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A contra-lateral comparison of the visual effects of a photochromic vs. non-photochromic contact lens

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ABSTRACT

Purpose: To compare the effects of a photochromic contact lens vs. a non-photochromic control lens on visual function.

Methods: A subject-masked, prospective contralateral eye design was used. Sixty-one subjects were enroled based on age (using a 2:1 allocation ratio for ages 18–39 and 40–65 years, respectively). The study lenses were senofilcon A with photochromic additive (Test) that filtered over the entire lens, compared to a non-photochromic Control with no tint. The Test lens was partially activated during testing with a steady-state transmittance of approximately 62%. Eligible subjects were tested using both study lenses, with Test and Control lens randomized by eye. Five visual function outcomes were tested: photostress recovery (PSR), glare disability (GD), glare discomfort (GDC), chromatic contrast (CC) and vernier acuity (VA). Iris colour and macular pigment density were assessed as control variables. PSR was measured as the time needed to recover sight of a target after an intense xenon flash exposure; GD was evaluated as the energy needed to veil a central target by a surrounding xenon annulus; GDC was measured using bio-imaging of the squint response and by self-report using a 9-item Likert scale; CC was measured as thresholds for a yellow grating target superposed on a 460-nm background; VA was determined by measuring vernier offsets of light lines through apertures.

Results: Based on our stimulus conditions, PSR was 43% faster using the Test vs. the Control. The eye wearing the Test had 38% less squint (GDC) compared to the Control. GD was improved by 36% in the Test vs. Control and CC was enhanced by 48% with the Test. There was no significant difference in VA.

Conclusions: There was a beneficial influence on visual function when comparing the photochromic with the non-photochromic contact lens. This benefit was seen specifically with respect to PRT, GDC, GD and CC thresholds.

1. Introduction

The evolution of contact lenses (reviewed by [1]), like many ideas in Vision Science, dates back to the work of luminaries, starting with the writings of Leonardo Da Vinci (1508), the experimental water tubes of Rene Descartes (1636) and later, fluid neutralization by Thomas Young (1801). In the late 1800s, actual contact between eye and lens was made, with glass covering the entire ocular surface. It was not until the mid-1900s however, that contact lenses started to resemble those in use today (e.g., gas permeable and smaller in diameter).

Since those original experiments, the evolution of contact lenses has largely been guided by a few basic goals: ease/comfort of use (e.g., going from hard to soft hydrogels), increased oxygen permeability, and correcting refractive errors (albeit using increasingly sophisticated approaches such as bifocals and orthokeratology). Less attention has been paid to contact lens designs that address other aspects of vision. This is significant because, of course, vision in the real world is limited by many other variables than simple refraction (e.g., myopia was historically rare [2]). One example is visual function under bright light conditions. Glare generally refers to a condition where individuals are exposed to a light source, either direct or indirect, that is in excess of their adaptive state [3]. Such light can cause both discomfort and

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disability (a reduction in visual performance). Not surprisingly, most organisms have evolved mechanisms for dealing with the bright light of the sun [4]. For example, humans have brow ridges and intraocular filters such as melanin and retinal macular pigments [5]. Contact lenses, in contrast, are generally transparent to visible light and hence generally do not influence visual function in bright light conditions; although they may, in some cases, increase scatter and worsen vision in such circumstances [6].

Improving vision in bright light conditions was the main motivation for the creation of tinted spectacle lenses (sunglasses) or the even more recent strategy of photochromic spectacles (e.g. [7]). Such lenses are well known to reduce glare issues [8] but appear to influence other aspects of vision as well. For instance, similar to natural intraocular filters [9], tinted lenses can improve chromatic contrast under real world conditions based on enhancing chromatic borders [9,10].

A less common strategy is the use of filtering contact lenses. Contact lenses with a fixed tint were tried some years ago in individuals who were very susceptible to visual issues under bright light conditions, namely athletes. Such lenses were successful (improved performance under naturalistic conditions, [11,12] but were not marketed for wide-scale use, in part because they also covered the sclera and hence were not aesthetically pleasing (not to be confused with coloured contacts which are designed, not to influence function but, rather, to change iris colour for aesthetic reasons). A different strategy is to vary the tint according to ambient light levels. Hence, the design of a photochromic contact lens that filters in a dose-dependent manner depending on the intensity and wavelength of light in the environment. In this study, we tested the hypothesis that a photochromic contact lens would improve visual function by reducing the deleterious effects of intense light and intraocular scatter: specifically, we used the endpoints glare disability and discomfort, photostress recovery, chromatic contrast and hyperacuity.

2. Methods

2.1. Ethics

The study was performed in accordance with ISO 14,155:2011 (Clinical investigation of medical devices for human subjects) and followed the tenets of the Declaration of Helsinki. Written and verbal informed consent was obtained from each participant prior to participation. All study related protocols and materials were approved by the Sterling Institutional Review Board; Atlanta, GA. The University of Georgia Institutional Review Board was also notified of all study-related procedures and maintained a copy of the study protocol and materials.

2.2. Subjects

This study utilized a prospective, randomized, subject-masked contralateral eye design (i.e. a different study lens in either eye). Subjects were required to be adapted wearers of spherical silicone hydrogel soft contact lenses and be in the age range of 18–65 years. Subjects were stratified into two age groups (18–39 years [M = 27.1, sd = 6.4 years] and 40–65 years [M = 51.9, sd = 6.9 years]) using a 2:1 allocation. The following inclusion criteria were applied: subjects were between 18–65 years of age and could read understand and sign a statement of informed consent; the subject was an adapted wearer of the test or control lens or other spherical silicone hydrogen soft contact lens in both eyes (adapted means at least five days per week, six hours per day for at least 30 days prior to the study); The subject's vertex corrected spherical equivalent distance refraction had to be in the range of −1.00 to −4.50 D in each eye and best corrected acuity was 20/25 or better in each eye. Exclusion criteria included: Currently pregnant or breastfeeding; Any ocular or systemic allergies or diseases that could interfere with contact lens wear; Any autoimmune disease or use of medication, which could interfere with contact lens wear; Entropion, ectropion, extrusions, chalazia, recurrent styes, glaucoma, history of recurrent corneal erosions, or aphakia; Any previous, or planned, ocular or interocular surgery (e.g., radial keratotomy, PRK, LASIK, etc.); Any grade 3 or greater slit lamp findings (e.g., edema, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival injection) on the FDA classification scale; any previous history or signs of a contact lens-related corneal inflammatory event (e.g., past peripheral ulcer or round peripheral scar), or any other ocular abnormality that may contraindicate contact lens wear; Any ocular infection; Any corneal distortion resulting from previous hard or rigid gas permeable contact lens wear; Toric or extended wear contact lens correction.

Participation in any contact lens or lens care product clinical trial within 14 days prior to study enrollment; Any history of binocular vision abnormality or strabismus; Any infectious disease (e.g., hepatitis, tuberculosis) or contagious immunosuppressive diseases (e.g., HIV) by self-report.

All of these issues were evaluated by the attending clinician (subjects were ineligible if they were grade three or higher using the FDA Slit Lamp Classification Scale [13]). A total of 61 subjects were enrolled (i.e. signed consent form) and, ultimately, 58 subjects met all eligibility criteria and were included for the final analysis. Of the subjects included in the final analysis, 45 (77.6%) subjects were female and 13 (22.4%) subjects were male. The majority of the subjects were Caucasian (n = 38, 65.5%). The average age for all subjects (SD) was 34.6 (12.9) years.

Iris colour, eye dominancy, and macular pigment optical density (MPOD)

Iris colour was classified based on matching hue to a photographic scale (ranging from light grey to dark brown, with blue, green and hazel variants in between) [14]. Determining eye dominancy was first attempted by the monocular blur in a binocular field test [15]. If this failed, then the sighting test was used [15]. MPOD was measured at peak absorbance (460 nm) using a one-degree test stimulus and a standardized method (customized heterochromatic flicker photometry; for details regarding equipment see [16] and for procedure see [17]).

2.3. Apparatus

The primary endpoints were 5 visual function outcomes: photostress recovery (PSR); glare disability (GD) and discomfort (GDC); chromatic contrast (CC); and vernier acuity (VA). These specific visual functions were selected based on past studies [7,9,18–21] showing visual characteristics that might be expected to be influenced by selective filtering such as that provided by a photochromic contact lenses. All tests (except VA) used the same apparatus, modified for each parameter (for details see [21]). The glare source (annulus/disk) and the visual target were produced by a 1000 W xenon arc point source lamp with a modified housing that allowed dual-channel exit (Newport Optics; Irvine, CA). Alignment of the subject's eye with the optical system was maintained with a forehead rest and a dental impression bite bar that was custom-fit for each subject. An auxiliary optical channel with a high-resolution camera and monitor was used to observe the pupil during testing to ensure proper fixation and sustained alignment, and was used along with biometric software (Amscope, Irvine, CA) to measure GDC.

All photometric calibrations (both in the visible and ultraviolet) were performed using an ILT 950 spectroradiometer (International Light Technologies, Peabdoy MA). Wedge and neutral density radiometric calibrations were performed using a Graseby Optronics United Detection Technology (UDT) instrument (Model S370, Orlando, FL). The same UDT instrument was used before every experimental session to ensure that the total light output of the optical system remained constant and consistent throughout the study.

2.4. Experimental contact lenses

The photochromic Test contact lenses and the untinted Control

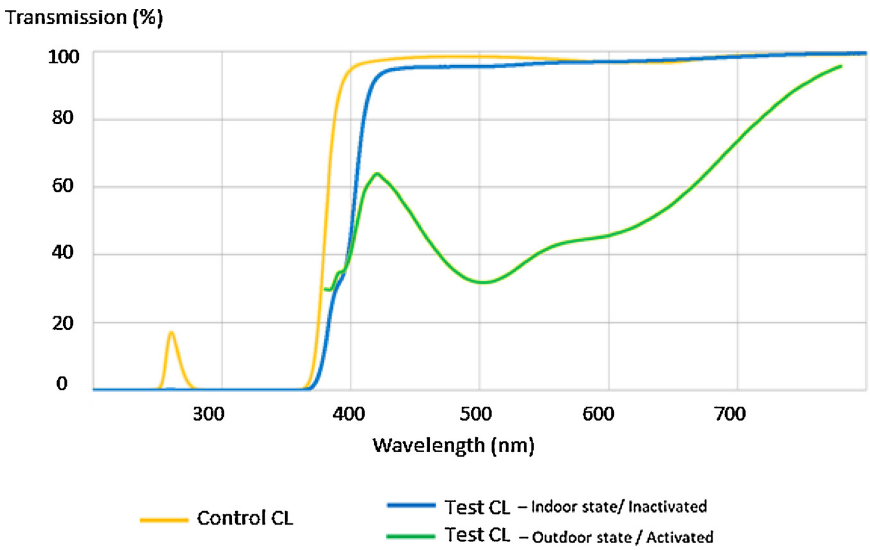

Fig. 1. Transmission profiles of the contact lenses used. The blue line shows the transmission of the clear control lens; the green line shows the photochromic lens in its activated state. A small control study (n = 3) was conducted to measure on-eye light transmission. During this study, the photochromic lens had an optical density of about 0.21 when activated.

contact lenses (of similar base monomer but no photochromic additive) used in the study were provided by Johnson & Johnson Vision Care, Inc. (Jacksonville, FL). The photochromic Test lens was a silicone-hydrogel contact lens that contained a photochromic additive throughout the entire lens. The transmission profile of the Test lens, at various levels of activation, and the Control lens is shown in Fig. 1. These lenses are able to transition between filtering and non-filtering states utilizing a photochromic additive.

We tested subjects who habitually wore contact lenses, and both Test and Control lenses were fitted by an attending clinician in a contralateral fashion. The eye wearing the Test lens was selected randomly. The Test photochromic contacts were tested partially activated at a steady state transmission of about 62%. This was determined for the experimental conditions in this study by testing the spectral sensitivity at 420, 460, 500, 540, 600, and 640 nm of three young subjects in the eye wearing the activated photochromic Test lens and the other eye wearing the Control lens (using identical conditions). Taking the difference of the two spectral sensitivity curves yielded a difference spectrum that represents wavelength absorbance. Across the wavelengths we measured the mean optical density was 0.21, SD = 0.06).

Activation of the photochromic was achieved using a violet activator consisting of LEDs that peaked at a wavelength of 400 nm (half bandpass = 10 nm). These LEDs were placed out of the optical path and an iris aperture was used to constrain the violet light to the approximate size of the contact lens. The violet LEDs were used, at a low constant rate, while all the visual measures (GD, CC, etc) were being collected in both conditions (the Test and Control lens). The overall energy at the plane of the eye was 24 mW (measured using an S370 Optometer, optimized at 400 nm). As a comparison, when the lights in the experimental room were turned on, the energy at the plane of the eye increased to 87 mW (i.e., the energy at the plane of the retina increased substantially by just turning on the overhead room lights). Hence, only a relatively low amount of energy from the violet LEDs was incident upon the eye during the experiment.

2.5. *The test target*

The visual target was the same in all the visual function tests (CC, GDC, GD, PSR), except for VA. The visual target was composed of a 580 nm 1.5°-diameter disk that contained a sine-wave grating with a spatial frequency of 16 lines/inch. This target was shuttered with one-second exposures separated by one-second delays.

2.6. *The background (annulus and solid field)*

The background channel was used to produce either an annulus (for GD; the bars of the annulus were 2° and the outer diameter was 15°) or a 15-degree background field (for GDC and PSR). A calibrated circular neutral density wedge was used to attenuate light in these fields when measuring GD and CC. For the chromatic contrast test, the same 15-degree background was filtered through a 460 nm interference filter (half bandpass = 8 nm; Edmund Optics; Barrington, NJ) in order to produce a monochromatic field. For GD, GDC and PSR, xenon was selected as the light source because of its characteristic broad band emission spectrum (as assessed by the SpectraScan colorimeter) with a CIE chromaticity of x = 0.35, y = 0.37, CCT = 4980 (see Fig. 1 in [21]). Xenon is widely regarded as a good match for sunlight. For example, in a study of 26 solar simulators [22], the authors noted that xenon-arc light sources match the most accurately. For PSR and GDC, subjects were exposed to the solid 15-degree field at high intensity (4.5 log Trolands) for five seconds.

In general, the procedure was similar to that reported in the past (see [21] for details). In brief, when measuring GD, subjects increased the intensity of the annulus until scatter was sufficient to veil the target. When measuring CC, the intensity of the blue field surrounding the target was increased to veil the central target. GDC was calculated as differences between the diameters of the palpebral fissure when not light stressed compared to the light stressed condition. After the photostressor was used to measure the squint response, subjects were also asked “how uncomfortable did you find the light that you just saw?” Their response was indicated by a scale from 1 (unbearable) to 9 (unnoticeable). PSR was determined by measuring the amount of time necessary for the subject to indicate (by pressing a buzzer) the reappearance of the target stimulus after the 5-second photostress exposure. Date from three trials per eye were collected for each visual function tested, except for PSR / subjective GDC, in which data from two trials per eye were collected.

2.7. *Vernier acuity*

VA was measured in negative mode, meaning the “lines” were actually thin rectangular apertures backlit with short-wave light (420 nm). Subjects sat 120 in. away from the target and the bars were 2 × 2 in. (0.05 in. wide). The bottom rectangular aperture was moved (the stimulus was blocked from sight while moving) and subjects performed a forced choice task indicating direction. Threshold was determined as the minimum distance required to accurately judge movement direction 75% of the time. Data from a total of 7 trials per eye were collected during the VA task.

2.8. Statistical analyses

PSR, GD, objective GDC (i.e. change in palpebral fissure height), CC thresholds and VA measurements were all analysed separately using a linear mixed model for repeated measures. Each model included lens type, age group, iris category, dominant eye indicator and MPOD as fixed effect factors. The two-way interactions between lens type and the remaining factors were also included in the model. A compound symmetry (CS) covariance structure was used to model the correlation between left eye and right eye measurements from the same subject. The Kenward and Roger method [23] was used for the denominator degrees of freedom. Comparisons between the Test and Control lenses were carried out using t-tests on the least-square means (i.e. adjusted means) differences (Test minus Control). All statistical tests were two-sided with 5% significance level. All data summaries and statistical analyses were performed using the SAS software Version 9.4 (SAS Institute, Cary, NC) [24].

3. Results

3.1. Photostress recovery and glare discomfort

Following intense light exposure, subjects wearing the photochromic Test contact lens were able to regain sight of the visual target significantly faster ($M = 5.98 \pm 2.69$ s) compared to the non-photochromic Control contact lens ($M = 9.60 \pm 3.44$ s). The least-square mean (LSM) difference was -4.03 s (95% CI: [-4.99, -3.08]; $p < 0.0001$). This corresponds to a significant improvement of 43% on average relative to the Control.

GDC was evaluated by the change in palpebral fissure height, in the absence of light (photostressor off) compared to the presence of the photostressor (photostressor on). While wearing the non-photochromic Control contact lens, participants' average change in palpebral fissure height was 1.89 ± 0.68 mm. When wearing the Test contact lens, participants' average change in palpebral fissure height was 1.12 ± 0.68 mm. The LSM difference estimate was -0.68 mm (95% CI: [$-1.00, -0.37$]; $p < 0.0001$). This corresponds to a significant improvement of 38% on average relative to the Control. Dominant eye was found to be a significant factor at 5% significance level in both models for PRS and GDC (dominant eye was more sensitive and had a narrower palpebral fissure during testing). No other adjustment factors including interactions by study lens were found to be significant (See Table 1).

3.2. Glare disability

GD was measured as the amount of broadband energy from the annulus (expressed as log relative energy, LRE) required to completely veil a central target. The Test contact lens required significantly more energy to veil the central target (M = 1.55 ± 0.25) compared to the non-photochromic Control contact lens ($M = 1.17 \pm 0.28$). The LSM difference between the Test and Control lenses was estimated to be 0.40 (95% CI: [0.30, 0.50]; $p < 0.0001$). This corresponds to a significant improvement of 36% on average relative to the Control (See Table 1).

3.3. Chromatic contrast

CC was measured as the amount of 460 nm energy (as LRE) (reflecting the peak of blue sky light) required to completely veil the central target. The Test contact lens required significantly more energy to veil the central target ($M = 1.58 \pm 0.43$), compared to the non-photochromic Control contact lens ($M = 1.13 \pm 0.28$). The estimated LSM difference between the Test and Control lenses was 0.47 (95% CI: [0.39, 0.55]; $p < 0.0001$). This corresponds to a significant improvement relative to the Control. Both age and MPOD were found to be significant factors. However, the performance of the Test lens across age and MPOD groups were found to be similar (See Table 1).

3.4. Vernier acuity

VA was quantified as the minimum distance needed for subjects to see offset light lines (thin backlit rectangular apertures). Unlike the other primary endpoints, we did not find differences in hyper-acuity when comparing the Test contact lens (662.61 ± 190.22 arc s) to the non-photochromic Control contact lens (666.49 ± 229.02 arc s). The estimated LSM difference was -15.25 (95% CI: [-95.45, 64.96]; $p = 0.71$). Age group was found to be a significant factor at the 5% significance level. No other adjustment factors were significant (See Table 1).

4. Discussion

In this within-subject, randomized clinical trial, we evaluated the visual performance of subjects wearing photochromic (Test) or non-photochromic (Control) contact lenses. All functional endpoints, except for vernier hyper-acuity, indicated there were significant differences between the Test and Control contact lenses. The photochromic Test lens, compared to the untinted Control lens, was related to significant improvements in glare disability and discomfort. This effect is likely based on simple filtering. By screening the retina from intense, scatter-prone light, glare disability and discomfort was lessened. Photostress recovery is a measure that is determined by the time necessary (in seconds) to recover function (e.g., contrast discrimination) following exposure to a bright glare source. Subjects wearing the photochromic Test lens recovered 43% faster than the non-photochromic Control lens. Like glare disability/discomfort, filtering is also likely the primary mechanism by which the photochromic contact reduces photostress recovery time (e.g., it prevents the bleaching of photopigment and time necessary for regeneration).

Improving visual function by reducing the deleterious effects of bright light has important practical implications. The glare source was

Table 1
Least squared means for each of the visual functions tested.

Endpoint[1]	LS-Mean ± StdErr.[2]				
	Test	Control	Difference	p-value[3]	Statistically Different?
Photostress Recovery (seconds)	5.76 ± 0.46	9.79 ± 0.45	−4.03 ± 0.48	< .0001	Yes (Favors Test)
Glare Discomfort (mm)	1.08 ± 0.14	1.76 ± 0.13	−0.68 ± 0.16	< .0001	Yes (Favors Test)
Glare Disability (LRE)	1.54 ± 0.04	1.14 ± 0.04	0.40 ± 0.05	< .0001	Yes (Favors Test)
Chromatic Contrast (LRE)	1.57 ± 0.04	1.10 ± 0.04	0.47 ± 0.04	< .0001	Yes (Favors Test)
Vernier Acuity (arc seconds)	630 ± 32	645 ± 31	−15 ± 40	0.71	No

[1]Each endpoint was analysed using a linear mixed model [2] LS-Mean: Least-Square Mean, StdErr: Standard Error [3] t-tests were performed using LS-Means at a 5% significance level LRE: log relative energy.

chosen to be as close as possible to the most common phase of sunlight (D6500). Under such real-world conditions, the photochromic contact lens would be expected to change optical density (we used only an activation of about 0.20 OD, but the lens is capable of significantly higher OD as shown in Fig. 1) in a manner concomitant to the light stress. The obvious benefit of reducing aversive bright light is evidenced by the fact that individuals who either work or engage in leisure activities outdoors will endeavor to improve their vision/comfort by wearing filtering lenses (e.g., sunglasses). Glare disability worsens with age but, in fact, most ocular conditions (from the anterior to the posterior pole of the eye; cataracts, vitreal detachments, retinal disease etc), as well as their treatment, are accompanied by an exacerbation of light sensitivity and glare problems. Martinez-Roda et al. [25] used direct double-pass methods to calculate modulation transfer functions and Strehl ratios in young eyes without ocular disease (18–30 years). Even for these young subjects, screened for good acuity, scatter indices varied by a factor of around three.

The photochromic contact lens was also related to a change in chromatic contrast compared to the non-photochromic contact lens. Any filter that is not spectrally flat would be expected to influence some wavelengths more than others (i.e., change contrast). Based on the measures of on-eye transmission however, for these experimental conditions, the optical density of the photochromic Test lens was about the same for the blue-sky background and the mid-wave target (the OD ranged from an average of 0.20–0.23) (even the direct measures off-eye are close, see Fig. 1). Hence, the customary explanation of differential filtering would seem unlikely as an explanation for this result. This was known, however, a priori. We were testing a slightly different question; what is the effect of filtering an area of the photopic curve where luminous efficiency is low (460 nm) vs. high (580 nm)? For example, based on the standard normalized curve, luminance efficiency is around 0.87 at 580 nm (the study target) and about 0.06 at 460 nm (the peak wavelength of blue sky light). Even if a filter is relatively neutral, its effect on a non-flat curve is not necessarily constant (i.e., there is more variability possible at the peak of a curve than the restricted range of its tail). This point was originally made by Clark [26], who argued that neutral-tinted spectacle lenses improved many aspects of visual function as well, or better, than their tinted analogues. In contrast to the evidence presented by Clark, there is evidence that yellow tinted filters may be superior at improving chromatic contrast under blue sky conditions [27]. The results of this study, however, suggest that such effects, may be simply additive: some of the effect may be due to overall luminance reduction (e.g., increased scatter can desaturate colours), shifts in sensitivity like the Bezold–Brücke effect [28], etc.

A simple effect of filtering on chromatic contrast is likely to be highly generalizable and may explain some of the popularity of sunglasses that are mostly spectrally flat. The preponderance of Rayleigh-scattered light (seen as “blue haze” and blue sky light) creates a natural situation where many targets are viewed on short-wave (blue) backgrounds. Sky light peaks at the same absorbance peak as used in this experiment, 460 nm, indicating the important ecological validity of this effect. The results of this study are consistent with the possibility that wearing a photochromic contact lens will improve border detection (and hence object perception) in real world scenarios.

The photochromic lens was not related to improved vernier acuity. Westheimer [29] originally used the term ‘hyperacuity’ to describe extremely detailed visual discriminations. A number of various stimulus configurations can generate thresholds of the hyperacuity type. One example, originally described by Wülfing in 1892, called vernier acuity, is essentially two vertically oriented and abutting edges (or nonius lines). In this scenario, one line is adjusted horizontally such that an offset from perfect alignment is introduced and the threshold is determined as the minimum offset required to obtain a just noticeable difference. In a hyperacuity task, offsets as small as 2-4″ of arc can be detected (i.e., less than the spacing of photoreceptors). In this study, we used reverse polarity. Apertures created the vernier bars and light was projected through. This created a situation where the hyperacuity task included scattered light. Essentially, subjects were required to align two bars of spreading light, the spread itself being determined by the amount of scattering within the eye. This task, however, does not reflect the amount of scatter in the eye since it is known to be driven by the centre of the scatter (as originally shown by Williams et al. [30]). In other words, despite the lateral extent of the spread, the centre of the distribution is what is actually aligned by the subject. Not surprisingly, the vernier alignment thresholds were not different between the photochromic and untinted contact lens. This finding is consistent with past studies showing minimal effects of even severe cataracts on Vernier acuity thresholds [31].

Taken together, the results of this study suggest that the photochromic contact lens is a viable means of improving aspects of visual function, not purely related to refraction, but necessary for optimal vision in a complex environment.

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Declaration of Competing Interest

This study was funded by Johnson & Johnson Vision Care, Inc. Authors JRB, JV and YT are employees of Johnson and Johnson Vision Care, Inc. Authors LRH and BRH have received consulting fees by Johnson and Johnson Vision Care, Inc.

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