SOUTHERN COLLEGE OF OPTOMETRY

Validation of Standardized Testing Protocol for the Clinical Application of Colored Filters

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BACKGROUND

For many years we have been evolving systems for using tinted lenses for the treatment of a number of vision/health conditions including: migraine, acquired brain injury, traumatic brain injury, seizure disorder and reading problems. To date, most clinical work in the field by the authors has involved patients in desperate need of help and willing to try just about anything.

The placebo effect can be very strong, particularly when the practitioner of his/her discipline believes in what they are doing. Since the color testing protocols being done with patients worldwide is almost purely subjective testing, and since most of the experience of Dr. Harris is with testing those in need of help, we performed this study to see how a group of subjects with no particular complaints responds to the same protocols.

Our hypothesis was that normal subjects, as defined as those who had not suffered any of the above named conditions, would go through the color testing protocol and would NOT select a therapeutic color. A secondary hypothesis is that subjects who have suffered any of the above named conditions should have a statistically significant probability of selecting a therapeutic color.

The Intuitive Colorimeter (IC) by Cerium ***(see Figure 1)*** was developed by Arnold Wilkins, DPhil at the University of Essex and provides a method whereby light of specific wavelength distributions and saturations can be accurately projected onto stimuli. The system uses a proprietary numbering system which substitutes for wavelengths ***(see Figure 2)***. A large wheel on the side of the device is rotated to move through the visible spectrum. The wheel has numbers on it which go from 0 to 360 as one moves through the full visible spectrum. Saturation can be varied from 0%, which has no hint of the color which will be seen as the saturation is increased, to 50% in the "B" setting ***(see Figure 3)***. We have found that for working with the medical conditions above, excluding the use of color to address reading problems, that saturations in the 50% range is where we begin to get therapeutic effects. For some of our patients with the above named medical conditions we need saturations or absorption numbers as high as 96%, which must be tested with other means. For the purpose of this study the first level of testing protocol using only the 0% saturation vs. the 50% saturation choices on the IC were probed.

Figure 1 shows the Intuitive Colorimeter by Cerium Technologies

Figure 2 is a close up of the wheel used to select the specific hue of the light. NOTE: that these numbers are proprietary to Cerium and this device only.

Figure 3 shows the saturation adjustment used. "0" represents white light and the light is the same at the "0" setting regardless of where the hue wheel is set. When the saturation is set at any other number some color is clearly seen. At the "50" setting the color is seen as saturated as the device is capable of showing.

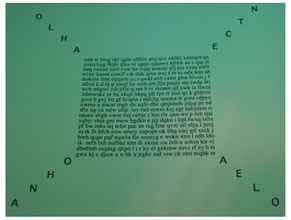

Figure 4 shows the combination of 210 hue and saturation 50 being cast onto the nonsense "words" chart which is inside the Intuitive Colorimeter.

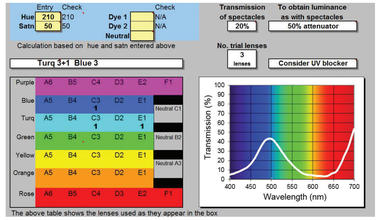

Figure 5 shows the output from the spreadsheet supplied by Cerium to determine the lens combination which will produce a view of the world similar to the light cast inside the IC. This shows that to make the transmission curve on the right will require three lenses; Blue C3, Turq C3 and Turq E1.

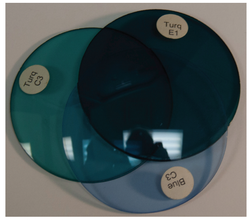

Figure 6 shows the three lenses as specified by the spreadsheet in figure 5.

Figure 7 shows a view of our research area shot through the filters from Figure 6.

Figure 8 shows the nonsense "word" target now seen through the combination of 300 hue and 50 saturation.

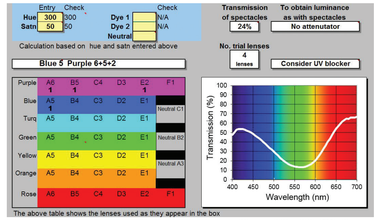

Figure 9 shows the spreadsheet again but this time with the transmission curve and lenses needed to make hue 300 and saturation 50.

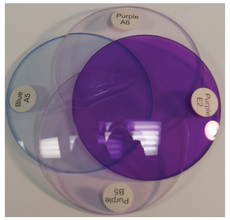

Figure 10 shows the four lenses needed to make hue 300 and saturation 50.

Figure 11 shows the view of our research room through the lenses shown in Figure 10. NOTE: In both figures of the room shot through the filters the colors seem more intense than what is seen on the nonsense target pictures. This is NOT what our subjects experience. They are subjectively very similar in real life.

METHODOLOGY

A testing protocol for color has been used in our research for several years but has only been used on patients with needs. We recruited 100 Southern College of Optometry students to participate in the study. Each subject who sat through the full protocol was given extra credit in one of their classes. The subjects were given a pretesting survey to answer which specifically asked about their history with migraines, mild traumatic brain injury (mTBI) and seizure disorders. If they responded yes to any one of these they were still tested but put into the group of those with symptoms. All those who responded no to all questions were considered as controls.

It surprised us that 21 of the 100 responded yes to one or more of the questions. Additionally, we let our faculty and staff know that we were looking for some additional subjects who had either migraines, mTBI or seizures to bolster the symptomatic group. Nine (9) additional subjects were found bringing the symptomatic group up to 30.

All 109 subjects were put through the exact same testing protocol. They were asked to look into the IC at a target of nonsense words. This target was used as it seems to put most subjects into more of a visual search mode looking for something that makes sense and heightens their connection to the visual stimuli. Twenty-four (24) color settings were used on the IC with 12 having 0% saturation and 12 having 50% saturation. The 0 to 360 scale was broken into 12 parts so testing occurred at: 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330 and 360(0). Subjects were asked to rate how looking at the nonsense target illuminated as such made them feel. This was done on a 5 point Likert scale with ratings from -2 (intense dislike) to +2 (extreme positive feeling). We moved through a pattern that began at hue 30, saturation 0 ***(see table at right)*** and continued until all 24 hue and saturation combinations had been shown.

TEST ORDER	HUE	SATURATION
1	30	0
2	30	50
3	60	50
4	60	0
5	90	0
6	90	50
7	120	50

Note was made of any +2 reports and we used the following decision tree to determine the best +2 response.

- *If only one +2 response existed we recorded that as the subject's selection*
- *If two different +2 responses were noted we conducted a playoff to allow the subject to select which of the two +2 responses were best.*
- *If more than two different +2 responses we conducted a round-robin playoff to find the best +2 response.*

Thus, for all cases where a +2 response was noted we were able to find a single "best" +2 response. Then, based on a spreadsheet from Cerium, the resulting hue and saturation numbers were put in and the resultant filtered lens combination that would produce the same luminance was shown to the subject and their subjective response when looking into a fully lit room was recorded.

RESULTS

Of the 79 normal non-symptomatic subjects 4 gave a potentially therapeutic lens (PTL) a +2 rating, while 21 of these same subjects gave a non-therapeutic lens (NTL) a +2 rating. One of those with a +2 on a PTL also had +2's on a number of NTL's and when show the PTL a second time did not prefer it. The wavelengths chosen by the three normal non-symptomatic subjects were 210, 240 and 270. See figures for samples of the 210.

Of the subjects in the symptomatic group 8 of the 30 showed lasting strong preferences for PTL's. All of these subjects found the colored lenses helpful and asked for them to be prescribed. The difference between the groups is significant to the p=.01 level. The wavelengths chosen by this group appear in the table at right.

NUMBER OF SUBJECTS	PREFERRED WAVELENGTH
1	120
1	180
3	210
1	270
1	300
1	360 (0)

CONCLUSIONS

This study shows two very important things. The first is that prior clinical work was not purely based on the placebo effect with patients in need selecting colors just because they hoped a color would help. This study helped to demonstrate the sensitivity of the testing process. In addition, it showed that not everyone with either a migraine, mTBI or seizure disorder can be helped with color.

Our small sample size of 30 with problems showed about 27% could be helped with color. This is much lower than the percentage of clinic patients sent over for color testing because of the medical problems noted. Of the first 35 or so clinic patients seen 28 or 80% did benefit from colored lenses. This may be due to the fact that the 35 clinic patients were in severe need of some kind of intervention as most had withdrawn from work or active involvement in daily living outside of the light-controlled home because of their situation. However, 20 of our 30 in the symptomatic group were what appeared to be healthy second and third year SCO students. They were placed in the symptomatic group based on prior history, not on current symptomology.

Future studies looking at those with only a history of these conditions vs. those currently suffering symptoms may help to differentiate better who can benefit from this emerging clinical approach.

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