

EFFECT OF GRAY-GREEN NIKE MAXSIGHT CONTACT LENSES ON COLOR VISION

by

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ABSTRACT

Background: Nike Maxsight sport contact lenses are a relatively new product with little published research. Claiming to enhance vision during sport, the lenses filter out several “undesirable” wavelengths from the visible spectrum in order to enhance particular components of sport. **Purpose:** The purpose of this study is to measure the effect on color vision by Nike Maxsight Gray-Green tinted contact lenses. Subjects’ color vision was tested immediately after insertion and after several hours of contact lens wear to determine whether adaptation occurs to improve color vision through the Maxsight lenses. Performance of subjects on the Farnsworth D-15 and the Lanthony D-15 with Maxsight lenses was compared to performance with habitual correction. **Methods:** The following study involved thirty five subjects who each played 18 holes of golf. Nine holes were played with Maxsight contact lenses and 9 holes were played with habitual correction. Each subject completed baseline Farnsworth D-15 and Lanthony D-15. Each of these tests were also completed after 9 holes of golf with habitual correction, immediately after inserting the Maxsight lenses, and after 9 holes of golf wearing the Maxsight lenses. **Results:** As expected, statistically significant findings ($p < .05$) were observed between wearing the Maxsight contact lenses and wearing habitual correction or baseline testing. More importantly, statistically significant findings were not observed between initial Maxsight color testing and post-9 holes of golf Maxsight testing. **Conclusions:** There is a significant shift in color perception presented to a contact lens wearer inserting the Maxsight contact lenses. Adaptation to this color shift does not appear to take place after a relatively

short (1-2 hour) time frame. When worn as prescribed (for sport activities only) and taken care of properly, the lenses are an appropriate tool to use on the playing field. Safety is compromised if the lenses are worn to drive or for other various daily activities.

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TABLE OF CONTENTS

LIST OF TABLES.....	vii
INTRODUCTION.....	1
METHODS.....	6
Subjects	
Study Design and Testing Protocol	
Test Conditions and Scoring	
RESULTS.....	8
DISCUSSION.....	11
REFERENCES.....	13
APPENDIX	
A. TABLES.....	14
B. APPLICATION FOR APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS INITIAL REVIEW.....	19
C. PARTICIPANT CONSENT FORM.....	27
D. DATA SHEET FOR FARNSWORTH D-15 AND LANTHONY DESATURATED D-15.....	30

LIST OF TABLES

Table	Page
1: Descriptive Statistics Farnsworth D-15	15
2: Descriptive Statistics Lanthony Desaturated D-15	16
3: Paired Samples T-Test for Farnsworth D-15	17
4: Paired Samples T-Test for Lanthony Desaturated D-15	18

INTRODUCTION

In a collaborative project by Nike and Bausch and Lomb the Nike Maxsight contact lens was created. The lens was marketed with claims to enhance athletic performance by filtering out certain wavelengths of light, allowing the remaining light to be manipulated and drawing attention to critical visual details of sport. The lens was created in two tints, Gray-Green and Amber. Gray green lenses are intended to enhance sports such as running and golf, while the amber lens is designed to enhance sports such as tennis, baseball, soccer and football.¹ Little published research was conducted to verify the claims of the lenses and since the initiation of this research the lens has been discontinued with Bausch and Lomb. The science behind the lenses and professional athlete testimonials were the primary means used to promote lens wear among athletes of various levels of training.

In a 2006 editorial from the Contact Lens Association of Ophthalmologists, the lenses were touted to reduce reflection and glare, improve field of view, eliminate prismatic effect and eliminate frames which can make sunglasses undesirable during sports. Several concerns were also cited in the article, including the market data that suggested that the primary group expected to express interest in the lenses is young men. The author expressed concern about whether the lenses would be worn responsibly and whether or not the lenses would be worn only during sport activity and not continuously. The risks of wearing the lenses continuously are great as visual contrast in low lighting and darkness can create significant problems and dangers to the wearer. The dK of the lens is also cited at only 8.4, far too low for extended wear. Overwearing the lenses could lead to hypoxic stress on the cornea.²

The theory behind the lenses involves visual thresholds for chromatic differences. By adapting the golfer to the gray green coloration of the lenses, thresholds for that color are lowered, allowing the golfer better and more sensitive discrimination in the green area of the spectrum, such as when reading a green on a golf course. Thresholds for colors farther away from this area of the spectrum are raised by the lenses, making a light colored ball stand out more against the sky or grass, potentially offering the golfer better tracking after completing a swing.⁶

The only previous research found that was completed on the Maxsight sport tinted lenses was a study investigating the contrast sensitivity of football players when wearing amber sport-tinted lenses or clear contact lenses. The article states that testing done at 3,6,12,18 cycles per degree of spatial frequency found statistically significant improvement with the lenses where $p < .05$. With examination of an emmetropic only subgroup, the same results were confirmed for 3 and 6 cycles per degree.³

The purpose of this study was to determine if golfers' color vision would adapt to Nike Maxsight colored contact lenses after two hours of wear. Previous studies on color vision adaptation have shown that there are several components to color vision adaptation. A study by Rinner and Gegenfurtner⁶ indicated that there were three components consisting of a slow component ($t \frac{1}{2}$ 20 s), a faster component ($t \frac{1}{2}$ 40-70 ms) and an extremely fast component with $t \frac{1}{2}$ about 10 ms. The research explored the temporal characteristics of color adaptation up to 2 minutes after initiating the experimental phenomena to their subjects. The synopsis reports that after two minutes chromatic adaptation has reached a steady state.⁶ Another

study by Werner, Sharpe and Zrenner indicated that aside from the temporal adaptation processes, there is also a wavelength selective process for middle-length wavelengths occurring during the first 5-10 s of adaptation. This adaptation takes place faster than long and short wavelength chromatic adaptation.⁷ A study by Good, Schepler and Nichols evaluated the reliability of the Lanthony D-15 test and determined that the test is good for assessing fine detail color discrimination but that there is within-subject variability in test results significant enough for the test to not be used in clinical testing or research. The results indicated that researchers and clinicians should consider three administrations of the test to gain the best understanding for the subject's mean discrimination ability.⁸ Early research in the field of color adaptation by Wright investigated the breakdown in a color match when a lens of varying wavelengths was inserted between the subject's eye and an object of light. The research concluded that the breakdown was due to a retinal receptor process and suggested that the processes of adaptation and intensity discrimination were indeed separate.⁹ In summary, no previous research has established any color adaptation occurring outside of a two minute time frame and research has identified three processes taking place within that time frame. The process is cortical and independent of color intensity discrimination.

The effects of the lenses on color vision were tested using the Farnsworth D-15 and Lanthony Desaturated D-15. The athletes participating in the study were asked to take the color tests four times: once to give baseline data, once immediately after inserting the contact lenses, once after 9 holes of golf with the contact lenses, and once after nine holes of golf with the habitual correction on. The purpose of multiple test results was to try to determine whether or not the athletes were able to adapt to the distortions in their color vision over time in order to

“reset” their color vision to select for certain critical details of the sport and enhance performance.

The Farnsworth Dichotomous Test for Color Blindness (or Farnsworth D-15, or D-15, as referenced in this text) is designed to “distinguish the functionally color blind from the moderately color defective and the normal” according to Farnsworth. The results are pass/fail, indicating that those who fail are more likely to experience challenges daily with color distinguishing tasks and may not be able to meet certain color requirements for a task. The test has one fixed cap and 15 moveable caps that are manipulated by the subject. The subject is told to study the fixed cap and then determine the cap that best matches that hue. This selected cap is used to determine the next cap, and so on.⁴

The Lanthony Desaturated Panel-15 test (or Lanthony D-15, or Lan-15 as referenced in this text) is very similar to the Farnsworth D-15 except that the colors are desaturated. Specifically, the colors are three units higher in Munsell value and two units lower in Munsell chroma according to Lanthony. The test is administered and scored the same as the Farnsworth D-15.⁴

Typically results are analyzed on a score form that presents a color circle including the color confusion lines for protan, deutan and tritan defects. Lines are drawn on the form by connecting the numbers on the circle according to the sequential order of the caps as arranged by the subject. Using the Color Vision Recorder, Bowman’s Color Confusion Index (CCI), the Bowman’s Age-Corrected Color Confusion index (AC-CCI) and the Vingrys and King-Smith

Confusion Index (VKSCI) were calculated. The data was analyzed by inputting the CCI, the AC-CCI and the VKSCI into a spreadsheet and importing into SPSS 14.0 for Windows for analysis.^{5,10}

The CCI is calculated by dividing the maximum radius obtained during testing (as determined by graph analysis of cap placement) by the maximum radius obtained for a perfect arrangement of caps. So a subject that arranges the caps perfectly will receive a CCI of 1.00.¹⁰ The AC-CCI factors in age effects on CCI.¹⁰ The VKSCI calculates a moment of inertia from the color difference vectors identified in testing – the confusion angle, the confusion index, and the scatter index. This method is capable of factoring in the amount of color vision loss from the confusion index and the amount of randomness of cap placement with the scatter index.⁵ This study only evaluated the VKS confusion index and not the confusion angle or scatter index.

METHODS

The Ferris State University Human Subjects Review Committee (HSRC) reviewed the methods and procedures for this project and allowed the use of human subjects for the experiment.

Thirty five subjects were recruited for this study. The subjects were all male and ages ranged from 19-61 years of age. Each subject completed a patient history form and underwent a complete eye health and refractive examination. The examination included visual acuity assessment, baseline manifest refraction, corneal biomicroscopy evaluation, corneal topography, keratometry, contact lens fitting characteristics and subjective "quotes" regarding the lenses. The day of testing, baseline color vision data was obtained.

The golf course used in this study was the Katke Golf Course on the campus of Ferris State University in Big Rapids, Michigan during mid-April. The testing was completed in the clubhouse. There were four color vision testing stations set up in a dark room. At each station was a Macbeth lamp with a color test underneath of it. The fixed cap was placed in the tray and the moveable caps were randomly scattered in front of the tray. The test was not timed. A member of the research team observed all color vision testing to ensure the test was completed correctly. After the test was completed the member of the research team recorded the cap placement.

Subjects were asked to play two rounds of nine holes of golf with both rounds occurring on the same nine holes. The subjects were randomly determined to wear the Nike Gray-Green lenses previously fit to them for the first nine holes or the last nine holes. Immediately after

inserting the lenses, color vision data was repeated. After golfing nine holes color vision testing was repeated. The golfers also repeated color vision testing after nine holes of golf with their habitual correction.

The golfers were shared between two research studies and performed additional tests including visual acuity assessment, brightness acuity testing and contrast sensitivity testing on the same day.

After cap placement data was obtained, the Color Vision Recorder¹¹ was used to complete Bowman's scores for the CCI, AC-CCI and VKSCI. The Bowman method of scoring gives a CCI value of 1.00 when the test has been performed correctly. Each error made adds to the score. Increasing errors thus leads to an increasing CCI score.

RESULTS

Using SPSS 14.0 for Windows, the data for 35 participants was analyzed. Table 1 reveals the descriptive means and standard deviations for the D-15 test. Table 2 reveals the descriptive means and standard deviations for the Lanthony desaturated D-15 test. Using SPSS, multiple paired-samples T-Tests were performed on the pre-baseline, the pre-initial MaxSight lens, the post 9-holes with MaxSight lens, and post 9-holes without MaxSight lens data for both the D-15 and Lanthony D-15 tests. Table 3 reveals that the T-Test did find a statistically significant difference at the $\alpha = 0.05$ level between the baseline D-15 CCI and the initial MaxSight Lens D-15 CCI ($t = -18.197, p < 0.000$). The following also had statistically significant differences: baseline D-15 AC-CCI and initial Maxsight D-15 AC-CCI ($t = -18.116, p < 0.000$), as well as the baseline D-15 VKSCI and initial Maxsight D-15 VKSCI ($t = -22.312, p < 0.000$). In other words, under all three indices evaluated, baseline D-15 testing paired with initial Maxsight D-15 testing yielded a statistically significant result. Similarly, with values not listed in this text but reference from Table 3, Initial Maxsight D-15 paired with post-9 holes D-15 yielded statistically significant results under all three indices as did post-9 holes with Maxsight D-15 and post-9 holes with habitual D-15. Results that are notable that are NOT statistically significant were initial mean scores compared to post-9 holes mean scores, indicating that adaptation to color distortion induced by the lenses did not occur over the time period spent golfing. Table 3 reveals that the T-Test did not find a statistically significant difference at the $\alpha = 0.05$ level between the Farnsworth D-15 mean CCI scores for the initial Maxsight colored lenses and the post-9 holes Maxsight colored lenses ($t = -0.248, p < 0.806$). The following also did not have statistically significant differences: Farnsworth D-15 mean AC-CCI scores for the initial Maxsight colored

lenses and the post-9 holes Maxsight lenses ($t = -0.231$, $p < 0.819$), as well as the Farnsworth D-15 mean VKSCI scores for the initial Maxsight colored lenses and the post-9 holes Maxsight lenses ($t = -0.114$, $p < 0.910$).

Under Lanthony testing (Table 4), statistically significant findings under CCI analysis include baseline Lan-15 CCI paired with initial Maxsight Lan-15 CCI ($t = -12.350$, $p < 0.000$), Baseline Lan-15 CCI paired with post 9-holes Maxsight Lan-15 CCI ($t = -14.887$, $p < 0.000$). Statistically significant findings under AC-CCI analysis include baseline Lan-15 AC-CCI paired with initial Maxsight Lan-15 AC-CCI ($t = -12.304$, $p < 0.000$), baseline Lan-15 ACCI paired with post-9 holes Maxsight Lan-15 AC-CCI ($t = -14.795$, $p < 0.000$). Statistically significant findings under VKSCI analysis include baseline Lan-15 VKSCI paired with initial Maxsight Lan-15 VKSCI ($t = -13.526$, $p < 0.000$), Baseline Lan-15 VKSCI paired with post 9-holes Maxsight Lan-15 VKSCI ($t = -15.550$, $p < 0.000$). Again, under all three indices evaluated, baseline Lan-15 testing paired with initial Maxsight Lan-15 testing yielded a statistically significant result. Similarly, with values not listed in this text but reference from Table 4, Initial Maxsight Lan-15 paired with post-9 holes Lan-15 yielded statistically significant results under all three indices as did post-9 holes with Maxsight D-15 and post-9 holes with habitual D-15. Again a notable finding that was NOT statistically significant is initial mean scores compared to post-9 holes mean scores for all three color indices, indicating no color adaptation was detected by the Lanthony testing either.

Table 4 reveals that the T-Test did not find a statistically significant difference at the $\alpha = 0.05$ level between the Lanthony D-15 means CCI scores for the initial Maxsight colored lenses and the post-9 holes Maxsight colored lenses ($t = -0.992$, $p < 0.328$). The following also

did not have statistically significant differences: Lanthony D-15 mean AC-CI scores for the initial Maxsight colored lenses and the post-9 holes Maxsight lenses ($t = -0.991$, $p < 0.329$), as well as the Lanthony D-15 mean VKSCI scores for the initial Maxsight colored lenses and the post-9 holes Maxsight lenses ($t = -0.553$, $p < 0.584$).

DISCUSSION

The subjects were asked to complete color vision tests while under “normal” visual conditions and immediately after introducing a change to their visual system and after a specified amount of time given to adapt to that change. The change was the MaxSight Gray-Green lenses and the results were measured under the MacBeth lamp using the Farnsworth D-15 and Lanthony D-15 color vision tests. As one would expect, the color perception of the individuals did change from baseline once a colored contact lens was placed on the eye. Participants subjectively reported that the test increased in difficulty after placing the lenses on the eye. The lenses do cause a shift in color perception and made it difficult to discern hues of green and blue. The lenses do have statements included in their marketing material that encourage users not to drive in the lenses.

In addition, there appeared to be no adaptation in the color vision perception from wearing the MaxSight lens and playing 9 holes of golf. A statistical analysis of the results indicated that the color test scores immediately after insertion of the lenses and after 9 holes of golf with the lenses on did not show a statistically significant difference.

While these tests supported our knowledge and suspicion that the MaxSight lenses do alter an individual’s color vision perceptions, it also proved to us that no adaptation appears to occur after wearing the lenses for a relatively short (1-2 hours) amount of time. Further study may include longer wear times of the contact lenses to investigate long term adaptation, but this is not suspected to be a significant difference. Additional future research could involve a different color vision test such as the Munsell 100 Hue.

Factors that could have affected the outcome of the study include subject exhaustion, variable lighting in the testing room as the sun changed position and the fact that we had an all male subject group. After golfing 9 or 18 holes in early spring weather in Big Rapids, Michigan, some subjects may have been tired enough to not care too much about whether they took the time to pick out the best cap order. Also, the best room available for testing had mini-blinds at the windows that blocked out most light, but not all natural light was able to be blocked. The all male subject group was not an intentional result, rather it was a factor of women not volunteering to participate in the study.

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APPENDIX A

TABLES

Table 1: Descriptive Statistics Farnsworth D-15

Paired Samples Statistics		Mean	N	Std. Deviation
Pair 1	Baseline D-15 CCI	1.02	32	0.07
	Initial Maxsight D-15 CCI	2.03	32	0.34
Pair 2	Baseline D-15 CCI	1.02	32	0.07
	Post 9 holes with Maxsight D-15 CCI	2.07	32	0.37
Pair 3	Baseline D-15 CCI	1.02	32	0.07
	Post 9 holes with Habitual D-15 CCI	1.04	32	0.15
Pair 4	Initial Maxsight D-15 CCI	2.07	35	0.35
	Post 9 holes with Maxsight D-15 CCI	2.09	35	0.44
Pair 5	Initial Maxsight D-15 CCI	2.07	35	0.35
	Post 9 holes with Habitual D-15 CCI	1.06	35	0.17
Pair 6	Post 9 holes with Maxsight D-15 CCI	2.09	35	0.44
	Post 9 holes with Habitual D-15 CCI	1.06	35	0.17
Pair 7	Baseline D-15 ACCCI	1.01	32	0.07
	Initial Maxsight D-15 ACCCI	2.02	32	0.34
Pair 8	Baseline D-15 ACCCI	1.01	32	0.07
	Post 9 holes with Maxsight D-15 ACCCI	2.06	32	0.37
Pair 9	Baseline D-15 ACCCI	1.01	32	0.07
	Post 9 holes with Habitual D-15 ACCCI	1.04	32	0.15
Pair 10	Initial Maxsight D-15 ACCCI	2.05	35	0.35
	Post 9 holes with Maxsight D-15 ACCCI	2.08	35	0.43
Pair 11	Initial Maxsight D-15 ACCCI	2.05	35	0.35
	Post 9 holes with Habitual D-15 ACCCI	1.05	35	0.18
Pair 12	Post 9 holes with Maxsight D-15 ACCCI	2.08	35	0.43
	Post 9 holes with Habitual D-15 ACCCI	1.05	35	0.18
Pair 13	Baseline D-15 VKSCI	1.03	32	0.12
	Initial Maxsight D-15 VKSCI	2.66	32	0.43
Pair 14	Baseline D-15 VKSCI	1.03	32	0.12
	Post 9 holes with Maxsight D-15 VKSCI	2.69	32	0.52
Pair 15	Baseline D-15 VKSCI	1.03	32	0.12
	Post 9 holes with Habitual D-15 VKSCI	1.08	32	0.25
Pair 16	Initial Maxsight D-15 VKSCI	2.67	35	0.42
	Post 9 holes with Maxsight D-15 VKSCI	2.68	35	0.53
Pair 17	Initial Maxsight D-15 VKSCI	2.67	35	0.42
	Post 9 holes with Habitual D-15 VKSCI	1.10	35	0.29
Pair 18	Post 9 holes with Maxsight D-15 VKSCI	2.68	35	0.53
	Post 9 holes with Habitual D-15 VKSCI	1.10	35	0.29

Table 2 Descriptive Statistics Lanthony Desaturated D-15

Pair 19	Baseline Lan-15 CCI	1.19	32	0.42
	Initial Maxsight Lan-15 CCI	2.46	32	0.37
Pair 20	Baseline Lan-15 CCI	1.19	32	0.42
	Post 9 holes with Maxsight Lan-15 CCI	2.55	32	0.47
Pair 21	Baseline Lan-15 CCI	1.20	31	0.42
	Post 9 holes with Habitual Lan-15 CCI	1.16	31	0.42
Pair 22	Initial Maxsight Lan-15 CCI	2.49	35	0.44
	Post 9 holes with Maxsight Lan-15 CCI	2.58	35	0.50
Pair 23	Initial Maxsight Lan-15 CCI	2.51	34	0.43
	Post 9 holes with Habitual Lan-15 CCI	1.20	34	0.47
Pair 24	Post 9 holes with Maxsight Lan-15 CCI	2.59	34	0.50
	Post 9 holes with Habitual Lan-15 CCI	1.20	34	0.47
Pair 25	Baseline Lan-15 ACCCI	1.12	32	0.39
	Initial Maxsight Lan-15 ACCCI	2.31	32	0.35
Pair 26	Baseline Lan-15 ACCCI	1.12	32	0.39
	Post 9 holes with Maxsight Lan-15 ACCCI	2.41	32	0.45
Pair 27	Baseline Lan-15 ACCCI	1.13	31	0.40
	Post 9 holes with Habitual Lan-15 ACCCI	1.09	31	0.40
Pair 28	Initial Maxsight Lan-15 ACCCI	2.35	35	0.42
	Post 9 holes with Maxsight Lan-15 ACCCI	2.43	35	0.48
Pair 29	Initial Maxsight Lan-15 ACCCI	2.36	34	0.42
	Post 9 holes with Habitual Lan-15 ACCCI	1.13	34	0.45
Pair 30	Post 9 holes with Maxsight Lan-15 ACCCI	2.44	34	0.48
	Post 9 holes with Habitual Lan-15 ACCCI	1.13	34	0.45
Pair 31	Baseline Lan-15 VKSCI	1.25	32	0.51
	Initial Maxsight Lan-15 VKSCI	3.16	32	0.48
Pair 32	Baseline Lan-15 VKSCI	1.25	32	0.51
	Post 9 holes with Maxsight Lan-15 VKSCI	3.22	32	0.51
Pair 33	Baseline Lan-15 VKSCI	1.26	31	0.52
	Post 9 holes with Habitual Lan-15 VKSCI	1.20	31	0.53
Pair 34	Initial Maxsight Lan-15 VKSCI	3.18	35	0.48
	Post 9 holes with Maxsight Lan-15 VKSCI	3.24	35	0.50
Pair 35	Initial Maxsight Lan-15 VKSCI	3.19	34	0.48
	Post 9 holes with Habitual Lan-15 VKSCI	1.26	34	0.60
Pair 36	Post 9 holes with Maxsight Lan-15 VKSCI	3.24	34	0.51
	Post 9 holes with Habitual Lan-15 VKSCI	1.26	34	0.60

Table 3 Paired Samples T-Test for Farnsworth D-15

Paired Samples Test		Paired Differences		t	df	Sig. (2-tailed)
		Mean	Std. Deviation			
Pair 1	Baseline D-15 CCI - Initial Maxsight D-15 CCI	-	0.316	-	31	0.000
Pair 2	Baseline D-15 CCI - Post 9 holes with Maxsight D-15 CCI	-	0.364	-	31	0.000
Pair 3	Baseline D-15 CCI - Post 9 holes with Habitual D-15 CCI	-	0.085	-1.803	31	0.081
Pair 4	Initial Maxsight D-15 CCI - Post 9 holes with Maxsight D-15 CCI	-	0.538	-0.248	34	0.806
Pair 5	Initial Maxsight D-15 CCI - Post 9 holes with Habitual D-15 CCI	-	0.315	18.964	34	0.000
Pair 6	Post 9 holes with Maxsight D-15 CCI - Post 9 holes with Habitual D-15 CCI	-	0.379	16.119	34	0.000
Pair 7	Baseline D-15 ACCCI - Initial Maxsight D-15 ACCCI	-	0.315	18.116	31	0.000
Pair 8	Baseline D-15 ACCCI - Post 9 holes with Maxsight D-15 ACCCI	-	0.360	16.497	31	0.000
Pair 9	Baseline D-15 ACCCI - Post 9 holes with Habitual D-15 ACCCI	-	0.084	-1.794	31	0.083
Pair 10	Initial Maxsight D-15 ACCCI - Post 9 holes with Maxsight D-15 ACCCI	-	0.534	-0.231	34	0.819
Pair 11	Initial Maxsight D-15 ACCCI - Post 9 holes with Habitual D-15 ACCCI	-	0.314	18.863	34	0.000
Pair 12	Post 9 holes with Maxsight D-15 ACCCI - Post 9 holes with Habitual D-15 ACCCI	-	0.375	16.153	34	0.000
Pair 13	Baseline D-15 VKSCI - Initial Maxsight D-15 VKSCI	-	0.414	22.312	31	0.000
Pair 14	Baseline D-15 VKSCI - Post 9 holes with Maxsight D-15 VKSCI	-	0.535	17.619	31	0.000
Pair 15	Baseline D-15 VKSCI - Post 9 holes with Habitual D-15 VKSCI	-	0.147	-1.961	31	0.059
Pair 16	Initial Maxsight D-15 VKSCI - Post 9 holes with Maxsight D-15 VKSCI	-	0.709	-0.114	34	0.910
Pair 17	Initial Maxsight D-15 VKSCI - Post 9 holes with Habitual D-15 VKSCI	-	0.484	19.231	34	0.000
Pair 18	Post 9 holes with Maxsight D-15 VKSCI - Post 9 holes with Habitual D-15 VKSCI	-	0.546	17.194	34	0.000

Table 4 Paired Samples T-Test for Lanthony Desaturated D-15

Pair 19	Baseline Lan-15 CCI - Initial Maxsight Lan-15 CCI	- 1.264	0.579	- 12.350	31	0.000
Pair 20	Baseline Lan-15 CCI - Post 9 holes with Maxsight Lan-15 CCI	- 1.363	0.518	- 14.887	31	0.000
Pair 21	Baseline Lan-15 CCI - Post 9 holes with Habitual Lan-15 CCI	0.041	0.296	0.764	30	0.451
Pair 22	Initial Maxsight Lan-15 CCI - Post 9 holes with Maxsight Lan-15 CCI	- 0.083	0.493	- -0.992	34	0.328
Pair 23	Initial Maxsight Lan-15 CCI - Post 9 holes with Habitual Lan-15 CCI	1.311	0.501	15.254	33	0.000
Pair 24	Post 9 holes with Maxsight Lan-15 CCI - Post 9 holes with Habitual Lan-15 CCI	1.391	0.429	18.890	33	0.000
Pair 25	Baseline Lan-15 ACCCI - Initial Maxsight Lan-15 ACCCI	- 1.191	0.547	- 12.304	31	0.000
Pair 26	Baseline Lan-15 ACCCI - Post 9 holes with Maxsight Lan-15 ACCCI	- 1.285	0.491	- 14.795	31	0.000
Pair 27	Baseline Lan-15 ACCCI - Post 9 holes with Habitual Lan-15 ACCCI	0.039	0.279	0.785	30	0.439
Pair 28	Initial Maxsight Lan-15 ACCCI - Post 9 holes with Maxsight Lan-15 ACCCI	- 0.078	0.467	- -0.991	34	0.329
Pair 29	Initial Maxsight Lan-15 ACCCI - Post 9 holes with Habitual Lan-15 ACCCI	1.236	0.477	15.102	33	0.000
Pair 30	Post 9 holes with Maxsight Lan-15 ACCCI - Post 9 holes with Habitual Lan-15 ACCCI	1.311	0.409	18.683	33	0.000
Pair 31	Baseline Lan-15 VKSCI - Initial Maxsight Lan-15 VKSCI	- 1.910	0.799	- 13.526	31	0.000
Pair 32	Baseline Lan-15 VKSCI - Post 9 holes with Maxsight Lan-15 VKSCI	- 1.964	0.715	- 15.550	31	0.000
Pair 33	Baseline Lan-15 VKSCI - Post 9 holes with Habitual Lan-15 VKSCI	0.061	0.381	0.886	30	0.382
Pair 34	Initial Maxsight Lan-15 VKSCI - Post 9 holes with Maxsight Lan-15 VKSCI	- 0.057	0.611	- -0.553	34	0.584
Pair 35	Initial Maxsight Lan-15 VKSCI - Post 9 holes with Habitual Lan-15 VKSCI	1.931	0.780	14.430	33	0.000
Pair 36	Post 9 holes with Maxsight Lan-15 VKSCI - Post 9 holes with Habitual Lan-15 VKSCI	1.984	0.684	16.921	33	0.000

APPENDIX B

APPLICATION FOR APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS INITIAL REVIEW

**APPLICATION FOR APPROVAL OF A PROJECT
INVOLVING HUMAN SUBJECTS
INITIAL REVIEW (and 5 yr. renewal)
HSRC**

Dr. Connie Meinholdt, Chair
College of Arts and Sciences
Ferris State University
Big Rapids, MI 49307
PHONE 231-591-2759
FAX 231-591-2541
E-Mail connie_meinholdt@ferris.edu

DIRECTIONS: Please complete the questions on this application using the instructions and definitions found on the attached sheets.

<p>1. Responsible Project Investigator: (Faculty or staff supervisor) Name: <u>Dr. Robert Buckingham</u> Social Security Number: <u>XXX-XX-9124</u></p>	<p>Additional Investigator(s): Name: <u>Amanda Umlandt</u> SS# or Student ID#: <u>10297532</u></p>
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<p>Department: _____ College: <u>Michigan College of Optometry</u></p>	<p>Name: _____ SS# or Student ID#: _____</p>
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<p>I accept responsibility for conducting the proposed research in accordance with the protections of human subjects as specified by HSRC, including the supervision of faculty and student co-investigators. Signature: _____</p>	<p>Name: _____ SS# or Student ID#: _____</p> <p>Name: _____ SS# or Student ID#: _____</p>
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2. Address: If there are more than two investigators, please indicate who should receive correspondence, and provide further addresses on a separate page.

<p>Responsible Project Investigator <u>Dr. Robert Buckingham</u> <u>1310 Cramer Circle</u> <u>Big Rapids, MI 49307</u> Phone #: <u>231-591-2202</u> Fax #: <u>231-591-3551</u> Email: <u>buckingr@ferris.edu</u></p>	<p>Additional Investigator(s) <u>Amanda J. Umlandt</u> <u>402 S Warren Apt 1</u> <u>Big Rapids, MI 49307</u> Phone #: <u>563-299-1274</u> Fax #: _____ Email: <u>amanda.umlandt@gmail.com</u></p>
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3. Title of Project: Effect of Nike Maxsight Lenses on Color Vision

<p>FOR OFFICE USE ONLY Subcommittee _____</p>	<p>Agenda _____</p>
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4. Funding (if any) NONE
 FSU Contracts and Grants app. # if applicable
5. Has this protocol been submitted to the FDA or are there plans to submit it to the FDA? No Yes
 If yes, is there an IND #? No Yes IND #
6. Does this project involve the use of Materials of Human Origin (e.g., human blood or tissue)?
 No Yes
7. When would you prefer to begin data collection? August 2007
 Please remember you may not begin data collection without HSRC approval.
8. Category (Circle a, b, or c below and specify category for a and b.
- a. This proposal is submitted as EXEMPT from full review.
 Specify category or categories:
 - b. This proposal is submitted for EXPEDITED review.
 Specify category or categories: 2Aii
 - c. This proposal is submitted for FULL sub-committee review.
9. Is this a Public Health Service funded, full review, multi-site project?
 No Yes
 If yes, do the other sites have a Multiple Project Assurance IRB that will also review this project?
 No. Please contact the HSRC office for further information about meeting the PHS/NIH/OPRR regulations.
 Yes. Please supply a copy of that approval letter when obtained.

10. **Project Description (Abstract):** Please limit your response to 200 words.

The purpose of this study is to determine whether or not Nike Maxsight lenses have any measurable effect on color vision. The lens claims to enhance performance by way of blocking out undesirable wavelengths of light. This study will measure the effects of the lenses on subjects. Nike Maxsight sport contact lenses are a new product with little published research. Claiming to enhance vision during sport, the lenses filter out several wavelengths from the visible spectrum. Subjects will be tested to determine whether or not the Nike Maxsight Gray-Green tint will affect the outcomes of the Farnsworth Dichotomous and the Lanthony Desaturated D-15 color vision tests. Subjects are expected to do poorly on color discrimination tasks that involve blue wavelengths. Color discrimination of red and green wavelengths is expected to be preserved. The data analysis on information from tests subjects will help clinicians provide better patient instruction when prescribing Nike Maxsight contact lenses.

Eligibility requirements require a pre-requisite primary care exam ruling out ocular infection or structural abnormalities. Subjects must be between 18 and 35 years old and have distance spherical correction between +4.00 to -6.00 (.25D steps) and -6.50 to -9.00 (.50D steps.)

Subjects will read and sign an informed consent form. Pre-requisite care services may be provided by the Michigan College of Optometry. If subjects have been previously unsuccessful with soft contact lenses they should not be included in this study.

11. **Procedures:** Please describe all project activities to be used in collecting data from human subjects. This also includes procedures for collecting materials of human origin and analysis of existing data originally collected from human subjects
- 1) **Initial visit / evaluation and fitting**
 - a. **Visual acuity assessment**
 - b. **Baseline manifest refraction**
 - c. **Corneal biomicroscopy examination**
 - d. **Corneal topography**
 - e. **Keratometry**
 - f. **Contact lens fitting characteristics**
 - g. **Subjective "quotes" regarding the lenses**
 - h. **Farnsworth D-15 without MaxSight Lenses**
 - i. **Lanthony Desaturated D-15 without MaxSight Lenses**
 - 2) **Follow-up visit**
 - a. **Objective Data**
 - i. **Farnsworth D-15 (with MaxSight and with Soflens 38 lenses)**
 - ii. **Lanthony Desaturated D-15 (with MaxSight and with Soflens 38 lenses)**

Each subject will be fit with both a pair of Nike Maxsight Grey-Green contact lenses and a pair of Soflens 38 contact lenses prior to testing. Fitting will consist of visual acuity assessment, baseline manifest refraction, corneal biomicroscopy examination, corneal topography, keratometry, Farnsworth D-15 and Lanthony Desaturated D-15. Once each subject has obtained the proper fitting lenses, testing under playing conditions will commence at Katke Golf Course here in Big Rapids, MI.

On the day of testing each subject will receive one of the two pairs of contact lenses they were fit with previously (either the Nike Maxsight or Soflens 38) and the Farnsworth D-15 and Lanthony Desaturated D-15 will be tested on each patient. Once the data is collected on the subject they will proceed to golf nine holes of the eighteen-hole golf course. Upon completion of the round of nine holes the subject will be retested using the Farnsworth D-15 and Lanthony Desaturated D-15. The volunteer will then remove the first set of lenses and the patient's second set of contact lenses will be inserted. Again, each subject will complete the Farnsworth D-15 and Lanthony Desaturated D-15. The subject will then continue another nine holes. After completion of the second nine holes, the Farnsworth D-15 and Lanthony Desaturated D-15 will be readministered.

Procedural Definition

Baseline Manifest Refraction

A standard clinical procedure that frequently entails the use of a phoropter which is a device that holds multiple lenses to determine a patient's prescription (refractive error) prior to initial contact lens fitting

Over-refraction

A manifest refraction over the patients contact lenses

Corneal Biomicroscopic Examination

A microscope (slit-lamp) is utilized to enable investigators to assess the overall corneal health, analyze the tear film, and evaluate the fit of the contact lenses. Procedure time is less that 5 minutes and is painless

Computerized corneal topography

Video photography is commonly used in clinical practice to measure and assess corneal curvature changes secondary to contract lens wear. Procedure time is less that 5 minutes and is painless

12. Subject Population: Describe your subject population. (e.g., high school athletes, women over 50 w/breast cancer, small business owners)

33 individuals, ages 18-35

- a. The study population may include (check each category where subjects may be included by design or incidentally):

Minors	[]
Pregnant Women	[X]
Women of Childbearing Age	[X]
Institutionalized Persons	[]
Students	[X]
Low Income Persons	[X]
Minorities	[X]
Incompetent Persons (or those with diminished capacity)	[]

- b. Number of subjects (including controls) __33__

- c. How will the subjects be recruited? (Attach appropriate number of copies of recruiting advertisement, if any.

Recruitment will be done through contacts at the local golf course.

- d. If you are associated with the subjects (e.g., they are your students, employees, patients), please explain the nature of the association.
- I am not associated with the subjects.
- e. If someone will receive payment for recruiting the subjects please explain the amount of payment, who pays it and who receives it.
- No one will receive payment for recruitment.
- f. Will the research subjects be compensated? No Yes.
If yes, details concerning payment, including the amount and schedule of payments, must be explained in the informed consent.
- g. Will the subjects incur additional financial costs as a result of their participation in this study? No Yes. If yes, please include an explanation in the informed consent.
- h. Will this research be conducted with subjects who reside in another country or live in a cultural context different from mainstream US society?
 No Yes.
- (1) If yes, will there be any corresponding complications in your ability to minimize risks to subjects, maintain their confidentiality and/or assure their right to voluntary informed consent as individuals?
 No Yes.
- (2) If your answer to h-1 is yes, what are these complications and how will you resolve them?

13. How will the subjects' privacy be protected?

In accordance with the HSRC, confidentiality will be preserved for each subject. Patients will be assigned a number, unassociated with the subjects' identity. The number will be used for data collection only. Patient files will be kept in a secured area accessed only by study investigators and study monitor.

See attached: Clinic Exam form and Color Vision Test form.

14. Risks and Benefits for subjects:

Possible side effects of contact lens wear include reversible blurred vision, allergy, discomfort, tearing, redness, and dryness. Rare risks include corneal ulcers, corneal swelling, and loss of vision.

Each subject will be advised to contact investigators (phone and pager numbers will be provided) should subjects experience any ocular discomfort, vision changes, redness of the eye or other problems. If patients are injured as a result of their participation in this research project, Ferris State University, will provide emergency medical care if necessary.

15. Consent Procedures

Please see attached.

CHECKLIST: Check off that you have included each of these items. If not applicable, state N/A:

- Completed application
- The correct number of copies of the application and instruments, according to the category of review
- Consent form (or script for verbal consent), if applicable
- Advertisement, if applicable
- One complete copy of the methods chapter of the research proposal

APPENDIX C

PARTICIPANT CONSENT FORM

Statement of Informed Consent

Evaluation of Color Vision while Wearing Nike Maxsight Contact Lens vs. Clear Contact Lens

Explanation of Study

You are being asked to participate involving the use of Nike Maxsight contact lenses. These are FDA approved contact lenses designed to correct distance vision. The purpose of this study is to determine if the new Nike MaxSight Contact Lenses alters color vision as compared to clear contact lenses.

This study will involve thirty three subjects who have healthy eyes. Each subject will be fit with the Nike Maxsight lens used standard fitting procedures. At the first visit the following procedures will be performed:

- Visual acuities (distance and near)
- Subjective refraction
- Corneal curvature assessment (keratometry readings and topography)
- Contact lens fitting assessment
- Refraction over the contact lens to determine best distance and near vision
- Farnsworth D-15 and Lanthony Desaturated D-15 color vision tests

The second time we meet will be at Katke golf course and the following tests will be done with each set of contact lenses:

- Farnsworth D-15 color vision test
- Lanthony Desaturated D-15 color vision test

You will be playing two 9-hole rounds on the same 9 holes. One round will be with the Nike Maxsight contact lenses and the other round will be a soft contact lens. Before and after each round, you will complete the Farnsworth D-15 and the Lanthony Desaturated D-15 color vision tests. After the first round, you will switch your lenses, perform the above tests, and you will play the 2nd 9 holes.

Risks/Benefits

Possible side effects of contact lens wear include allergy, discomfort, tearing, redness, dryness, superficial corneal abrasion and very rarely infection.

Benefits may include enhanced distance vision while wearing the contact lenses.

Voluntary Participation/Withdrawal from study

Participation in this study is voluntary and you may withdraw from this study at any time during the study. Refusal to participate or to complete this study or voluntary withdrawal from the study will not involve any penalty or loss of benefits to which you are otherwise entitled. The investigators may terminate your participation in the study if it's believed to be in your best interest. If this occurs, the study lenses must be returned to the investigators.

You will be made aware of any significant new findings that may develop during the study that may affect your willingness to continue participation.

Questions or Complications

Any pertinent question about the study or about your rights as a study subject may be directed to Dr. Connie Meinholdt, Chairperson of the Ferris State University Human Subjects Review Committee (HSRC) at 231-591-2759. If you experience any study related illness or injury during the study or after the study, please contact the principle study investigator, Dr. Robert Buckingham at 231-591-2202.

Confidentiality

All study records will be maintained with strict confidentiality. The HSRC may inspect the investigators' records pertaining to you as a participant in this clinical study. The results of this study may be used for medical and/or scientific publications or meetings. In any event, your identity will not be disclosed in any manner. You are asked not to disclose information regarding this study to anyone other than the study investigators without first obtaining written permission from the investigators.

Subjects Name (Print)

Subject's Signature Date

Investigator's Name (Print)

Investigator's Signature

Address

City/State/Zip

Telephone _____ 24 Hour Emergency

APPENDIX D

DATA SHEET FOR FARNSWORTH D-15 AND LANTHONY DESATURATED D-15

Effect of Maxsight Lenses on Color Vision
Data Sheet for Farnsworth D-15 and Lanthony Desaturated D-15

Patient Number: _____ Which lens worn first: _____

Baseline Information

Farnsworth D-15

Lanthony D-15

Initial Test With Nike Maxsight Lenses

Farnsworth D-15

Lanthony D-15

After 9 holes of Golf With Nike Maxsight Lenses

Farnsworth D-15

Lanthony D-15

After 9 holes of Golf With Habitual Lenses

Farnsworth D-15

Lanthony D-15
