Refitting Existing Contact Lens Wearers With A Second Generation Silicon Hydrogel Lens, Designed for Daily, Flexible And Extended Wear

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Abstract

This prospective single-masked, open-label, multi-centre study evaluated the clinical and subjective performance of a new, second generation silicone hydrogel lens designed for daily/flexible/extended wear (DW/FW/EW), when refitting adapted lens wearers of monthly contact lenses with it. 230 adapted lens wearers were re-fitted and followed for 1 month. Subjects were masked to test lens brand and sponsor. The habitual 1-month disposable-type soft contact lenses were the control products. The new lens showed good visual acuity, biomicroscopy findings and lens fit throughout the study. Subjects rated the new lens highly overal, for comfort at the end of the day and were satisfied. They also showed a higher preference for the new lens then for the habitual one.

1. Introduction

Oxygen supply is key in safe contact lens wear. Limbal hyperemia is a sign of oxygen deprivation due to contact lens wearing [1] [2-6]. While there is less bulbar conjunctival hyperemia in high Dk/t wearers [4], long-term data suggest that this trend is less consistent than the limbal hyperemia [6,7]. Corneal neovascularisation occurred in 30% of patients wearing low Dk/t hydrogel lenses [8]. An obvious emptying of the limbal blood vessels was observed when previous wearers of low Dk/t lenses were refitted with high Dk/t silicone hydrogels [9]. Silicone hydrogel lenses have a higher oxygen permeability (Dk) and transmissibility (Dk/t) then ordinary hydrogel lenses. High Dk/t lenses cause less suppression of central corneal epithelial basal cell proliferation [10], in other words, the cornea is better capable of fending off inflammation and infections. Silicone hydrogels have thus virtually eliminated all of the clinical hypoxic signs associated with extended wear [2-7]. There is documented [8] and mounting anecdotal evidence that even DW of low Dk/t hydrogel lenses produces clinical signs of chronic hypoxia.

Studies form the Cornea & Contact Lens Research Unit (CCLRU) and the Cooperative Research Centre for Eye Research & Technology (CRCERT) showed that 97% of contact lens wearers would prefer to wear their lenses on an EW/continuous wear (CW) basis [11]. Recent surveys show that many people, although wearing DW lenses, occasionally sleep or nap while wearing lenses [12]. This indicates, that there is a need for high oxygen transmissible lenses that are especially designed for DW/FW/EW. This poster reports on the experience in refitting experienced wearers with such a new, second generation silicone hydrogel lens, designed for DW, FW and EW for up to 6 nights).

2. Methods

2.1. Subjects

Nine investigators (1 ophthalmologist & 8 optometrists) enrolled 230 adapted lens wearers (175 females & 55 males). They wore the test lens, O2Optix™ (CIBA Vision), for 1 month. (O2Optix is a second generation silicone hydrogel lens with monthly replacement.) Subjects had at least 3 months experience with one of the control lenses. Characteristics of the test and control lenses are listed in Table 1.

	O2Optix	Biomedics 55[a]	Frequency 55[b] & Frequency 55 Aspherique[b]	PureVision[c]	Proclear Compatibles[d]
Material	Lotrafilcon B	Ocufilcon D	Methafilcon A	Balafilcon A	Omafilcon A
Water cont.	33%	55%	55%	36%	62%
Dk	110	19.7	17	99	27
Dk/t	138	28.2	24	110	41.5
Geometry	Aspheric	Spherical	Spherical & Aspheric	Spherical	Spherical
Diameter (mm)	14.2	14.2	14.2 (sph); 14.4 (asph)	14	14.2
Base curve(s) (mm)	8.6	8.6; 8.9	8.6; 8.9 (sph) 8.4; 8.7 (asph)	8.6	8.6

[a] Biomedics 55 is a tradenmark from OSI, [b] Frequency 55, Frequency 55 aspheric & [d] Proclear Compatibles are trademarks from Cooper Vision, [c]Pure Vision is a trademark from Bausch & Lomb O2Optix is a trademark from CIBA Vision

Table 1: Lens parameters of the test (O2Optix) and the control lenses

2.2. Study Design

Subjects in this prospective, single-masked, open-label study were selected from the contact-lens patient population at each investigational site. They were masked for test lens brand and sponsor and told that they could wear the test lenses as they did their habitual lenses or as long as they liked during the day, even sleep while wearing their lenses for up to 6 nights in a row. They returned for follow-up visits after app. 2 weeks and 1 month and continued to use their habitual lens care system.

2.3. Clinical Parameters

Lens fit was rated at baseline visit for the habitual and the test lens. The fit was either unacceptable, acceptable or optimal. The follow-up visits only looked at the test lens. New refraction and best corrected visual acuity (BCVA) was recorded. Flat and steep keratometer values (K-readings) were obtained for both eyes. Biomicroscopy was done at baseline (reference), 2-week follow-up and 1-month follow-up visits, using the Efron grading scale [13].

2.4. Lens Rating

At each of the visits, subjects completed a questionnaire and scored several items regarding their habitual lens and the test lens on a scale from 1 (=poor) to 10 (=excellent). Preference was noted at the 2-week follow-up and 1-month follow-up visits. At the 1 month visit, subjects were also asked about their preference without the possibility to rate both lenses as equal (forced choice).

2.5. Wearing Habits

DW and FW wearing habits of the subjects were obtained for both the test and habitual lenses. Subjects were asked about their hours per day of lens wear, occurr-ence and frequency of naps and overnight sleeping, while wearing lenses.

2.6. Data Analysis

Results for both eyes are grouped where applicable and descriptive statistics were calculated. The paired t-test was used to evaluate changes from baseline in lens rating. Wilcoxon paired signed rank test was used to evaluate differences in biomicroscopy scores between baseline and follow-up, and to evaluate preferences. A binomial test was used for the forced choice preference and to evaluate changes in power (in-/decrease) or in BCVA (worse/better) of test lens vs habitual lens, excluding the being equal score. Change vs baseline in lens fit and from reference in wearing behavior were evaluated by McNemar's test in case of 2x2 symmetry or by Bowkers test in case of 3x3 symmetry.

3. Results:

3.1. Participants

Of the 230 subjects, 59 used Biomedics 55, 60 Frequency 55, 40 Proclear and 71 Pure Vision lenses as their habitual lens. Subjects were on average 29 years old (range 17-63). 216 subjects wore the test lens for 1 month. The most frequently reported pre-existing condition (by the investigator) was symptoms of dry eyes (35/230 subj.; 15%). Dry eyes occurred most frequently in the Proclear group (18/40 subj.; 35%), whereas in the other groups between 3 and 9 subj. (5%-13%) were reported as having symptoms of dry eyes.

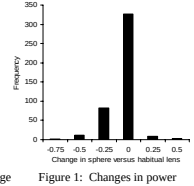

Figure 1: Changes in power

3.2. Refraction / Lens Power / BCVA

52 % of all subjects had a cylinder of -0.25 diopters to -1.00 diopters with 75% of them having a horizontal axes (+/- 20), 14% a vertical (+/-20) and the remaining 11% an oblique axis. The average spectacle power was –3.00 D (range –7.00, -0.25) and the average habitual lens power was also –3.00 D (range –6.25; -0.75). At the 1-month follow-up, 75% had an equal sphere power as with their habitual lens, 22% an increased sphere power and 3% a decreased one (Figure 1). The difference between subjects with an increased and decreased power was more pronounced in the Biomedics 55 group (35% versus 1%) and less pronounced in the Frequency 55 group (app. 13% versus 2%). This may be attributable to the aspheric, aberration controlled optics of the test lens. BCVA with spectacles was on average 1.00 (6/6) (range 0.5 to 1.4) and 1.00 (range 0.9 to 1.7) for the habitual lens. At the 1-month follow-up, 35% of the subjects had a better BCVA with the test lens compared to habitual, while 38% were equal and 27% had a lower BCVA (p=0.065). The percentage of subjects with a better BCVA was higher than the percentage of subjects with a lower BCVA in all subgroups.

3.3. Lens Fit

Average K-readings were 7.82 (range 7.0 to 8.6) for flat and 7.71 (7.0 to 8.4) for steep. Mean flat and steep was 7.77 (range 7.1 to 8.5) (see also Figure 2 for distribution). Test lens fit was judged at each visit. A graphical presentation of the test lens fit versus the K-readings is provided in Figure 2. At baseline, fit was acceptable for 25% of the subj. and optimal for 75%. After 1 month, the fit of test lens was optimal in 77% of the cases and acceptable in 23%. Average K-reading of the subject that discontinued due to unacceptable fit was 7.77. At the fitting visit, for 88% of the subj. the test lens fitted as good as (67%), or even better than (21%) their habitual lens (p<0.001). This was most pronounced in the Pure Vision group, where 28% of the subj. had an improvement in fit compared to their habitual lens and only 11% fitted worse (p=0.002). In the Biomedics 55 group, 18% fitted better and 3% fitted worse (p<0.001). In the Proclear and Frequency 55 groups, 19% and 17% fitted better, while 21% (p=0.853) and 15% (p=0.746) fitted worse.

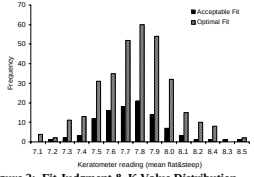

Figure 2: Fit Judgment & K Value Distribution

3.4. Wearing habits

91% of all subj. use their habitual lenses on a DW basis, 5% reported FW and 4% EW. At 1-month follow-up, 80% said DW and 20% FW (p<0.001). At baseline, 1/3 of the subj. in the PureVision group used their lens as a FW or EW (26/75; 35%), this increased to 47% (32/68) at 1 month. In each of the other groups, less than 3% did FW with their lens. At the end of the study, FW increased to 6% (min.) and 19% (max.). While only 0 to 3% of the subjects said they were on a FW schedule, 14 to 33% reported occasionally sleeping while wearing their lenses, with the maximum being in the Frequency 55 group (33%), even more than in the Pure Vision group (18%).

Items mean (SD)	Biomedics 55 (n = 59)	Frequency 55 (n = 60)	Proclear (n = 40)	Pure Vision (n = 70)	All (n = 230)
Provide crisp, clear vision					
- Reference[a]	9.2 (1.00)	9.1 (1.08)	8.5 (1.81)	8.8 (1.26)	8.9 (1.29)
- 1 Month FU	-0.1 (1.58)	**-0.8 (1.89)**	+0.3 (1.84)	-0.1 (1.59)	**-0.2 (1.74)**
Feel comfortable upon insertion					
- Reference[a]	8.1 (2.02)	8.4 (1.73)	8.4 (1.52)	8.3 (1.73)	8.3 (1.76)
- 1 Month FU	**+1.0 (2.20)**	+0.1 (2.34)	-0.3 (2.46)	**+0.7 (1.75)**	**+0.5 (2.19)**
Feel comfortable in my eyes during the day					
- Reference[a]	7.7 (1.80)	7.5 (2.00)	7.5 (2.17)	8.0 (1.71)	7.7 (1.90)
- 1 Month FU	**+0.6 (2.30)**	+0.3 (2.41)	+0.1 (3.06)	+0.3 (1.96)	**+0.4 (2.4)**
Feel comfortable at the end of the day					
- Reference[a]	6.0 (2.32)	6.2 (2.28)	6.3 (2.04)	6.9 (2.28)	6.4 (2.26)
- 1 Month FU	**+1.4 (2.95)**	+0.8 (3.20)	+0.8 (3.09)	**+0.6 (2.49)**	**+0.9 (2.90)**
Do not make my lenses feel dry during the day					
- Reference[a]	7.0 (2.45)	7.2 (2.24)	6.8 (2.15)	7.5 (2.14)	7.1 (2.25)
- 1 Month FU	**+1.4 (2.34)**	+0.5 (3.05)	**+1.3 (2.5**	**+0.5 (2.13)**	**+0.9 (2.52)**
Do not make my lenses feel dry at the end of the day					
- Reference[a]	5.7 (2.55)	6.1 (2.56)	5.7 (2.20)	6.4 (2.43)	6.0 (2.45)
- 1 Month FU	**+1.8 (2.96)**	+0.9 (3.60)	**+1.7 (2.7)**	**+1.0 (2.59)**	**+1.3 (3.01)**
Being lenses you can sleep overnight					
- Reference[a]	2.1 (2.17)	3.1 (2.97)	2.4 (2.43)	6.1 (3.39)	3.7 (3.30)
- 1 Month FU	**+4.3 (3.50)**	**+4.2 (3.91)**	**+3.5 (4.20)**	+0.7 (2.96)	**+3.0 (3.90)**

Items were scored on a scale from 1 (= poor) to 10 (= excellent). A positive difference score indicates a more positive evaluation versus the reference lens. n: number of subjects; SD: standard deviation; FU: follow-up, **bold** = statistically significant change, p ≤ 0.05, [a] actual value for habitual lens

Table 2 Scores on various items by control group

The latter is, however, the only group with subj. reporting regularly sleeping while wearing their lenses (another 18%). In this group, the percent of subj. taking occ. naps with their lenses was also very high, 71% (62 % occ. and 9% reg.). For all, there was a statistically significant increase in sleeps with lenses (+0.8; p=0.013) for those who actually slept while wearing their lenses (data not shown); strongest difference was in the Frequency 55 group (up 1.9 nights per month, to 4 nights (p=0.006). At the 1-month follow-up app. 41 % (88) of the subj. said they would probably sleep with the test lenses.

3.5. Lens Ratings

Subjects scored test and habitual lenses for different items on a scale form 1 (= poor) to 10 (= excellent). Baseline scores for habitual lenses and mean changes in ratings with the test lenses are shown in Table 3. The habitual lens scored below 5 for 'being lenses you can sleep overnight' (overall score of 3.7). This is also the item with the largest difference (+3.0 after 1 month). In the Pure Vision group, this item scored 6.1 for habitual lenses; test lenses were rated 0.7 better (1-month follow-up). For all subj. and all habitual lenses, test lenses scored significantly better (with p<0.001) at both, the 2 week and the 1 month follow-up visits for: comfort at the end of the day, dryness of the lenses during the day and at the end of the day, and lenses you can sleep with overnight. Further statistically significant differences (with p<0.05) in favor of test lenses was seen for: comfort upon insertion, comfort during the day and letting oxygen into my eyes.

	Biomedics 55		Frequency 55		Proclear		Pure Vision		All	
	#	%	#	%	#	%	#	%	#	%
Comfort at the End of the Day										
- Strongly prefer T	16	29	12	21	17	49	15	22	60	28
- Slightly prefer T	15	27	15	26	10	29	18	26	58	27
- Both the same	14	25	8	14	2	6	15	22	39	18
- Slightly prefer H	8	14	11	19	2	6	10	15	31	14
- Strongly prefer H	3	5	11	19	4	11	10	15	28	13
p value[a]	**<0.001**		0.642		**<0.001**		0.144		**<0.001**	
Quality of Vision										
- Strongly prefer T	10	18	6	11	4	11	8	12	28	13
- Slightly prefer T	9	16	12	21	9	26	15	22	45	21
- Both the same	30	54	22	39	16	46	29	43	97	45
- Slightly prefer H	5	9	7	12	4	11	9	13	25	12
- Strongly prefer H	2	4	10	18	2	6	7	10	21	10
p value[a]	**0.008**		0.619		0.184		0.446		**0.059**	
Overall Preference										
- Strongly prefer T	13	23	11	19	11	31	16	24	51	24
- Slightly prefer T	19	34	18	32	14	40	16	24	67	31
- Both the same	15	27	9	16	5	14	16	24	45	21
- Slightly prefer H	6	11	9	16	1	3	12	18	28	13
- Strongly prefer H	3	5	10	18	4	11	8	12	25	12
p value[a]	**<0.001**		0.39		**0.003**		0.072		**<0.001**	
Forced Choice										
- Test lenses	35	65	29	53	25	74	34	52	123	59
- Habitual lenses	19	35	26	47	9	26	32	48	86	41
p value[b]	**0.029**		0.686		**0.006**		0.806		**0.01**	

[a] Wilcoxon matched pairs singed rank test, [b] Binomial test #: number of subjects; %: percent of subjects; T: test lens; H: habitual lens; **bold:** statistically significant, p ≤ 0.05

Table 3 Scores on various items by control group

3.6. Preference rating (at 1 month follow-up)

55% of the subjects preferred the test lenses (slightly (27%)/strongly (28%)) with regard to comfort at the end of the day (see Table 3) (p<0.001). Only 27% of subj. preferred (slight (14%) / strong (13%) the habitual lenses. Preference for test lenses was highest in the Proclear group, where 77% had a preference (slight (29%)/strong (49%)) for the test lenses (p<0.001). At the end of the study, 45% of the subj. had no preference with regard to quality of vision. 61% (73) of the 119 subj. who expressed a preference, preferred test lenses and 39% preferred habitual lenses (46/119). This preference for test lenses was statistically significant in the Biomedics 55 group (p=0.008). At the end of the study, 55 % (118/216) of all subj. had an overall preference for test lenses, only 25% (53/216) preferred the habitual lenses (p<0.001). 69% (118) of those, who expressed a preference (171), preferred test lenses and 31% their habitual lens (53/171). This was statistically significant in the Biomedics 55 and Proclear groups, where 57% and 71% of subj. preferred test lenses, compared to 16% (p<0.001) and 14% (p=0.003) who preferred habitual lenses. In the Frequency 55 and PureVision groups, preference for test lenses was 51% and 47%, respectively. 33% (p=0.390) and 29% (p=0.072), respectively, preferred the habitual lens. When forced to choose either test lenses or habitual lenses, 59% preferred the test lens (p=0.010). 53% (p=0.686) of Frequency 55 and 52% (p=0.806) of the PureVision users chose the test lens while 74% (p=0.006) in the Proclear and 65% (p=0.029) in the Biomedics 55 group chose the test lens.

4. Conclusion

In this study, O2Optix lens performed significantly better, particularly in relation to comfort, preference & biomicroscopy.

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