CLINICAL TRIAL

The Effect of a Photochromic Contact Lens on Visual Function Indoors: A Randomized, Controlled Trial

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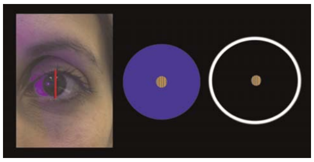
SIGNIFICANCE: Photochromic soft contact lenses contain light-sensitive additives that allow them to darken when exposed to ultraviolet or violet light. One question, however, is whether the lenses influence vision indoors (minimally activated). In this study, we found that the minimally activated lenses improved many aspects of visual function under bright light.

PURPOSE: Photochromic contact lenses were designed to darken when exposed to outdoor sunlight. The filtering that results improves visual function under bright light conditions. Not all bright light exposures occur outdoors. In this study, we tested whether a photochromic contact lens improved visual function under conditions where the lens was minimally activated (i.e., no more than it normally would be in an indoor environment).

METHODS: A subject-masked contralateral design was used comparing a photochromic contact lens randomized to one eye against a nonphotochromic contact in the other eye of the same subject. Sixty subjects (mean = 34.90 ± 11.24 years) were tested. The primary endpoints consisted of four visual function outcomes: photostress recovery, glare disability, glare discomfort, and chromatic contrast. Photostress recovery was quantified by measuring the time needed to recover visual acquisition of a grating target after 5 seconds of an intense xenon white flash exposure; glare disability was evaluated as the energy in a surrounding xenon white annulus necessary to veil a central grating target; and glare discomfort was assessed using bioimaging of the squint response. Chromatic contrast was measured as thresholds for a green-yellow (580 nm) grating target superposed on a blue (460 nm) background.

RESULTS: The minimally activated photochromic contact demonstrated improved visual performance compared with the nonphotochromic control across all visual functions tested ($P < .01$).

CONCLUSIONS: Even under conditions of exiguous activation (e.g., as would be expected indoors or while driving at night), a photochromic contact will improve many of the more deleterious aspects of bright light.



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A relatively recent innovation in soft contact lenses has been the addition of a photochromic molecule. This additive, as the name implies, will darken when exposed to ultraviolet and/or high-energy visible light such as that encountered outdoors on a sunny day. The basic idea behind this photolabile additive is that it helps to modulate light entry into the eye according to ambient illumination. Hence, it is darkest in bright light and mostly clear or minimally activated in dim light. A recent empirical study has shown that the lens demonstrates reduced visual issues, such as glare disability and discomfort, while speeding photostress recovery.[1] Renzi-Hammond et al.[1] used a violet activator to test the lens as it would be expected to be darkened in a typical outdoor situation. The photochromic lenses, however, are meant to be worn inside as well. Hence, the question of how these lenses influence vision indoors (e.g., in a building or inside a motor vehicle) is also relevant.

People do encounter high-energy light in environments that are human made. Most ordinary window glass, for instance, transmits at least half of the incident ultraviolet-A,[2,3] including the side windows of cars.[4] A number of sources of artificial light contain a significant amount of violet wavelengths and sometimes even ultraviolet wavelengths. Sayre et al.[5] measured a variety of low-wattage light sources that are widely used for interior lighting and found the following:

> *Indoor light sources including fluorescent, quartz halogen, and even tungsten filament incandescent lamps provided ultraviolet-A, ultraviolet-B, and sometimes ultraviolet-C emissions. Intensities of some emissions were of similar magnitude to those in sunlight.*

Since the original assessment by Sayre et al.,[5] blue light–emitting diodes have been introduced and have revolutionized the lighting industry by making light-emitting diode–based bulbs that could yield white light. This also means that indoor illumination contains even higher levels of short-wave energy than was previously encountered with less efficient sources such as tungsten. As white light-emitting diodes age, the polymer-epoxy coating degrades, and the amount of high energy short-wave light emitted by the light-emitting diode increases.[6] A number of studies have suggested that this more energy-efficient illumination poses even greater risk for human health including direct risk for ocular actinic damage.[7–9] Certainly, individuals who are sensitive to damage due to ultraviolet light (e.g., patients with photosensitizing conditions such as erythropoietic protoporphyria) are cautioned to also wear ultraviolet blockers inside because of the prevalence of ultraviolet sources indoors.[5]

Ambient light drives overall adaptive state, and what is considered bright or glaring is relative to that state, for example, the perception of intense brightness when opening a refrigerator in the middle of the night. In fact, one of the most nonlinear psychometric functions in sensory science deals with the perception of brightness.[10] In a typical magnitude estimation experiment, the brightness response is magnified at low energies. That is, its aversiveness is amplified at low energy and is compressed at high energy.

Taken together, it seems possible that a photochromic contact lens could activate to some degree when an individual is not outdoors (e.g., in a building or vehicle) and that such activation, despite being relatively minimal, could have a meaningful influence on visual function when compared with a clear lens that does not change. In this study, we used a contralateral subject-masked design to compare visual effects across a nonphotochromic and minimally activated photochromic lens. We selected a range of variables that were consistent with those we previously measured on a different sample with the photochromic activated using a violet activator[1]: photostress recovery time, glare disability, glare discomfort, and chromatic contrast.

METHODS

Ethics

The study was performed in accordance with ISO 14155:2011 (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 all subjects, and the protocols were approved by the Sterling Institutional Review Board, Atlanta, GA.

Subjects

This study used a prospective, randomized, subject-masked contralateral design. Subjects were required to be adapted wearers of spherical silicone hydrogel soft contact lenses and be in the age range of 18 to 65 years. All subjects were required to have vertex-corrected spherical equivalent distance refraction in the range of −1.00 to −4.50 D and best-corrected visual acuity of 20/25 or better in each eye. Subjects were excluded if they reported ocular or systemic issues that could interfere with testing or contact lens wear, such as corneal distortion from previous hard or rigid-gas permeable contact lens wear. These items were evaluated by the attending clinician.

Sixty-two subjects were enrolled from a single clinical site in this study (Georgia Center for Sight, Greensboro, GA) (Table 1). Of the 62 subjects originally enrolled, 60 subjects (96.8%) were assigned and administered at least one study lens, whereas two subjects (3.2%) were screen failures or not assigned. Of the total assigned subjects, all 60 subjects (96.8%) completed the study. Of these 60 subjects, 39 people were aged 18 to 39 years, and 21 people were 40 to 65 years old. Assessment of iris color (Table 1) was based on visual evaluation and comparison against a standard scale by a single trained rater, similar to Mackey et al.[11]

TABLE 1. Sample demographics

Age (y)	Sex	Racial and ethnic background	Iris color
34.9 ± 11.2	85% Female	59.3% White/Caucasian	66.7% Dark irides
	15% Male	38.9% Black/African American	33.3% Light irides
		1.8% Other	

Experimental Test and Control Contact Lenses

The photochromic test contact lenses and the nonphotochromic control contact lens (see Fig. 1 for absorption spectra), composed of the same polymer matrix and senofilcon A, but with no photochromic additive (which served as the within-subject control), were provided by Johnson & Johnson Vision Care, Inc. (Jacksonville, FL). Differences in visual performance between the control lens and the test lens were measured during a single clinic visit. Based on internal data from the manufacturer, there were no differences in the lens properties (e.g., wettability, mechanicals, water content, or oxygen permeability), optical quality, and morphological parameters (diameter, base curve, and power) because of the addition of the photochromic additive or the transitioning of the photochromic compared with the control lens, other than the transmission properties.

Apparatus

As stated previously, the primary endpoints were four visual function outcomes: photostress recovery time, glare disability, glare discomfort, and chromatic contrast. These specific visual functions were selected based on our recent studies using the same apparatus with an activated photochromic contact lens. All tests used the same apparatus, modified for each parameter (for details, see Renzi-Hammond et al.[1]). The glare source (annulus/disk; simulating noon-day sunlight) 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). Stimuli were presented in Maxwellian view, and the contralateral eye was patched. 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 monitor the pupil during testing to ensure proper fixation and sustained alignment and was used, along with biometric software (Amscope, Irvine, CA), to measure glare discomfort.

All photometric calibrations (both in the visible and ultraviolet) were performed using an ILT950 spectroradiometer (International Light Technologies, Peabody, MA). Wedge and neutral density radiometric calibrations were performed using a Graseby Optronics United Detection Technology instrument (Orlando, FL). The same instrument was used before every experimental session to ensure that the total light output of the optical system remained consistent throughout the study.

We tested subjects who habitually wore contact lenses, and both test and control lenses were fitted by an attending clinician in a contralateral fashion. Subjects were randomized to either wear the test lens in the left eye and the control lens in the right eye or

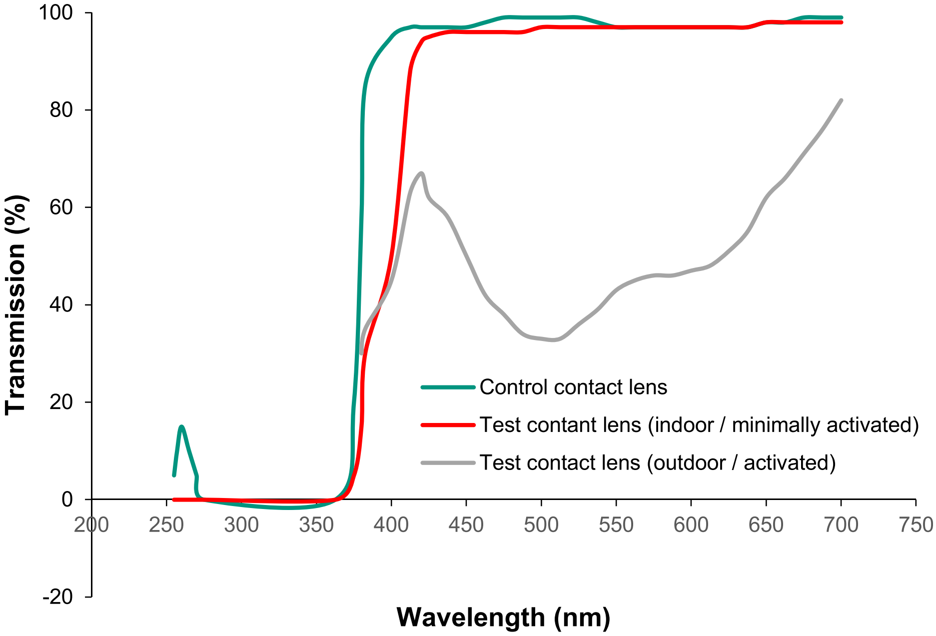

FIGURE 1. Transmission spectral for the test and control lens. These data were obtained from the manufacturer and were obtained using bench measurements. The control lens used for the measurement was –1.00 D (70-μm center thickness), and the photochromic test lens was –0.25 D (85-μm center thickness), taken through the central 6-mm portion. All the radiometric measures for the control and inactivated (indoor) photochromic state were obtained using a PerkinElmer ultraviolet (UV)/visible (VIS) spectrophotometer with a measurement range of 200 to 780 nm in the absence of ambient light. The radiometric measure for the activation photochromic state used a proprietary UV/VIS spectrophotometer with an ancillary activation source (UV outside the measurement range) with a measurement range of 380 to 780 nanometers (nm).

the control in the left eye and the test right eye (i.e., eye and order were randomized).

The Test Target

The visual target was the same in all the visual function tests. The visual target was composed of a 580-nm 2°-diameter disk that contained a sine-wave grating with a spatial frequency of 16 lines per inch. This target was shuttered with 1-second exposures separated by 1-second delays, to prevent adaptation to the target.

The Background (Annulus and Solid Field)

The background channel was used to produce either an annulus for glare disability testing (the bars of the annulus were 2°, and the outer diameter was 16°) or a 17.7° background field for glare discomfort and photostress recovery time testing. A calibrated circular neutral density wedge was used to attenuate light in these fields when measuring glare disability and chromatic contrast. For the chromatic contrast test, the same 17.7° background was filtered through a 460-nm interference filter (half-power bandwidth, 8 nm; Edmund Optics, Barrington, NJ) to produce a monochromatic field. For glare discomfort, glare disability, and photostress recovery time testing, xenon was selected as the light source because of its characteristic broad band emission spectrum (as assessed by the SpectraScan colorimeter) with a chromaticity of u′ = 0.25, v′ = 0.53 (see Fig. 1 in Hammond et al., 2013[12]). For photostress recovery time and glare discomfort testing, subjects were exposed to the solid 17.7° field at high intensity (5.3 log Trolands) for 5 seconds.

In general, the procedure was similar to that reported in the past.[1] In brief, when measuring glare disability, subjects increased the intensity of the annulus until scatter was sufficient to veil the target. When measuring chromatic contrast, the intensity of the blue field surrounding the green-yellow target was increased to veil the central target. Glare discomfort was calculated as differences between the diameters of the vertical palpebral fissure when not light stressed compared with the light stressed condition (measured using images analyzed with biometric software). After the photostressor was used to measure the squint response, subjects were also asked “How bothersome was the glare that you just experienced?” Their response was indicated as either extremely bothersome, very bothersome, somewhat bothersome, a little bothersome, or not at all bothersome. Photostress recovery time 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. Three trials were collected for each experimental condition, per eye, with the exception of photostress recovery time and glare discomfort, for which two trials were collected per eye.

Statistical Analysis

Photostress recovery time, glare disability, self-reported glare discomfort, objectively measured glare discomfort, and chromatic contrast thresholds were all analyzed separately using a linear mixed model for repeated measures. Each model included lens type, age group, iris category, and dominant eye indicator as fixed-effect factors. The two-way interactions between lens type and the remaining factors were also included in the model. A compound symmetry covariance structure was used to model the correlation between left eye and right eye measurements from the same subject. The Kenward and Roger method[13] was used for the denominator degrees of freedom. Comparisons between the test and control lenses

TABLE 2. Results of visual function testing

	Control lens				Test lens				
Visual function	**Mean**	**SD**	**LSM**	**SE**	**Mean**	**SD**	**LSM**	**SE**	**Statistically significant?**
Photostress recovery time (s)	17.28	15.23	—	—	8.83	8.67	—	—	Yes, $P < .01$
Discomfort glare (mm)	2.90	1.57	2.83	0.27	2.26	1.25	2.18	0.24	Yes, $P < .01$
Disability glare (log relative energy)	0.98	0.17	0.97	0.02	1.16	0.14	1.16	0.02	Yes, $P < .01$
Chromatic contrast sensitivity (log relative energy)	1.03	0.18	1.03	0.02	1.21	0.15	1.22	0.02	Yes, $P < .01$

LSM = least square mean; SD = standard deviation; SE = standard error.

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).

RESULTS

In general, we found that even in its minimally activated state, a photochromic contact lens, relative to a visibly clear lens, improved visual function. For example, as shown in Table 2, the eye with the minimally activated photochromic (mean = 1.16 ± 0.14) was able to withstand significantly more energy ($P = .001$) before losing sight of the central grating target (glare disability) compared with the clear comparison in the other eye (mean = 0.98 ± 0.17). Similarly, in our measure of glare discomfort, the eye with the minimally activated photochromic lens (mean = 2.26 ± 1.25 mm) squinted significantly less ($P = .001$) than the eye with the nonphotochromic control (mean = 2.90 ± 1.57 mm). The subjective responses to the photostressor are listed in Table 3.

Recovery time to the visual stressor was also reduced. The eye with the minimally activated photochromic lens (mean = 8.83 ± 8.67 seconds) recovered significantly faster ($P = .001$) than the eye with the nonphotochromic lens (mean = 17.28 ± 15.23 seconds). Finally, as shown in Table 2, chromatic contrast thresholds were significantly better ($P = .001$) in the eye with the minimally activated photochromic lens (mean = 1.21 ± 0.15) compared with the nonphotochromic control lens (mean = 1.03 ± 0.18).

DISCUSSION

In general, this study found that the inactivated photochromic led to reduced glare disability, improved photostress recovery, reduced glare discomfort, and improved chromatic contrast. Glare disability thresholds (change in log relative energy level) were measured by exposing subjects to a white-light annulus of adjustable intensity and quantified by the log relative energy level necessary to obscure a central grating target. Glare discomfort was assessed by exposing subjects to a bright, homogeneous, circular broadband light and then measuring the height of their vertical palpebral fissures before and after exposure.[14] After the exposure, we also asked participants about the extent to which that light stimulus was bothersome (using a rating scale, shown in Table 3). Photostress recovery time was measured during the glare discomfort task by exposing subjects to the intense light source and recording the time necessary to regain site of the grating target after exposure. Chromatic contrast thresholds (change in log relative energy level) were evaluated using a 580-nm central grating target presented on a short-wave (460 nm) sky-light background and was quantified as an increment threshold. In general, we found that the improvement in glare disability, glare discomfort, and chromatic contrast was about half of what we had previously seen[1] using similar measures but an activated photochromic lens (improvements around 15% vs. around 30%).

Although reduced, the fact that we found significant improvements across measures was unexpected. Unlike our previous study, we did not use a dedicated side activator to darken the photochromic during testing. We also tested visual function using an optical system that was composed of a series of achromatic lenses and wedges that filtered most of the ultraviolet light in the optical system. Hence, we expected the lens to be inactive, at least as much as one would see when in contact with the eye (body heat can change the lability of the photochromics and result in some small activation) and when exposed to the light actually used for our measurements. For some of the measures, this was likely significant. For example, the light used for photostress recovery and glare discomfort was exposed for about 5 seconds using intense (5.3 log Troland) and broadband xenon white.[1]

As shown in Fig. 1, even when the lens is in its inactive state (as assessed *in vitro*), it is still absorbing a small amount of light especially in the short-wave region (not so small, at very short wavelengths; light reduction is about 50% at 400 nm). There is some evidence that short-wave light has an exaggerated effect on visual function, especially glare,[15] so absorbance at these wavelengths is likely meaningful. Xenon light (like the sun and even some other artificial light sources) likely contains enough energy in the low violet region of the spectrum to partially activate a photochromic lens, presumably in a manner that would be similar to instances of brightness one might encounter indoors, such as wearing the lens near a window illuminated by sunlight. This interpretation is consistent with our results for photostress recovery time. In our previous study, we had found an improvement with the activated

TABLE 3. Discomfort glare subjective response

How bothersome was the glare that you just experienced?	Control raw, n (%)	Test raw, n (%)
Extremely	9 (16.7)	13 (24.1)
Very	18 (33.3)	20 (37.0)
Somewhat	18 (33.3)	11 (20.4)
A little	7 (13.0)	7 (13.0)
Not at all	2 (3.7)	3 (5.6)
Total	54 (100)	54 (100)

photochromic of about 40%.[1] In this study, we found a similar improvement but used a significantly more intense photostressor to find a similar magnitude of improvement. Taken together, our results suggest that this small but strategic increment filtering, adjusted specifically to the incident light stressor, has visual meaningful consequences.

Does this experimental situation mimic what individuals likely encounter in vehicles or indoors? A perusal of artificial light scenarios and indoor conditions suggests that partial activation of the photochromic lens indoors is likely under numerous human-made circumstances. For example, in efforts to make buildings more energy-efficient (about 14% of electricity is devoted to lighting), many architects are now designing buildings aimed at exploiting natural sunlight (e.g., more windows and an increased use of skylights[16]).

Is partial activation the only possible reason why a photochromic contact yields visual improvement indoors? For the chromatic contrast measurement, we tested increment thresholds for a green-yellow (580 nm) grating target on a sky blue (460 nm) background. For this testing, the stimulus was not particularly intense; nor did it contain significant energy in the low violet region of the spectrum (the blue background, for example, was produced by a relatively narrow interference filter). Nonetheless, we found a 16% improvement with the minimally activated photochromic lens compared with the nonphotochromic control lens. The mechanism underlying this difference is unclear.

These results do suggest that a photochromic contact lens could improve visual quality even when worn in a motor vehicle or inside buildings. Buch et al.[17] showed that, relative to a matched clear contact, the photochromic contact (the same control and test lens as used in this study) improved sign recognition at a distance by 19% during nighttime driving (i.e., conditions of minimal activation). The question of whether it is the actual change in filtering or some other quality of the lens is not clear.

At least part of the indoor benefits we are observing may be related to the lens' ability to aid in adapting to changes in perceived brightness. Although sensory systems are well adapted to handling gradual changes in the intensity of stimuli, the ability of the visual system to quickly handle changes in brightness seems particularly poor or at least nonlinear.[10] The variation in luminance that we experience in modern life is likely quite different than we encountered for most of our evolutionary history,[18] so we may be poorly adapted to handle the constant and ever-changing nature of modern illumination. One obvious example is disruption of sleep patterns by artificial light,[19] but many argue that there is currently an epidemic of disorders linked to our inability to handle variation in light produced by human-made sources.[20]

CONCLUSIONS

Past studies (e.g., Stevens and Stevens, 1963[10]) using magnitude estimation have found that brightness curves are very nonlinear (a small increase in energy at the low end has a disproportionately large effect on brightness perception). Our study suggests the reverse may also be true, a small amount of filtering may have a disproportionately large effect on the aversiveness of bright light.

ARTICLE INFORMATION

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