

**OVERALL GOLF PERFORMANCE EVALUATION:
NIKE MAXSIGHT GREY-GREEN SPORT-TINTED CONTACT LENSES**

by

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This paper is submitted in partial fulfillment of the
requirements for the degree of

Doctor of Optometry

Ferris State University
Michigan College of Optometry

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Has been approved

May, 2009

APPROVED:

, Faculty Advisor

Ferris State University
Doctor of Optometry Senior Paper
Library Approval and Release

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I, Rachael A. Peterson and Bradley A. Wruble, hereby release this Paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

Doctoral Cand

Doctoral Candidate

Date

ABSTRACT

BACKGROUND: Sports vision aids are becoming a more integral part of an athlete's equipment. Tinted contact lenses are available to athletes for various sports. The purpose of this study was to compare golfers' performance while wearing the Nike MAXSIGHT grey-green contact lenses in the areas of contrast sensitivity, performance, glare, and visual acuity with that of the golfers preferred choice of eye wear while playing golf.

METHODS: Participants played nine holes of golf wearing the Nike MAXSIGHT Contact Lenses and repeated the nine holes wearing their normal correction or visa-versa. Contrast sensitivity, glare, and visual acuity were assessed before each nine holes. A survey composed of sixteen subjective questions were completed after each nine holes played by the participants to rate their visual performance on a scale from zero to one hundred. **RESULTS:** Although the participant subjective responses tended to indicate that the Nike MAXSIGHT Grey-Green contact lenses had a negative effect on their performance while golfing, in some areas the contact lenses objectively out performed the participants' regular correction. Crisp vision, vision in the shade, finding golf balls, vision in buildings, and tracking the golf ball in flight were all found to be statistically significant better without Nike MAXSIGHT sport-tinted contact lenses.

CONCLUSION: Nike MAXSIGHT contact lenses do not significantly increase the objective performance of golfers. However, some patients found that the contact lenses did subjectively increase their visual performance, while others felt it has a negative affect on their visual performance.

Acknowledgements

The authors wish to thank Baush & Lomb for providing the Nike MAXSIGHT contact lenses for the present study. The authors have no financial interest in any of the issues contained in this article. The authors would also like to thank Dr. Josh Lotoczky, Dr. Amy Dinardo-Lotoczky, Dr. Robert Buckingham, and Amanda Umlandt for the assistance in the study. Also, thank you to: Kevin Tucci, PGA professional of Katke Golf Course for allowing us to use the club house and course, and to Derek Shelbourne, President of the Professional Golf Management Program at Ferris State University, for volunteer recruitment of participants.

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BACKGROUND

Nike MAXSIGHT soft contact lenses introduced by Bausch & Lomb in 2005 are the first and only FDA approved sport contact lens. Nike MAXSIGHT soft contact lenses are tinted to filter out 95% UVA and UVB along with 90% of harmful blue light.¹ These contact lenses have benefits for both athletes and recreational wear providing a quality visual performance. Nike MAXSIGHT sport-tinted contact lenses eliminate glare, increase contrast sensitivity by blocking specific wavelengths of light, increase peripheral vision, and reduce internal exposure to UV.¹

The patented light architecture selectively filters specific wavelengths of light to visually enhance key elements in sport, such as a ball, filtering most of the blue light and manipulating the remaining colors of the visible spectrum to enhance critical details in the sporting environment.² Blue light is focused in front of the retina decreasing contrast and increasing chromatic aberrations. Controlling chromatic aberration helps improve the athlete's target recognition, allowing them to see and track the ball with extreme precision.

The Nike MAXSIGHT contact lens filters blue light from light incident on the eye decreasing chromatic aberrations, increasing contrast, and enhancing clarity. Chromatic aberration control allows the individual to recognize detailed contours with sharp visual contrast, and reduces distracting visual noise. Overall, controlling chromatic aberrations has the potential to increase the persons' reaction time and improve their overall athletic performance.

The Nike MAXSIGHT is available as either grey-green or amber tinted contact lenses depending on the individuals sporting needs. Grey-green tinted contact lenses are recommended for athletes in bright sunlight (golf and running) to enhance green and red portions of the visual spectrum to improve visual detail and contour recognition. Amber tinted contact lenses are recommended for athletes that require tracking a fast-moving ball (tennis, soccer, football, baseball) to filter blue and green wavelengths of the spectrum so the ball pops off the background.

For golfers, this would eliminate any fogging, scratching, or sweating sometimes associated with prescription glasses or sunglasses. It would increase subtle contours on the golf course especially while reading putting greens. The contacts could increase visual contrast and reduce squinting and its associated eye strain. With all of the possible improvements, a couple of questions are raised that could have a negative impact on performance. Dawn, dusk, and shadows from clouds and vegetation could present the golfer with difficulty in reading putts, finding their golf ball, and judging distances on the course. Another concern other than performance of the golfer would be the issue of patient compliance. If the patient needed to remove the contact lenses on the golf course, the patient would not be able to properly wash their hands and clean the lenses.

Bausch & Lomb stated that the Nike MAXSIGHT sport-tinted contact lenses will improve contrast sensitivity and peripheral vision. The grey-green tinted lenses enhance the green and red portions of the visual spectrum to make it easier to read putting surfaces and track the golf ball in flight. They also reduce glare from the sun and contrast between shade and non-shade possible giving athletes an advantage over the rest of the competition. Optometrists are hesitant to prescribe the contacts due to the minimal wearing time and the limited use of the contact lenses. The contacts are designed specifically for athletes, recreational or professional, during athletic performance. They

will decrease visual acuity in darkness which can be hazardous while performing daily activities in poorly lit situations.

Since the start of this project Bausch & Lomb discontinued the Nike MAXSIGHT sport-tinted contact lenses. The lenses were classified as Group I non-ionic and low water. The wearing schedule of the contact lenses fell under the category of daily wear with a one month replacement schedule. They were made of polymacon and had a Dk of only 8.4, which could lead to complications such as neovascularization, corneal edema, and/or hypoxia. The only base curve radius produced was 8.7 with a overall diameter of 14.3 mm. Spherical powers ranged from +4.00 to -9.00 (.25D steps to -6.00 and .50D steps to -9.00).¹

METHODS

January 2008 through April 2008, eye examinations were performed on thirty-four subjects. Each participant aged 18 to 30 years old with no ocular pathology was fit with an Amber Nike MAXSIGHT sport-tinted contact lenses. The Amber tint was used for fitting purposes to spare the stock of grey-green tinted lenses for the actual testing day. Spherical equivalents were used for most patients, however, if visual acuity was not found to be better than or equal to entering visual acuity the Nike MAXSIGHT sport-tinted contact lens was piggy-backed over the patient's toric contact lenses. If optimal correction was still not achieved, the participant was thanked for their time and excluded from the study. Fitting was performed and each contact lens was required to have .25 to .75mm of movement, adequate coverage over the cornea in primary gaze, and a positive push-up test. If the participant met all qualifications, they were scheduled to play eighteen holes of golf along with completing visual acuity testing, contrast sensitivity testing, and brightness acuity testing on either Tuesday April 8, 2008 or Saturday April 12, 2008.

Due to scheduling conflicts with half of the participants, testing was completed on two separate occasions four days apart. Even with this inconvenience, testing was completed in similar testing conditions over the two days of scheduled testing.

By randomization, 19 participants received the Nike MAXSIGHT sport-tinted contact lenses to wear during their first nine holes of golf and 15 participants wore their regular golfing visual correction if any at all. The Nike MAXSIGHT sport-tinted contact lens group was allowed to let the lenses settle before testing. Visual Acuity, Brightness Acuity, and Contrast Sensitivity were recorded for each patient before golfing their first nine holes. After completing the first nine holes of golf, the participants score was recorded and were asked to fill out a survey (Appendix C) rating each statement between zero (strongly disagree) to one hundred (strongly agree). Upon completion of the survey, the participants switched from the Nike MAXSIGHT sport-tinted contact lenses to their regular correction (or visa-versa), and repeated the testing performed earlier. The participants then completed the same nine holes they previously golfed, and filled out the same survey. Upon completion of the survey, each participant was thanked for their cooperation and given the opportunity to keep the Nike MAXSIGHT sport-tinted contact lenses.

All participants had contrast sensitivity measured on the Pelli-Robson Contrast Sensitivity Chart binocularly with the Nike MAXSIGHT sport-tinted contact lenses and their regular golfing vision correction. The Pelli-Robson (**P-R**) Contrast Sensitivity

Chart, is a large wall-mounted chart, 59 cm wide and 84 cm high, that consists of 16 triplets of letters each subtending 2.8 deg at the intended 1 m test distance, arranged in 8 rows of two triplets each.³ The three letters within each triplet have constant contrast, whereas the contrast across triplets, reading from left to right, and continuing on successive lines, decreases by a constant factor ($1/\sqrt{2}$).³ Instead of the letters decreasing in size; they decrease in contrast. The final triplet that the patient read 2 of 3 letters correctly determines the log contrast sensitivity for that participant, which can be read off a score sheet that relates each triplet to a log contrast sensitivity value.³ A Pelli-Robson score of 2.0 indicates normal contrast sensitivity of 100 percent. Participant scores less than 2.0 signify decreased overall contrast sensitivity. Pelli-Robson contrast sensitivity score of less than 1.5 is consistent with visual impairment and a score of less than 1.0 represents visual disability.⁴

Each participant's visual acuity was tested monocularly at 10 feet on the Bailey-Lovie Chart both with the Nike MAXSIGHT sport-tinted contact lenses and their regular mode of golfing visual correction. The advantages of this chart include: geometric progression of letter sizes, equal number of letters per line, and a standard scoring system.

Glare disability was tested monocularly wearing the Nike MAXSIGHT sport-tinted contact lenses and the participant's regular mode of golfing visual correction. The Brightness Acuity Test was used and can simulate three bright light conditions: 1) Direct overhead sunlight; 2) Partly cloudy day; 3) Bright overhead commercial lighting.⁴ The visual acuity was measured using the high (400 ft. lamberts)⁴ light settings of the BAT, which is equivalent to being outside on a bright sunny day. If the participant's vision falls with the BAT, then the patient is deemed to have glare disability. The test was performed at 10ft in a dark room with the Bailey-Lovie Chart visual acuity chart. There are three potential outcomes when the Brightness Acuity: no change in acuity, reduction in acuity, or improvement of acuity.

Finally, a General Electric Type 214 Light Meter was used to measure illumination on the golf course and inside the testing area.

RESULTS

Thirty-four subjects participated ranging in age from 18 to 30 years old. All subjects were Professional Golf Management students or golfers with a handicap below 8. Ninety-seven percent of the participants were Caucasian and three percent were Asian. All participants that golfed and completed the survey were successfully fit with the Nike MAXSIGHT sport-tinted contact lenses. Ten of the thirty-four participants (29%) were emmetropic and fit with plano Nike MAXSIGHT sport-tinted contact lenses. Twelve of the thirty-four participants (35%) were either myopic or hyperopic without an astigmatic correction. Twelve of the thirty-four participants (35%) had an astigmatic correction, 2 two of which were piggy-backed with the patient's regular toric contact lenses (6%).

Surprisingly, when all the dust settled, there was no significant statistical difference in performance between the participant's regular visual correction and the Nike MAXSIGHT sport-tinted contact lenses in the areas of contrast sensitivity, visual acuity, and brightness acuity. However, there were some statistically significant differences and non-significant statistics worth mentioning.

Of the sixteen survey question presented to the participants, participants preferred the Nike MAXSIGHT contact lenses in three categories including; elimination of glare, elimination of squinting, and elimination of stray light. However, none of these were of statistical significance. In response to the sixteen question survey (Appendix C), a significant difference was found for five of the statements. Crisp vision ($P=0.013$), vision in the shade ($P=0.034$), vision inside buildings ($P=0.012$), ability to find golf balls ($P=0.00$), and the ability to track the golf ball in flight ($P=0.001$) were all found to be statistically significantly better with the participants regular vision correction.

Even though only some of the results were of statistical significance, it is questionable whether there is any significant effect in golfing performance while wearing these lenses. Although the participant subjective responses tended to indicate that the Nike MAXSIGHT Grey-Green contact lenses had a negative effect on their performance while golfing, the contact lenses in some areas, objectively out performed the participants' regular correction. With a P value of .065, just outside of statistical significance, the average golf score decreased by one stroke (improved by one stroke) if the participant wore the Nike MAXSIGHT contact lenses during the second nine holes of golf (Table 1). The average score for the first round of nine holes of golf while wearing their regular vision correction was 41. The average score for the second nine holes while wearing their regular vision correction was 43. The average score for the first round of nine holes of golf while wearing the Nike MAXSIGHT sport-tinted contact lenses was 44. The average score for the second round of nine holes while wearing the Nike MAXSIGHT sport-tinted contact lenses was 42.

Finally, the General Electric Type 214 Light Meter measured the illumination on the golf course and inside the testing area. The illumination varied from 40-94 footcandles inside and outside between 240 to 625 footcandles in direct sunlight.

DISCUSSION

There have not been any documented studies of monitoring performance with the grey-green MAXSIGHT contact lenses. A very recent report on the visual performance of football players with amber tinted contact lenses compared with clear contact lenses showed that, in a sample of 35 sets of eyes from 35 football players, contrast sensitivity was significantly improved with the Amber MAXSIGHT tinted contact lenses, although whether this was clinically significant was questioned by the author.⁵ There was also a study done with myopic starters of a university baseball team with the Amber MAXSIGHT lenses showing an improvement in batting average by 14-30%.⁶

After the completion of our study, looking back there are a few things we would have done differently. Our data collection was completed over a total of nearly ten hours on two different occasions. The study may have been too short in two aspects: the participants were only in the lenses for a short time before golfing and completing the objective testing, and the participants only completed two rounds of nine holes of golf. Finally, the number of participants were small (34) and may not accurately represent the golfing population.

The data for our project was collected over the course of two different days covering nearly ten hours. During that time testing conditions were constantly changing.

In a project of this size, we believe testing conditions need to be as unchanged as possible.

Our project was limited to the length of time we could allow for data collection. Due to curriculum requirements, the data collection team was only able to collect data in the spring when course conditions are less than optimal. In future projects, our recommendation would be to spread the data collection over the course of a whole golfing season including numerous rounds of golf for participants and ample time for the participants to adjust to wearing the contact lenses. If testing could not be done over the course of a season, a solution would be to give the participants the contact lenses weeks before testing to allow time for adaptation. In our study the participants had less than one-half hour to adapt the contact lenses before objective testing and golf. By allowing the participants to familiarize themselves with the contact lenses we believe the subjective and objective results may change.

Due to scheduling conflicts and a limited number of data collection assistants, the participant number was limited to thirty four for the project. Including more project members would allow for a larger sample size and more data collection days.

Other suggestions include: recording the number of putts, recording the length of made putts, and recording the number of times each participant was unable to find their golf ball without assistance.

CONCLUSION

The Nike MAXSIGHT sport-tinted contact lenses did not significantly improve or inhibit the objective performance of the participants. However, subjectively, the sport-tinted contact lenses did significantly inhibit the visual performance of the participants in the areas of crisp vision, vision in the shade, finding golf balls, vision in buildings, and tracking the golf ball in flight. It should also be mentioned that while the Nike MAXSIGHT sport-tinted contact lenses did not significantly improve the participants subjective or objective performances, some of the participants requested more lenses to use for the upcoming summer golfing season. In the areas of contrast sensitivity, brightness acuity, and visual acuity there was no significant difference between the two types of correction. Further, more in-depth study is required.

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APPENDIX A
HSRC Form

**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

1. Responsible Project
Investigator:
(Faculty or staff supervisor)
Name: Dr. Josh Lotoczky

Social Security Number: 365-04-
7366

Department:

College: Michigan College of
Optometry

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:

Additional Investigator(s):

Name: Rachael A. Peterson_____
SS# or Student ID#:
10240957

Name: Bradley A. Wruble
SS# or Student ID#:
10198389

Name:

SS# or Student ID#:

Name:

SS# or Student ID#:

2. Address: If there are more than two investigators, please indicate who should receive correspondence, and provide further addresses on a separate page.

Responsible Project Investigator
1310 Cramer Circle
Big Rapids, MI
49307

Additional Investigator(s)
Rachael A.
Peterson
314 Morrison
#2

_____ Big Rapids, MI
49307 _____

Phone #: _231-591-
2178 _____
Fax #: _231-591-
2394 _____

Phone #: _248-425-6060 _____
Fax #: _____

Email:
_lotoczkj@ferris.edu _____

Email:
_Peterson_25@hotmail.com

3. Title of Project: _Comparison of golfers overall performance when wearing Nike Maxsight Grey-Green Lenses or clear contact lenses _____

FOR OFFICE USE ONLY

Subcommittee _____ Agenda _____

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 [XX] 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 [XX] 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 [XX] 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 Nike Maxsight contact lens provides any clinical benefits or advantages in terms of contrast sensitivity, decreased glare, patient comfort, and overall performance. This sports tinted contact lens by Bausch and Lomb is made of polymacon. Nike Maxsight is a soft lens available in two glare reducing tints; amber and grey-green. Its patented Light Architecture selectively filters specific wavelengths of light in the visual spectrum to enhance key elements in sports. It supposedly provides crisp, clear vision without anything getting in its way.

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 have read and signed and 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
- 2) Follow-up visit
 - a. Subjective Data
 - i. Quality of Lens Questionnaire (see attached)
 - ii. Visual Acuity
 - iii. Contrast Sensitivity
 - iv. Brightness Acuity Test (BAT) for glare
 - v. 9 holes of golf wearing Nike Maxsight

- vi. 9 holes of golf wearing Clear contact lenses
- b. Objective Data
 - i. Lens centration and movement assessment
 - ii. Use a photometer to measure light conditions

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, and keratometry. 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 visual acuity, contrast sensitivity, and BAT testing will be taken outdoors; the photometer will be used at this point to assess the lighting conditions under which these tests were administered and is in no way harmful to the subject. 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 asked to fill out the attached subjective questioner. After completing the questioner, the subjects first set of lenses will be removed and the patients second set of contact lenses will be inserted. Again, visual acuity, contrast sensitivity, and BAT testing will be done outdoors with the new contact lenses in place. Upon completion of the tests, the subject will proceed to golf the same nine holes they played earlier. After completing the second round of the same nine holes the subject will again be asked to complete the same subjective questioner as done after the first nine holes. The subject will be debriefed and thanked for participation in our study.

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

Brightness Acuity Test or BAT

The BAT provides measurements of visual acuity in three common bright light

conditions. Procedure time is less than 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)

25 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
Women of Childbearing Age
Institutionalized Persons
Students
Low Income Persons
Minorities
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.

We are 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 be receiving 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.

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.

APPENDIX B

Statement of Informed Consent

Statement of Informed Consent

Evaluation of 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 design of an approved

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 using Fluorescein
- Refraction over the contact lens to determine best distance and near vision

If an adequate fit and vision is determined the lenses will be ordered and dispensed. The dispensed lenses will be checked for proper fit and good distance and near vision. Instructions on lens wear and a wearing schedule will be given to you. A follow-up examination will be scheduled in one week. At the follow up examination the following tests will be done:

- Visual acuity at distance and near
- Subjective vision and comfort rating
- Subjective symptoms
- Slit lamp evaluation
- Fitting assessment
- Notation of a subject “quote” regarding what you think of the lenses

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. Josh Lotoczky at 231-591-2178.

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 C

Survey

Nike Maxsight Grey-Green contact lenses verses the Soft Lens 38.

On a scale from 0 (strongly disagree) to 100 (strongly agree) please rate the following statements.

1. These contact lenses gave me crisp vision. _____
2. These contact lenses provided comfortable vision. _____
3. These contact lenses helped to eliminate glare. _____
4. These contact lenses helped to eliminate squinting. _____
5. These contact lenses provided suitable vision in transient cloud cover. _____
6. These contact lenses provided suitable vision in and out of shade. _____
7. These contact lenses provided suitable vision in and out of buildings. _____
8. Overall, I rate my performance as improved with these contact lenses. _____
9. Overall, these contact lenses reduced environmental factors affecting my performance. _____

10. Overall, these contact lenses helped me find golf balls on the course. _____
11. Overall, these contact lenses helped me read putting greens. _____
12. Overall, these contact lenses helped determine pin location for approach shots. _____

13. Overall, these contact lenses helped in tracking the golf ball in flight. _____
14. Overall, these contact lenses were comfortable. _____
15. Overall, these contact lenses helped judge distances on the course. _____
16. Overall, these contact lenses helped reduce stray light. _____

Table 1

Figure 1 Mean Golf Scores by Round

