THE EFFECT OF TEMPORAL FREQUENCY AND HUE ON THE PERCEIVED LEVEL OF CAUTION ADOPTED DURING DRIVING

by

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18 April, 2018

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Ferris State University
Doctorate of Optometry Senior Research Paper
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ABSTRACT:

Background: The purpose of this study was to determine the effect of flicker frequency and hue on the perceived level of caution adopted by motorists when viewing emergency vehicle lights. *Methods*: Adult subjects (n=15) with normal acuity and color vision, rated their perceived level of caution of 2-degree equiluminant circular hue patches (Red, Green, Blue) flickered at 6 temporal frequencies (1, 2, 4, 8, 16, and 24Hz) using a magnitude estimation psychophysical technique. Stimuli were generated using Matlab and presented on a DELL LCD monitor. Six hue pairs (R, G, B, R/G, B/R, and B/G) were presented at each of six temporal frequencies which were interleaved randomly within a single experimental session. Subjects rated their perceived level of caution using a continuous 1-10 scale, with 10 being the most heightened sense of caution. *Results*: The perceived level of caution of subjects increased with increasing temporal frequency of flicker up to about 6.5 Hz, and declined progressively for higher temporal frequencies. The temporal frequency at which perceived caution was highest varied with the hue condition. The maximal rated caution also varied with hue condition and temporal frequency. Mean perceived caution rating for the R/B condition far exceeded the mean caution rating derived with R-only or B-only condition, suggesting a faciliatory interaction between these combined hues. The same trend was not evident with R/G and B/G hue pair. *Conclusion*: Higher rates of flicker increases perceived ratings of caution up to about 6.5 Hz. Red and blue hues are generally associated with higher perceived

ratings of caution then green hue, especially when they are flickered consecutively as a pair. This latter finding may reflect the role of a societal conditioned bias.

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CHAPTER 1

INTRODUCTION

Motorists are confronted with various warning signals and signs while driving. Most emergency vehicles use flickering lights with hues of either blue or red, while other maintenance and service vehicles use hues of yellow or green. Recently it was noticed that municipal road maintenance vehicles had altered the hue of their flashing warning lights from yellow to green. The reason as to why this change may have occurred according to articles by Yates and Lorenzo et al, is that white is the most visible warning light, followed by green then red, while a more yellow-green color may be best for emergency vehicles.[1,2] An article by a local new station in Marquette, Michigan states that the change over to green lights on plow trucks was done due to the human eye being able to detect green light better than the older orange/amber lights.[3] However, there seems to be a paucity of research on the association of hue, hue combinations, and flicker frequency on the perceived level of caution they evoke, especially when driving.

One study conducted by the Minnesota Department of Transportation states that low luminance targets doubled the threshold for discrimination of approaching snowplows. They also stated that as the flash conditions were increased from a steady light to three flashes and then 5 flashes, this threshold from discrimination increased as the flash number increased.[4] This study raised the hypothesis that perhaps by increasing the temporal frequency of flashing stimuli, the perceived level of caution adopted by drivers may be affected. According to an article by Molnar, the human visual system perceives a blue light as moving toward the visual system while a red light is perceived as moving away when being viewed at night.[5] This article further states that steady lights can help the human visual system better identify a vehicle's location compared to flashing lights.[5,6] However, while the article comments on drivers theoretically being able to better perceive a vehicle's location with steady stimuli, it does not comment on the average driver's level of caution between steady and flashing stimuli. This study attempts to provide additional insight into this issue.

This study was undertaken to provide insight into the interaction between hue, hue pairs, and temporal frequency on the level of caution adopted when driving. It is our hope that through this study, traffic warning signals, emergency responders and law enforcement agencies may adopt more informed strategies by which to modulate the sense of caution of drivers, specifically by manipulating hue, hue pairs and temporal frequency.

CHAPTER 2

METHODS

A total of fifteen observers participated in this study. All participants were adult subjects between the ages of 21 and 27. Participants were current drivers (range of driving duration: 6 to 11 years) with normal color vision (scored 14 out of 14 on the Ishihara color plates) and monocular visual acuities of 20/20 or better, in each eye, at both distance and near (40cm). The experimental protocol was approved by the Ferris State University IRB, and all participants provided signed informed consent prior to their participation in the study.

The stimulus was a 2 degree circular target that was presented on a Dell computer monitor against a dark background (0.28cd/m^2) using the Psychophysics Toolbox function and Matlab.

Determination of Isoluminance

Prior to conducting the main study, the isoluminant point was determined for the 3 hues (Red (R), Green (G), and Blue (B)) employed in the main study. The stimulus and mode of presentation was identical to the main stimulus outlined above. Hue pairs were temporally interleaved at 30 Hz (R/B, G/B). The blue hue was used as the reference hue and was presented at maximal luminance (9.5 cd/m2) by setting the color look up table to [0:0:255]. Each participant adjusted the luminance of R and G hues using the keyboard until the perceived heterochromic flicker was either minimal or imperceptible. The isoluminant point was calculated as the mean of five adjustments for both R and G when individually interleaved with the reference hue B.

Measurement of Perceived Caution

Prior to the start of the main experiment, each participant was read the following text to ensure equivalence in instructions given to participants:

"*A light patch of a specific color will be flickered on and off at a specific flicker rate for 4 seconds on a computer screen. You will be required to assume that the flickering light patch represents warning signals on a road or on an emergency vehicle that is traveling at night. A 1 to 10 scale will appear on the computer screen immediately following the flickering light duration. You will use the mouse of the computer to select the number (from 1 to 10) that most closely matches the level of caution you would adopt if you were a driver viewing these flashing lights if driving at night. A value of 1 on the scale will represent the lowest level of caution and 10 represents your highest level of caution. You will complete your ratings for lights flashed with different combinations of colors and flicker rates. These combinations will be presented in random order. Do you understand these instructions? Do you have any questions about what you are required to do in this experiment?"*

All participants were presented with stimuli of random combinations of hue and temporal frequencies. They were presented with a flashing stimuli of either red (R), green (G), or blue (B) in isolation, or as a combination of either: R/G, B/G, or R/B. The flicker was accomplished by modulating the luminance of each hue using a square wave temporal profile. The stimuli were presented at temporal frequencies of 1, 2, 4, 8, 16, and

24 hertz (Hz) in a random order, with each stimulus being presented at each temporal frequency a total of five times within a completed experimental session. In the case of isolated hues (R, B and G), the luminance was modulated in an ON/OFF sequence. In the case of the paired hue conditions (R/G, R/B, G/B), each hue was interleaved consecutively at the respective temporal frequency. All data collection was performed in a dark room. The flickered stimulus was presented for four seconds, followed immediately by the presentation of a continuous scale (1 to 10 using 4 decimal precision) on the monitor. Participants then used the mouse and selected the value that corresponded most closely to their perceived level of caution invoked by the flickered stimulus, with 1 representing the least level of caution and 10 representing the highest.

Determination of Stimulus Size

A separate pilot study was also done to determine the effects of mean luminance and stimulus size on the mean level of caution and also to determine what luminance and stimulus size to use for the main study described above. This was done with 3 subjects rating their perceived level of caution for the same hues and hue combinations as described above with different sized stimuli (0.5, 1 and 2 degrees). Furthermore, the luminance of each hue was varied in separate tests for each target size. In one instance, the test subject viewed the flickering stimuli of a given size at maximum luminance (Color-look-up-table 255 for all colors). In an additional presentation of the flickering stimuli at the same given size, the luminance was adjusted to present a 1 log unit decrease in the luminance of each hue (Color-look-up-table R= 96, G= 94, B= 84). Each stimulus size was presented 5 times, in a random order, at each of the following temporal frequencies. 1, 2, 4, 8, 16, and 24 Hz.

CHAPTER 3

RESULTS

After concluding the testing of our subjects, it was determined that all results were valid from all participants, except participant 13 whose perceived ratings failed to vary with stimulus temporal frequency and hue. We had no apriori reason for this outlier in response as all experimental procedures were identical compared to that of all other subjects. We thus proceeded to interpret the data without this participant's data.

This study showed fairly consistent trends across all stimuli presentations. Table 1 shows the mean level of caution from all fifteen subjects for each stimuli presentation. All of the different stimuli presentations showed that the peak level of caution was induced when the stimuli was flickered at either four or eight hertz. The level of caution increased until the peak level at either four or eight hertz for each stimuli hue or hue combination, then proceeded to decrease as the temporal frequency increased past four or eight hertz. The stimulus hue with the lowest peak level of caution was green. Also, for stimuli made up of a combination of hues, the results consistently showed that the combinations with a green hue had lower peak levels of caution compared to stimuli with either red or blue hues. The stimulus combination of R/B by far had the highest mean peak level of caution of 8.5237 (+/-1.266), with the next highest peak level of caution found with the red only stimulus that produced a peak mean level of caution of 6.9727 (+/-1.723).

Another trend noted is that all green stimuli, whether it was green alone or a combination of R/G or B/G, seemed to have a lower mean level of caution compared to all other stimuli. The peak mean level of caution for the green only stimulus was 5.3106 (+/-2.019), which was much lower than the peak mean level of caution for either of the other single hue stimuli. The next closest was over a point higher on the caution scale, with the blue only stimuli producing a mean peak level of caution of 6.3787 (+/-1.518).

Table 1: Subjects' mean level of caution to all stimuli

Temporal Frequency (Hz)	**1**	**2**	**4**	**8**	**16**	**24**
Average Level of Caution (Red)	5.1015 (+/-2.163)	5.8812 (+/-1.718)	6.9727 (+/-1.723)	6.6211 (+/-1.868)	4.7807 (+/-2.278)	3.9455 (+/-2.05)
Average Level of Caution (Green)	3.1018 (+/-1.493)	3.8084 (+/-1.741)	5.3106 (+/-2.019)	5.2272 (+/-2.131)	3.4201 (+/-1.135)	2.6938 (+/-1.179)
Average Level of Caution (Blue)	3.5109 (+/-1.743)	4.7135 (+/-1.655)	6.2129 (+/-1.731)	6.3787 (+/-1.518)	4.2 (+/-1.517)	3.2774 (+/-1.057)
Average Level of Caution (R/G)	4.1374 (+/-1.530)	5.7029 (+/-1.850)	6.3387 (+/-1.996)	5.7372 (+/-2.261)	3.7074 (+/-1.728)	3.2475 (+/-1.956)
Average Level of Caution (R/B)	5.5118 (+/-1.819)	6.9424 (+/-1.128)	8.3037 (+/-1.270)	8.5237 (+/-1.266)	4.9275 (+/-1.648)	4.2467 (+/-1.421)
Average Level of Caution (G/B)	3.9105 (+/-1.533)	5.3516 (+/-1.647)	6.0956 (+/-1.795)	5.9279 (+/-2.011)	2.9243 (+/-1.421)	2.2297 (+/-1.150)

Table 1 compares the average level of caution for each stimulus hue or hue combination at each temporal frequency

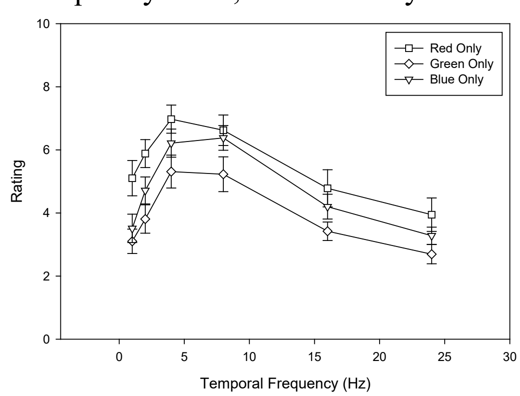
Table 2 also highlights that any red only stimulus had a much higher mean level of caution over all temporal frequencies, compared to any other stimulus with only one hue. This is illustrated by the red only stimulus having a mean peak level of caution of 7.0001 (+/-2.486) and the next closest single hue stimulus, blue only, with a mean peak level of caution of 6.6655 (+/-2.235). Table 2 also shows that the R/B combination stimulus also had a much higher mean peak level of caution over all temporal frequency presentations of 8.3452 (+/-2.690), compared to the next highest hue combination, G/B, at 6.7231 (+/-2.157).

Table 2: Mean Peak TF and Mean Peak Level of Caution for each Stimulus Hue

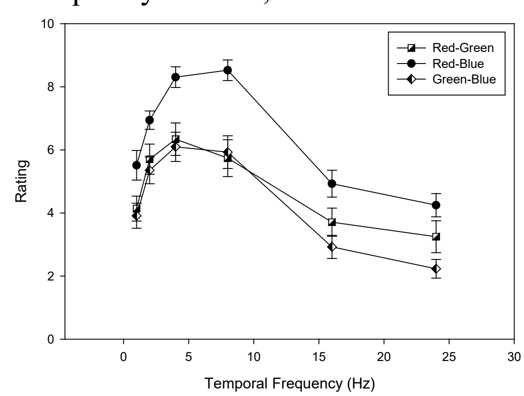
	Red Only	Green Only	Blue Only	Red/Green	Red/Blue	Green/Blue
Mean Peak Temporal Frequency	6.0911 (+/-3.629)	5.3279 (+/-2.295)	6.3865 (+/-1.766)	6.4807 (+/-4.418)	5.1815 (+/-2.043)	5.8891 (+/-2.469)
Mean Peak Level of Caution	7.0001 (+/-2.486)	5.5540 (+/-2.433)	6.6655 (+/-2.235)	6.6387 (+/-2.468)	8.3452 (+/-2.690)	6.7231 (+/-2.157)

Table 2 compares the mean peak level of caution and the correlating mean peak level of caution for each stimulus hue and hue combination

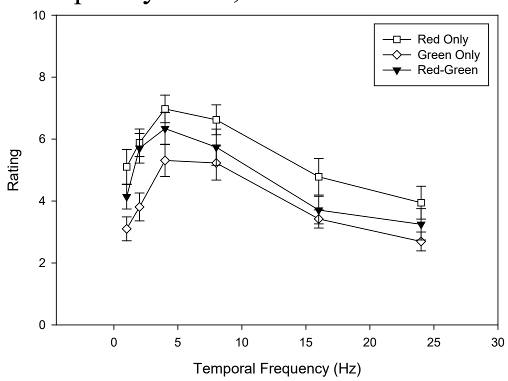
Graph 1 shows the comparison of mean level of caution over each temporal frequency for R, G and B only stimuli.



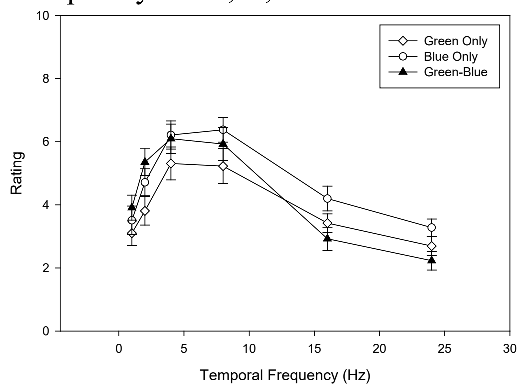
Graph 2 shows the comparison of mean level of caution over each temporal frequency for R/G, R/B and G/B stimuli.



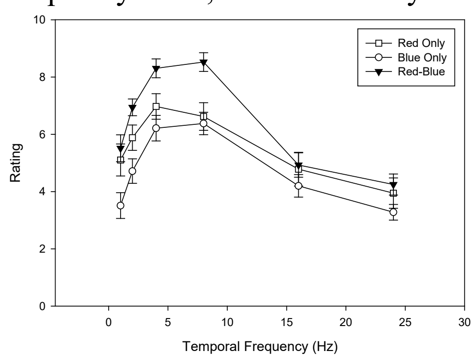
Graph 3 shows the comparison of mean level of caution over each temporal frequency for R, G and R/G stimuli.



Graph 4 shows the comparison of mean level of caution over each temporal frequency for G, B, and G/B stimuli.



Graph 5 shows the comparison of mean level of caution over each temporal frequency for R, B and R/B only stimuli.



Graph 1 shows the comparison of level of caution rating and TF for all three individual hue stimuli, illustrating that red had the highest mean peak level of caution at 7.0001. Graph 2 shows the comparison of the level of caution and TF for the three hue combination stimuli. This graph illustrates that the combination of red and blue hues produced a much higher mean peak level of caution at 8.3452 compared to either of the other hue combination stimuli. Graphs 3, 4 and 5 compare the mean peak level of caution and TF for each hue combination stimuli to the two hue only stimuli that make up that combination. For example, Graph 3 compares the red/green stimulus to the red only and green only stimulus. Graph 3 shows that the red only stimulus has the highest mean peak level of caution (7.001), followed by red/green (6.6387) and then green only (5.5540). Graph 4 shows that the blue only stimulus had the highest mean peak level of caution (6.6655) followed by green/blue (6.7231) and then green only. Finally Graph 5 shows that red/blue (8.3452) had the highest peak level of caution followed by red only and then blue only.

Table 3 Sources of Variation

Source of Variation	DF	SS	MS	F	P
Subject	14	450.609	32.186		
Color	5	351.319	70.264	13.565	<0.001
Color x Subject	70	362.588	5.180		
TF	5	819.482	163.896	28.040	<0.001
TF x Subject	70	409.152	5.845		
Color x TF	25	63.806	2.552	3.733	<0.001
Residual	350	239.299	0.684		
Total	539	2696.255	5.002		

Table 3 Compares different sources of variation and various statistics.

Table 3 shows that there is a significant effect of hue on the level of caution: $F(5,539) = 13.565$, $p<0.001$. It also shows that there is a significant effect of temporal frequency on the level of caution: $F(5,539) = 28.040$, $p < 0.001$. Finally, table 3 also shows there is a significant interaction between hue and temporal frequency: $F(25,539) = 3.733$, $p < 0.001$. Thus, these interaction effects show that the perceived rating of caution depended on both the hue and temporal frequency of the stimulus.

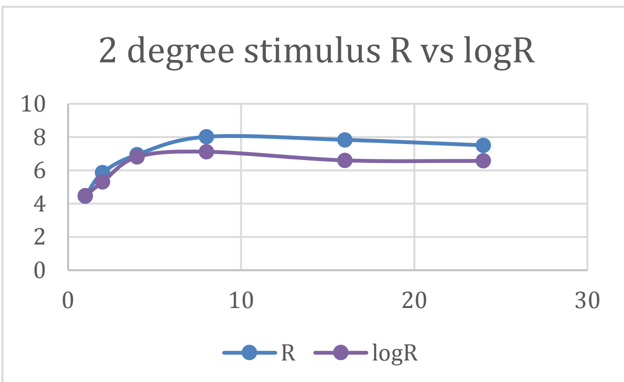
Determination of Stimulus Size

When comparing the mean peak level of caution for the 0.5 degree presentation, the red only, green only, and blue only stimuli each had its peak at the TF of 8 Hz producing peak levels of caution at 7.725, 4.798, and 7.29 respectively. When looking at the 1 degree stimulus presentation, the red only and blue only stimuli had their mean peak level of caution at 8 Hz with values of 8.183 and 8.523 respectively. While the green only stimulus had its peak at 16 Hz with a value of 6.699. Finally, for the 2 degree stimulus presentation, red only and blue only again had their peak mean level of caution at 8 Hz with values of 8.026 and 7.126 respectively. While the green only stimulus again peaked at 16 Hz with a value of 7.343.

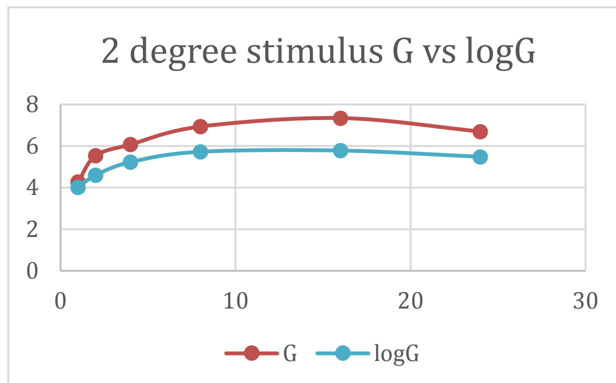
The effect of mean luminance on each stimulus revealed that a reduction in luminance by 1 log unit decreased the mean peak level of caution for each stimulus size. For the 0.5 degree stimulus the mean peak level of caution was reduced for the red only, green only and blue only stimuli from 7.725 to 6.804, from 4.796 to 5.105, and from 7.29 to 6.99 respectively. For the 1 degree stimulus the mean peak level of caution was reduced for the red only, green only and blue only stimuli from 8.183 to 7.357, from 6.699 to 5.698, and from 8.523 to 7.267 respectively. For the 2 degree stimulus the mean peak level of caution was reduced for the red only, green only and blue only stimuli from

8.026 to 7.126, from 7.342 to 5.78, and from 8.952 to 7.404 respectively. These trends for the 2 degree stimulus are illustrated below in graphs 6, 7 and 8.

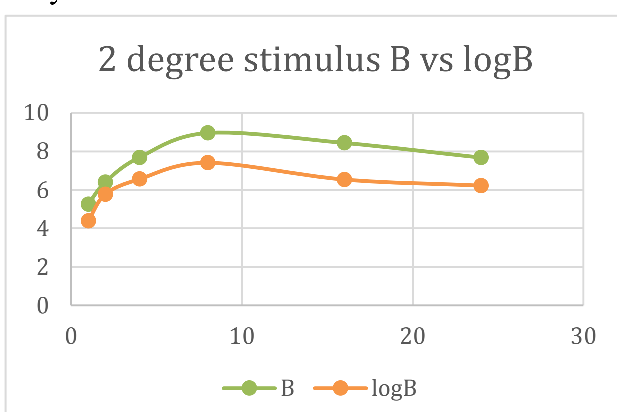
Graph 6 shows the comparison of mean level of caution for the R only and log reduction R only stimuli



Graph 7 shows the comparison of mean level of caution for the G only and log reduction G only stimuli



Graph 8 shows the comparison of mean level of caution for the B only and log reduction B only stimuli



CHAPTER 4

DISCUSSION

A pilot study was conducted to ascertain if the results for level of caution would vary significantly if the stimulus was smaller than the 2 degree stimulus that was adopted for this study. The pilot study results showed that the mean peak level of caution did decrease slightly with both the 1 degree and 0.5 degree stimuli.

The effect of temporal frequency on perceived level of caution:

The results depicted in Table 1 and Graphs 1 – 5 provides unequivocal evidence that the perceived level of caution increased with flicker temporal frequency up to about 6 Hz, and decreases with further increases in temporal frequency, regardless of hue or hue pair. One hypothesis why the level of caution may not have increased unabated with temporal frequency is that the perceived magnitude of flicker may have decreased with temporal frequencies beyond ~6-8Hz. The temporal contrast sensitivity function shows that the human visual system is most sensitive to flicker at a temporal frequency of 6-8Hz for achromatic stimuli. Furthermore, flickering stimuli are usually perceived as stationary beyond a temporal frequency of 45-50Hz (i.e. temporal frequencies > critical fusion frequency (CFF)). However, the CFF is much lower for chromatic stimuli (~10-20Hz) compared to the CFF for achromatic stimuli.[7] Consequently, as the temporal frequency tends towards this range, it is conceivable that the flicker becomes less evident (or perhaps imperceptible), which could lower the perceived rating of caution. It is also noteworthy that the stimuli were approximately isoluminant; as such a reduction in the magnitude of perceived flicker is expected as the chromatic CFF is approached. A second possibility, which is not mutually exclusive to the first hypothesis, is that increasing the TF beyond ~6 Hz is also accompanied by a reduction in the magnitude of perceived brightness. The perceived brightness of a light source is brighter when flickered at about 8-10Hz compared to a steady light of the same luminance. Further increases in temporal frequency beyond 8-10 Hz results in a progressive decrease in perceived brightness (Brücke-Bartley Effect). The results of the pilot studies mentioned earlier may provide some credence to this possibility. For a given stimulus size, peak perceived caution decreased with a decrease in stimulus luminance by 1 log unit. However, the magnitude of perceived caution was most impacted (reduced) for temporal frequencies higher than ~6-8Hz with a 1 log unit reduction in luminance. Thus, the reduction in the perceived salience of flicker and a decrease in perceived brightness may be joint contributors to a reduction in perceived caution as temporal frequency increases beyond 6 Hz.

The effect of hue and hue combination on perceived level of caution:

A clear result of this study is that Red and Blue hues in isolation or as a hue pair produced much higher magnitudes of perceived caution than green hues either in isolation or when paired with Red or Blue. Additionally, a surprising result is that when green was paired with either Red or Blue, the perceived caution as a function of TF was approximately mid-way between the perceived rating of the individual hues. This result could be reasonably modelled by a bayesian algorithm in which perceived caution of a hue pair (R/G or G/B) was equivalent to the weighted sum of the perceived caution of isolated hues (R) and (G) or (B) and (G). The weights in this case being proportional to the inverse variance of caution ratings for individual hues. However, this trend was not consistent with the R/B hue pair. Perceived caution far exceeded the caution ratings for individual hues; thereby suggesting that the B/R hue pair exhibits a faciliatory interaction. This behavior could be modelled by raising the weighted sum of caution ratings for individual hues by an exponent representing the faciliatory index.

In the United States, blue, red or a combination of the both occur on most emergency vehicles like ambulances and fire trucks, but also most noticeably on police vehicles. Participants may have ranked red, blue or R/B combination stimuli at a higher perceived level of caution due to a subconscious bias of already being extra cautious towards flickering lights with those specific hues. The article by Molnar states that one of the reasons why police cruisers continue to use red and blue lights is that we are trained from an early age that red means danger or to stop.[4] Thus supporting that the red stimulus having the highest level of caution may have a bias component as well.

It could be inferred from these results that green may be the worst choice of any of the hues tested, due to any hue combination containing it and the green only stimuli being much lower than any stimulus not containing a green hue. Thus, green may not be the most logical choice for emergency or road maintenance vehicles since the average driver may not be as cautious as they would be around a blue or red signal. This may help to answer our original question for this study of whether road maintenance vehicles should really switch to green lights instead of the original yellow. These results point toward the switch to green lights as a poor choice, and that emergency and road maintenance vehicles may be better off by avoiding the use of green flashing lights or limiting their use only to certain situations or road conditions. It may be prudent to use a green stimulus in lower hazard conditions and reserving the use of red and blue stimuli for higher hazard conditions. The results of our study also suggest that increasing the luminance of the stimulus may enhance the perceived caution, even for green hues.

On the other end of the spectrum, red may be the best single hue stimulus to use on emergency vehicles as it produced the highest overall level of caution out of any single hue stimulus. Also, the combination of R/B hues into one stimulus should be the most highly considered stimulus hue for emergency vehicles, as its peak mean level of caution was over one and half points higher than any other stimulus, whether it was presented as a single hue or in a combination of hues. Also, this points back to our original purpose for this study: road maintenance vehicles may be better off by switching the hue of their lights to either blue, red or a combination, instead of switching towards green.

Overall, while the peak level of caution may be idiosyncratic, this study shows that the perceived level of caution can be modulated by both the stimulus' hue and flicker temporal frequency.

While this was a relatively small study that produced consistent results, a larger study with more participants of varied ages and varied driving experiences may be required to further support our results. Furthermore, a different study may find other results if they were to use a larger sample size and have participants from various countries. Having participants from various countries or ethnicities would be very advantageous due to other countries using different hues on their emergency vehicles.

One example would be that police vehicles in Dubai use a hue combination of green and white on their police cars, instead of the standard R/B hue combination used here in the United States.

Another interesting aspect that follow-up studies could incorporate into their research would be the addition of sound or separation of sound from the stimulus, as the separation may create the illusion of motion. This may be yet another variable to consider in future studies. It would be intriguing to see if and how much more cautious the addition of sound to various stimuli combinations would make drivers. As an example, would the average driver be more cautious around road maintenance vehicles if they used a siren or other sound as well as flashing lights?

Lastly, another point of possible contention for this study could be for drivers that have reduced vision. While all participants in our study exhibited 20/20 vision and perfect color vision, there are plenty of other drivers out on the roads that do not have 20/20 vision. So, one could question whether this reduced vision would affect the perceived caution of the driver. One could hypothesize that if the uncorrected refractive error was large enough it could lead to altered perception of the temporal frequency and thus possibly alter the perceived level of caution. This is just one hypothesis and this idea could be an avenue for a future study where participants perform the tests both with and without optical correction to see if blurred vision does indeed alter their perceived level of caution.

Our study does support, to a point, the study done by the Minnesota Department of Transportation which concluded that the threshold for discrimination of a stimulus increases as the number of flashes increased.[4] Our study also suggests that as the temporal frequency of a flashing stimulus increases, the level of caution increases. However, our study shows that this is only true up to a certain temporal frequency, between 5 and 6.5 Hz, before the level of caution lowers as temporal frequency continues to increase.

We envision these results to impact various issues. Firstly, it expands the current understanding of the effect of hue and temporal frequency on the perceived level of caution and the factors that underlie such interactions, such as stimulus size and luminance. Secondly, it provides empirical evidence for guiding the road commission, emergency medical services and law enforcement agencies on methods by which to modulate the level of caution of drivers specifically using the parameters manipulated in this study. Thirdly, it provides an additional metric (perceived level of caution) by which to assess the efficacy of warning signals that are utilized to inform drivers of hazardous conditions or situations. Taking all these findings into consideration, we hope this study may eventually produce safer day-to-day motorway operations and maintenance activities for emergency vehicles, road maintenance vehicles, and the everyday driver.

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APPENDIX A

IRB APPROVAL FORM

Date: May 18, 2018

To: Avesh Raghunandan
From: Gregory Wellman, R.Ph, Ph.D, IRB Chair
Re: IRB Application IRB-FY17-18-158 The effect of temporal frequency and hue on the perceived level of caution adopted during driving.

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, " The effect of temporal frequency and hue on the perceived level of caution adopted during driving." (IRB-FY17-18-158) and Approved this project under Federal Regulations Expedited Review 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Approval has an expiration date of one year from the date of this letter. As such, you may collect data according to the procedures outlined in your application until May 18, 2019. Should additional time be needed to conduct your approved study, a request for extension must be submitted to the IRB a month prior to its expiration.

Your protocol has been assigned project number IRB-FY17-18-158. Approval mandates that you follow all University policy and procedures, in addition to applicable governmental regulations. Approval applies only to the activities described in the protocol submission; should revisions need to be made, all materials must be reviewed and approved by the IRB prior to initiation. In addition, the IRB must be made aware of any serious and unexpected and/or unanticipated adverse events as well as complaints and non-compliance issues.

Understand that informed consent is a process beginning with a description of the study and participant rights with assurance of participant understanding, followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document and investigators maintain consent records for a minimum of three years.

As mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) the IRB requires submission of annual reviews during the life of the research project and a Final Report Form upon study completion. Thank you for your compliance with these guidelines and best wishes for a successful research endeavor. Please let us know if the IRB can be of any future assistance.

Regards,

Gregory Wellman, R.Ph, Ph.D, IRB Chair
Ferris State University Institutional Review Board
Office of Research and Sponsored Programs