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TITLE: Optical Quality, Threshold Target Identification, and Military Target Task Performance After Advanced Keratorefractive Surgery

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b> The purpose of the present study is to investigate the effect of advanced refractive surgery on task performance in a military operational setting. In this prospective, randomized treatment trial we will enroll 224 nearsighted soldiers to undergo wavefront-guided (WFG) photorefractive keratectomy (PRK), WFG laser in situ keratomileusis (LASIK), wavefront optimized (WFO) PRK or WFO LASIK (56 in each group). Subjects will undergo extensive clinical and military visual performance testing pre- and postoperatively. Night Vision and Electronic Sensors Directorate (NVESD) performance prediction models (the Target Task Performance [TTP] metric) will analyze data derived from the contrast sensitivity function to predict whether there is a significant difference in either the range at which target identification can be made or the time a target can be detected. Military task performance will be further evaluated by the NVESD program (threshold target identification) in which tracked vehicle targets will be presented to observers at a sufficient distance to stress the eye response. The percentage of correctly identified stimuli will be plotted as a function of range to produce a psychometric function. Finally, night firing range performance will be determined before and after surgery. Study design will enable comparison to preoperative performance as well as comparisons between treatment groups.					
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## INTRODUCTION

Visual performance is critical for the successful execution of many military tasks including target detection and identification. Although refractive surgery offers substantial benefits on the battlefield when compared to glasses, surgically induced higher order optical aberrations (HOA) may affect quality of vision in terms of contrast sensitivity, glare, haloes, and reduced night vision. Because most military operations occur in low light/low contrast setting, any further degradation of vision as a result of refractive surgery can adversely impact military task performance. Wavefront optimized (WFO) and wavefront guided (WFG) surgery aim to minimize HOA to improve postoperative quality of vision. The purpose of the present study is to investigate the utility of these advanced refractive surgery technologies in the military. In a prospective, randomized treatment trial we will enroll 224 nearsighted soldiers to WFG photorefractive keratectomy (PRK), WFG LASIK, WFO PRK or WFO LASIK (56 in each group). This is a collaborative effort between the U.S. Army Warfighter Refractive Surgery Research Center at Fort Belvoir (WRSRC) previously known as Center for Refractive Surgery at Walter Reed Army Medical Center (WRAMC), the Walter Reed National Military Medical Center (WRNMMC) previously known as the National Naval Medical Center (NNMC), and the US Army Night Vision and Electronic Sensors Directorate (NVESD). Human subjects will be seen only after approval by the WRAMC and NNMC Institutional Review Boards and the USAMRMC Human Research Protection Office. We will evaluate refractive surgery results in terms of subjective visual performance, objective optical quality, military task performance and performance prediction modeling. Participants will be enrolled in three phases:

**Table 1: Summary of study phases:**

<p>The study will be conducted in three phases randomizing WFG and WFO treatment modalities:</p> <p><b>Phase 1</b> (112 patients) – <b>subjective visual performance and objective optical quality</b></p> <p><b>Phase 2</b> (56 patients) - subjective visual performance, objective optical quality, and <b>military task performance</b> at the night firing range (NVESD)</p> <p><b>Phase 3</b> (56 patients) - subjective visual performance, objective optical quality, and <b>performance prediction modeling</b> using target detection and identification (NVESD)</p>
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## BODY

With the 2005 Base Realignment and Closure Act (BRAC), Walter Reed Army Medical Center and the National Naval Medical Center in Bethesda merged and formed a new Walter Reed National Military Medical Center (WRNMMC) in the north capital area and Fort Belvoir Community Hospital (FBCH) in the south. As part of that realignment beginning in 2011, the Ophthalmology Services at the respective centers combined to form an integrated ophthalmology service responsible for staffing at both hospitals.

In response to the BRAC and personnel changes, the principal investigator (PI), along with the WRSRC staff, determined that the following modifications would best serve the long term success of the research activities:

- To address personnel changes, a modification was submitted requesting the addition of Dr. Karin Thomas as an associate investigator.
- Due to inadequate temperature and humidity controls in the FBCH laser room, the WRNMMC laser vision center was selected to accommodate both WFG and WFO treatments. A modification was submitted requesting enrollment, study informed consent, screening, pre- and post-operative eye exams all be conducted at FBCH. All WFG treatments would be conducted at WRNMMC. WFO treatments would take place either at WRNMMC or at FBCH, when available. During the transition, the WRNMMC IRB granted this study a multisite status with WRNMMC and FBCH as the two sites. This multisite status change will be reflected in IRBNet as part of the annual continuing review in August 2012.

To accommodate BRAC changes requested by the integrated WRNMMC IRB, the following modifications were submitted:

- A WRAMC continuing review was submitted and approved on 26 July 2011 describing BRAC changes and updates.
- A transition document was submitted to the WRNMMC IRB to indicate the course of action and patient communication plan for the study during BRAC.
- As part of the transition, the NNMC protocol (IRBNet # 352274) for this study was closed 24 June 2011.
- Modifications were submitted to update the WRAMC consent form to the current WRNMMC DRP format and to incorporate both FBCH and WRNMMC as study sites.

All of the aforementioned modifications have been approved by the WRNMMC IRB. The following modification was submitted and is currently pending review:

- Due to additional personnel changes, a request to change the site PI from Dr. Michael Mines to Dr. Edward Trudo was requested. In addition, a change in medical monitor was requested from Dr. Andrew Eiseman to Dr. Jay Riddle.

The currently approved consent form and approval letters for the modifications are attached as **Appendix 1** at the conclusion of this report.

Due to the BRAC, study surgeries were discontinued as of 21 March 2011. This decision was in the best long-term interest of the study to allow for already enrolled patients to complete their scheduled follow ups in a timely manner with minimal BRAC disruption, even though it did place us significantly behind the original timeline outlined in the grant proposal. An extension was filed for the Testing Services Agreement between HJF and NVESD to accommodate the delays in enrollment and we anticipate requesting a no cost extension for the WRSRC. Nevertheless, patient recruitment restarted for Phase I LASIK and Phase II PRK with the first enrollments on 4 November 2011 at FBCH and surgeries commencing at WRNMMC on 29 November 2011.

To prepare for the first enrollments in Phase II, the research staff at FBCH visited the night firing range at NVESD to coordinate study standard operating procedures. Mr. Clifford Surrett Sr., the Night Firing Range supervisor, provided dates in November 2011-present for preoperative and 6 week postoperative firing appointments. To prepare for the first enrollments in Phase III PRK, the research staff at FBCH visited the night vision lab at NVESD and has met at FBCH to review the target detection and identification task using the Recognition of Combat Vehicle (ROC-V) program. We anticipate the first enrollments in Phase III PRK to occur in June 2012.

**Tables 2 and 3** lists the current enrollment and follow up rates by Phase at FBCH and the Night Firing Range (Phase II).

**Table 2: Summary of wavefront-optimized (O) and wavefront-guided (G) treatment enrollment and follow up rates by Phase:**

Phase I	Enrolled			1M		3M		6M		12M	
	PRK (O/G)	LASIK (O/G)		PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)
Total required	28/28	28/28	Seen for Visit	26/28	16/14	25/27	14/12	26/26	11/11	25/26	9/11
Withdrawn	2	0	Missed Visit	0	0	1/1	0	0/2	0	1/2	1/0
Enrolled	26/28	16/14	Total Eligible	26/28	16/14	26/28	14/12	26/28	11/11	26/28	10/11
	92.9%/100%			100%	100%	96.2%/96.4%	100%	100%/92.9%	100%	96.2%/92.9%	90%/100%
NVL Phase II	Enrolled			1M		3M		6M		12M	
	PRK (O/G)	LASIK (O/G)		PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)
Total required	14/14	14/14	Seen for Visit	14/10	0	6/5	0	1/0	0	0	0
Withdrawn	0	0	Missed Visit	0	0	0	0	0	0	0	0
Enrolled	14/13	0	Total Eligible	14/10	0	6/5	0	1/0	0	0	0
				100%	-	100%	-	100%	-	-	-

**Table 3 Follow up rates at the night firing range (NFR) Phase II:**

Phase II NFR	Preop		6W		6M	
	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)
Seen for Visit	14/13	0	14/9	0	0	0
Missed Visit	0	0	0	0	0	0
Total Eligible	14/13	0	14/9	0	0	0
	100%	-	100%	-	-	-

There were no adverse events reported since the last annual report.

## **KEY RESEARCH ACCOMPLISHMENTS**

- When evaluating the changes in simulated keratometry induced by myopic WFG and WFO PRK, a preliminary review of 54 patients (WFG, n=28; WFO, n=26) found WFG and WFO PRK induce equivalent amount of change to the corneal curvature for every unit of refractive change in treating myopia. (Appendix 2)
- A comparison of the contrast threshold (CT) of Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) PRK in 33 WFG and 31 WFO participants found the following (Appendix 3):
  - ❖ Results show there is no significant difference in binocular contrast threshold when comparing WFG to WFO PRK over time.
  - ❖ There is no significant difference between WFG and WFO PRK contrast sensitivity at each time point except at 12 months when WFG participants have better CS at a 3.0cpd spatial frequency (SF) than WFO. Additional study will determine if this is an anomaly or if WFG performs better at certain SF.
  - ❖ Ongoing testing in this study will determine if WFG or WFO generated optical quality affects task performance.
- A comparison of visual acuity and contrast sensitivity results after WFG and WFO PRK in 33 WFG and 31 WFO participants found the following (Appendix 3):
  - ❖ Night vision contrast performance was comparable between WFO PRK and WFG PRK. However, WFG PRK appears to be superior to WFO PRK when comparing high and low contrast acuity over time.

## **REPORTABLE OUTCOMES**

None

## **CONCLUSION**

None

## **REFERENCES**

None

## **SUPPORTING DATA**

None

## **APPENDICES**

**Appendix 1** Current consent form and WRAMC, NNMC, and WRNMMC approval letters

**Appendix 2** Abstract of results presented at the American Society of Cataract and Refractive Surgery Annual Meeting

**Appendix 3** Posters presenting results at the Annual Research in Vision and Ophthalmology  
Annual Meeting

**FORT BELVOIR COMMUNITY HOSPITAL (FBCH)  
FORT BELVOIR, VA**

**This Clinical Trial consent form is valid only if it contains the IRB stamped date.**

**Consent for Voluntary Participation in a Clinical Trial (a type of research study) Entitled:  
“Optical Quality, Threshold Target Identification, and Military Target Task Performance  
After Advanced Keratorefractive Surgery”.**

**Principal Investigator: LTC Michael J. Mines, MC, Ophthalmology Service, Department of  
Surgery, phone (571) 231-1600.**

**Study Site: XX FBCH, XX WRNMMC**

**1. INTRODUCTION OF THE STUDY**

You are being asked to be in this research study because you are an active duty U.S. military personnel, age 21 or older, will be located in the national capital region for at least 1 year, and wear either glasses or contact lenses for either nearsightedness and/or astigmatism (unequal curvature of the eyeball). Your participation is voluntary. Refusal will not result in any penalty or loss of benefits to which you are otherwise entitled, nor will refusal have any affect on your military career status.

**2. PURPOSE OF THE STUDY**

The purpose of this research project is to evaluate the outcomes of visual performance in nighttime military settings before and after receiving wavefront guided or wavefront optimized laser assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) surgery. Although daytime vision is often excellent following refractive surgery, there have been reports of night vision changes resulting from PRK and LASIK.

Studies have shown LASIK and PRK to be safe and effective in the treatment of nearsightedness, farsightedness and astigmatism (e.g. corneal or refractive power asymmetry) in civilians and in U.S. ~~Army~~ military personnel. In nearsightedness, farsightedness or astigmatism, the clear front surface of your eye, the “cornea”, does not have the proper focusing power. To correct this deficiency you must wear lenses, either glasses or contacts, either in front of the cornea or on the cornea in order to see clearly.

Both LASIK and PRK use a machine called an excimer laser to reshape your cornea to try and give it the proper focusing power. In the LASIK procedure a “flap” is made in the cornea using another laser, called a femto-second laser. The flap is lifted and the excimer laser is used to reshape the cornea underneath. The flap is then replaced and allowed to heal. In the PRK procedure no flap is made. Instead, the outer layer of cells on the clear part of your eye, the corneal epithelium, is removed exposing the layer to be treated by the laser. Use of both lasers to make the flap and reshape the

cornea is approved by the Food and Drug Administration (FDA) and the procedure is not considered investigational (experimental). These are the exact same procedures that other soldiers are receiving at Fort Belvoir Community Hospital (FBCH) and Walter Reed National Military Medical Center (WRNMMC) and are considered 'standard of care.'

Both LASIK and PRK surgeries can be either wavefront guided or wavefront optimized. The wavefront guided procedure customizes the laser treatments based on the individual characteristics of the eye being corrected. The wavefront optimized procedure uses laser treatment software that has been designed with certain wavefront corrections pre-programmed, and a customized wavefront plan is not employed.

### **3. PROCEDURES TO BE FOLLOWED**

This study will be conducted in three sequential phase. You will only be in a single phase. The phase you are in will depend upon when you agree to be in the study.

**Phase I** will consist of a preoperative evaluation and testing at FBCH, the surgery that will be either wavefront optimized (at FBCH or WRNMMC) or wavefront guided (at WRNMMC), and post-operative evaluations at FBCH. Phase I will consist of a total of 112 subjects.

**Phase II** will consist of a preoperative evaluation and testing at FBCH, a pre-operative indoor M16 night fire range at Ft. Belvoir, the surgery that will be either wavefront optimized (at FBCH or WRNMMC) or wavefront guided (at WRNMMC), and post-operative evaluations at FBCH and post-operative M16 night fire range at 6 wks and 6 mos. Your marksmanship skill will be evaluated with an M16-A2 rifle on a modified range under low light or nighttime conditions. The purposes of these tests are to evaluate the effect of the types of surgeries on night vision in a military environment. You will undergo testing in the night firing range at the Night Vision and Electronic Sensors Directorate at Ft. Belvoir a total of three times (before surgery, 6 weeks and 6 months after surgery). You will need to arrange your own transportation to Ft. Belvoir and this will result in some cost to you if you use a POV. Testing will be during normal business hours in a facility that simulates nighttime conditions. Phase II will consist of a total of 56 subjects.

**Phase III** will consist of a preoperative evaluation and testing at FBCH, a pre-operative computer simulation at Ft. Belvoir requiring you to identify images of military vehicles at Ft. Belvoir, the surgery that will be either wavefront optimized (at FBCH or WRNMMC) or wavefront guided (at WRNMMC), and post-operative evaluations at FBCH, post-operative evaluations at FBCH and post-operative computer simulation requiring you to identify images of military vehicles at Ft. Belvoir. The training and testing you will receive will consist of identifying and recognizing thermal images of military vehicles displayed on a computer monitor. Vehicles will be at various resolutions and in different background environments, simulating real world nighttime conditions. Your responses will be scored and evaluated. The purposes of these tests are to evaluate the effect of the types of surgeries on night vision in a military environment. You will undergo testing in the Human Perception Laboratory at the Night Vision and Electronic Sensors Directorate at Ft. Belvoir a total of three times (before surgery, 6 weeks and 6 months after surgery). You will need to arrange your own

transportation to Ft. Belvoir and this will result in some cost to you if you use a POV. You will also be required to pass a pretest each time before you can begin testing. The pretest will ascertain if you know the military vehicles well enough to undergo testing. If you do not pass the pre-test, you will not be allowed to test. Testing will be during normal business hours in a facility that simulates nighttime conditions. Phase III will consist of a total of 56 subjects.

### **All Phases**

If you agree to be in this study you will be randomly assigned (similar to the flip of a coin) to receive either a wavefront optimized ablation pattern or a wavefront guided ablation pattern. You will NOT be randomly assigned either PRK or LASIK and that decision will be up to you and your doctor. Your chances of being assigned to each group are equal. Depending on your assigned group, you will be treated at either Fort Belvoir Community Hospital in Fort Belvoir, VA or Walter Reed National Military Medical Center in Bethesda, MD. If you are receiving surgery at WRNMMC, you may drive directly to WRNMMC on the day of surgery, but depending on where you are traveling from, you may incur additional cost.

Demographic data, such as age and gender, will be collected during your screening exam in order to provide a correlation with clinical data. You will undergo eye testing before surgery and at 1, 3, 6 and 12 months after the surgical procedure at Fort Belvoir Community Hospital as part of the standard of care (SOC). This will involve measuring vision, refraction (the need for glasses), eye pressure, corneal (the clear transparent outer layer of the eye) curvature, corneal clarity, corneal thickness, and contrast sensitivity [the ability to distinguish vertically oriented lines of different sizes and levels of contrast (e.g. black & white v. shades of gray)]. On several examinations, some of these tests will be repeated after your eyes have been dilated with eye drops.

As part of this study, you will be asked to undergo some additional eye testing for research purposes at the eye examination before surgery and at the examinations done 1, 3, 6, and 12 months after surgery. Your vision will be measured using standard visual acuity chart and 2 charts with low contrast letters (e.g. low contrast=faded, light grey letters). You will also be asked to complete a questionnaire before surgery and 1, 3, 6 and 12 months after surgery to determine your satisfaction with your laser eye surgery. It will take you approximately 5 minutes to complete the questionnaire each time it is given. A topographic (surface) map of your eye will be obtained using a Wavefront Analyzer. Contrast sensitivity will be measured using a computer, which displays spatial gratings (e.g. vertical stripes) on a monitor. The computer will vary the size of the vertical stripes and the level of contrast of the stripes (e.g. black & white v. shades of gray). Your task will be to identify which side of the monitor the spatial grating appears. This will take you approximately 20 minutes to complete. Each clinic appointment will last from one to two hours.

If you are a woman capable of having children, you will be asked to have a urine pregnancy test before the surgical procedure. If this test is positive, you will not be able to continue in this study. Additionally, if you plan to become pregnant in the next 12 months you can not be in this study since pregnancy has been shown to cause a change in the spectacle prescription.

The FBCH Clinic can be contacted at (571) 231-1600 and the WRNMMC clinic can be reached at (301) 295-1339.

#### **4. AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY**

You will be part of this study for slightly more than 12 months. The amount of time required to complete this study will depend on which phase of the experiment you take part in.

**Phase I, Phase II, and Phase III:** During phase I, you will be asked to visit the FBCH clinic up to 10 times. Additionally, you may have to go to the WRNMMC to receive surgery. You will be seen at FBCH the day after surgery, 3 or 4 days after surgery, and one week after surgery. Each visit will last about 15 to 30 minutes. Additional follow-up evaluations will be at 1 month, 3 months, 6 months and 12 months following your surgery. These visits will last up to 1 to 2 hours each. Over the entire twelve months, this will require as much as 10 hours of examination time after the surgery (postoperatively). The standard amount of time for patients not involved in research is about eight hours. Research candidates can expect an additional two hours of testing.

**Phase II:** In addition to your follow-ups at FBCH, you will be asked to fire an M16 at a range at Ft. Belvoir preoperatively, at 6 weeks post-operatively, and at 6 months post-operatively. You will not be asked to qualify at this range, but to shoot at a target located at variable distance from you location. This requirement is expected to take approximately 60 minutes. The standard amount of time for patients not involved in research is about eight hours. Research candidates in phase II can expect an additional 5 hours of testing.

**Phase III:** In addition to your follow-ups at FBCH, you will be asked to visit the Night Vision Laboratories a total of 3 times (before surgery and at 6 weeks and 6 months after surgery) to participate in the night vision sensor testing. You will be provided training software to complete on your own. This will take approximately 4 hours. Prior to testing at Ft. Belvoir you will undergo refresher training that may last up to 4 hours, depending on your skill. The testing period will last up to 3 hours. Research subjects in Phase III can expect to expend an extra 21 hours of testing.

#### **5. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY**

There will a total of 224 people in total taking part in this study. A total of 112 will be enrolled in phase I, 56 patients will be in phase II, and 56 patients will be in phase III.

#### **6. POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY**

There are no significant risks that may develop as a result of participation in this study other than those associated with the surgery itself. Given that the surgery is NOT experimental and would be performed as standard of care outside of this research project, those risks are not addressed in the research consent form. The surgeon will discuss the risks associated with the surgery when you review the surgical consent form.

None of the testing procedures pose any risk beyond a normal eye examination, viewing a computer monitor, or military training.

Any additional risks that may develop as a result of your participation in this study, other than those associated with the procedure itself are related to the M16-A3 night firing range. Military personnel trained in the use of night vision devices and small arms range activities will supervise all operations of this part of the study. Strict adherence to all range safety instructions will mitigate any risk of injury. The risks of injury are expected to be similar to those of any military supervised rifle range activity.

None of the contrast sensitivity (the ability to distinguish vertically oriented lines of different sizes and levels of contrast (e.g. black & white v. shades of gray) testing or the night vision sensor testing has any risks other than those associated with looking at a computer monitor. However, because of the travel required to Ft. Belvoir in addition to the required pre-test training, Phase III has the largest time commitment of the three phases. This will be further discussed on the NVESD Informed consent. Additionally, you may incur additional costs associated with driving to Ft. Belvoir.

While all risks that we know about have been listed above, other risks about which we do not know may occur or be discovered during future studies. If we find that there was a major risk to you that was not known at the time of your participation in the study, and the risk might have some effect on your health, you will be informed.

## **7. POSSIBLE BENEFITS FROM BEING IN THIS STUDY**

The information we gain from you being in will help us gain important knowledge regarding the visual performance of Soldiers who receive the wavefront optimized and wavefront guided surgery. This knowledge will assist us in providing the best possible refractive surgery procedures to future Soldiers.

## **8. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS**

The principal investigator will keep records of your being in this study. These records may be reviewed by individuals from the Walter Reed Department of Research Programs (DRP), the Walter Reed Institutional Review Board, Fort Belvoir Community Hospital Clinical Investigations, Human Research Protection Office (HRPO) of the U.S. Army Medical Research & Materiel Command (USAMRMC), the Army Clinical Investigation Regulatory Office (CIRO), and other government agencies as part of their duties. These duties include making sure that research subjects are protected. Collaborators of the study will not have access to your medical records. Confidentiality of your records will be protected to the extent possible under existing regulations and laws. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study.

When you enter this study you will be given a study ID number which will not contain any part of your social security number. This study ID number, not your name or social security number, will be used to label your data for analysis. However, because you are also a patient we will maintain your name and personal information in your study (paper) chart. This will assist us in prescribing you medication if you might need it. The randomization table linking your study ID number with your personal identifying information will be kept in a locked file at Fort Belvoir Community Hospital, Ft. Belvoir, VA, and access to it will be restricted to the principal investigator and his designee(s). All clinical and research data will be kept for 7 years.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA authorization form for this study will be provided to you separately, and you will be asked to sign that form.

## **9. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT**

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you become ineligible for medical care at military hospitals. The principal investigator may terminate your participation in this study if you fail to attend the baseline or follow-up examinations or elect not to undergo the laser procedure.

## **10. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY**

You will not be paid for your participation in this research study.

## **11. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE**

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost to you. You will not receive any compensation (payment) for injury. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in-home care or nursing home care.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project, and you are enrolled at WRNMMC, you should contact the Department of Research Programs (DRP) at WRNMMC at 301-295-2275. If you are enrolled at FBCH you should contact Fort Belvoir Clinical Investigations at 571-231-4020

## **12. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY**

There are no additional costs for taking part in this study other than returning to FBCH for your follow-up appointments, driving to Ft. Belvoir, or lost duty time.

Additionally, if your surgery is conducted at WRNMMC, you may have to drive directly to WRNMMC.

### **13. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY**

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible. By leaving this study, you do not risk losing your right to medical care. Some testing or period of observation by the investigators may be recommended for you in order for you to safely stop taking part in this study. Any new significant finding during the course of this study that might affect your willingness to continue participation will be communicated to you.

### **14. STEPS TAKEN BEFORE AND DURING THIS STUDY TO PROTECT YOU**

The surgery will be conducted according to manufacturer's guidelines and in the same way as it would be done if you were not taking part in this study. Additionally, we will follow the "standard of care" or "best clinical practices" in all preoperative and postoperative evaluations and you will be carefully monitored for complications of the surgery. Any undesired, clinically significant change in the eye or eyes operated on will be evaluated and treated by investigators.

To monitor for glaucoma, your intraocular pressure (pressure inside the eye) will be measured while you are taking topical steroid drops. We will use a technique called applanation tonometry with either a tonopen or a Goldmann Applanation tonometry. These devices measure the pressure inside your eyes by gently touching the front of your eyes until a predetermined circular area is achieved. Your post-operative medications will be changed when necessary if your eye pressure is significantly increased.

If you are pregnant or if you plan to become pregnant, you will not be eligible for surgery. Women of childbearing age must take a urine pregnancy test before starting this study. The order for the pregnancy test will be submitted during the preoperative evaluation. The pregnancy test must be completed by an accredited US Department of Defense laboratory. You can either do it at the FBCH laboratory which located at level 1 of the Oaks Pavilion (telephone no. 571-231-4154) or you can complete the test at the lab located at your home station. If this test is positive, you cannot take part in this study.

### **15. WHAT ARE THE UNKNOWN RISKS TO YOU OR AN UNBORN CHILD/FETUS**

It is not known whether this treatment or the medication associated with the surgery might harm an unborn child. Therefore, you should not be in this study if you are pregnant. Also, you should not be in this study if you are breast-feeding since the medications may be passed from mother to child. A period of six month must elapse from the cessation of breast feeding before a soldier is eligible for refractive surgery. This is a requirement for ALL refractive surgery patients, not just refractive surgery patients. This is to ensure refractive stability has been achieved.

You should avoid becoming pregnant while you are taking part in this study as it has been shown that pregnancy can change a patient's spectacle prescription. If you plan to become pregnant during the study period, you are not eligible for surgery as a study subject. Please inform the research director and you may receive surgery as a regular patient. However, you should avoid becoming pregnant for at least six months after receiving the treatment. The reason for avoiding pregnancy for at least 6 months after the surgery is because of the possibility that re-treatment may be necessary

To avoid becoming pregnant you should either have no sexual relations or use a reliable type of birth control. Except for removal of the uterus (womb) for women and vasectomy (surgical cutting of the tubes that carry sperm) for men, birth control methods are not totally effective in preventing pregnancy. The only ways to completely avoid this risk of the treatment to an unborn baby are (1) avoid pregnancy, or (2) do not take this treatment.

#### **16. OTHER PROCEDURES OR TREATMENTS THAT YOU COULD CHOOSE**

You may choose to be treated for your nearsightedness without taking part in this study. Should you decide not to participate in this research study, you have the option of continuing to wear either glasses, contact lenses or have these procedures (or other refractive procedure) completed elsewhere. You may also choose to have PRK or LASIK done outside of this study. PRK and LASIK are done at Walter Reed as a standard of care procedures without participation in any research study. Surgical alternatives to PRK and LASIK include laser subepithelial keratectomy (LASEK) and epithelial LASIK (epi-LASIK), radial keratotomy and lens implants. Your doctor can provide you with more information about your nearsightedness, farsightedness and astigmatism and the benefits and risks of the different treatments available. You are encouraged to discuss this with your doctor.

#### **17. IMPORTANT NEW FINDINGS THAT MAY AFFECT YOUR WILLINGNESS TO STAY IN THE STUDY**

If we learn new information during the study that could affect your decision to be in this study, we will tell you this information. For example, if we learn about new severe side effects of the treatment, we will tell you about these side effects. The results of the research will be provided to you if you so desire.

#### **18. YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care nor will it affect your military career status.

#### **19. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION**

The Federal Health Insurance Portability and Accountability Act (**HIPAA**) includes a Privacy Rule that gives special safeguards to Protected Health Information (**PHI**) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

**(1) What information will be collected?**

For this research study, we will be collecting information about your eye examinations, refractive surgery, eye health status, any side effects that you are experiencing, and how the treatment affects your comfort. These include vision, refraction (the need for glasses), eye pressure, corneal (the clear transparent outer layer of the eye) curvature, corneal clarity, corneal thickness, wavefront analysis, and contrast sensitivity (testing your vision under different dark to light contrast conditions). Some patients will have additional testing in night vision performance that will be also be collected. We will also be collecting your (PHI) such as your name, age, telephone, and fax numbers, email address and your social security number .

**(2) Who may use your PHI within the Military Healthcare System?**

The members of the Center for Refractive Surgery research team will have access to your health information in order to find out if you qualify to participate in this study, to plan and conduct your surgery, to administer research medication, to monitor your progress, and to analyze the research data. Additionally, your PHI may be made available to health oversight groups such as the Walter Reed Department of Research Programs, Fort Belvoir Community Hospital Clinical Investigations, and the Walter Reed Institutional Review Board.

**(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?**

No one outside the Military Healthcare System will receive your PHI.

**(4) What is the purpose for using or disclosing your PHI?**

Your protected health information will be collected and used during the course of the research study, to monitor your health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests and procedures.

The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

**(5) How long will the researchers keep your PHI?**

The research team in the Center for Refractive Surgery will keep the research data for up to seven years after the end of the study. At the end of this time the data will be destroyed.

**(6) Can you review your own research information?**

Because the research includes blinding research participants to their study group, you will not be able to look at your research information until your participation in the study has ended.

**(7) Can you cancel this Authorization?**

Yes. If you cancel this Authorization, you will no longer be included in the research study. However, the information that has already been collected will be kept by the research team to assure patient safety.

If you want to cancel your Authorization, please contact the Principal Investigator in writing.

If you decide to participate in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke your Authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

**(8) What will happen if you decide not to grant this Authorization?**

If you decide not to sign this Authorization, you will not be able to participate in this research study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

**(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?**

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Army Clinical Investigation Regulatory Office, the Food and Drug Administration, the Department of

Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

**(10) Who should you contact if you have any complaints?**

If you believe your privacy rights have been violated, you may file a written complaint with (if you are enrolled at WRNMMC) the Walter Reed Privacy Officer, located at 8901 Wisconsin Avenue, Bethesda, MD 20889-5600, telephone 301-319-4775 or (if you are enrolled at FBCH) the FBCH Privacy Officer, FBCH Privacy Office, located at 9300 Dewitt Loop, Oaks Pavilion, Fort Belvoir, VA 22060 at 571-231-3319.

Your signature at the end of this document acknowledges that you authorize the WRNMMC/ FBCH personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

**20. CONTACTS FOR QUESTIONS ABOUT THE STUDY**

If you have questions about the study, or if you think you have a study-related injury you should contact the principal investigator at 571-231-1600 at FBCH. For questions about your rights as a research participant, if you are enrolled at WRNMMC contact the Walter Reed Department of Research Programs at 301-295-2275 or the Walter Reed Staff Judge Advocate Office at 301-295-2215. If you are enrolled at FBCH, contact FBCH Clinical Investigations at 571-231-4020 or the Office of the Command Staff Judge Advocate in the Sunrise Pavilion at 571-231-2877.

A copy of this consent form will be provided to you.

**SIGNATURE OF RESEARCH SUBJECT**

I have read the information in this consent form. I have been given a chance to ask questions and all of my questions have been answered to my satisfaction.

**BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.**

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Subject's Printed Name

**SIGNATURE OF INVESTIGATOR**

I have explained the research to the volunteer and answered all of his/her questions. I believe that the volunteer/subject understands the information described in this document and freely consents to participate.

---

Investigator's Signature

---

Date (must be the same as the participant's)

---

Investigator's Printed Name



DEPARTMENT OF THE NAVY  
NATIONAL NAVAL MEDICAL CENTER  
8901 WISCONSIN AVENUE  
BETHESDA MARYLAND 20889-5600

IN REPLY REFER TO

6500  
14IV00/324

JUL 28 2011

From: Commander, National Naval Medical Center  
To: CDR D. Cute, MC, USN

Subj: CLOSURE REPORT FOR RESEARCH PROJECT NPMC.2009.0051,  
"OPTICAL QUALITY, THRESHOLD TARGET IDENTIFICATION, AND  
MILITARY TARGET TASK PERFORMANCE AFTER ADVANCED  
KERATOREFRACTIVE SURGERY

Ref: (a) SECNAVINST 3900.39D  
(b) Email of 23 Jun 11  
(c) Chair, Institutional Review Board (IRB)  
Endorsement on IRBNet of 24 June 11

1. References (a) and (b) were reviewed and endorsed by reference (c), the Chair, IRB. The report will be recorded in the 14 July 2011 IRB meeting minutes, and will be forwarded to the Director, Human Research Protection Program, Bureau of Medicine and Surgery.

2. Please do not hesitate to contact the Responsible Conduct of Research Services staff at (301) 295-2275 for any concerns or assistance.

*S. I. Gaines*  
S. I. GAINES  
By direction



**DEPARTMENT OF THE ARMY**  
WALTER REED ARMY MEDICAL CENTER  
WALTER REED HEALTH CARE SYSTEM  
WASHINGTON, DC 20307-5001

REPLY TO  
ATTENTION OF

DATE: July 29, 2011

TO: LTC Michael Mines, MC, USA

FROM: MAJ Jessica Zaret, MC, Chief, Research Review Service

SUBJECT: IRBNet ID: [20481-18] and Work Unit # 08-6967 - Continuing Review

COMMITTEE APPROVAL DATE: July 26, 2011

REVIEW TYPE: Full Committee Review

STUDY TITLE: Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery

Dear Dr. Mines,

1. The continuing review report for this protocol was reviewed and approved in accordance with Federal Human Subject Protection Requirements for continuation for one year. This study is open for accrual. The updated stamped Informed Consent Form(s) (ICFs) should be used for future enrollment and are available in IRBNet under Reviews.
2. The approval of this continuing review expires on August 11, 2012. You will receive automatic reminder notices when the next continuing review is due.
3. POC for this action is Angela Quispe, Continuing Review, (202) 782-7833.

MAJ Jessica Zaret, MC  
Chief, Research Review Service  
Department of Clinical Investigation

"Electronic Signature Notice: In accordance with the "Government Paperwork Elimination Act" (GPEA) (Pub.L. 105-277; codified at 44 USC 3504); Federal and DOD applicable instructions, directives and regulations, documents have been electronically signed and authorized by all who have been required to do so. These signatures have the same effect as their paper-based counterparts. Verification is retained within our protected electronic records and audit trails."



**DEPARTMENT OF THE NAVY**  
**WALTER REED NATIONAL MILITARY MEDICAL CENTER**  
**8901 WISCONSIN AVENUE**  
**BETHESDA MARYLAND 20889-5600**

IN REPLY REFER TO

6500  
14IV00/  
December 7, 2011

From: Commander, Walter Reed National Military Medical Center  
To: LTC Michael Mines, MC, USA

Subj: WRNMMC IRB2 REVIEW OF 20481-20

PROJECT TITLE: [20481-20] Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery

REFERENCE #: 08-6967

SUBMISSION TYPE: Amendment

ACTION: APPROVED

APPROVAL DATE: November 29, 2011

EXPIRATION DATE: August 11, 2012

REVIEW TYPE: Expedited Review

1. Thank you for your submission of your amendment materials for this research study. The WRNMMC IRB2 has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.
2. Your request to change the enrollment, consent form, screening, pre- and post-operative eye exam to be done at Ft. Belvoir due to BRAC has been reviewed under the provisions of 32 CFR 219.110(b) (2) and 21 CFR 56.110 and is approved. This change to research project was documented in the 15 December 2011 IRB meeting minutes.
3. Enclosure (1) is the IRB approved, stamped consent form. Enclosure (1) is to be duplicated and used to enroll subjects. Keep the signed original consent form in your project file; give each subject a copy of their signed documents; and place a copy of the signed documents in each subject's medical record.
4. Be sure to maintain complete records concerning this change with your original project file.
5. You are reminded to provide all amendments, internal adverse event reports, deviations, and any other relevant information pertaining to your research protocol to the Department of Research Programs through IRBNet.
6. Please do not hesitate to contact the Department of Research Programs (DRP) staff at (301) 295-8239 for any assistance or concerns.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.



**DEPARTMENT OF THE NAVY**  
**WALTER REED NATIONAL MILITARY MEDICAL CENTER**  
**8901 WISCONSIN AVENUE**  
**BETHESDA MARYLAND 20889-5600**

IN REPLY REFER TO

6500  
14IV00/  
January 20, 2012

From: Commander, Walter Reed National Military Medical Center  
To: LTC Michael Mines, MC, USA

Subj: WRNMMC IRB2 REVIEW OF 20481-22

PROJECT TITLE: [20481-22] Optical Quality, Threshold Target Identification, and Military Target Task Performance after Advanced Keratorefractive Surgery

REFERENCE #: 08-6967

SUBMISSION TYPE: Amendment

ACTION: APPROVED

APPROVAL DATE: January 5, 2012

EXPIRATION DATE: August 11, 2012

REVIEW TYPE: Expedited Review

1. Thank you for your submission of your amendment materials for this research study. The WRNMMC IRB2 has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.
2. Your request to add CDR K. Thomas, MC, USN as an associate investigator has been reviewed under the provisions of 32 CFR 219.110(b) (2) and is approved. This change to research project was documented in the 19 January 2011 IRB meeting minutes.
3. Be sure to maintain complete records concerning this change with your original project file.
4. You are reminded to provide all amendments, internal adverse event reports, deviations, and any other relevant information pertaining to your research to the Department of Research Programs through IRBNet.
5. Please do not hesitate to contact the Department of Research Programs (DRP) staff at (301) 295-8239 for any assistance or concerns.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

## **Wavefront-guided vs. Wavefront-optimized PRK: a comparison of simulated keratometric changes after myopic ablation.**

*R.K. Sia, D.S. Ryan, R.D. Stutzman, M.J. Mines, D.Cute, K.S. Bower*

Purpose: To evaluate the changes in simulated keratometry induced by myopic wavefront-guided and wavefront-optimized Photorefractive keratectomy (PRK).

Methods: This is a prospective study of 54 patients aged 21 or older, randomized to undergo wavefront-guided (WFG, n=28) or wavefront-optimized PRK (WFO, n=26) for myopia or myopic astigmatism. WFG PRK was performed using VISX STAR S4 Excimer Laser and WFO PRK with Allegretto Wave Excimer Laser System. Subjective manifest refraction and corneal curvature were determined preoperatively and 6 months postoperatively. Corneal curvature was measured as simulated keratometry (simK) using the Oculus Pentacam. Relationship between the calculated change ( $\Delta$ ) in MSE and in simK was explored using regression analysis.

Results: PRK was performed on 108 eyes, 56 underwent WFG and 52 underwent WFO. Mean preop MSE was  $-3.53D \pm 1.95$  in WFG and  $-3.32D \pm 1.79$  in WFO eyes ( $P=0.57$ ). Mean preop simK was  $43.88D \pm 1.65$  in WFG and  $43.58D \pm 1.52$  WFO eyes ( $P=0.34$ ). There was a statistically strong positive correlation between  $\Delta$ simK and  $\Delta$ MSE in WFG PRK ( $r^2=0.84$ ,  $P<0.001$ ) and WFO PRK ( $r^2=0.92$ ,  $P<0.001$ ). There was a greater increase in the  $\Delta$ simK for every increase in the  $\Delta$ MSE seen in WFG ( $\beta=0.765$ ) than WFO PRK ( $\beta=0.733$ ), but this was not statistically significant ( $P=0.59$ ).

Conclusion: WFG and WFO PRK induce equivalent amount of change to the corneal curvature for every unit of refractive change in treating myopia.



# Comparison of Contrast Threshold after Wavefront-guided vs. Wavefront-optimized Photorefractive keratectomy (PRK)

ARVO Program Number 1474

D. S. Ryan<sup>1</sup>, L. Peppers<sup>1</sup>, R.K. Sia<sup>1</sup>, M. J. Mines<sup>2</sup>, D. Cute<sup>2</sup>, R.D. Stutzman<sup>2</sup>, R.S. Howard<sup>3</sup>, K. S. Bower<sup>4</sup>  
<sup>1</sup> U.S. Army Warfighter Refractive Surgery Research Center at Fort Belvoir, Fort Belvoir, VA, USA  
<sup>2</sup> Ophthalmology, Walter Reed National Military Medical Center, Bethesda, MD, USA  
<sup>3</sup> Department of Research Programs, Walter Reed National Military Medical Center, Bethesda, MD, USA  
<sup>4</sup> The Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD, USA

## PURPOSE

To compare the contrast threshold (CT) of Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) PRK.

## INTRODUCTION

Even with the most modern technology refractive surgery outcomes continue to be imperfect. As a byproduct of refractive surgery, optical aberrations are induced, degrading the overall optical quality of the human eye.<sup>1</sup> Refractive surgery decreases 2<sup>nd</sup> order aberrations, but it increases the magnitude of higher-order aberrations (HOA). Elevated HOAs have been positively correlated with a decrease in contrast sensitivity.<sup>1-4</sup>

Technological advances have reduced the amount of optical aberrations induced by refractive surgery, resulting in improvements in postoperative quality of vision. The two most prominent advances in this regard are the use of customized wavefront-guided (WFG) and wavefront-optimized (WFO) ablations. The advent of wavefront aberrometry brought the potential of correcting not only myopia and astigmatism but other, smaller optical aberrations.<sup>5</sup> In WFG treatments, aberrometers are coupled with excimer lasers resulting in customized laser ablations to each individual's eye. WFO ablations attempt to preserve the cornea's asphericity by adding peripheral treatment to minimize aberrations.<sup>7</sup>

Patients treated with WFG ablations perform better on contrast sensitivity testing than patients treated with conventional laser treatments.<sup>8</sup> Patients treated with WFO PRK or LASIK ablations do not have significantly induced HOA profiles.<sup>9</sup> As our ability to measure and quantify aberrations improves, detection in changes of HOAs prompts us to examine optical quality of the eye.

## METHODS

Participants randomized to receive WFG PRK (VISX Star S4, Abbot Medical Optics) or WFO PRK (Wavelight Allegretto Wave Eye-Q, Alcon Surgical) underwent binocular testing to determine their contrast threshold (CT) preoperatively with correction and at 1, 3, and 6 months postoperatively without correction. After an initial demonstration of the CSF test procedure, the CT was measured by the Metropsis Visual Stimulus Generation Device (ViSaGe, Cambridge Research Systems Ltd.) at five different spatial frequencies (SF): 1.5, 3.0, 6.1, 13.1, and 19.7 cycles per degree (cpd). The protocol used a 2 alternative forced choice, linear staircase adaptive procedure using a 90° Gabor stimulus with a mean luminance of 50.0 cd/m<sup>2</sup>. Metropsis software calculated the average % CT for each spatial frequency. A repeated measures analysis of variance (RM-ANOVA) was used to compare WFG vs. WFO PRK at each spatial frequency over time. To look specifically at each SF, an independent samples t-test was performed to compare WFG vs. WFO contrast sensitivity (CS) at each time point and means were used to generate a contrast sensitivity function for each modality at each time point. The area under the log contrast sensitivity function (AULCSF) was calculated for each subject at each time point. A RM-ANOVA was used to compare WFG vs. WFO AULCSF over time. A p-value <0.05 was considered significant.

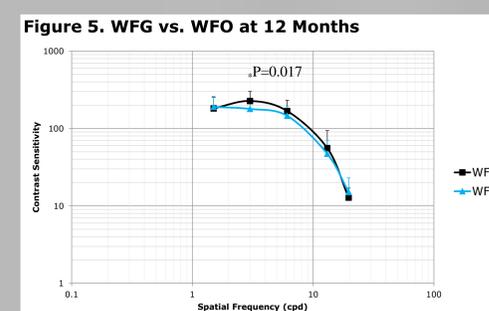
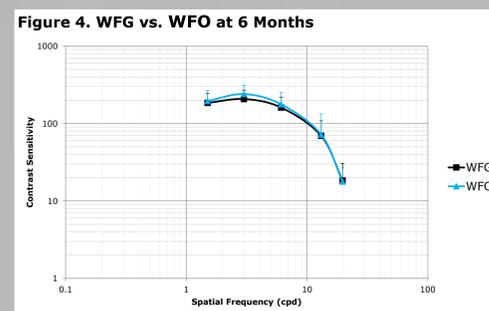
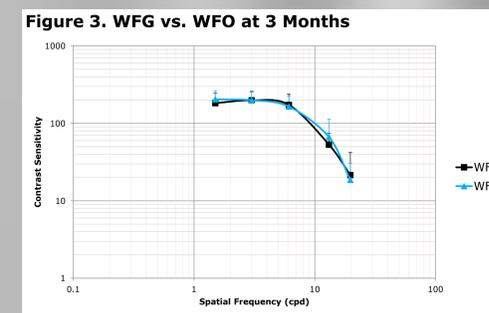
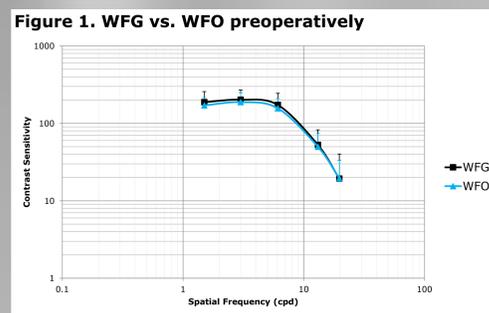
## RESULTS

PRK was performed on 33 WFG and 31 WFO participants. There were no significant differences in preoperative age or manifest spherical equivalent (MSE): Age: 31.1 ±7.1 years (y) WFG vs. 30.4 ±5.3y (WFO), p=0.62; MSE: -3.50±1.89 Diopters (D) WFG vs. -3.32±1.63 WFO, p=0.70. Binocular results of the CT at each spatial frequency are presented in Table 1. There was no difference in the AULCSF over time between groups P=0.23.

**Table 1.** Binocular mean % contrast threshold (CT) of WFG (wavefront-guided) and WFO (wavefront-optimized) PRK at each spatial frequency. Smaller values of CT represent increased contrast sensitivity. P<0.05 was considered significant.

Spatial Frequency (cycles per degree)	Preoperative WFG/ WFO (mean ± SD)	1 Month WFG/ WFO (mean ± SD)	3 Months WFG/ WFO (mean ± SD)	6 Months WFG/ WFO (mean ± SD)	12 Months WFG/ WFO (mean ± SD)	Comparing WFG vs. WFO PRK over Time P-Value
1.5	0.60± 0.20/ 0.64± 0.19	0.65± 0.26/ 0.61± 0.20	0.60± 0.17/ 0.53± 0.18	0.61± 0.16/ 0.57± 0.18	0.65± 0.24/ 0.59± 0.19	0.66
3.0	0.52± 0.13/ 0.54± 0.15	0.51± 0.13/ 0.62± 0.27	0.53± 0.15/ 0.55± 0.20	0.51± 0.20/ 0.45± 0.14	0.50± 0.26/ 0.61± 0.16	0.098
6.1	0.67± 0.35/ 0.70± 0.21	0.71± 0.34/ 0.87± 0.56	0.62± 0.18/ 0.74± 0.47	0.70± 0.30/ 0.70± 0.37	0.71± 0.40/ 0.78± 0.30	0.70
13.1	2.44± 1.79/ 2.71± 1.83	3.33± 2.00/ 4.55± 3.44	2.16± 1.14/ 2.53± 2.30	2.30± 2.00/ 2.31± 1.98	2.48± 1.37/ 3.05± 2.31	0.44
19.7	7.60± 4.00/ 6.49± 2.94	8.95± 3.61/ 9.32± 4.21	6.22± 2.78/ 7.52± 3.78	7.45± 3.60/ 7.27± 3.29	8.55± 2.74/ 8.31± 3.29	0.39

**Figures 1-5. Contrast sensitivity function at each time point:** There was no significant difference between WFG and WFO contrast sensitivity at any time point. (Larger values of CS represent increased contrast sensitivity.) \* P<0.05 was considered significant.



## CONCLUSIONS

➤Results show there is no significant difference in binocular contrast threshold when comparing WFG to WFO PRK over time.

➤There is no significant difference between WFG and WFO PRK contrast sensitivity at each time point except at 12 months when WFG participants have better CS than WFO. Additional study will determine if this is an anomaly or if WFG performs better at certain SF.

➤Ongoing testing in this study will determine if WFG or WFO generated optical quality affects task performance.

## REFERENCES

1. Yamane N, Miyama K, Samejima T et al. Ocular Higher-Order Aberrations and Contrast Sensitivity after Conventional Laser In Situ Keratomileusis. Invest Ophthalmol Vis Sci 2004; 45(11):3986-90.
2. Oshika T, Okamoto C, Samejima T, et al. Contrast Sensitivity Function and Ocular Higher-Order Wavefront Aberrations in Normal Human Eyes. Ophthalmology 2006; 113:1807-1812.
3. Quesnal NM, Lovasik JV, Feremi C et al. Laser In Situ Keratomileusis and the Contrast Sensitivity Function. J Cataract Refract Surg 2004; 30:1209-1218.
4. Hiraoka T, Okamoto C, Ishii Y. et al. Contrast Sensitivity Function and Ocular Higher-Order Aberrations following Overnight Orthokeratology. Invest Ophthalmol Vis Sci 27;48:550-6.
5. Liang J, Grimm B, Goelz S, Bille JF. Objective measurement of wave aberrations of the human eye with the use of a Hartmann-Shack wave-front sensor. J Opt Soc Am A 1994;11(7):1949-57.
6. Mrochen M, Donitzky C, Wüllner C, et al. Wavefront-optimized ablation profiles: Theoretical Background. J Cataract Refract Surg 2004;30:775-785.
7. Tuan KM, Liang J. Improved contrast sensitivity and visual acuity after wavefront-guided laser in situ keratomileusis: in-depth statistical analysis. J Cataract Refract Surg 2006;32(2):215-20.
8. Randleman JB, Perez-Straziota CE, Hu MH, Et al. Higher-order Aberrations after Wavefront-Optimized photorefractive keratectomy and laser in situ keratomileusis. J Cataract Refract Surg 2009;35:260-4.



# Visual Performance Comparison of Wavefront-optimized and Wavefront-guided Photorefractive Keratectomy (PRK)

ARVO Program Number 1473 Board #A429

L. Peppers<sup>1</sup>, R.K. Sia<sup>1</sup>, M. J. Mines<sup>2</sup>, D. S. Ryan<sup>1</sup>, D. Cute<sup>2</sup>, R.D. Stutzman<sup>2</sup>, K. S. Bower<sup>3</sup>

<sup>1</sup> U.S. Army Warfighter Refractive Surgery Research Center at Fort Belvoir, Fort Belvoir, VA, USA

<sup>2</sup>Ophthalmology, Walter Reed National Military Medical Center, Bethesda, MD, USA

<sup>3</sup>The Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD, USA

## PURPOSE

To compare visual acuity and contrast sensitivity results after wavefront-guided (WFG) and wavefront-optimized (WFO) PRK.

## INTRODUCTION

It has been shown that higher order aberrations (HOAs) have a different impact on vision and can positively or negatively influence visual performance<sup>1</sup>. Positive relationships have been identified between elevated higher order aberrations and decreases in contrast sensitivity, as well as increases in the symptoms of glare, halos, starbursts, and monocular diplopia. However, the relationship between optical quality, characterized by monochromatic aberrations, and visual performance is complex and not perfectly understood. The advent of customization in corneal laser surgery has improved optical and visual outcomes of the refractive surgery procedure<sup>2-3</sup>. Previous studies have demonstrated fewer HOAs exist following WFG and WFO treatments when compared to conventional treatments<sup>4-7</sup>, with the potential of minimized degradation of optical quality following WFG treatments.

Wavefront-optimized (WFO) laser treatments attempt to preserve the eye's pre-existing optical aberrations using adjustments based on population averages and optimizing the asphericity of the cornea<sup>8</sup>. WFO ablations add peripheral treatment to minimize spherical aberration, the principal high order aberration generated by the surgery.

Wavefront-guided (WFG) laser treatments measure and treat not only lower order aberrations, such as sphere and cylinder, but also higher order aberrations.

## METHODS

In a prospective randomized study, participants underwent visual acuity and contrast sensitivity testing before and after either WFG or WFO PRK. WFG surgeries were performed using the VISX Star S4 (Abbot Medical Optics) and WFO surgeries were performed on the Wavelight Allegretto Wave Eye-Q (Alcon Surgical). The Amoils brush (Innovative Excimer Solutions) was used for epithelial debridement. All contrast and visual acuity testing was performed monocularly using best corrected distance visual acuity (CDVA) preoperatively and with best CDVA at 1, 3, 6 and 12 months postoperatively. Night vision testing was conducted with a back-illuminated chart (25% Contrast Acuity) and green night vision goggle filter. High and low contrast acuity testing was performed using the Variable Contrast 4 meter Rabin Super Vision Test. A repeated measures analysis of variance (RM-ANOVA) was used to compare WFO vs. WFG PRK over time and a p-value <0.05 was considered significant.

Room illumination was standardized for all acuity measurements. Acuity measurements were recorded as the Snellen equivalent. At least 3 letters had to be correctly identified to score a line. The number of letters missed or the number of letters correctly identified in the next line were recorded. For the 5% contrast, 25% contrast and high contrast supervision test, a credit of 0.02 logMAR units was calculated for each letter correctly identified. For the low contrast supervision test, a credit of 0.05 logCS units was calculated for each letter correctly identified.



Figure 1. Low Contrast 5% SLOAN Translucent Eye Chart (Precision Vision - Lasalle, Ill)



Figure 2. Low Contrast 25% SLOAN Logarithmic Visual Acuity Chart (Precision Vision - Lasalle, Ill)

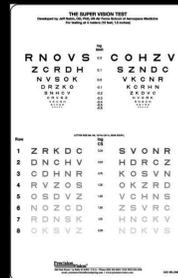


Figure 3. Variable Contrast Rabin Super Vision Test (Precision Vision - Lasalle, Ill)



Figure 4. Low Contrast 25% SLOAN Logarithmic Visual Acuity Chart with Night Vision Goggle Filter (Precision Vision - Lasalle, Ill)

## RESULTS

PRK was performed on 33 WFG and 31 WFO participants. There were no significant differences in preoperative age or ablation depth (AD): Age: 31.1 ±7.1 years (y) WFG vs. 30.4 ±5.3y WFO, p=0.53; AD: 56.7±23.4microns (μ) WFG vs. 51.8±21.9μ WFO, p=0.23.

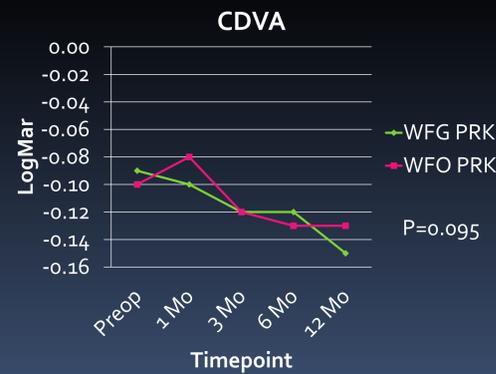


Figure 5. Corrected Distance Visual Acuity (CDVA) 100% contrast - WFO PRK and WFG PRK. High Contrast (HC) - negative shift equals improvement.

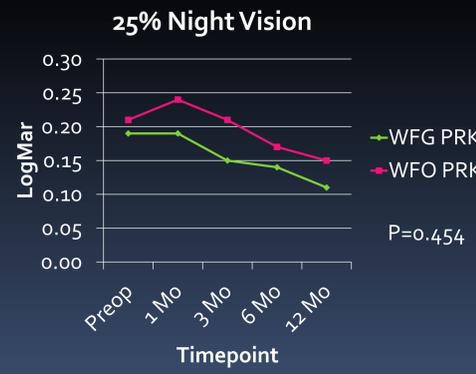


Figure 6. 25% Night Vision Goggle Filter - WFG PRK and WFO PRK. HC negative shift equals improvement

## SuperVision High Contrast

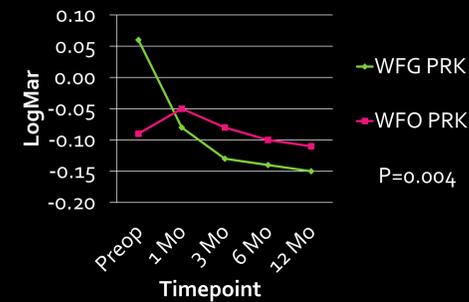


Figure 7. SuperVision High Contrast (HC)- WFG PRK and WFO PRK. HC: negative shift equals improvement

## SuperVision Low Contrast

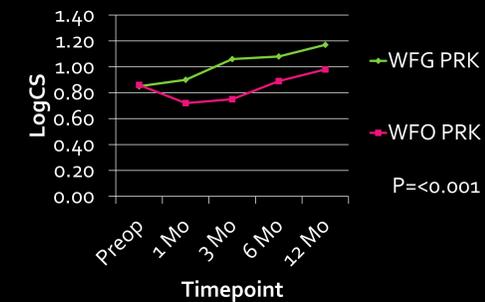


Figure 8. SuperVision Low Contrast (LC) - WFG PRK and WFO PRK. LC positive shift equals improvement

## CONCLUSION

Night vision contrast performance was comparable between WFO PRK and WFG PRK. However, WFG PRK appears to be superior to WFO PRK when comparing high and low contrast acuity over time.

## REFERENCES

- Lombardo M, Lombardo G. Wave aberration of human eyes and new descriptors of image optical quality and visual performance. J Cataract Refract Surg 2010; 36:313-331.
- Mrochen M, Donitzky C, Wüllner C, Löffler J. Wavefront-optimized ablation profiles: Theoretical background. J Cataract Refract Surg 2004; 30: 775-785.
- Cheng AC. Wavefront-guided versus wavefront-optimized treatment. J Cataract Refract Surg 2008; 34(8): 1229-30.
- Mastropasqua L, Toto L, Zuppari E, et al. Photorefractive keratectomy with aspheric profile of ablation versus conventional photorefractive keratectomy for myopia correction: six-month controlled clinical trial. J Cataract Refract Surg 2006; 32:109-116.
- Vongthongsri A, Phusitphoykai N, Nariphapan P. Comparison of wavefront-guided customized ablation vs. conventional ablation in laser in situ keratomileusis. J Refract Surg 2002 May; 18:S332-335.
- Mastropasqua L, Nubile M, Ciancaglini M, et al. Prospective randomized comparison of wavefront-guided and conventional photorefractive keratectomy for myopia with the meditec MEL 70 laser. J Refract Surg 2004; 20:422-31.
- Nassiri N, Safi S, Amiri MA, Shebani K, Safi H, Panahi N, Nassiri N. Visual outcome and contrast sensitivity after photorefractive keratectomy in low to moderate myopia: Wavefront-optimized versus conventional methods. J Cataract Refract Surg 2011; 37:1858-1864
- Myrowitz EH, Chuck RS. A comparison of wavefront-optimized and wavefront-guided ablations. Curr Opin Ophthalmol 2009; 20(4): 247-50.