TITLE PAGE

Immediate and Extended Wear Impact of Color Correcting Lenses on Color Vision Deficiency

Protocol with statistical analysis and approved informed consent.

No NCT Number Assigned Yet.

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Title of Study

Immediate and Extended Wear Impact of Color Correcting Lenses on Color Vision Deficiency

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Location of Research

All data collection and research analyses will take place in an air-conditioned research lab (Rm. 268) fully equipped with all systems necessary to obtain color vision performance data (UIW Rosenberg School of Optometry, 9725 Datapoint Drive, SA, TX 78229). Informed consent may occasionally be administered in and adjacent study room.

Purpose

The long-term objectives of this study is to extend upon our initial research (Rabin, J., Silva, F., Trevino, N. et al. Performance enhancement in color deficiency with color-correcting lenses. Eye 36, 1502–1503 (2022). https://doi.org/10.1038/s41433-021-01924-0) in which we showed improvements in CVDs with CCLs and after wearing CCLs. But the spectacles varied significantly between CVDs (some outdoor, some indoor), control measures were minimal, there were limitations on the full impact of brainwave measures and new and improved CCLs have just been introduced which apply to both green and red color deficiency. Moreover, we found that potential changes in the brain can occur from wearing theses lenses in as little as 1 week or even less vs. what we reported thus far in the seminal research of Werner and colleagues (Werner JS, Marsh-Armstrong B, Knoblauch K. Adaptive Changes in Color Vision from Long-Term Filter Usage in Anomalous but Not Normal Trichromacy, Current Biology, 2020, 3011-3015. https://doi.org/10.1016/j.cub.2020.05.054) which only reported 12 day results. Finally, we wish to conduct our comprehensive vision research to correct limitations stated above AND within the proper parameters of a randomized clinical trial in which proper controls will be implemented for ALL CVD subjects to reach more definitive conclusions. Hence we wish to evaluate a larger sample of CVD subjects with a design which minimizes sources of variability, includes controls, and tests that better account for real-world performance. Moreover, we are recording both brainwaves and eye-waves to assess the retina, optic nerve and brain to localize where changes may be occurring in the visual system in responses to wearing CCLs. Finally, we believe these lenses have potential occupational applications for CVDs excluded from certain jobs as well as in acquired CVD from eye and other diseases.

Equipment to Be Used

1. Precision Vision, Inc. "Super Vision Test" to measure high contrast visual acuity (VA) and Small Letter Contrast Sensitivity (CS).
2. Oculus HMC red-green anomaloscope to diagnosis color vision normal (CVN) and color vision deficiency (CVD) individuals.
3. Ishihara 15-plate color vision book tests to diagnose CVN vs. CVD subjects.
4. Cone Specific Contrast Sensitivity Test (CCT, Innova Systems, Inc.) administered on a calibrated Microsoft Surface Display.
5. Cone Contrast Naming Test administered on a calibrated Microsoft Surface Display.
6. Cone specific VA, small letter CS, and large letter CS administered on a calibrated Microsoft Surface Display.
7. Cone Specific Supra-threshold Color Matching Test administered on a calibrated Microsoft Surface Display.
8. "Cockpit" color identification test displayed on a 17" calibrated LCD monitor.
9. Cone specific visual brainwaves (visual-evoked potentials VEPs) and flash and pattern eye waves (electroretinograms, ERGs) recorded from a large LCD monitor (Diagnosys, LLC). Ear clip, surface and ERG electrodes DTL fiber electrodes (Diagnosys, LLC) will be used for recordings after appropriate cleansing of surface skin areas and application of conductive electrode paste as specified in detail in the methodology section.
10. All CVD subjects will be tested with and without the newest indoor version of the EnChroma color vision correcting lenses (www.enchroma.com) as well as placebo neutral gray lenses which transmit the same amout of visible light but do not alter color) in a registered randomized clinical trial with crossover (to be explained in methodology and design sections). Five CVN control subjects will also be tested with the EC lenses on the same battery of tests to determine if they alter color vision for CVNs, and 15 CVNs will be tested without CCLs or placebo lenses on the computer-based letter charts and electro-diagnostic tests to establish normative values for these tests.

Duration

We are requesting a total of 2 years for subject recruitment, comprehensive testing, data analyses and preparation of multiple abstracts for research presentation and multiple papers to submit for peer-reviewed publication.

Funding

The research and majority of researchers are being funded internally. Two student researchers (Kiana Hall and William Price) are being funded for by our NIH/NEI T35 Research Grant #1T35EY032441-01A1. EnChroma (www.enchroma.com) is donating CCLs and placebo lenses to each CVD subject and two pair to use in-house for color measurements but is providing no funding or is involved in the design, data collection or data analyses.

Financial Conflict of Interest

Does any member of the project team hold financial interest in the funding organization or any similar organization (stocks, board membership, etc)?

- ○ Yes
- ◉ No

Hypothesis

Null Hypothesis: CCLs have no significant impact on color vision performance in CVDs.

Experimental Hypothesis: CCLs can promote immediate improvement in color vision performance in CVDs and performance after one-week of daily wear. As reported previously, performance enhancement after one week of wear may persist if when not wearing the lenses indicating possible neuro-adaptive change.

Statistical Design and Analysis

A double blind randomized clinical crossover trial will be used to assess the immediate and long-term effects on color vision of CCLs in CVDs. Parametric within and between subjects ANOVA with post-hoc t-tests corrected for multiple comparisons will be utilized with primary focus on within-subject comparisons including normal vs. defective cone responses. Although subjects who wear the CCL lenses during week one may show carry-over of this exposure to week two when wearing the placebo lenses, we believe this may offer additional insight into the time course and longevity of any effects from presumed neuro-adaptive changes.

Background and Review of Literature

Normal color vision (CVN) depends on normal red, green, and blue sensitive cone photoreceptors. 8% of males and 0.5% (1/200) females are color vision deficient (CVD), a non progressive hereditary condition in which the red or green cone is missing, or more commonly shifted in peak color sensitivity making it more difficult to tell colors apart and correctly identify colors (1,2). In addition to hereditary CVD, color vision can be decreased at a clinical or subclinical level as an early sign of ocular, systemic and/or neurological disease. (3-7). CVN is required for aviation, military specialties, transportation, and law enforcement wherein color identification and discrimination may be the only cue for critical decisions (3,4). A novel approach using notch filter spectacles (selective wavelength blocking filters to increase differences in stimulation to red and green cones) was implemented by EnChroma®. Extended use by CVDs for two weeks demonstrated improvements in red-green color perception even without wearing the glasses at the 2-week testing point indicating possible neuro-adaptive/brain changes (8). We extended this evaluation by including both threshold (just visible) and supra-threshold testing (readily visible) and found similar results (11). However, a major difference was that our testing was cone specific allowing us to more specifically compare findings from the defective and normal cones in red and green cone CVDs. Limitations of our initial pilot study included a large variability in the type of CCL glasses used (outdoor vs. indoor, red vs. green specific). In addition, since we previously demonstrated enhanced binocular VEP responses in CVDs suggesting neural compensation without CCLs (10), we will be conducting monocular VEP and ERG cone specific tests on all subjects to better identify CCL induced immediate and long term changes on retinal, optic nerve and cortical objective responses. Finally, no study thus far using these CCLs has adhered to the tenets of a registered randomized clinical control cross-over design which we are conducting to definitively address the findings presented in prior studies.

Significance

This research has potential significant impact on occupational uses of CCLs, use of CCLs in acquired CVD, and to significantly expand our knowledge of how neural plasticity can occur in adulthood, a common theme in multiple diseases including glaucoma, Alzheimer and Parkinson disease.

Subject Criteria

We wish to test 20 CVDs and 15 CVNs. Based on high significance achieved with 8 CVD subjects (Werner et al., 8) and 13 (Rabin etal., 11) we believe this will be sufficient to reveal significant within and between subject differences, particularly when conducted as a double-blind clinical trial with cross-over. Five of the 15 CVN control subjects will be tested with and without the CCLs to investigate any impact of these lenses on normal color vision, and 15 will be tested without CCLs on the computer-based letter charts, cockpit display test, and electrodiagnostic tests to establish initial normal values.

Inclusion Criteria: Age 18 or older, no exclusion based on gender or ethnicity. Subjects must have no evidence of active eye, neurological or uncontrolled systemic disease (e.g., uncontrolled diabetes) and VA of at least 20/30 in each eye. Only (1) hereditary CVDs will be included in this study verified by the failing scores on the red-green anomaloscope (outside system normal range) and Ishihara testing (3 or more errors on 14 testable plates). CVNs must pass the two tests using the same criteria.

Recruitment and Informed Consent: Subjects will be recruited from CVD patients seen at RSO, subjects in the community with self-reported CVD with focus on UIW and RSO, relatives/friends of our Team and those who participated in prior studies (but not those involving the CCL lenses). Additionally, a flyer will be circulated via email, the Word newsletter and UIWRSO social media to recruit subjects as needed. After initial recruitment based on email/telephone subjects will be scheduled for three visits at RSO (CVDs) and one visit for CVNs. Upon arrival, each subject will be thoroughly briefed on the nature of the study, minimal risks, time per session (~2.5 hrs. per session but not likely to exceed 2 hours), and compensation (CVDs keep their CCL glasses; CVNs will receive $10 HEB gift cards). All research team members will collect deidentified data, enter these data into our cloud-based PW protected database, participate in analysis and preparation of deidentified results for presentation and submission for publication. Only the PI will have access to identified PHI.

Potential Benefit to Subjects
CVD subjects will learn very specific information about the type and severity of their color deficiency and may benefit from the color vision correcting lenses.

Privacy and Confidentiality. Security Measures for Data Storage and Collection
A PW protected cloud-based drive will be used for deidentified data to be accessible ONLY to the research team. The list of participants with identifiable PHI will be stored by the PI on a single PW protected encrypted computer and in a locked filing cabinetonly accessible to the PI or designees when needed.

Methods

After study briefing and subject provision of written informed consent, the following sequence of tests will be conducted. Half of the 20 CVD subjects will be randomized to initial treatment (CCLs) and half to initial or control groups (placebo neutral lenses). Baseline testing will be conducted with and without the lenses, then be requested to wear the lenses for a minimum of three hours per day, followed by retesting with/without lenses 7 days later. On the next 1-3 days the subject will then: cross-over to the lens not yet worn, undergo testing, and be tested again 7 days later. Neither subjects or Interns administrating the tests will be aware of which lenses the subject is wearing (double-blind clinical trial). On all tests the order of testing with with and without lenses will be randomized across subjects to control for potential order effects. Those tests marked by an asterisk will be retested on CVD subjects during each session. Additional controls for order effects are specified below.

1. Precision Vision, Inc. "Super Vision Test" to measure high contrast visual acuity (VA) and Small Letter Contrast Sensitivity (CS) in right and left eyes at 4m in a darkened room; only at baseline.
2. Oculus HMC anomaloscope to diagnosis CVN and CVD subjects; only at baseline.
3. Ishihara 15-plate (14 testable plates, one demo) color vision book test to diagnose CVN vs. CVD; only at baseline.
4. *Cone Specific Contrast Sensitivity Test (CCT, Innova Systems, Inc.) administered binocularly in a darkened room on a calibrated Microsoft Surface Display at 3 ft. (91.44 cm). A cone specific letter appears in the center of the display and the subject uses a mouse to choose the letter seen from an adjacent matching display. A response driven staircase determines the lowest red, green and blue cone contrast seen (cone CS; 100-point scale) with testing conducted with and without CCLs and placebo lenses.
5. *Cone Contrast Naming Test (CCNT) administered binocularly at 3 ft. in a darkened room on a calibrated Microsoft Surface Display. Red, green and blue cone specific letters and black/white luminance letters of varying contrast appear in the display center
6. and the subject identifies the letters seen and their color names with the lowest contrast seen (cone CS) and number and type of color names correct scored on a 100-point scale. Letter sequence and testing with and without CCLs and placebo lenses.
7. *Cone specific VA, small letter CS, and large letter CS administered on a calibrated Microsoft Surface Display using computer generated letter charts at 3 ft. (91.44 cm) in a darkened room. CVD subjects will be tested with/without CCLs and placebo in separate session with VA and CS scored as the number of letters read correctly in log MAR units for VA and log CS for cone CS.
8. *Cone Specific Supra-threshold Color Matching Test administered on a calibrated Microsoft Surface Display binocularly in a darkened room at 60 cm for each session. Red Cone Test for red CVDs: a red letter “E” will be displayed on the left half of the screen and three green Letter E's on displayed vertically on the right half of the screen with contrasts of 16 – 8% in 0.15 log steps with contrast order randomized and numbered letters numbered 1 - 3. On each of three trials the subject will match the perceived visibilityand brightness of the red letter (displayed individually in randomized contrasts ranging from 16 – 8% in 0.15 log steps) to the number of the green letter it matches. The subject will then conduct the same task matching each green letter shown individually on the left to a series of three green letters on the right. The Green Cone Test for green cone CVDs will require the subject to match a single green cone letter to a series of red cone letters on the right using the same contrasts specified above, followed a match between red to red. As in prior studies, it is anticipated that CVDs will match higher contrasts of their defective cone type to lower contrasts of their normal cone type. Testing will be conducted with/without CCLs.
9. *The "Cockpit" color identification test displays 35 small colored airplane symbols with five of each of seven colors (red, green, blue, purple, yellow, orange, grey) on a 17" calibrated LCD display. On each trial the subject will be told to eliminate one of the four colors, and then immediately uses the mouse to click on the five airplane symbols of the specified color as fast as possible. On each of the seven trials the 35 symbols appear in randomized placement on a black background and the program tabulates the time taken to complete all five symbols, total time and errors made. All subjects will be tested binocularly at 50-60 cm with and without the CCLs.
10. *Cone specific visual brainwaves (visual-evoked potentials, VEPs, 10,11) and flash and pattern eye waves (electroretinograms, ERGs) will be recorded monocularly from the subject’s stated preferred eye with the fellow eye occluded by an eye patch. For VEPs, ear clip electrodes will be applied to each earlobe with conductive electrode paste after cleaning each earlobe with an electrode skin cleanser (Nu-Prep, Diagnosys, LLC) and an alcohol pad. The back of the head will be cleaned with the same agents 1cm above the inion and a gold cup electrode will be taped to this active site with conductive paste and secured by a headband. The active electrode will be at the back of the head with reference electrode on the ipsilateral earlobe and ground on the opposite earlobe. VEPs will be recorded to red, green and blue cone checkerboard patterns presented at

57 cm in a darkened room in pattern onset mode (10,11). Pattern onset ERGs will be recorded at 57 cm from the same display with check sizes of 3 degrees for red and green cones and a 5 degree check size for blue cones in pattern onset mode. Flash ERGs will recorded at a distance of 30 cm from the display to fill the atient's field with an onset red, green and blue cone flash ERG with the subject supported by a chin and headrest. For ERGs the ear clip electrodes will again serve as reference and ground, and the active electrode will be an FDA approved disposable DTL micro-fiber electrode (Diagnosys, LLC; FDA Approved Class II https://www.accessdata.fda.gov/scripts) which is attached to adhesive discs on each end which are affixed to the corners (inner and outer canthi) of each eye. Prior to electrode application, 1 drop of the ocular anesthetic (Proparacaine Hydrochloride Ophthalmic Solution www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?ApplType=A&ApplNo=040277#22240) will be instilled after ensuring that the subject has no allergy to this medication. The adhesive discs will then be attached to the canthi of each eye and the filament will be draped over the white of the eye below the limbus (lower border of colored part of eye). If the subject does not wish to use this electrode an infraorbital skin electrode (gold cup with electrode paste) will be taped on the lower lid directly below the center of the eye. During testing, electrode impedance (resistance) will be maintained at no more than 5 kiloohms in accord with international standards (www.iscev.org). ERG and VEP order of testing will be randomized across subjects and this testing will be conducted at each of the three sessions in CVD.

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UIW Informed Consent Document

Protocol Title: Immediate and Extended Wear Impact of Color Correcting Lenses on Color Vision Deficiency

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1. **Key Information:**
   a. **Research Statement.** You have been asked to volunteer as one of 35 subjects in the research project named above.
   b. **Background and Purpose of the Research:** Color blindness, or color vision deficiency, affects 8% of males and only 1 in 200 females. It is not true "color blindness" but a decrease or deficiency in the ability to tell colors apart and name colors correctly. In the past, colored filters have been used to try to correct color deficiency but with very little success. In this research study our purpose is to determine if newer color vision correcting glasses can improve color vision in individuals with mild to moderate color deficiency.
   c. **What you are being asked to do:** If you have color deficiency, you will be asked to participate in one baseline testing session and 2 additional sessions each 1-week later for a total of two weeks. Each session will last no more than 2.5 hours. In session one, you will take a battery of color vision tests both with and without the lenses we give you which will either wrap around your glasses or can be worn without glasses. Following this baseline test session, we will ask you to wear the glasses you tested with, at home/school/work 3 hours per day mainly during indoor tasks but you may wear them outdoors as well and we will give you an electronic or hard copy log to record the number of hours you wore the lenses each day. You will then return to our research area 7 days later and be retested on the same tests with and without the lenses we gave you. We will then ask you to return on the next day or within 3 days to again be tested with and without lenses we give you, and again you to wear these lenses for a minimum of 3 hours/day for 7 days and then return for the final test session in which the same tests will be repeated with and without the lenses. At this point, we will ask you to answer a brief questionnaire and will then be given the lenses you felt most beneficial in improving your color vision. Color vision normal subjects will be tested within a single 1.5 - 2.5-hour session and be given a $10 HEB card for participation. During each session you will be asked to participate in the following tests:
      i. Visual acuity (smallest letters you can see) and contrast sensitivity (dimmest letters you can see; session 1 only).
      ii. Ability to match a mixture of red and green to an adjacent yellow (session 1 only.)
      iii. Ability to identify colored numbers in a color book test (session 1 only).
      iv. Ability to identify smallest and dimmest (low contrast) red, green, and bluish letters using several computer tests, and in one test you will be asked to name the color your see.
      v. Ability to identify colored aircraft symbols using a mouse on a computer display and your ability to match the brightness and visibility of red and green colored letter "E's".
      vi. Visual brainwaves (visual evoked potentials) and eye waves (electroretinograms) in response to red, green, and blue color patterns which flash on and off on a computer screen. We will tape an electrode to the back of your head to record brain waves and ear-clip electrodes to each earlobe with conductive paste. We will also instill one drop of anesthetic to your preferred eye and apply an FDA-approved very thin filament electrode just above your lower lid to record eye waves. Both tests are clinically very common, painless, involves no risk and your earlobes and back of your head will be cleaned with an alcohol pad after testing.
      vii. You will be asked to complete a brief written questionnaire after completion of the study.

2. **What are the possible risks of being in this study?** There is no expected discomfort associated with this study. There are no risks involved beyond those experienced during a standard eye exam which includes reading letters from charts and displays. The brainwaves and eye waves are standard FDA-approved procedures with no greater risk than a standard eye exam.

3. **Precautions for Female Subjects:** There are no precautions required for female subjects.

4. **Benefits:** If you have color deficiency, you may retain the color correcting glasses after completion of the study to hopefully enhance your color vision.

5. **Compensation:** If do not you have color vision deficiency you may keep the colored glasses you were wearing during the two-week period and if color vision normal be given a $10 HEB gift card.

6. **Confidentiality:** Everything we learn about you in the study will be confidential. If we publish results of the study, you will not be identified in any way.

7. **Clinical Findings:** After completion of your participation, we will share any results we find with you at your request, including clinical findings on all tests. If any finding is unusual or deemed abnormal, we will notify you and assist you in scheduling an appropriate eye appointment.

8. **What are the alternatives to being in this research study?** Instead of being in this research study, you can choose not to participate.

9. **Stop the Study:** Your decision to take part in the study is voluntary. You are free to choose not to take part in the study or to stop taking part at any time. If you choose not to take part or to stop at any time, it will not affect your current or future status at UIW, RSO, or any job, school, or company you are affiliated with.

10. **Consent for Future Use of Data (please initial one of the following):**
    _____I give permission for my deidentified data to be used in the future for additional analysis or other relevant research studies. I understand that no additional informed consent for this use will be sought. I understand that my deidentified data can be stored indefinitely.
    _____I give my permission for my data to be used for this research study only. I do not give permission for any future use beyond the scope of this research study. I understand that my data will be destroyed within 5 years after completion of this study.

11. **COVID-19 Precautions:** COVID-19 preventive measures will be enforced to ensure optimal health and safety for all participants and study personnel to minimize spread of infection as specified by our UIW Approved Clinic Safety Plan:
    a. All research will be conducted in accord with the current UIW-approved Clinic Safety Plan.
    b. All equipment will be thoroughly cleaned prior to subject testing**.**
    c. Participants will be given the option to wear a protective mask (provided) during testing.
    d. All research personnel will wear a protective mask when in close proximity to you.

12. **Questions, Clarification or Concerns:** If you have any questions now, feel free to ask us. If you have additional questions later or wish to report a problem that may be related to the study, please contact the UIW Human Subjects Institutional Review Board: Phone (210) 805-3565, email: koaustin@uiwtx.edu

If you agree to participate, will be given a signed copy of this consent form after study completion. Your signature indicates that you (1) consent to take part in this research study, (2) that you have read and understand the information given above, and (3) that the information above was explained to you. You will be given a signed copy of this consent form.

_____ _____
Signature of Participant Date

_____ _____
Signature of Principal Investigator or Designee Date