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Daily Disposable Contact Lenses versus Spectacles in Teenagers

Andrew J. Plowright BSc (Hons) MSc, Carole Maldonado-Codina PhD MCOptom
FAAO, Gillian F. Howarth BSc (Hons) MCOptom, Jami Kern MBA PhD, and Philip B.
Morgan PhD MCOptom FAAO

Eurolens Research, The University of Manchester, Manchester, United Kingdom
(AJP, CMC, GFH, PBM); Alcon Research Ltd, Fort Worth, Texas (JK).

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Corresponding author:

Andrew J. Plowright

Correspondence address:

Eurolens Research

The University of Manchester

Dover Street

Manchester

M13 9PL

United Kingdom

Tel: + 44 161 306 8762

Fax: +44 161 306 4442

30 Email: andrew.plowright@manchester.ac.uk

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ABSTRACT [300/300 word count]

Purpose: To compare clinical and subjective quality of life (QoL) data for teenagers wearing daily disposable contact lenses or spectacles.

Methods: This open-label study randomized subjects with no previous contact lens wear experience, aged 13–19 years, to nelfilcon A (DAILIES® AquaComfort Plus®) contact lenses or spectacles for 6 months. A full clinical workup, as well as subjective QoL measures using the Pediatric Refractive Error Profile (PREP) and QoL Impact of Refractive Correction (QIRC) questionnaires, was conducted at baseline and at Week 4 and Months 3 and 6, with an additional study visit at Week 2 for subjects randomized to wear contact lenses.

Results: A total of 110 teenagers were enrolled in the study; 13 discontinued before study completion, 10 (17.5%) from the contact lens group and three (5.7%) from the spectacle group ($p = 0.04$). Visual acuity was good for both groups at all study visits. Biomicroscopy assessments were similar at baseline for both groups. Significant differences in PREP responses were noted between vision correction groups across visits for appearance ($p < 0.001$), satisfaction ($p < 0.001$), activities ($p < 0.001$), peer perception ($p = 0.003$), and overall score ($p < 0.001$). For QIRC, the contact lens group gave more favorable responses than the spectacle group ($p = 0.02$). After 6 months of wearing contact lenses for 6 months, teenagers had a more positive subjects' attitude towards contact lenses were more favorable regarding comfort, vision, and safety with contact lenses, both compared with baseline and spectacle wearers. No serious adverse events were reported during the study.

Conclusions: The daily disposable lenses used in this study are suitable for vision correction for teenagers, offering improvements in QoL measures during the first month of wear, including appearance, satisfaction, activities, and peer perceptions, without negatively impacting vision or eye health. Teenagers were able to handle contact lenses with the same amount of confidence as spectacles.

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63 **Key words** [list at least 5]: daily disposable; contact lens; teenagers; quality of life;

64 randomized controlled study

For teenagers who require vision correction, contact lenses are a viable alternative compared with spectacles.¹⁻⁴ Previous studies have demonstrated that contact lens wear can have a positive impact for teenagers, particularly those who participate in sport, and for those who wish to improve self-perception of appearance and acceptance by peers.⁴⁻⁶ These effects ultimately lead to the wearer having greater satisfaction with his/her vision correction method.^{4,6} Teenagers who wear contact lenses tend to have a longer total vision correction time per week compared with those who correct their vision with spectacles alone.¹ Nevertheless, some eye care practitioners may be reluctant to prescribe contact lenses for teenagers. This, in part, may be because of concerns regarding the anticipated time required to educate young wearers about the safe use and correct care of contact lenses. Eye care practitioners may also have general concerns regarding safety and overall compliance in this age group. Recent studies, however, have shown that daily disposable contact lenses are suitable for vision correction in teenagers.^{1,3,4} Moreover, children younger than 14 years appear to be at lower risk of ocular events that interrupt contact lens wear compared with older teenagers or young adults.^{7,8}

Daily disposable contact lenses are designed to be worn once, then replaced with a new pair of lenses the following day, with the advantage that there is no lens care system or overnight storage required. In a 3-year prospective study, subjects wearing daily disposable lenses reported better subjective vision, comfort and overall satisfaction than those wearing frequent replacement lenses.⁹ Furthermore, many recently-developed daily disposable contact lenses have enhanced lubricating agents, which have been shown to reduce symptoms such as dryness and redness, as well as biomicroscopy signs and ocular allergies.^{10,11} The lens type used in this study was DAILIES® AquaComfort Plus® (Alcon Inc., Fort Worth, TX) daily disposable contact lenses made from nelfilcon A, which elutes polyvinyl alcohol (PVA) as the wearer blinks to reduce discomfort and irritation, and to support a stable tear

film^{10,12,13}, it is also supplied in a lens blister containing two wetting agents, polyethylene glycol and hydroxypropyl methylcellulose.¹⁴ Daily disposable contact lenses may be a suitable alternative to spectacles for teenagers who require vision correction.

By understanding the perceived benefits of contact lens wear in teenagers, as well as gaining insight into their wear experience, eye care practitioners will be better able to discuss vision care choice with this demographic group. The aim of this study was to compare clinical and self-assessed quality of life (QoL) data for current full-time spectacle-wearing teenagers randomized to wear spectacles or nelfilcon A daily disposable contact lenses for vision correction over a 6-month study period.

METHODS

This was a randomized, controlled, open-label, parallel-group study. Teenagers with no previous contact lens wear experience were randomized to wear either spherical nelfilcon A daily disposable contact lenses or spectacles for 6 months. Subjects assigned to the spectacle group selected a new pair of spectacles at the start of the study. Ophthalmic lenses were chosen as advised by an optometrist or dispensing optician. All subjects were asked to wear their study vision correction (contact lenses or spectacles) for a minimum of 8 hours per day for a minimum of 5 days per week, and for at least 2 hours prior to study visits.

The main inclusion criteria were subjects aged 13–19 years, who were current full-time spectacle wearers with no previous contact lens experience; could attain at least 6/9 vision in each eye with study optical correction; had refractive cylinder in each eye of 0.75D or less; and vision could be corrected in the range of ± 10.00 D to ± 6.00 D (ocular refraction). The main exclusion criteria included any ocular or

systemic disorder that would contraindicate contact lens wear; current use of topical ocular medication; previous cataract or corneal refractive surgery; keratoconus; pregnancy or lactation; any infectious disease such as hepatitis; any immunosuppressive disease such as human immunosuppressive virus; diabetes; and participation in any other clinical research within 2 weeks of starting the study.

Subjects attended six study visits: an information and consent visit, an initial study visit, a collection/dispensing visit, and three follow-up visits at Week 4 and Months 3 and 6. An additional follow-up visit at Week 2 was required for the subjects in the contact lens group only. As part of the collection visit, all subjects randomized to receive contact lenses were instructed on lens handling, usage, and care before being dispensed with contact lenses. An additional handling session was arranged before contact lenses were dispensed if further training was required. The contact lens group had their lens fit assessed using the following evaluations: horizontal and vertical centration, corneal coverage and movement. For an acceptable fit, centration and movement were within currently accepted clinical criteria (between -1 and $+1$ on a -2 to $+2$ Grading Scale).¹⁵ All participants were questioned verbally at study visits to ascertain whether or not they were adhering to the study protocol regarding the time they wore their study vision correction method.

This study followed the tenets of the Declaration of Helsinki and was granted approval by the University of Manchester Senate Committee on the Ethics of Research on Human Beings. All subjects and guardians (if a subject was younger than 16 years) gave informed consent/assent prior to study enrollment.

Study Assessments

Full clinical workups, as well as subjective QoL measures using the Pediatric Refractive Error Profile (PREP)³ and Quality of Life Impact of Refractive Correction (QIRC) questionnaires,¹⁶ were conducted at baseline and study visits at Week 4, Month 3, and Month 6, with an additional study visit at Week 2 for subjects randomized to wear contact lenses. The full clinical workup included refraction and distance monocular logMAR visual acuity (both high and low contrast), auto-keratometry measures, and slit lamp biomicroscopy. Signs from the slit lamp biomicroscopy included: conjunctival redness, limbal redness, corneal neovascularization, epithelial microcysts, corneal edema, corneal staining, location of staining, conjunctival staining, and papillary conjunctivitis. Signs were scored to the nearest 0.1 in the best judgment of the investigator using Efron Grading Scales.

The PREP questionnaire, designed to quantify QoL measures in children who are affected only by refractive error, comprises 26 statements grouped into 10 scales: Overall vision, near vision, far vision, symptoms (i.e. statements regarding eye, nose, or ear pain), appearance, satisfaction, activities (i.e. statements about playing outdoors, sports, or dancing), academics (i.e. statements regarding achievement at school or on tests), handling and peer perceptions. The participants read the statements and marked them with “strongly agree,” “agree,” “neutral,” “disagree,” or “strongly disagree”. Each item is then scored from 1 (negative) to 5 (positive) then scaled from 0 (poor quality of life) to 100 (excellent quality of life). Each of the 10 scales are is scored by averaging the scores of the statements that make up the scale. The overall PREP score is the average of all 26 items.³ The QIRC questionnaire quantifies QoL of people with refractive correction by spectacles, contact lenses, or refractive surgery.¹⁶

Scores for subjective vision and happiness and vision were collected weekly using automated short message service (SMS). Subjects were asked to rate both their happiness and vision with their corrective type according to the following rating scale: 1, “very poor”; 2, “poor”; 3, “neither”; 4, “good”; and 5, “very good.” Subjects were instructed to respond “N” if they were not wearing their spectacles or contact lenses. An “Attitudes to contact lenses” questionnaire was also conducted at study start and Month 6 (Exit Visit).¹⁷ Participants were asked to score five statements on a 5-point Likert scale (1, strongly disagree; 2, disagree; 3, neither agree nor disagree; 4, agree; 5, strongly agree).

For safety assessments, pre-existing conditions were documented as “existing” and adverse events (AEs) that occurred during the study period were recorded.

Statistical Analyses

Differences between the two groups for the number of discontinuations were compared using the Fisher’s test for proportions. Results from biomicroscopy and the PREP and QIRC questionnaires were compared for study visits at Week 4, Month 3, and Month 6 using linear regression model with age, sex, visit, and correction type (contact lenses or spectacles) as the factors of interest. The values at baseline were compared using a paired t-test to ratify the randomized study design. Visual acuity was assessed using the same linear regression model for study visits at baseline and Week 4, Month 3, and Month 6.

RESULTS

Population Demographics and Baseline Characteristics

A total of 113 subjects were recruited, of whom 110 were enrolled in the study (Fig. 1). Baseline characteristics were comparable for both the study groups (Table 1). Thirteen subjects discontinued before study completion, 10 (17.5%) from

the contact lens group and three (5.7%) from the spectacle group. The difference in discontinuation rates for the two groups was statistically significant ($p = 0.04$). Most of the contact lens group discontinuations ($n = 8$) were at or before the Week 4 study visit. Four subjects in the contact lens group discontinued due to discomfort, three of these discontinuations took place during or after the Week 2 visit. Reasons for study discontinuation are listed in Table 2.

Visual Acuity

Visual acuity was good for both the contact lens and spectacle group at all study visits (high-contrast visual acuity: ranged between mean $\pm$ standard deviation logMAR -0.07 ± 0.08 and -0.05 ± 0.08 for the contact lens group, and between logMAR -0.10 ± 0.07 and -0.08 ± 0.08 for the spectacle group; low-contrast visual acuity: ranged between 0.16 ± 0.10 and 0.17 ± 0.10 for the contact lens group, and 0.13 ± 0.08 and 0.14 ± 0.09 for the spectacle group). Although there were significant differences between the two groups for visual acuity recorded at the collection visit, the actual differences were small. For example, at the collection visit, subjects in the spectacles group scored approximately half a line better than the contact lens group for high-contrast visual acuity ($p = 0.03$). Spectacle wearers also scored between one and two letters better than contact lens wearers ($p = 0.02$) for low-contrast visual acuity; this difference is not normally considered to be clinically meaningful. No other significant differences were observed between the study groups for visual acuity at other time points.

Contact Lens Fit and Surface Characteristics

All subjects in the contact lens group had acceptable contact lens fit in each eye at all study visits, except for the Month 3 visit when 98% of subjects had acceptable contact lens fit. One subject had excessive lens movement of the study lens in one

eye during the study visit at Month 3 only as reported by the investigator. No differences were observed in contact lens surface characteristics across visits for deposition, post-lens debris, or wettability.

Biomicroscopy Assessments

Biomicroscopy assessment scores were similar at baseline for both study groups (Table 3). No significant differences between study groups were observed across all subsequent study visits for conjunctival hyperemia, limbal hyperemia, corneal vascularization, microcysts, edema, corneal staining, or papillary conjunctivitis ($p > 0.05$). Across all follow-up visits, higher levels of corneal staining ($p < 0.001$) and conjunctival staining ($p < 0.001$) were seen in contact lens wearers compared with spectacle wearers (0.26 of a grading unit for each biomicroscopic sign); however, within the contact lens group, the visit and group interaction was significant ($p = 0.02$). Post-hoc assessments showed significantly lower conjunctival staining scores at the Month 6 visit compared with those at the Week 4 or Month 3 visits ($p < 0.05$ for both comparisons). No significant difference was seen between the scores at Week 4 and Month 3.

Quality of Life

The PREP questionnaire baseline results showed no significant differences between the two study groups. Significant differences in PREP responses were noted for each group across different study visits for appearance ($p < 0.001$), satisfaction ($p < 0.001$), activities ($p < 0.001$), peer perception ($p = 0.003$), and overall score ($p < 0.001$). In each case, post-hoc analysis indicated that the key difference was at the Month 1 visit where scores for the contact lens group were greater than those for the spectacle group at the $p = 0.05$ level. These differences were not seen at later study visits. A significant group-by-visit interaction was also noted for handling ($p = 0.03$). Post-hoc analysis indicated that the key difference was between the

Month 1 and Month 6 visits for contact lens wearers, with the score at Month 1 being highest and the score at Month 6 being lowest.

For the academics subscale (regarding whether the participant did better at school or tests while wearing the study visual correction method) and overall vision PREP scores, no such significant interaction term was demonstrated. However, differences were seen for the two groups ($p < 0.001$ for both academics and overall vision) suggesting that the differences were seen across all study visits. No difference was observed between the two study groups for “symptoms”.

The age of the subject was shown to influence PREP scores, regardless of vision correction method, with scores significantly increasing with age for the overall PREP scores ($p = 0.01$) and for some of the individual components of the PREP questionnaire (“overall vision,” $p = 0.005$; “far vision,” $p = 0.004$; “near vision,” $p = 0.04$; “symptoms,” $p = 0.01$; “satisfaction,” $p < 0.001$; “handling,” $p = 0.04$). Similarly, the sex of the subjects was shown to influence PREP scores: “appearance” was scored approximately 10 points lower by females compared with males ($p < 0.001$), “satisfaction” was scored approximately 6 points lower by females compared with males ($p = 0.04$), and “activities” were scored approximately 8 points higher by females compared with males ($p = 0.01$). The differences in PREP scores corresponding to age and sex were apparent at all study visits.

For the QIRC questionnaire results, the contact lens group gave more favorable responses than the spectacle group ($p = 0.02$). Over the course of the study period, mean QIRC scores were as follows: at baseline, 43.9 versus 46.2; Week 4, 49.0 versus 46.7; Month 3, 48.6 versus 46.3; and Month 6, 48.0 versus 45.1 for the contact lens versus spectacles groups, respectively. There was no difference between the two groups at the initial visit ($p=0.10$).

219

220 After wearing contact lenses for 6 months, subjects' attitudes towards contact lens
221 wear were generally more favorable regarding the comfort, vision, and safety of
222 contact lenses compared with subjects who had been wearing spectacles and also
223 compared with attitudes at baseline. This was demonstrated by the responses to the
224 "Attitudes to contact lens wear" questionnaire. There were significant differences
225 between the two study groups. For the statement "I think contact lenses are a good
226 way of making me see well," significant differences were seen in terms of vision
227 correction group with contact lens wearers scoring higher than spectacle wearers
228 ($p < 0.001$). Furthermore, both groups also scored higher at the exit visit compared
229 with baseline ($p < 0.001$). Similar differences were observed for the statements "I
230 think contact lenses are a good way of making me look good," "I think contact lenses
231 are comfortable," and "I intend to wear contact lenses in the future" (Table 4).

232

233 The SMS data showed similar responses for vision and happiness over time for both
234 study groups, with scores for each parameter increasing slightly over time. No
235 differences were observed between vision correction types for either happiness
236 ($p = 0.59$) or vision ($p = 0.10$).

237

238 **Safety**

239 No serious AEs were reported during the study. Four contact lens-related AEs
240 occurred in four subjects (contact lens peripheral ulcer (CLPU), $n = 1$; inactive
241 corneal scar, $n = 3$). The 19-year-old female subject with CLPU discontinued the
242 study at Month 3 because of subsequent topical medication (chloramphenicol) and
243 the CLPU was resolved at a follow-up visit 21 days later leaving a small scar. There
244 were no reported compliance issues with this subject. The three subjects with
245 inactive corneal scars were also female, aged between 14 and 18 years. None of the

subjects with inactive corneal scar required additional treatment and all were resolved at presentation.

DISCUSSION

This randomized, controlled study demonstrated that nelfilcon A contact lenses offer a satisfactory alternative to spectacles for vision correction in teenagers. Visual acuity was generally good for both correction types, with mean high-contrast acuity scores better than 20/20 for both correction types at all visits. A slight advantage in vision was observed for the spectacle group over the contact lens wearers at the collection visit, but this may have been a result of the restriction in the clinical study of using only spherical contact lenses. In a general contact lens practice environment, many of the subjects with 0.75 diopters of cylinder (DC) refractive astigmatism would have been offered a toric contact lens and similar visual performance to spectacles would be expected.

Contact lens fit was good for all but one subject across all visits, and all other fits were classified as adequate or better. No differences in contact lens surface characteristics were observed at any study visit, as would be expected for daily disposable contact lenses. Eye care practitioners should expect a high level of fitting success (close to 100%) when fitting this lens type to children in the age group studied here. There were no problems with contact lens handling among this age group, with PREP “handling” scores for the contact lens group similar to scores for the spectacles group (Fig. 2). Moreover, the teenagers who participated in this study showed that they could easily learn to wear contact lenses. The vast majority of subjects had a single, successful handling session. Two subjects were unable to handle lenses – one subject withdrew consent after a single handling session, and one failed three handling sessions and was thus discontinued.

274 There were more subjects who discontinued in the contact lens group compared with
275 the spectacles group. Discontinuation from contact lens wear was more likely to
276 happen within the first month; this included discontinuations due to discomfort, which
277 mainly took place at, or just after, the Week 2 study visit as a result of a range of
278 adaptation factors (Table 2b). These results are similar to discontinuation rates for
279 silicone hydrogel wearers in adults.¹⁸ A follow-up visit within 2 weeks of starting
280 contact lens wear is likely to be important to address any queries that a new wearer
281 might have (e.g. comments on lens comfort) and to maximize the likelihood of
282 contact lens success.

283
284 No differences in biomicroscopy scores were observed between the two vision
285 correction groups for limbal hyperemia, conjunctival hyperemia, corneal
286 vascularization, microcysts, edema, or papillary conjunctivitis. Although no
287 differences might have been expected for vascularization, microcysts, and edema –
288 as these are usually related to moderate levels of hypoxia unlikely to be present with
289 the nelfilcon A contact lens used in this study – some differences might have been
290 expected for the other monitored signs. Papillary conjunctivitis is commonly
291 associated with ongoing contact lens wear. The lack of difference between the
292 contact lens wearers and the spectacle wearers by the Month 6 study visit suggests
293 a minimal response of the tarsal conjunctiva to the contact lens surface, which may
294 have been aided by the type of daily disposable contact lenses used in this study.
295 The absence of hyperemia in this study for the contact lens wearers suggests
296 minimal physiological changes related to ocular surface oxygenation and mechanical
297 impact with the study contact lens. However, contact lens wearers scored 0.25
298 grading units higher than spectacle wearers for both corneal staining and conjunctival
299 staining. Although the difference is interesting to note, the level of staining would not
300 be considered clinically significant. Furthermore, the absolute mean scores were
301 around 0.4 and 0.5 grading units for corneal and conjunctival staining, respectively,

showing minimal physiological response to the study contact lens. The biomicroscopy findings are in agreement with the overall safety findings in the study. The rate of AEs in the short term (up to 6 months) is low for teenagers who are new contact lens wearers.

The PREP questionnaire responses, in relation to contact lens wearer responses, were more favorable at the Week 4 study visit for appearance, satisfaction, activities, peer perceptions, and overall score. These higher scores tended to diminish at subsequent study visits. Within the spectacle wearer group, scores for all of the PREP categories remained stable, suggesting that the score change over time observed for the contact lens wearer group is not an artifact or a result of questionnaire fatigue. The change in score for the contact lens wearers is most likely attributed to an adaptation process of the wearers, since contact lens performance was likely to be similar at Week 4 and Month 6. At Week 4, the contact lenses are still new and the improvements delivered in terms of appearance and satisfaction are easy for the wearer to compare with the “pre-contact lens” situation. However, after several months of contact lens wear, comparisons are less easy to make and it is likely that the wearer’s frame of reference has been altered. In other words, the benefits of contact lens wear are no longer seen as exciting and new, but simply as the “new normal.” As all subjects were prior spectacle wearers, the subjects in the spectacles group did not have a novel comparison in terms of reference and their scores remained consistent over the 6-month study period. As all subjects had prior experience of spectacles but none had experience of contact lenses, this introduces a **potential bias** ~~confounding factor~~ when it comes to interpreting the PREP responses. Other studies have shown that appreciation changes over time.^{19,20} In light of these findings, eye care practitioners may find it beneficial to arrange an additional follow-up visit at around 4 weeks after initiating contact lens wear to reinforce the positive performance of contact lenses at this stage, and reflect on this

at later visits when subjective perception might be lower, resulting from increasing familiarity with contact lenses as a vision correction option. Importantly, the group experienced some clear, overall benefits in wearing contact lenses. After 6 months of wearing contact lenses, teenagers in this group had a more positive attitude towards contact lenses in terms of comfort, safety, and vision compared with their attitudes at baseline ~~and also compared with subjects in the spectacle group (i.e. who had no contact lens experience).~~

Psychological differences occurred for PREP scores depending on the age of subjects, reflecting how the maturity of the subjects affects questionnaire interpretation – scores tended to increase with age for both the contact lens group and spectacle group. In addition, for some assessments, such as appearance or activity, female and male subjects tended to give different responses, with girls giving lower “appearance” scores but higher “activity” scores compared with boys. These differences may be important when considering contact lenses for a given individual.

QoL was shown to favor contact lens wear over spectacles, based on the QIRC questionnaire. The QoL data is supported by the changes in attitudes to contact lenses from the start of the study compared with the study end. Contact lens wearers generally gave more positive responses compared with spectacle wearers. Furthermore, for the contact lens group, the overall impression of their contact lenses was better after 6 months’ experience using contact lenses than their initial expectations.

Other studies have investigated contact lens wear in teenagers, but not all have investigated QoL measures.^{3,21,22} One study that did assess QoL in children and teenagers who had vision correction with either contact lenses or spectacles showed that appearance and activities are the areas of most benefit with contact lenses,

which led to an overall improvement in satisfaction with contact lenses compared with spectacles.³ Walline et al. showed that there are benefits for teenagers wearing contact lenses rather than spectacles for vision correction for at least 3 months (study duration) in terms of improved PREP scores from baseline to study end.³

The results from this current study highlight the potential benefits of contact lenses in this age group; however, the findings are not without limitations. Longer-term data would be required to see whether PREP scores are sustained for periods longer than 6 months. In addition, this study included current spectacle wearers; therefore, comparisons have been made between a familiar method of vision correction (spectacles) and a novel method of vision correction (contact lenses) for the participant. This may have introduced a novelty bias to the new vision correction method; however, as attitudes to contact lenses remained positive after 6 months experience, this suggests that the benefits of wearing contact lenses did not decline over time. Furthermore, as only one type of contact lens was tested, the results of this current study may not predict the experience with other types of daily disposable contact lenses.

In conclusion, results from the present study showed that nelfilcon A daily disposable contact lenses are suitable for vision correction for teenagers, offering improvements in QoL measures during the first month of wear, including appearance, satisfaction, activities, and peer perceptions, without negatively impacting vision or eye health. Moreover, teenagers were able to handle contact lenses with the same amount of confidence as when handling spectacles.

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Conflicts of Interest

Jami Kern is an employee of Alcon Research Ltd. Andrew J. Plowright, Carole Maldonado-Codina, Gillian F. Howarth, and Philip B. Morgan have no conflicts of interest to declare.

Previous Presentations

Interim results from this study were presented at the American Academy of Optometry (AAO) Annual Meeting: October 24–27, 2012; Phoenix, Arizona. This study was presented in part at the British Contact Lens Association Annual Meeting: June 6–9, 2013; Manchester, United Kingdom; and AAO Annual Meeting: October 23–26, 2013; Seattle, Washington.

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477 **TABLE 1.**

478 Subject demographics and baseline characteristics

	Contact lenses	Spectacles	Total subjects
	(n = 57)	(n = 53)	(n = 110)
Male, n (%)	25 (43.9)	22 (41.5)	47 (42.7)
Age, years*	16.2 ± 1.8	16.3 ± 2.0	16.2 ± 1.9
Best sphere, DS	−2.20 ± 2.15 (−9.13 to 4.75)	−1.35 ± 2.28 (−5.88 to 4.75)	−1.79 ± 2.25 (−9.13 to 4.75)
Cylinder, DC*	−0.32 ± 0.28 (−0.75 to 0.00)	−0.29 ± 0.28 (−0.75 to 0.00)	−0.30 ± 0.28 (−0.75 to 0.00)

479 *Data are the mean ± standard deviation (range).

480 DC, diopters of cylinder; DS, diopters of sphere

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1 **TABLE 2.**

2 Reasons for discontinuation (a) and details of discontinuation due to discomfort (b)

3 (a)

	Contact lenses	Spectacles
n (%)	(n = 57)	(n = 53)
Number of subjects who discontinued	10 (17.5)	3 (5.7)
Failure to attend study visits	1 (1.8)	1 (1.9)
Failed training sessions	2 (3.6)	0
Failure to pick up study spectacles/contact lenses	1 (1.8)	2 (3.8)
Lens discomfort	4 (7.0)	0
Adverse event	1 (1.8)	0
Personal reasons	1 (1.8)	0

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(b)Subject	Right eye	Wearing schedule	Reason for discontinuation
16-year-old female	-2.50/-0.25x170	5 days per week, 8 hours per day	Dry and itchy eyes after first 4 hours of wear
14-year-old male	-4.50/-0.25x160	6 days per week, 5 hours per day	Poor comfort/vision with lenses
15-year-old male	-1.75/0.00	7 days per week, 8 hours per day	Some discomfort with lenses
16-year-old female	+3.75/-0.25x10	6 days per week, 15 hours per day	Lenses took a while to settle, eyes felt dry and sore

7 **Table 3.**

8 Slit lamp biomicroscopy results

		Initial visit*	Week 2	Week 4	Month 3	Month 6
No. of subjects	Contact lenses	57	52	46	47	47
	Spectacles	53	NA	42	48	50
Conjunctival hyperemia	Contact lenses	0.91 ± 0.20	0.88 ± 0.24	0.85 ± 0.23	0.92 ± 0.22	0.88 ± 0.17
	Spectacles	0.91 ± 0.20	NA	0.92 ± 0.23	0.90 ± 0.23	0.90 ± 0.21
Limbal hyperemia	Contact lenses	0.79 ± 0.24	0.76 ± 0.25	0.73 ± 0.28	0.79 ± 0.22	0.78 ± 0.21
	Spectacles	0.81 ± 0.21	NA	0.79 ± 0.25	0.77 ± 0.26	0.78 ± 0.24
Corneal vascularization	Contact lenses	0.00 ± 0.03	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.01
	Spectacles	0.00 ± 0.00	NA	0.00 ± 0.00	0.00 ± 0.01	0.00 ± 0.01
Microcysts	Contact lenses	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
	Spectacles	0.00 ± 0.00	NA	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Edema	Contact lenses	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
	Spectacles	0.00 ± 0.00	NA	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Corneal staining	Contact lenses	0.15 ± 0.21	0.39 ± 0.40	0.34 ± 0.39	0.44 ± 0.39	0.37 ± 0.37

	Spectacles	0.13 ± 0.20	NA	0.10 ± 0.1 9	0.14 ± 0.29	0.13 ± 0.24
Conjunctival staining	Contact lenses	0.22 ± 0.14	0.53 ± 0.32	0.53 ± 0.29	0.58 ± 0.33	0.42 ± 0.20
	Spectacles	0.22 ± 0.16	NA	0.20 ± 0.15	0.28 ± 0.19	0.26 ± 0.17
Papillary conjunctivitis	Contact lenses	0.95 ± 0.21	0.99 ± 0.22	0.99 ± 0.28	1.02 ± 0.20	1.05 ± 0.21
	Spectacles	0.97 ± 0.28	NA	0.97 ± 0.2 0	0.95 ± 0.22	0.99 ± 0.23

9 Values are mean ± standard deviation Efron Grading Scale scores for each treatment group at study visit (scored to the nearest 0.1 in the best
10 judgment of the investigator). *The initial visit took place before the study contact lenses or spectacles were dispensed. NA, not applicable.

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14 **TABLE 4.**

15 Subject attitudes to contact lens wear

Question	Initial visit		Exit visit		p value	
					Contact	
	Contact lenses (n = 57)	Spectacles (n = 52)	Contact lenses (n = 46)	Spectacles (n = 50)	lenses vs. spectacles*	Exit visit vs. initial visit
I think contact lenses are a good way of making me see well	4.40 ± 0.70	4.00 ± 0.86	4.96 ± 0.21	4.24 ± 0.77	< 0.001	< 0.001
I think contact lenses are a good way of making me look good	3.89 ± 0.92	4.04 ± 0.74	4.26 ± 0.71	4.08 ± 0.86	0.81	0.04
I think contact lenses are safe	4.12 ± 0.71	3.71 ± 0.85	4.41 ± 0.78	3.64 ± 0.80	< 0.001	0.27
I think contact lenses are comfortable	3.19 ± 0.58	3.04 ± 0.63	4.46 ± 0.62	2.96 ± 0.57	< 0.001	< 0.001
I intend to wear contact lenses in the future	4.11 ± 0.86	3.81 ± 1.05	4.74 ± 0.53	4.12 ± 0.87	0.003	< 0.001

16 Data are mean ± standard deviation, based on scores 1–5 where 1 = strongly disagree and 5 = strongly agree. All visit and group interaction
 17 terms $p > 0.05$.

18 *p values were calculated using a linear regression model.

19 **FIGURE LEGENDS**

20 **FIGURE 1.**

21 Study flow diagram

22 *n = 53 subjects in total; of these one discontinued at study visit, 52 had valid
23 datasets (one ongoing visit significant out of range).

24 †n = 49 subjects continuing; of these 46 had valid datasets (three significantl
25 range).

26 ‡n = 49 subjects in total; of these, 47 continuing, two discontinued at study vi
27 47 had valid datasets (two ongoing visit significantly out of range).

28 §n = 50 subjects continuing; of these 42 had valid datasets (four subjects fail
29 attend; four visits significantly out of range).

30 ¶n=50 subjects continuing; of these 48 had valid datasets (two visits significa
31 of range).

32

33 **FIGURE 2.**

34 Pediatric refractive error profile (PREP) scores for individual components du
35 6-month study period. The PREP questionnaire comprises 26 statements wh
36 marked as “strongly agree,” “agree,” “neutral,” “disagree,” or “strongly disagr
37 Each item is scored from 1 (negative) to 5 (positive) then scaled from 0 (poor
38 of life) to 100 (excellent quality of life). Ten scales are scored by averaging th
39 that make up the scale. The overall PREP score is the average of all 26 item
40 numbers at each time point were as follows: initial – contact lenses, n=56 (e.
41 the “near vision” and “activities” measures where n=55, and for the “satisfact
42 measure where n=57), spectacles, n=53 (except for the “satisfaction” measu
43 n=54); 2 weeks – contact lenses, n=53; 4 weeks - contact lenses, n=49, spe
44 n=46; 3 months – contact lenses, n=49; spectacles, n=49; 6 months – contac
45 n=47, spectacles, n= 49 (except for the “satisfaction” measure where n=50).
46 bars represent standard deviations.

[To authors: The revised figure 2 is included below for your review. It will, however, be submitted separately as requested.]