / Pain										
None	0	0	0	0	0	0	2	33	2	25
Mild	0	0	2	100	0	0	1	17	3	38
Moderate	0	0	0	0	0	0	1	17	1	13
Severe	0	0	0	0	0	0	0	0	0	0
Lens edge awareness										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1	17	1	13
Severe	0	0	0	0	0	0	0	0	0	0
Burning/Stinging										
None	0	0	2	100	0	0	4	67	6	75
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Dryness										
None	0	0	2	100	0	0	4	67	6	75
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Itching										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	1	17	1	13
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Redness										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	1	17	1	13
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Blurred vision										
None	0	0	0	0	0	0	4	67	4	50
Mild	0	0	2	100	0	0	0	0	2	25
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Photophobia										
None	0	0	2	100	0	0	4	67	6	75
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0

A2 Table 5D (cont.)
Symptoms, Problems and Complaints by Visit, Tabulated by Eyes and Incident Rates

Discontinued Test Eyes

Grade	FU1 (Optional)		FU2		FU3		Unsched.		Total	
	#	%	#	%	#	%	#	%	#	%
Haloes										
None	0	0	2	100	0	0	4	67	6	75
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Tearing										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1	17	1	13
Severe	0	0	0	0	0	0	0	0	0	0
Secretion										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1	17	1	13
Severe	0	0	0	0	0	0	0	0	0	0
Lens needs cleaning										
None	0	0	2	100	0	0	4	67	6	75
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0
Other										
None	0	0	2	100	0	0	3	50	5	63
Mild	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1	17	1	13
Severe	0	0	0	0	0	0	0	0	0	0
Eyes not recorded	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**33**	**2**	**25**
Total Eyes	**0**		**2**		**0**		**6**		**8**	
Positive eyes	0	0	2	100	0	0	2	33	4	50
Negative eyes	0	0	0	0	0	0	2	33	2	25
Total Evaluations	**0**		**26**		**0**		**52**		**78**	
Positive evaluations	0	0	4	15	0	0	8	15	12	15
Negative evaluations	0	0	22	85	0	0	44	85	66	85

A2 Table 5Ds
Symptoms, Problems and Complaints - 'Other' Explanations

Discontinued Test Eyes

Subject	Eye	Visit	Date	Grade	Description
02/32/JS	Right	Unsched.	7-Dec	Moderate	Lens not settling 2 days ago.

A2 Table 6A
Visual Acuity (VA) Results with Contact Lens at Final Visit
(6m Snellen)

Completed Control Eyes

Initial Best Corrected	Number of Eyes	Final Contact lens VA 6/3 #	6/3 %	6/4 #	6/4 %	6/5 #	6/5 %	6/6 #	6/6 %	6/7.5 #	6/7.5 %	6/9 #	6/9 %	Not Reported #	Not Reported %	Totals #	Totals %
6/3	2	0	0	0	0	2	100	0	0	0	0	0	0	0	0	2	100
6/4	8	0	0	2	25	4	50	2	25	0	0	0	0	0	0	8	100
6/5	16	0	0	0	0	9	56	6	38	0	0	0	0	1	6	16	100
6/6	13	0	0	0	0	2	15	10	77	1	8	0	0	0	0	13	100
6/7.5	1	0	0	0	0	0	0	0	0	0	0	1	100	0	0	1	100
Totals	**40**	**0**	**0**	**2**	**5**	**17**	**43**	**18**	**45**	**1**	**3**	**1**	**3**	**1**	**3**	**40**	**100**

Visual Acuity Summary

Number of eyes with initial best correct VA of 6/9 or better: 40

Number of eyes with final VA with lens of 6/9 or better: 39

Number of eyes with final VA with lens within ±1 line of best correct: 35

Number of eyes with final VA with lens worse than ±1 line of best correct: 4

Listing of eyes that changed 2 or more Snellen lines

Subject	Eye	Initial VA	Final VA	Reason
01/20/CB	Right	6/3	6/5	Deposits on lens.
01/20/CB	Left	6/3	6/5	Deposits on lens.
01/07/LT	Right	6/4	6/6	VA was 6/5 with +0.25/-0.75x112 over-refraction.
01/13/SB	Left	6/4	6/6	VA was 6/4 with -0.25/-0.75x60 over-refraction.

A2 Table 6B
Visual Acuity (VA) Results with Contact Lens at Final Visit
(6m Snellen)

Completed Test Eyes

Initial Best Corrected	Number of Eyes	Final Contact lens VA 6/3 #	6/3 %	6/4 #	6/4 %	6/5 #	6/5 %	6/6 #	6/6 %	6/7.5 #	6/7.5 %	6/9 #	6/9 %	Not Reported #	Not Reported %	Totals #	Totals %
6/3	3	1	33	2	67	0	0	0	0	0	0	0	0	0	0	3	100
6/4	16	0	0	7	44	8	50	1	6	0	0	0	0	0	0	16	100
6/5	40	0	0	0	0	28	70	10	25	1	3	1	3	0	0	40	100
6/6	22	0	0	1	5	6	27	7	32	4	18	4	18	0	0	22	100
6/7.5	1	0	0	0	0	0	0	0	0	1	100	0	0	0	0	1	100
Totals	**82**	**1**	**1**	**10**	**12**	**42**	**51**	**18**	**22**	**6**	**7**	**5**	**6**	**0**	**0**	**82**	**100**

Visual Acuity Summary

Number of eyes with initial best correct VA of 6/9 or better: 82

Number of eyes with final VA with lens of 6/9 or better: 82

Number of eyes with final VA with lens within ±1 line of best correct: 74

Number of eyes with final VA with lens worse than ±1 line of best correct: 8

Listing of eyes that changed 2 or more Snellen lines

Subject	Eye	Initial VA	Final VA	Reason
01/05/SJ	Right	6/5	6/9	Deposits on lens.
01/14/AC	Left	6/6	6/4	A 2 line improvement in VA.
01/18/MH	Right	6/4	6/6	VA was 6/5 with -0.50/-0.50x160 over-refraction.
03/47/HM	Left	6/6	6/9	VA was 6/6 with Plano/-0.75x15 over-refraction.
03/53/MS	Left	6/6	6/9	VA was 6/7.5 with +0.75/-0.50x165 over-refraction.
03/55/AF	Right	6/6	6/9	Deposits on lens.
03/55/AF	Left	6/6	6/9	Deposits on lens.
03/64/KL	Left	6/5	6/7.5	VA was 6/6 with +0.50/-0.50x80 over-refraction.

A2 Table 6C
Visual Acuity (VA) Results with Contact Lens at Final Visit
(6m Snellen)

Discontinued Control Eyes

Initial Best Corrected	Number of Eyes	Final Contact lens VA 6/3 #	%	6/4 #	%	6/5 #	%	6/6 #	%	6/7.5 #	%	6/9 #	%	Not Reported #	%	Totals #	%
6/4	2	0	0	0	0	0	0	0	0	0	0	0	0	2	100	2	100
Totals	**2**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**100**	**2**	**100**

Visual Acuity Summary

Number of eyes with initial best correct VA of 6/9 or better: 2

Number of eyes with final VA with lens of 6/9 or better: 0

Number of eyes with final VA with lens within ±1 line of best correct: 0

Number of eyes with final VA with lens worse than ±1 line of best correct: 0

A2 Table 6D
Visual Acuity (VA) Results with Contact Lens at Final Visit
(6m Snellen)

Discontinued Test Eyes

Initial Best Corrected	Number of Eyes	Final Contact lens VA 6/3 #	6/3 %	6/4 #	6/4 %	6/5 #	6/5 %	6/6 #	6/6 %	6/7.5 #	6/7.5 %	6/9 #	6/9 %	Not Reported #	Not Reported %	Totals #	Totals %
6/5	2	0	0	0	0	0	0	0	0	0	0	0	0	2	100	2	100
6/6	4	0	0	0	0	0	0	0	0	0	0	0	0	4	100	4	100
Totals	**6**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**6**	**100**	**6**	**100**

Visual Acuity Summary

Number of eyes with initial best correct VA of 6/9 or better: 6

Number of eyes with final VA with lens of 6/9 or better: 0

Number of eyes with final VA with lens within ±1 line of best correct: 0

Number of eyes with final VA with lens worse than ±1 line of best correct: 0

A2 Table 7A
Average Wear Time per Visit

Completed Control Subjects

Wearing Time	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Average Daily Wearing Time (hrs)										
0 to 4.0	0	0	0	0	0	0	0	0	0	0
4.1 to 6.0	0	0	1	5	0	0	0	0	1	2
6.1 to 8.0	0	0	1	5	1	5	0	0	2	5
8.1 to 10.0	1	100	5	25	3	15	0	0	9	22
10.1 to 12.0	0	0	6	30	9	45	0	0	15	37
12.1 to 14.0	0	0	1	5	5	25	0	0	6	15
14.1 to 16.0	0	0	5	25	2	10	0	0	7	17
16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
>18.0	0	0	0	0	0	0	0	0	0	0
Not Reported	0	0	1	5	0	0	0	0	1	2
Total	**1**		**20**		**20**		**0**		**41**	
Average Wearing Time per Visit	9.0		11.8		12.2		-		11.9	

A2 Table 7B
Average Wear Time per Visit

Completed Test Subjects

Wearing Time	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Average Daily Wearing Time (hrs)										
0 to 4.0	0	0	0	0	0	0	0	0	0	0
4.1 to 6.0	0	0	3	7	2	5	0	0	5	6
6.1 to 8.0	0	0	3	7	3	7	0	0	6	7
8.1 to 10.0	0	0	10	24	7	17	0	0	17	21
10.1 to 12.0	0	0	8	20	8	20	0	0	16	20
12.1 to 14.0	0	0	8	20	9	22	0	0	17	21
14.1 to 16.0	0	0	7	17	10	24	0	0	17	21
16.1 to 18.0	0	0	2	5	2	5	0	0	4	5
>18.0	0	0	0	0	0	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Total	**0**		**41**		**41**		**0**		**82**	
Average Wearing Time per Visit	-		11.8		12.3		-		12.0	

A2 Table 7C
Average Wear Time per Visit

Discontinued Control Subjects

Wearing Time	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Average Daily Wearing Time (hrs)										
0 to 4.0	0	0	0	0	0	0	0	0	0	0
4.1 to 6.0	0	0	0	0	0	0	0	0	0	0
6.1 to 8.0	0	0	0	0	0	0	0	0	0	0
8.1 to 10.0	0	0	1	100	0	0	0	0	1	100
10.1 to 12.0	0	0	0	0	0	0	0	0	0	0
12.1 to 14.0	0	0	0	0	0	0	0	0	0	0
14.1 to 16.0	0	0	0	0	0	0	0	0	0	0
16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
>18.0	0	0	0	0	0	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Total	**0**		**1**		**0**		**0**		**1**	
Average Wearing Time per Visit	-		9.0		-		-		9.0	

A2 Table 7D
Average Wear Time per Visit

Discontinued Test Subjects

Wearing Time	FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched. #	%	Total #	%
Average Daily Wearing Time (hrs)										
0 to 4.0	0	0	0	0	0	0	1	33	1	25
4.1 to 6.0	0	0	0	0	0	0	0	0	0	0
6.1 to 8.0	0	0	0	0	0	0	0	0	0	0
8.1 to 10.0	0	0	0	0	0	0	1	33	1	25
10.1 to 12.0	0	0	0	0	0	0	0	0	0	0
12.1 to 14.0	0	0	1	100	0	0	0	0	1	25
14.1 to 16.0	0	0	0	0	0	0	1	33	1	25
16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
>18.0	0	0	0	0	0	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Total	**0**		**1**		**0**		**3**		**4**	
Average Wearing Time per Visit	-		14.0		-		9.8		10.6	

A2 Table 8A
Discontinued Subjects Tabulated by Completed Visits and Reasons for Discontinuation with Incidence Rates

Control Subjects

Reason for Discontinuation	Baseline	FU1 (Optional)	FU2	FU3	Unsch.	Aggre. Disc.	% Incidence
Unacceptable SLF	0	0	1	0	0	1	4.8
Total	**0**	**0**	**1**	**0**	**0**	**1**	**4.8**

Total subjects = 21

A2 Table 8B
Discontinued Subjects Tabulated by Completed Visits and Reasons for Discontinuation with Incidence Rates

Control Subjects

Reason for Discontinuation	Baseline	FU1 (Optional)	FU2	FU3	Unsch.	Aggre. Disc.	% Incidence
Adverse Reaction	0	0	0	0	1	1	2.3
Unacceptable comfort	0	0	0	0	1	1	2.3
Lost to Follow-up	0	0	0	0	1	1	2.3
Total	**0**	**0**	**0**	**0**	**3**	**3**	**6.8**

Total subjects = 44

A2 Table 9A
Trend analysis profile (TAP)

Control Eyes

	Baseline	FU1 (Optional)	FU2	FU3	Total
Time in Study	-	1-week	2-week	1-month	-
Total # eyes	42	2	42	40	126
D/C eyes	0	0	0	2	2
Average wearing time (daily)	-	9.0	11.7	12.2	11.8
All adverse reactions	0	0	0	0	0
All corneal ulcers	0	0	0	0	0
All iritis	0	0	0	0	0
Total reports corn. staining	28	2	26	24	80
Staining reports >GR2	0	0	1	1	2
Total reports conj. staining	20	2	36	40	98
Staining reports >GR2	1	0	2	2	5
Total Eyes Reporting Staining					**42**
Total reports limbal hyperaemia	34	2	37	38	111
Limbal hyperaemia reports >GR2	0	0	2	0	2
Total reports bulbar hyperaemia	38	2	40	40	120
Bulbar hyperaemia reports >GR2	0	0	1	0	1
Total reports upper palpebral hyperaemia	38	2	38	38	116
Upper palpebral hyperaemia reports >gr2	0	0	2	0	2
Total reports lower palpebral hyperaemia	40	2	38	38	118
Lower palpebral hyperaemia reports >gr2	0	0	0	0	0
Total Eyes Reporting Hyperaemia					**42**
Total reports upper palpebral roughness	36	2	36	36	110
Upper palpebral roughness reports >gr2	1	0	0	0	1
Total reports lower palpebral roughness	34	2	33	34	103
Lower palpebral roughness reports >gr2	0	0	0	0	0
Total Eyes Reporting Roughness					**41**
Total reports other findings	4	1	3	3	11
Other findings reports >GR2	0	0	0	0	0
Total Visits	**21**	**N/A**	**20**	**20**	**62**
Total Missed Visits	0	N/A	1	0	1

A2 Table 9B
Trend analysis profile (TAP)

Test Eyes

	Baseline	FU1 (Optional)	FU2	FU3	Total
Time in Study	-	1-week	2-week	1-month	-
Total # eyes	88	0	84	82	254
D/C eyes	0	0	4	2	6
Average wearing time (daily)	-	-	11.9	12.3	12.1
All adverse reactions	0	0	0	0	0
All corneal ulcers	0	0	0	0	0
All iritis	0	0	0	0	0
Total reports corn. staining	34	0	52	53	139
Staining reports >GR2	0	0	3	0	3
Total reports conj. staining	44	0	74	74	192
Staining reports >GR2	0	0	10	8	18
Total Eyes Reporting Staining					**84**
Total reports limbal hyperaemia	80	0	74	78	232
Limbal hyperaemia reports >GR2	1	0	2	1	4
Total reports bulbar hyperaemia	88	0	79	80	247
Bulbar hyperaemia reports >GR2	0	0	0	0	0
Total reports upper palpebral hyperaemia	82	0	80	78	240
Upper palpebral hyperaemia reports >gr2	2	0	2	4	8
Total reports lower palpebral hyperaemia	82	0	77	75	234
Lower palpebral hyperaemia reports >gr2	0	0	0	1	1
Total Eyes Reporting Hyperaemia					**88**
Total reports upper palpebral roughness	80	0	74	76	230
Upper palpebral roughness reports >gr2	3	0	2	2	7
Total reports lower palpebral roughness	75	0	66	68	209
Lower palpebral roughness reports >gr2	2	0	1	0	3
Total Eyes Reporting Roughness					**88**
Total reports other findings	22	0	20	27	69
Other findings reports >GR2	0	0	0	0	0
Total Visits	**44**	**N/A**	**42**	**41**	**127**
Total Missed Visits	0	N/A	0	0	0

A2 Table 10A
Lens surface characteristics

Completed Control Eyes

Lens Surface Characteristic		FU1 (Optional)		FU2		FU3		Unsched		Total	
		#	%	#	%	#	%	#	%	#	%
Film Deposits											
None	0	0	0	18	45	18	45	0	0	36	44
	1	1	50	17	43	11	28	0	0	29	35
	2	1	50	3	8	6	15	0	0	10	12
	3	0	0	0	0	3	8	0	0	3	4
Heavy	4	0	0	0	0	1	3	0	0	1	1
Average		1.5		0.6		0.9		-		0.8	
White Spot Deposits											
	None	2	100	20	50	19	48	0	0	41	50
	1-5 spots	0	0	12	30	13	33	0	0	25	30
	6-10 spots	0	0	4	10	6	15	0	0	10	12
	11-15 spots	0	0	0	0	1	3	0	0	1	1
	>15 spots	0	0	2	5	0	0	0	0	2	2
Average		0.0		2.8		2.3		-		2.5	
Break-up Time											
	0 to 4.0	0	0	8	20	6	15	0	0	14	17
	4.1 to 6.0	0	0	9	23	9	23	0	0	18	22
	6.1 to 8.0	0	0	11	28	8	20	0	0	19	23
	8.1 to 10.0	2	100	1	3	10	25	0	0	13	16
	10.1 to 12.0	0	0	4	10	2	5	0	0	6	7
	12.1 to 14.0	0	0	3	8	3	8	0	0	6	7
	14.1 to 16.0	0	0	2	5	0	0	0	0	2	2
	16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
	>18.0	0	0	0	0	1	3	0	0	1	1
Average		9.5		7.7		7.9		-		7.8	
PLTF Quality											
Dry	0	0	0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	0	0
	1.5	0	0	0	0	0	0	0	0	0	0
	2	0	0	2	5	2	5	0	0	4	5
	2.5	0	0	8	20	2	5	0	0	10	12
	3	2	100	9	23	10	25	0	0	21	26
	3.5	0	0	15	38	20	50	0	0	35	43
Perfect	4	0	0	4	10	5	13	0	0	9	11
Average		3.0		3.1		3.3		-		3.2	
Not Reported		0	0	2	5	1	3	0	0	3	4
Total Eyes		2		40		40		0		82	

A2 Table 10B
Lens surface characteristics

Completed Test Eyes

Lens Surface Characteristic		FU1 (Optional) #	%	FU2 #	%	FU3 #	%	Unsched #	%	Total #	%
Film Deposits											
None	0	0	0	41	50	35	43	0	0	76	46
	1	0	0	28	34	31	38	0	0	59	36
	2	0	0	11	13	9	11	0	0	20	12
	3	0	0	1	1	6	7	0	0	7	4
Heavy	4	0	0	0	0	1	1	0	0	1	1
Average		-		0.7		0.9		-		0.8	
White Spot Deposits											
	None	0	0	54	66	40	49	0	0	94	57
	1-5 spots	0	0	18	22	30	37	0	0	48	29
	6-10 spots	0	0	3	4	7	9	0	0	10	6
	11-15 spots	0	0	0	0	2	2	0	0	2	1
	>15 spots	0	0	6	7	3	4	0	0	9	5
Average		-		2.8		2.4		-		2.6	
Break-up Time											
	0 to 4.0	0	0	9	11	6	7	0	0	15	9
	4.1 to 6.0	0	0	12	15	18	22	0	0	30	18
	6.1 to 8.0	0	0	20	24	16	20	0	0	36	22
	8.1 to 10.0	0	0	18	22	14	17	0	0	32	20
	10.1 to 12.0	0	0	5	6	13	16	0	0	18	11
	12.1 to 14.0	0	0	4	5	3	4	0	0	7	4
	14.1 to 16.0	0	0	6	7	5	6	0	0	11	7
	16.1 to 18.0	0	0	1	1	1	1	0	0	2	1
	>18.0	0	0	6	7	6	7	0	0	12	7
Average		-		9.9		9.8		-		9.8	
PLTF Quality											
Dry	0	0	0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	1	1	0	0	1	1
	1	0	0	0	0	1	1	0	0	1	1
	1.5	0	0	0	0	3	4	0	0	3	2
	2	0	0	3	4	1	1	0	0	4	2
	2.5	0	0	5	6	3	4	0	0	8	5
	3	0	0	25	30	22	27	0	0	47	29
	3.5	0	0	38	46	37	45	0	0	75	46
Perfect	4	0	0	10	12	14	17	0	0	24	15
Average		-		3.3		3.3		-		3.3	
Not Reported		0	0	1	1	0	0	0	0	1	1
Total Eyes		**0**		**82**		**82**		**0**		**164**	

A2 Table 10C
Lens surface characteristics

Discontinued Control Eyes

Lens Surface Characteristic		FU1 (Optional)		FU2		FU3		Unsched		Total	
		#	%	#	%	#	%	#	%	#	%
Film Deposits											
None	0	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0
	3	0	0	2	100	0	0	0	0	2	100
Heavy	4	0	0	0	0	0	0	0	0	0	0
Average		-		3.0		-		-		3.0	
White Spot Deposits											
	None	0	0	0	0	0	0	0	0	0	0
	1-5 spots	0	0	2	100	0	0	0	0	2	100
	6-10 spots	0	0	0	0	0	0	0	0	0	0
	11-15 spots	0	0	0	0	0	0	0	0	0	0
	>15 spots	0	0	0	0	0	0	0	0	0	0
Average		-		2.5		-		-		2.5	
Break-up Time											
	0 to 4.0	0	0	2	100	0	0	0	0	2	100
	4.1 to 6.0	0	0	0	0	0	0	0	0	0	0
	6.1 to 8.0	0	0	0	0	0	0	0	0	0	0
	8.1 to 10.0	0	0	0	0	0	0	0	0	0	0
	10.1 to 12.0	0	0	0	0	0	0	0	0	0	0
	12.1 to 14.0	0	0	0	0	0	0	0	0	0	0
	14.1 to 16.0	0	0	0	0	0	0	0	0	0	0
	16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
	>18.0	0	0	0	0	0	0	0	0	0	0
Average		-		3.5		-		-		3.5	
PLTF Quality											
Dry	0	0	0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	0	0	0	0	0	0
	1	0	0	2	100	0	0	0	0	2	100
	1.5	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0
	2.5	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0
	3.5	0	0	0	0	0	0	0	0	0	0
Perfect	4	0	0	0	0	0	0	0	0	0	0
Average		-		1.0		-		-		1.0	
Not Reported		0	0	0	0	0	0	0	0	0	0
Total Eyes		**0**		**2**		**0**		**0**		**2**	

A2 Table 10D
Lens surface characteristics

Discontinued Test Eyes

Lens Surface Characteristic		FU1 (Optional)		FU2		FU3		Unsched		Total	
		#	%	#	%	#	%	#	%	#	%
Film Deposits											
None	0	0	0	1	50	0	0	0	0	1	13
	1	0	0	1	50	0	0	1	17	2	25
	2	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0
Heavy	4	0	0	0	0	0	0	0	0	0	0
Average		-		0.5		-		1.0		0.7	
White Spot Deposits											
	None	0	0	1	50	0	0	0	0	1	13
	1-5 spots	0	0	1	50	0	0	1	17	2	25
	6-10 spots	0	0	0	0	0	0	0	0	0	0
	11-15 spots	0	0	0	0	0	0	0	0	0	0
	>15 spots	0	0	0	0	0	0	0	0	0	0
Average		-		1.5		-		2.0		1.7	
Break-up Time											
	0 to 4.0	0	0	0	0	0	0	1	17	1	13
	4.1 to 6.0	0	0	0	0	0	0	1	17	1	13
	6.1 to 8.0	0	0	0	0	0	0	0	0	0	0
	8.1 to 10.0	0	0	1	50	0	0	0	0	1	13
	10.1 to 12.0	0	0	0	0	0	0	0	0	0	0
	12.1 to 14.0	0	0	1	50	0	0	0	0	1	13
	14.1 to 16.0	0	0	0	0	0	0	0	0	0	0
	16.1 to 18.0	0	0	0	0	0	0	0	0	0	0
	>18.0	0	0	0	0	0	0	0	0	0	0
Average		-		12.0		-		3.5		7.8	
PLTF Quality											
Dry	0	0	0	0	0	0	0	0	0	0	0
	0.5	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	0	0	0	0	0	0	0
	1.5	0	0	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0	0	0
	2.5	0	0	0	0	0	0	1	17	1	13
	3	0	0	2	100	0	0	1	17	3	38
	3.5	0	0	0	0	0	0	0	0	0	0
Perfect	4	0	0	0	0	0	0	0	0	0	0
Average		-		3.0		-		2.8		2.9	
Not Reported		0	0	0	0	0	0	4	67	4	50
Total Eyes		**0**		**2**		**0**		**6**		**8**	

APPENDIX 3

Statistical Analysis

APPENDIX 3

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A3 Table 1: Summary of biometric data

Parameter		Control		Test
No. Subjects / Eyes		21 / 42		44 / 88
Sex (n/%)	Male	4 / 19%		11 / 25%
	Female	17 / 81%		33 / 75%
Age (Years)	Mean	27	*	33
	SD	8		10
	Min	16		17
	Max	44		56
Spectacle Refraction Sphere (D)	Mean	-2.90		-3.16
	SD	1.47		1.61
	Min	-6.25		-8.50
	Max	-0.50		-0.75
Spectacle Refraction Cylinder (D)	Mean	-0.43		-0.37
	SD	0.29		0.28
	Min	-1.00		-1.00
	Max	0.00		0.00
High Contrast VA with Spec Rx (logMAR)	Mean	-0.09		-0.08
	SD	0.09		0.08
	Min	-0.30		-0.30
	Max	+0.10		+0.18
Horizontal Visible Iris Diameter (mm)	Mean	11.29		11.32
	SD	0.90		0.56
	Min	8		10
	Max	12		12
Palpebral Aperture (mm)	Mean	9.82		9.83
	SD	1.26		0.92
	Min	8		8
	Max	14		12
K Steepest (mm)	Mean	7.61		7.58
	SD	0.30		0.21
	Min	6.93		7.15
	Max	8.34		7.95
K Flattest (mm)	Mean	7.75		7.76
	SD	0.30		0.32
	Min	7.05		7.29
	Max	8.44		9.95
K Mean (mm)	Mean	7.68		7.67
	SD	0.30		0.25
	Min	6.99		7.22
	Max	8.39		8.86

N.B. Asterisks indicate statistically significant differences by unpaired analysis (see A3 Table 6), * $P \leq 0.05$.

A3 Table 2: Summary of comfort, lens fit, wettability and lens deposits.

Variable		Dispensing Control	Dispensing Test	2-week Control	2-week Test	1-month Control	1-month Test
No. of Eyes		42	88	40	84	39[a]	82
Comfort (0-10)	Mean	9.18	8.85	8.09	8.41	8.34	8.51
	SD	0.94	1.17	2.04	1.79	1.77	1.47
	Min	5.1	5.1	2.2	0.0	1.5	1.0
	Max	10	10	10	10	10	10
Centration (0-3)	Mean	1.86	1.66	1.78	1.75	1.56	1.77
	SD	0.84	0.60	0.86	0.60	0.60	0.59
	Min	1	1	1	1	1	1
	Max	3	3	4	3	3	3
Corneal Coverage	(%)	100%	100%	95%	100%	100%	100%
Post-blink Movement (0-4)	Mean	2.17	2.09	2.25	2.19	2.33	2.21
	SD	0.62	0.49	0.54	0.51	0.66	0.54
	Min	1	1	1	1	1	0
	Max	3	3	3	3	3	3
Tightness on push-up (%)	Mean	50.4	50.4	51.9	51.9	52.7	52.0
	SD	7.7	7.0	12.9	8.5	7.3	8.7
	Min	35	38	10	35	30	25
	Max	70	75	75	75	70	75
Overall Fit (0-4)	Mean	3.49	3.56	3.26	3.51	3.28	3.47
	SD	0.42	0.38	0.52	0.38	0.38	0.38
	Min	2.5	2.5	2	3	2	2.5
	Max	4	4	4	4	4	4
Overall fit ≥ Grade 2	(%)	100%	100%	100%	100%	100%	100%
Tear Break-up Time (s)	Mean	9.40	9.20	7.45	9.95	7.92	9.76
	SD	5.20	6.62	3.64	6.63	4.29	5.80
	Min	1	0	2	2	2	2
	Max	23	43	16	40	26	35
Pre-lens Tear Film Quality (0-4)	Mean	3.46	3.40	3.04	3.28	3.31	3.26
	SD	0.39	0.48	0.71	0.46	0.48	0.67
	Min	2.5	2	1	2	2	0.5
	Max	4	4	4	4	4	4
Film Deposits (0-4)	Mean	-	-	0.73	0.65	0.92	0.87
	SD			0.82	0.76	1.09	0.97
	Min			0	0	0	0
	Max			3	3	4	4
White Spots (n)	Mean	-	-	2.75	2.73	2.31	2.37
	SD			5.02	6.83	3.16	3.98
	Min			0	0	0	0
	Max			25	39	12	20

N.B. No statistically significant differences were found by unpaired analysis (see A3 Table 6).
a One subject reported for the 1-month visit only wearing one lens.

A3 Table 3: Summary of wearing time, symptoms and problems.

Variable		2-week Control	2-week Test	1-month Control	1-month Test
No. of Subjects / Eyes		20 / 40	42 / 84	20 / 40	41 / 82
Wearing Time on Day of Visit (hrs)	Mean	4.0	4.3	3.9	4.2
	SD	2.5	2.5	2.3	2.2
	Min	1	1	1	1
	Max	11	14	9	9
Average Wearing Time (hrs)	Mean	11.7	11.9	12.2	12.3
	SD	3.0	3.1	2.2	3.1
	Min	5	6	8	6
	Max	16	18	16	18
Weekly Wearing Time (days)	Mean	6.0	6.3	5.6	6.4
	SD	1.1	0.8	1.1	0.9
	Min	4	3	4	4
	Max	7	7	7	7
Discomfort/Pain (0-3)	Mean	0.35	0.37	0.15	0.10
	SD	0.70	0.71	0.43	0.34
	Min	0	0	0	0
	Max	2	3	2	2
Lens Edge Awareness (0-3)	Mean	0.23	0.17	0.15	0.10
	SD	0.58	0.43	0.48	0.34
	Min	0	0	0	0
	Max	2	2	2	2
Burning or Stinging (0-3)	Mean	0.08	0.04	0.03	0.05
	SD	0.35	0.24	0.16	0.27
	Min	0	0	0	0
	Max	2	2	1	2
Dryness (0-3)	Mean	0.60	0.55	0.60	0.48
	SD	0.63	0.83	0.74	0.69
	Min	0	0	0	0
	Max	2	3	3	2
Itching (0-3)	Mean	0.05	0.07	0.25	0.07
	SD	0.32	0.26	0.54	0.38
	Min	0	0	0	0
	Max	2	1	2	3
Redness (0-3)	Mean	0.18	0.13	0.15	0.10
	SD	0.38	0.49	0.36	0.30
	Min	0	0	0	0
	Max	1	3	1	1
Blurred Vision (0-3)	Mean	0.35	0.26	0.18	0.30
	SD	0.70	0.52	0.45	0.58
	Min	0	0	0	0
	Max	2	2	2	2

N.B. No statistically significant differences were found by unpaired analysis (see A3 Table 6).

A3 Table 3 (cont.): Summary of wearing time, symptoms and problems.

Variable		2-week Control		2-week Test	1-month Control	1-month Test
No. of Subjects / Eyes		20 / 40		42 / 84	20 / 40	41 / 82
Photophobia (0-3)	Mean	0.15		0.02	0.00	0.01
	SD	0.66		0.15	0.00	0.11
	Min	0		0	0	0
	Max	3		1	0	1
Haloes (0-3)	Mean	0.10	*	0.00	0.05	0.00
	SD	0.30		0.00	0.22	0.00
	Min	0		0	0	0
	Max	1		0	1	0
Tearing (0-3)	Mean	0.03		0.10	0.05	0.06
	SD	0.16		0.43	0.22	0.29
	Min	0		0	0	0
	Max	1		3	1	2
Eye Secretion (0-3)	Mean	0.00		0.10	0.15	0.07
	SD	0.00		0.40	0.48	0.34
	Min	0		0	0	0
	Max	0		2	2	2
Lens Needs Cleaning (0-3)	Mean	0.30		0.40	0.38	0.26
	SD	0.79		0.75	0.81	0.62
	Min	0		0	0	0
	Max	3		2	3	3
Other (0-3)	Mean	0.18		0.11	0.05	0.05
	SD	0.50		0.38	0.22	0.22
	Min	0		0	0	0
	Max	2		2	1	1

N.B. Asterisks indicate statistically significant differences by unpaired analysis (see A3 Table 6), * $P \leq 0.05$.

A3 Table 4: Summary of vision.

Variable		Dispensing Control	Dispensing Test	2-week Control	2-week Test	1-month Control	1-month Test
No. of Eyes		42	88	40	84	39[a]	82
Visual Acuity (logMAR)	Mean	-0.05	-0.05	-0.03	-0.06	-0.04	-0.06
	SD	0.08	0.09	0.11	0.09	0.07	0.10
	Min	-0.20	-0.30	-0.18	-0.28	-0.20	-0.30
	Max	+0.18	+0.18	+0.30	+0.18	+0.18	+0.18
Normalised Visual Acuity (logMAR)	Mean	-0.04	-0.03	-0.06	-0.03	-0.04	-0.02
	SD	0.07	0.08	0.09	0.08	0.07	0.08
	Min	-0.26	-0.26	-0.38	-0.26	-0.22	-0.24
	Max	+0.08	+0.32	+0.08	+0.32	+0.08	+0.28
Over-refraction - Sphere (D)	Mean	+0.12	+0.08	+0.13	+0.16	+0.21	+0.16
	SD	0.27	0.26	0.29	0.30	0.30	0.28
	Min	-0.50	-0.75	-0.50	-0.50	-0.50	-0.50
	Max	+0.75	+0.75	+1.00	+1.25	+1.00	+0.75
Over-refraction - Cylinder (D)	Mean	-0.35	-0.26	-0.36	-0.29	-0.35	-0.30
	SD	0.32	0.27	0.26	0.27	0.29	0.26
	Min	-1.00	-1.00	-0.75	-1.00	-1.00	-0.75
	Max	0.00	0.00	0.00	0.00	+0.25	+0.25
Visual Acuity With Over-ref. (logMAR)	Mean	-0.07	-0.10	-0.09	-0.09	-0.09	-0.09
	SD	0.08	0.11	0.08	0.08	0.07	0.08
	Min	-0.20	-0.80	-0.28	-0.30	-0.22	-0.30
	Max	+0.18	+0.10	+0.10	+0.18	0.00	+0.10
Normalised Visual Acuity With Over-ref. (logMAR)	Mean	-0.02	* +0.02	-0.00	+0.01	+0.00	+0.01
	SD	0.05	0.11	0.04	0.07	0.05	0.07
	Min	-0.20	-0.30	-0.10	-0.26	-0.18	-0.14
	Max	+0.08	+0.68	+0.08	+0.38	+0.10	+0.38
Vision Quality (%)	Mean	89.3	87.3	90.0	87.1	89.9	87.8
	SD	9.0	10.8	7.2	12.0	6.4	9.7
	Min	55	50	70	25	70	65
	Max	100	100	100	100	100	100

N.B. Asterisks indicate statistically significant differences by unpaired analysis (see A3 Table 6), * $P \leq 0.05$.
a One subject reported for the 1-month visit only wearing one lens.

A3 Table 5: Summary of slit lamp findings.

Variable		Baseline Control	Baseline Test	2-week Control	2-week Test	1-month Control	1-month Test
No. of Eyes		42	88	40	84	40	82
Limbal Hyperaemia (0-4)	Mean	0.60	0.86	0.95	1.02	0.91	1.01
	SD	0.39	0.52	0.67	0.63	0.42	0.51
	Min	0	0	0	0	0	0
	Max	1.5	3	3	3	1.5	2.5
Bulbar Hyperaemia (0-4)	Mean	0.75 **	1.09	1.05	1.24	1.06	1.22
	SD	0.40	0.37	0.48	0.51	0.44	0.45
	Min	0	0.5	0.5	0	0.5	0
	Max	1.5	2	2.5	2	2	2
Upper Palpebral Hyperaemia (0-4)	Mean	0.90	0.90	1.16	0.98	1.00	1.02
	SD	0.51	0.53	0.64	0.52	0.48	0.56
	Min	0	0	0	0	0	0
	Max	2	2.5	3	2.5	2	2.5
Upper Palpebral Roughness (0-4)	Mean	0.94	0.93	1.03	0.85	1.03	0.92
	SD	0.66	0.58	0.54	0.55	0.59	0.56
	Min	0	0	0	0	0	0
	Max	2.5	2.5	2	2.5	2	2.5
Lower Palpebral Hyperaemia (0-4)	Mean	0.95	0.92	1.10	1.05	0.93	1.09
	SD	0.49	0.48	0.57	0.59	0.42	0.60
	Min	0	0	0	0	0	0
	Max	2	2	2	2	1.5	2.5
Lower Palpebral Roughness (0-4)	Mean	0.80	0.88	0.80	0.86	0.80	0.89
	SD	0.61	0.60	0.59	0.76	0.50	0.58
	Min	0	0	0	0	0	0
	Max	2	2.5	2	5	1.5	2
Corneal Staining (Extent) (0-4)	Mean	0.54 *	0.30	0.58	0.65	0.49	0.63
	SD	0.47	0.43	0.64	0.68	0.54	0.61
	Min	0	0	0	0	0	0
	Max	1.5	2	3	3	2.5	2
Corneal Staining (Depth) (0-4)	Mean	0.67 *	0.39	0.65	0.60	0.60	0.65
	SD	0.48	0.49	0.53	0.49	0.50	0.48
	Min	0	0	0	0	0	0
	Max	1	1	2	1	1	1
Conjunctival Staining (0-4)	Mean	0.37	0.38	0.98	1.22	1.13	1.21
	SD	0.54	0.49	0.66	0.90	0.77	0.75
	Min	0	0	0	0	0.5	0
	Max	2.5	2	2.5	3.5	3.5	3
Other SLF (0-4)	Mean	0.08	0.25	0.06	0.24	0.04 *	0.30
	SD	0.27	0.51	0.23	0.51	0.13	0.52
	Min	0	0	0	0	0	0
	Max	1	2	1	2	0.5	2

N.B. Asterisks indicate statistically significant differences by unpaired analysis (see A3 Table 6), * $P \leq 0.05$, ** $P \leq 0.01$.

A3 Table 6: **Summary of unpaired analysis -** the two-sample t-test (T) was used on normal data and Mann-Whitney U-test (MW)was used on non-normal data.

Variable	Baseline/Disp.		2-week		1-month		Test
	P	T/U	*P*	T/U	*P*	T/U	
Number of subjects	65		62		61		
Age	**0.02**	**-2.36**	-		-		2s tt
Spec. Rx Sphere	0.53	0.63	-		-		2s tt
Spec. Rx Cylinder	0.28	385.5	-		-		MW
HC VA with Spec Rx	0.73	-0.34	-		-		2s tt
HVID	0.88	-0.15	-		-		2s tt
Palpebral Aperture	0.95	-0.06	-		-		2s tt
K Flattest	0.62	0.50	-		-		2s tt
K Steepest	0.85	-0.20	-		-		2s tt
K-Mean	0.89	0.15	-		-		2s tt
WT on Day of Visit	-		0.53	379	0.58	374	MW
Average Wearing Time	-		0.84	406.5	0.71	386	MW
Weekly Wearing Time	-		0.19	339.5	**0.007**	**248**	MW
Comfort (VAS)	0.38	400	0.60	385	0.74	388	MW
Discomfort/Pain	-		0.82	407	0.55	388.5	MW
Lens Edge Awareness	-		0.85	411.5	0.93	407	MW
Burning or Stinging	-		0.94	418	1.00	410	MW
Dryness	-		0.44	375	0.49	370.5	MW
Itching	-		0.75	411	**0.03**	**330**	MW
Redness	-		0.40	386	0.32	372	MW
Blurred Vision	-		0.91	414.5	0.33	363.5	MW
Photophobia	-		0.57	408.5	0.48	400	MW
Haloes	-		**0.04**	**378**	0.15	389.5	MW
Tearing	-		0.51	399.5	1.00	410	MW
Eye Secretion	-		0.22	390	0.45	389	MW
Lens Needs Cleaning	-		0.39	378	0.61	386	MW
Other	-		0.70	405	0.50	391	MW
Visual Acuity	0.76	0.31	0.40	0.84	0.37	0.89	2s tt
Normalised VA	0.43	-0.79	0.12	-1.56	0.27	-1.12	2s tt
Over-ref. Sphere	0.49	0.70	0.52	-0.65	0.55	0.61	2s tt
Over-ref. Cylinder	0.29	388.5	0.34	357.5	0.53	369.5	MW
Visual Acuity (O-ref.)	0.16	1.42	0.92	0.10	0.58	0.56	2s tt
Normalised VA (O-ref.)	**0.05**	**-2.02**	0.44	-0.77	0.51	-0.66	2s tt
Vision Quality	0.71	426	0.29	350	0.68	383.5	MW
Break-up Time	0.90	0.13	0.11	-1.63	0.23	-1.22	2s tt

A3 Table 6 (cont.): **Summary of unpaired analysis -** the two-sample t-test (T) was used on normal data and Mann-Whitney U-test (MW)was used on non-normal data.

Variable	Baseline/Disp.		2-week		1-month		Test
	P	T/U	*P*	T/U	*P*	T/U	
Number of subjects	65		62		61		
PLTF Quality	0.62	427.5	0.24	344	0.84	397.5	MW
Centration	0.56	422.5	0.75	399.5	0.13	318.5	MW
Post-blink Movement	0.59	0.55	0.65	0.45	0.35	0.93	2s tt
Tightness on Push-up	0.99	0.02	1.00	0.00	0.77	0.30	2s tt
Fit Acceptance	0.40	404.5	0.09	309	0.08	300.5	MW
Film Deposits	-		0.74	399	0.98	408.5	MW
White Spots	-		0.24	348	0.79	393.5	MW
Limbal Hyperaemia	0.07	337.5	0.58	384.5	0.51	368.5	MW
Bulbar Hyperaemia	**0.002**	**253.5**	0.09	308.5	0.16	321	MW
Upper Palp. Hyperaemia	0.69	435	0.19	335	0.91	403	MW
Upper Palp. Roughness	0.98	460.5	0.12	318.5	0.40	356.5	MW
Lower Palp. Hyperaemia	0.86	449.5	0.68	393	0.31	345	MW
Lower Palp. Roughness	0.59	424.5	0.83	406	0.57	373.5	MW
Corneal Staining Extent	**0.03**	**319**	0.54	380	0.51	367.5	MW
Corneal Staining Depth	**0.03**	**318.5**	0.69	395	0.64	382	MW
Conjunctival Staining	0.66	432.5	0.34	357.5	0.37	352.5	MW
Other SLF	0.20	395	0.20	355.5	**0.02**	**290.5**	MW

APPENDIX 4

Questionnaire Results

APPENDIX 3

Table of Contents

A4 Table 1: Summary of background questionnaire

Question		Control	Test
No. Subjects		21	44
Q1:	What is your current brand of contact lens?		
	Acuvue 2	4 / 19%	12 / 27%
	Focus Dailies	4 / 19%	7 / 16%
	1·Day Acuvue	4 / 19%	4 / 9%
	Acuvue Advance	0 / 0%	5 / 11%
	Proclear Compatibles	1 / 5%	3 / 7%
	Biomedics 1 Day	1 / 5%	2 / 5%
	Acuvue	1 / 5%	1 / 2%
	Boots Daily Disposable	1 / 5%	1 / 2%
	Night & Day	1 / 5%	1 / 2%
	Soflens One Day	0 / 0%	2 / 5%
	Specsavers Monthly	1 / 5%	1 / 2%
	Acuvue Colours	1 / 5%	0 / 0%
	Biomedics 55	0 / 0%	1 / 2%
	Freshlook Colours	0 / 0%	1 / 2%
	O2 Optics	1 / 5%	0 / 0%
	Soflens 66	0 / 0%	1 / 2%
	Specsavers Dailies	1 / 5%	0 / 0%
	Not reported	0 / 0%	2 / 5%
Q2:	What is your current brand of lens care system?		
	AO Sept Plus	3 / 14%	3 / 7%
	Cyclean	0 / 0%	5 / 11%
	Optifree Express	0 / 0%	5 / 11%
	Complete	1 / 5%	3 / 7%
	Complete Moisture Plus	0 / 0%	3 / 7%
	Specsavers	1 / 5%	3 / 7%
	All in one light	1 / 5%	0 / 0%
	Boots own One Step	0 / 0%	1 / 2%
	Focus Aqua	1 / 5%	0 / 0%
	ReNu Moisture Lock	0 / 0%	1 / 2%
	ReNu Multiplus	0 / 0%	1 / 2%
	Sauflon Multipurpose	1 / 5%	0 / 0%
	Sainsbury's	1 / 5%	0 / 0%
	Tesco's own brand	1 / 5%	0 / 0%
	Unknown	0 / 0%	1 / 2%
	Not Applicable (Daily disposable wearer)	11 / 52%	16 / 36%
	Not reported	0 / 0%	2 / 5%
Q18:	Please indicate your ethnic background		
	Caucasian (white)	16 / 76%	38 / 86%
	Asian	2 / 10%	2 / 5%
	African	0 / 0%	1 / 2%
	African/Chinese	1 / 5%	0 / 0%
	Anglo-Japanese	1 / 5%	1 / 2%
	Chinese	1 / 5%	0 / 0%
	Unknown	0 / 0%	1 / 2%

N.B. Asterisks indicate statistically significant differences by unpaired analysis (see Table 3), * $P<0.05$.

A4 Table 2: Summary of evaluation questionnaire

Question		Control	Test
No. Subjects		20	42
Q2:	How would you rate the overall performance of the study lens care system?		
	Excellent (4)	7 / 35%	7 / 17%
	Very good (3)	8 / 40%	19 / 45%
	Good (2)	5 / 25%	10 / 24%
	Fair (1)	0 / 0%	5 / 12%
	Poor (0)	0 / 0%	1 / 2%
	Mean (SD)	3.10 (0.79)	2.62 (0.99)
Q3:	How does the overall performance of the study lens care system compare to your previous lens care system?		
	Much better than previous (+2)	2 / 10%	2 / 5%
	Somewhat better than previous (+1)	2 / 10%	10 / 24%
	Same as previous (0)	12 / 60%	13 / 31%
	Somewhat worse than previous (-1)	1 / 5%	8 / 19%
	Much worse than previous (-2)	0 / 0%	1 / 2%
	Not Applicable	3 / 15%	8 / 19%
	Mean (SD)	0.29 (0.77)	0.12 (0.95)
Q4:	How would you rate the overall comfort with the study lens care system?		
	Excellent (4)	7 / 35%	6 / 14%
	Very good (3)	7 / 35%	20 / 48%
	Good (2)	5 / 25%	10 / 24%
	Fair (1)	1 / 5%	3 / 7%
	Poor (0)	0 / 0%	3 / 7%
	Mean (SD)	3.00 (0.92)	2.55 (1.06)
Q5:	How does the overall comfort of the study lens care system compare to your previous lens care system?		
	Much better than previous (+2)	1 / 5%	3 / 7%
	Somewhat better than previous (+1)	6 / 30%	11 / 26%
	Same as previous (0)	10 / 50%	13 / 31%
	Somewhat worse than previous (-1)	2 / 10%	7 / 17%
	Much worse than previous (-2)	0 / 0%	1 / 2%
	Not Applicable	1 / 5%	7 / 17%
	Mean (SD)	0.32 (0.75)	0.23 (0.97)
Q6:	How would you rate the cleaning performance of the study lens care system?		
	Excellent (4)	4 / 20%	8 / 19%
	Very good (3)	9 / 45%	16 / 38%
	Good (2)	5 / 25%	9 / 21%
	Fair (1)	2 / 10%	6 / 14%
	Poor (0)	0 / 0%	3 / 7%
	Mean (SD)	2.75 (0.91)	2.48 (1.17)

N.B. There were no statistically significant differences by unpaired analysis (see Table 3).

A4 Table 2 (cont.): Summary of evaluation questionnaire

Question		Control	Test
No. Subjects		20	42
Q7:	How does the cleaning performance of the study lens care system compare to your previous lens care system?		
	Much better than previous (+2)	1 / 5%	4 / 10%
	Somewhat better than previous (+1)	2 / 10%	7 / 17%
	Same as previous (0)	10 / 50%	14 / 33%
	Somewhat worse than previous (-1)	3 / 15%	6 / 14%
	Much worse than previous (-2)	0 / 0%	1 / 2%
	Not Applicable	3 / 15%	10 / 24%
	Mean (SD)	0.06 (0.77)	0.22 (1.01)
Q10:	How likely are you to switch from your previous lens care system and purchase the study lens care system?		
	Very Likely (+2)	1 / 5%	3 / 8%
	Likely (+1)	5 / 26%	8 / 21%
	Unsure (0)	7 / 37%	11 / 28%
	Unlikely (-1)	6 / 32%	7 / 18%
	Very Unlikely (-2)	0 / 0%	10 / 26%
	Mean (SD)	0.05 (0.91)	-0.33 (1.28)

N.B. There were no statistically significant differences by unpaired analysis (see Table 3).

A4 Table 3: **Summary of unpaired analysis -** the two-sample t-test (T) was used on normal data and Mann-Whitney U-test (MW)was used on non-normal data.

Variable	P	T/U	# Control	# Test	Test
Q2 - Performance (study)	0.08	311.5	20	42	M-W
Q3 - performance (comparison)	0.64	267	17	34	M-W
Q4 - Comfort (study)	0.13	325.5	20	42	M-W
Q5 - Comfort (comparison)	0.79	318.5	19	35	M-W
Q6 - Cleaning (study)	0.47	374.5	20	42	M-W
Q7 - Cleaning (comparison)	0.56	231	16	32	M-W
Q10 - Switch	0.26	305	19	39	M-W

APPENDIX 5

Grading System

GRADING SYSTEM

All assessments to be made using a slit lamp biomicroscope
Variables may be graded in half increments (e.g. 3.5)

NIBUT
NIBUT is the time taken in seconds for the appearance of a break in the pre-lens tear film or complete thinning of the aqueous at some point on the lens. Observe using a Keeler Tearscope.

PLTF Quality
0 Should not be worn
1 Should not be dispensed but no immediate danger. Poorly wetting, severe debris and/or dry spots
2 Minimum acceptance, early review reasonable wetting, moderate debris and/or transient dry spots
3 Not perfect, OK to dispense, well wetting, some adherent debris and/or transient dry spots
4 Perfect wetting no debris

Centration:
Assessed in primary gaze, interblink, from each lens edge to the respective limbus.
Centered
Mild Decentration <0.3 mm
Moderate Decentration 0.3 to 0.7 mm
Excessive Decentration >0.7 mm

Corneal Coverage:
Y Yes, full corneal coverage at all times
N No , incomplete corneal coverage

Post Blink Movement:
Amount of movement immediately after the blink (lower lid to be depressed only if necessary for observation.
0 Excessive, unacceptable movement
1 Moderate, but acceptable movement
2 Optimal movement
3 Minimal, but acceptable movement
4 Insufficient, unacceptable movement

Tightness:
Assessment of lens tightness by push-up test using 0%-100% continuous scale (to the nearest 5%).
100% No movement
50% Optimum
0% Falls from cornea without lid support

Overall Fit Acceptance:
Based on lens fit alone (not comfort or vision).
0 Should not be worn
1 Should not be dispensed although no immediate danger
2 Borderline, can be worn, but would prefer to refit
3 Can be worn, but fit could be improved
4 Can be worn without reservation, all ratings are near to optimal

Lens Condition – white spot deposits
Count number of white spots present on lens surface. Initially assessed on-eye but confirmed off-eye when assessing film deposits.

Lens Condition – film deposits (Modified Rudko)
Analysed off-eye after cleaning lenses with multi-purpose solution and rinsing with saline. Use dark field illumination and approx. x10 slit lamp magnification and grade to nearest 0.5.

0 No film
1 Slight film visible only under magnification.
2 Moderate film only under magnification.
3 Moderate film visible to the naked eye.
4 Heavy film visible to the naked eye.

Injection (Hyperaemia) Limbal, Bulbar)
0 None
1 Slight injection of conjunctival vessels
2 Mild injection
3 Moderate injection
4 Severe injection

Injection (Hyperaemia) Palpebral
0 None
1 Slight injection of vessels
2 Mild injection
3 Moderate injection
4 Severe injection

Extent of Corneal Staining
0 None
1 1 - 20 punctate diffuse spots
2 21 - 40 punctate spots
3 40 diffuse spots and/or coalescing patches
4 Diffuse confluent patches

Location of Staining
C Central (1/3 corneal diameter)
N Nasal quadrant excluding central area
T Temporal
I Inferior
S Superior

Conjunctival Staining
0 None
1 Minimal diffuse punctate
2 Coalescent punctate
3 Confluent
4 Deep confluent