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

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14. ABSTRACT

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 post-operatively. 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.

15. SUBJECT TERMS
Military, Refractive Surgery, PRK, LASIK, Night Vision, Wavefront Optimized, Wavefront Guided, Visual Performance, Quality of Vision, Outcomes, Contrast Sensitivity

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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:

The study will be conducted in three phases randomizing WFG and WFO treatment modalities: **Phase I** (112 patients) – **subjective visual performance and objective optical quality** **Phase II** (56 patients) - subjective visual performance, objective optical quality, and **military task performance** at the night firing range (NVESD) **Phase III** (56 patients) - subjective visual performance, objective optical quality, and **performance prediction modeling** using target detection and identification (NVESD)

BODY

Laser refractive surgery has proven enormously positive in terms of improving quality of life for the large majority of patients. Several important advances have reduced the amount of higher order aberrations (HOA) induced by refractive surgery. Wavefront aberrometers are now coupled with computer controlled, flying spot excimer lasers resulting in WFG laser ablations customized to each individual's eye. WFO ablations add peripheral treatment to minimize spherical aberration, the principal HOA generated by the surgery. WFG surgery measures and treats not only lower order aberrations, such as sphere and cylinder, but also higher order aberrations. With the advent of wavefront aberrometry, the potential promise of correcting not only myopia and astigmatism but other, smaller optical aberrations has produced an explosion of research.

Research Administrative Updates: the following personnel and study changes at both WRSRC and WRNMMC were submitted to the WRNMMC IRB:

- A continuing review was submitted and approved effective 16 August 2013 which included a change in PI and medical monitor and the removal of an AI.

- An unanticipated event probably not related to research procedures was filed 27 December 2012 and was acknowledged 1 February 2013. A patient had uneventful PRK and was seen post-operatively on days 1, 3, 4, 9, week 4 and 6 and month 3 with expected clinical findings. At the 6 month postoperative visit, anisocoria, or unequal size of pupils, was noted during examination and the patient was referred to the Ophthalmology staff on duty. In this case, MRI/MRA of the head, neck, and apex of the lung was requested to rule out life-threatening causes of Horner syndrome. The patient's MRI showed a lesion in the left lobe of the thyroid and malignancy was ruled out by biopsy. This unanticipated event was not due to a breach of standard of care and was not due to participation in this study. No changes in the protocol or the study consent form were recommended after this event.

- A protocol deviation was filed 20 February and acknowledged 22 February 2013 to start enrollment in phase III LASIK while we await ammunition resupply for phase II LASIK due to several supply issues at the night firing range (sequestration, ammunition freeze, shortage of ammunition).The phases of the study are independent, so the order of enrollment is not relevant to the study outcomes and will not affect randomization as each phase is randomized independently. As the consent form addresses all three phases, no change to the consent form was required.

- A change in PI was submitted and approved effective 1 March 2013.

All of the aforementioned modifications have been approved or acknowledged by the WRNMMC IRB. The currently approved consent form, approval letters for the modifications, and acknowledgement letters are attached as **Appendix 1** at the conclusion of this report.

A no cost extension was requested and approved extending funds for this study through May 2014.

TASK 1: Screen and enroll patients, perform preoperative clinical exam, perform pre-operative visual function testing, perform surgery.

A) Begin Screening and enrolling patients

B) Perform pre-operative cycloplegic refraction and ocular health examination

C) Measure subject's contrast sensitivity function

D) Measure subject's wavefront aberration map

- **Task 1 A-B**

Screening and enrollment are complete for all phases of PRK. We are still actively enrolling in Phase II and Phase III LASIK. Ocular health examination, contrast sensitivity function and wavefront aberrometry are completed at the pre-operative examination and at the one month, three month, six month, and 12 month follow up examinations. **Table 2** summarizes the progress of enrollment and follow up rates by Phase at FBCH up to May 2013.

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

	Enrolled			**1M**		**3M**		**6M**		**12M**	
Phase I	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	28/26	25/27	28/26	26/26	25/24	25/26	17/18
Withdrawn	2/1	0/2	Missed Visit	0	0	1/1	0	0/2	0	1/2	1/0
Enrolled	26/27	28/26	Total Eligible	26/28	28/26	26/28	28/26	26/28	25/24	26/28	18/18
	92.9%/ 96.4%	100%/ 96.4%		100%	100%	96.2%/ 96.4%	100%	100%/ 92.9%	100%	96.2%/ 92.9%	94.4%/ 100%

	Enrolled			1M		3M		6M		12M	
NVL Phase II	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	14/13	4/4	14/13	¾	13/12	0	12/9	0
Withdrawn	0/1	0	Missed Visit	0	0	0	0	0	0	0	0
Enrolled	14/13	4/4	Total Eligible	14/13	4/4	14/13	¾	13/12	0	12/9	0
	100%/ 92.9%	100%		100%	100%	100%	100%	100%	-	100%	-

	Enrolled			1M		3M		6M		12M	
NVL Phase III	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	13/14	4/3	13/14	0	9/11	0	0/2	0
Withdrawn	1/0	0/1	Missed Visit	0	0	0	0	0	0	0	0
Enrolled	13/14	12/8	Total Eligible	13/14	4/3	13/14	0	9/11	0	0/2	0
	92.9%/ 100%	100%/ 88.8%		100%	100%	100%	100%	100%	-	100%	-

Preliminary data and results:

- **Task 1-C**

(Presented at ARVO May 2012[1])

An initial comparison of the contrast threshold (CT) of Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) PRK was conducted.

PRK. Epithelial removal was performed with the Amoils epithelial scrubber (Innovative Excimer Inc, Toronto, ONT). WFG photoablation was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Sta. Ana, CA) while WFO photoablation was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX). Prophylactic use of mitomycin C (MMC) was based on the study sites' standard operating procedure. For all WFG treatments, MMC was used on eyes with central ablation depth of greater than 49.5 microns or cylinder >1.25D. For all WFO treatments, MMC was used on eyes with central ablation depth of greater than 75 microns. Postoperative medications regimen was the same for both groups and included: topical moxifloxacin 0.5%, one drop four times daily for one week; fluorometholone 0.1%, 1 drop four times daily for the first month, followed by a six week taper; carboxymethylcellulose 0.5%, one drop four to eight times daily for two weeks and then as needed; topical ketorolac tromethamine 0.4%, one drop up to four times daily for the first 48 hours after surgery as needed.

Participants underwent binocular testing to determine their contrast threshold (CT) preoperatively with correction and at one, three, and six 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 two-alternative forced choice, linear staircase adaptive procedure using a 90º Gabor stimulus with a mean luminance of 50.0 cd/m^2. 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.

In PRK 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 3**. There was no difference in the AULCSF over time between groups P=0.23.

Table 3. 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 1a-e. Contrast sensitivity function at each time point. In PRK patients, 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.

Figure 1a. WFG vs. WFO preoperatively

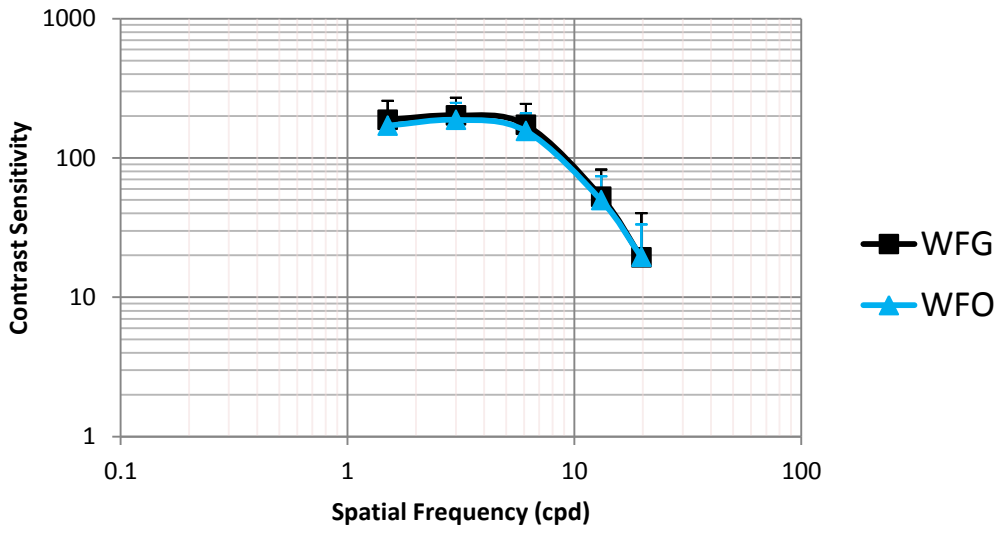


Figure 1b. WFG vs. WFO at 1 Month

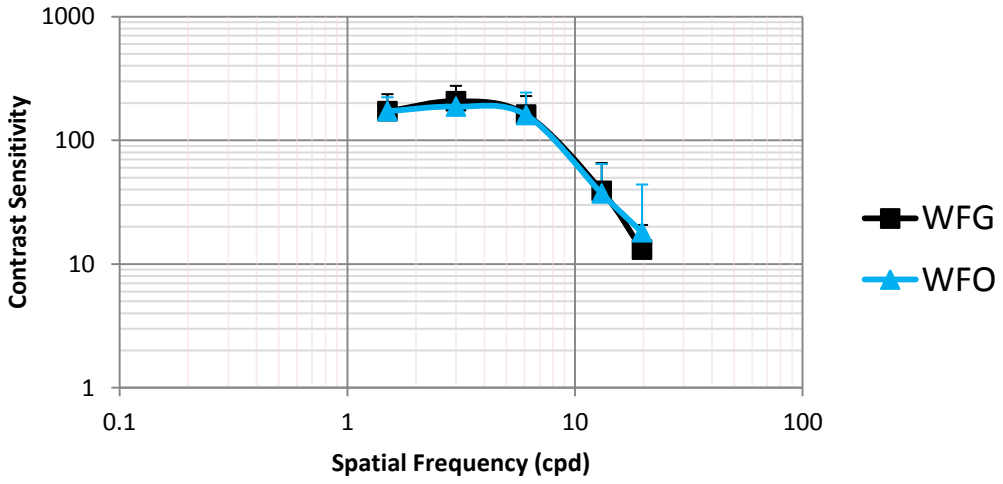


Figure 1c. WFG vs. WFO at 3 Months

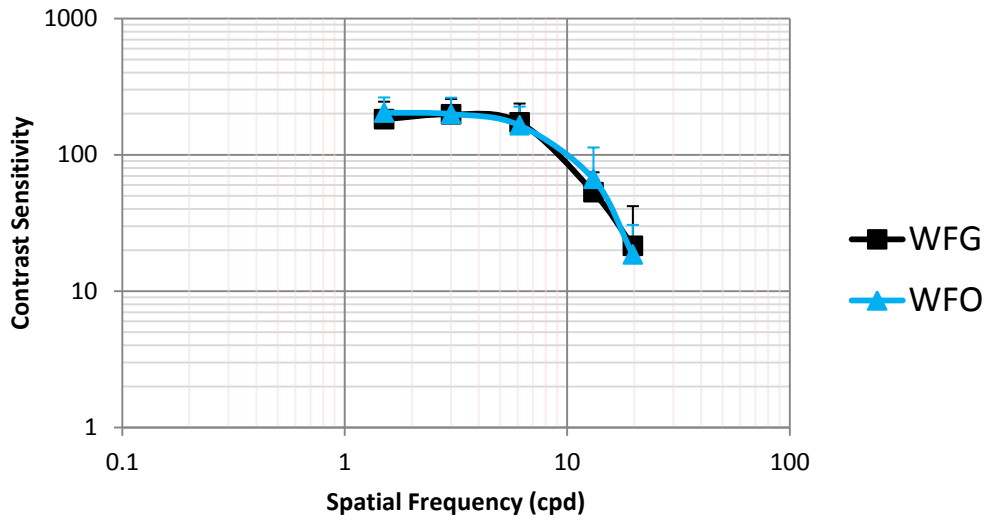
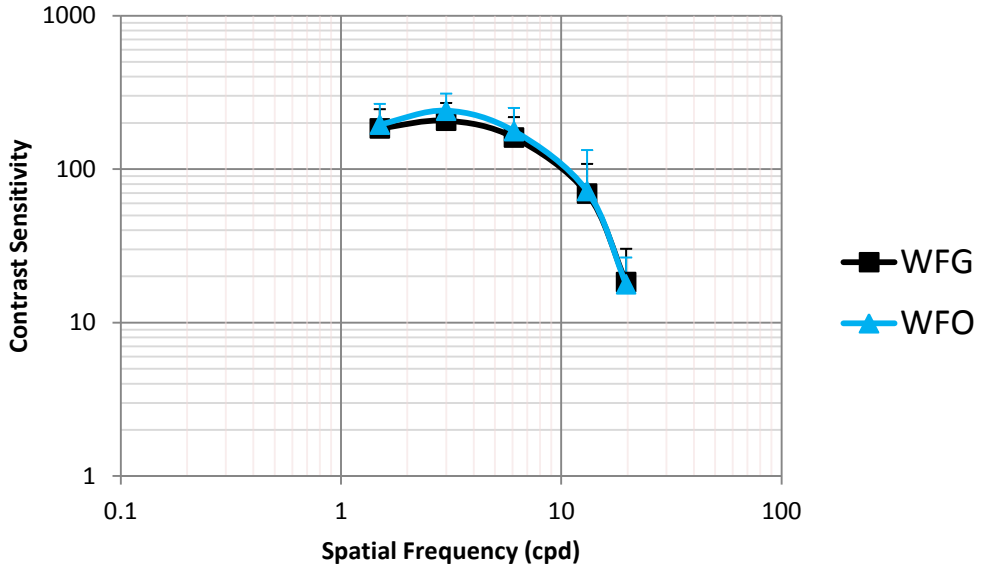
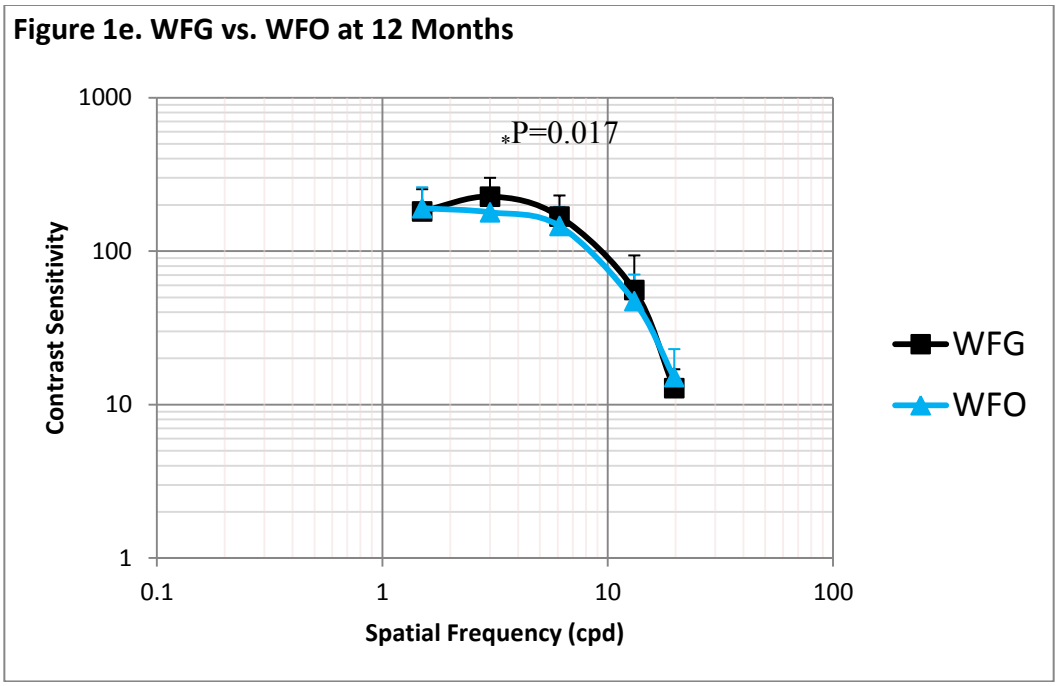


Figure 1d. WFG vs. WFO at 6 Months





Preliminary 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 testing will determine if this is an anomaly or if WFG performs better at certain SF.

- **Task 1-D**

(Presented at ARVO May 2013[2])

A preliminary comparison of higher order aberration (HOA) root mean square (RMS) and participant satisfaction of postoperative vision after WFG vs. WFO PRK was conducted.

Subjective manifest refraction, UDVA and CDVA were determined preoperatively and at six months postoperatively. The Complete Ophthalmic Analysis System (COAS, Abbott Medical Optics, Sta. Ana, CA) was used to measure wavefront aberrations. All measurements were done on natural pupils under mesopic light conditions. No dilating or cycloplegic drugs were used. Four different pupil sizes (4, 5, 6, and 7mm) were used for RMS HOA analysis. A repeated measures analysis of variance (RM-ANOVA) was used to compare WFG vs. WFO PRK HOA RMS at each pupil size over time [**Figure 6**]. A p-value <0.05 was considered statistically significant.

In addition to wavefront analysis, participants responded to a questionnaire preoperatively and six months postoperatively. Subjective visual quality in terms of 1) visual difficulties in

performing daily activities; 2) glare and 3) halo were assessed and total scores of each category were calculated. Patient satisfaction was also evaluated:

- In comparison to what you expected before you had surgery, has your overall vision turned out to be:
  Much better than expected (1)----------(10) Much Worse
- Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:
  Definitely would have surgery (1)----------(10) Definitely would NOT

Table 4 lists the baseline demographic data while **Tables 5-6** present questionnaire results evaluated in this cohort.

Table 4. Demographic and baseline characteristics

	WFG PRK	**WFO PRK**	***P-value****
No. of participants (eyes)	26 (52)	26 (52)	-
Age (years)	30.0 ±7.0	29.9 ±5.6	0.90
Male/Female	19/7	18/8	0.50†
Sphere (Diopters)	-3.13 ±1.87	-3.00±1.69	0.70
Cylinder (Diopters)	-0.70 ±0.49	-0.65D ±0.54	0.60
MSE (Diopters)	-3.49 ±1.88	-3.32 ±1.79	0.66
Preop UDVA (logMAR)	1.07 ±0.38	1.04 ±0.34	0.76
Central corneal thickness (µm)	547.0 ±33.2	553.5 ±36.6	0.34
Ablation depth (µm)	56.3 ±23.9	51.6 ±23.4	0.31
Mitomycin C treated (%)	57.7	23.1	0.001†

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Table 5. Difference in WFG vs. WFO PRK preoperative and postop questionnaire results.

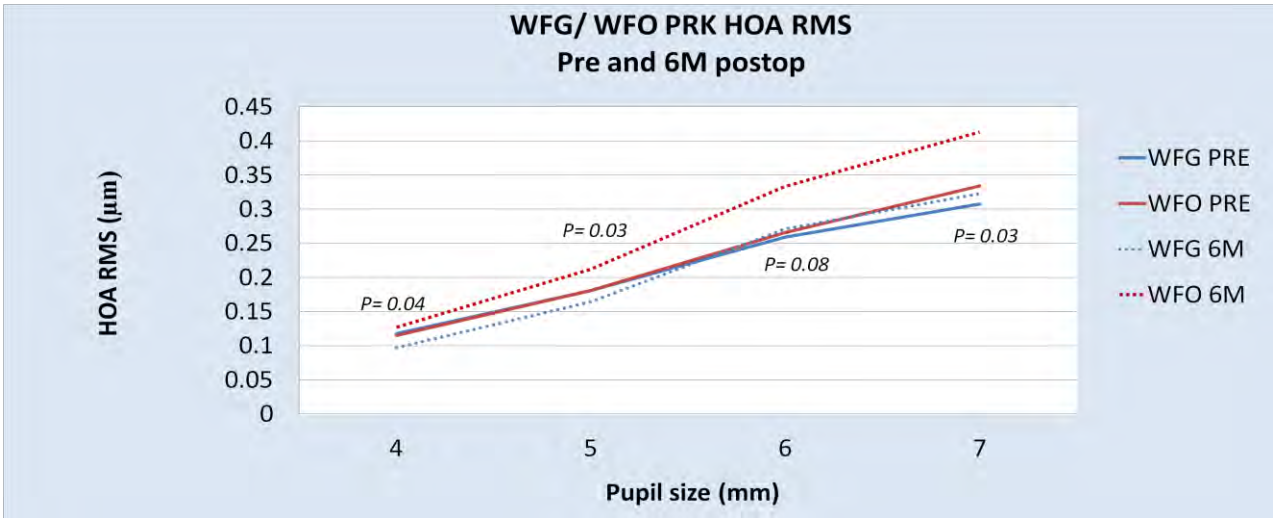
Preoperatively	**WFG**	**WFO**	***P-value****
Daily Activities	11.50±5.65	10.72±4.56	*0.59*
Glare	12.27±9.33	10.27±8.03	*0.41*
Halo	7.08±3.06	7.85±5.67	*0.55*
6 Month Post	**WFG**	**WFO**	***P-value****
Daily Activities	10.73±4.57	9.65±3.87	*0.36*
Glare	9.85±6.42	7.77±2.75	*0.14*
Halo	8.88±6.57	6.46±2.02	*0.08*

*t-test was used to compare patient satisfaction of postoperative vision, *P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores

are presented as mean ± standard deviation.

Table 6. Vision and overall expectation and satisfaction scores at six months postop.			
	WFG PRK	WFO PRK	*P-value**
MSE (Diopters)	0.09 ±0.38	-0.02 ±0.31	0.09
Postop UDVA (logMAR)	-0.11 ±0.09	-0.10 ± 0.07	0.74
Expectations: Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.			
Overall visual expectations	1.81 ±1.13	1.65 ±1.02	0.61
If given the opportunity, would have surgery again	1.27 ±0.87	1.19 ±0.57	0.71
• *At 6 months postop, 14out of 26 WFG PRK patients (53.8%) versus 16 of 26 WFO PRK patients (61.5%) reported that their vision was much better than expected (scored 1 on a 10-point scale).* • *Of those who underwent WFG PRK, 23 out of 26 patients (88.5%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).* • *Of those who underwent WFO PRK, 23 out of 26 patients (88.5%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).*			
*t-test, *P<0.05 statistically significant*			

Figure 2. Comparison of WFG vs. WFO PRK higher order aberrations (HOA) root mean square (RMS) at each pupil size.



Initial results show there is a significant difference in RMS HOA when comparing WFG vs. WFO PRK over time. Although there was a significant increase in HOA RMS of WFO PRK patients postoperatively, questionnaire results showed no significant difference in daily activities, glare, halo or satisfaction with the procedure when comparing WFG vs. WFO PRK. Ongoing testing in this study will determine if either WFG or WFO generated optical quality affects military task performance.

➢ **Task 1-D**
(Presented at ARVO May 2013[3])
Similar to the preliminary comparison for PRK, we compared HOA RMS and patient satisfaction of postoperative vision after WFG vs. WFO LASIK.

LASIK. A superior-hinged flap was created using a femtosecond laser system (Intralase, Abbott Medical Optics, Sta. Ana, CA). WFG photoablation was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Santa Ana, CA) while WFO photoablation was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX). Postoperative medications regimen was the same for both groups and included: topical moxifloxacin 0.5%, one drop four times daily for one week; Prednisolone acetate 1.0%, 1 drop every two hours for the first three days, then one drop four times daily for one week; carboxymethylcellulose 0.5%, one drop four to eight times daily for two weeks and then as needed; topical ketorolac tromethamine 0.4%, one drop up to four times daily for the first 48 hours after surgery as needed.

Subjective manifest refraction and uncorrected and corrected distance visual acuities were determined preoperatively and at six months postoperatively. Wavefront aberrations were measured using the Complete Ophthalmic Analysis System (COAS, Abbott Medical Optics, Sta. Ana, CA). All measurements were done on natural pupils without the use of any dilating or cycloplegic drugs under mesopic light conditions. RMS HOA was determined at four different pupil sizes (4, 5, 6, and 7mm) **[Figure 3]**. Participants responded to questionnaires preoperatively and at the 6-month postoperative visit. Subjective visual quality in terms of 1) visual difficulties in performing daily activities; 2) glare and 3) halo were assessed and total scores of each category were calculated. Patient satisfaction was also evaluated:

- In comparison to what you expected before you had surgery, has your overall vision turned out to be:
  Much better than expected (1)----------(10) Much Worse
- Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:
  Definitely would have surgery (1)----------(10) Definitely would NOT

Tables 7-9 list the demographic and baseline information of the cohort evaluate along with questionnaire results.

Table 7. Demographic data and baseline clinical characteristics.

	WFG LASIK	**WFO LASIK**	***P-value****
No. of participants (eyes)	22 (44)	21 (42)	-
Age (years)	32.7 ±8.1	32.0 ±8.0	0.68
Male/Female	16/6	17/4	0.72[†]

Sphere (Diopters)	-3.05 ±1.36	-3.26 ±1.52	0.51
Cylinder (Diopters)	-0.57 ±0.49	-0.69D ±0.67	0.34
MSE (Diopters)	-3.26 ±1.37	-3.60 ±1.54	0.27
Preop UDVA (logMAR)	1.07 ±0.28	1.06 ±0.34	0.87
Central corneal thickness (µm)	561.1±30.1	572.6±34.7	0.11
Ablation depth (µm)	55.4 ±17.0	57.1 ±21.2	0.68

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Table 8. Difference in preop vs. 6months postop questionnaire results.

WFG LASIK	**Pre**	**6 M Post**	***P-value****
Daily Activities	10.1 ±3.7	9.9 ±4.0	0.88
Glare	11.8 ±6.9	12.0 ±8.3	0.94
Halo	8.3 ±4.1	11.4 ±7.5	0.03
WFO LASIK	**Pre**	**6 M Post**	***P-value****
Daily Activities	9.9 ±4.3	9.8 ±4.9	0.95
Glare	8.9 ±6.1	9.7 ±7.3	0.70
Halo	6.8 ±5.6	8.5 ±5.6	0.29

**t-test, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

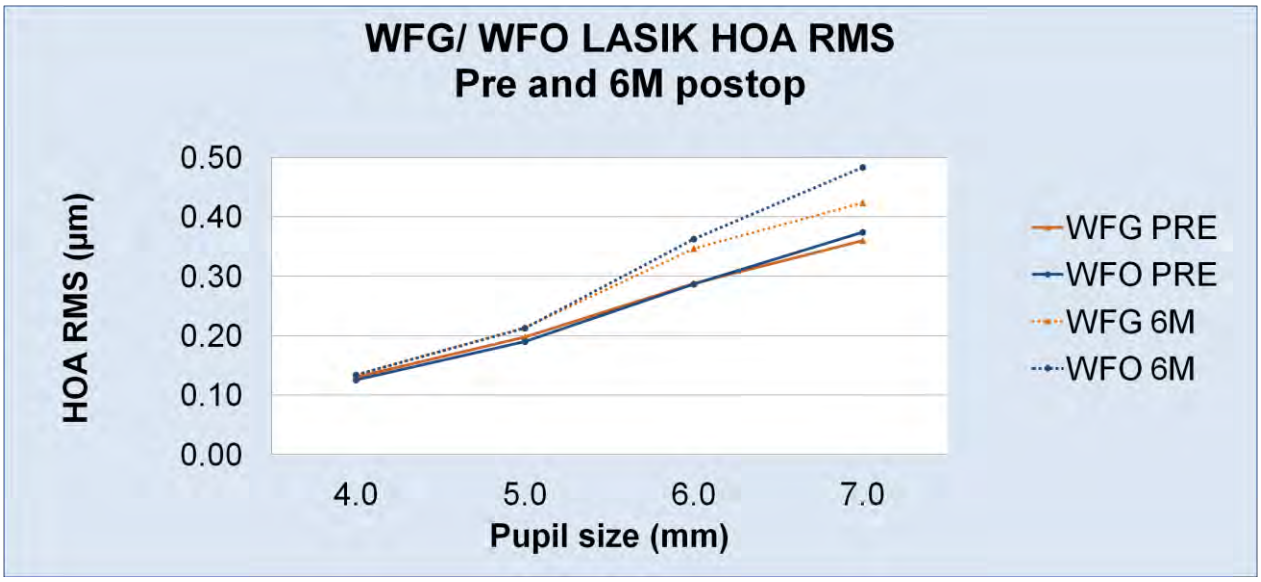
Table 9. Visual symptoms, overall expectation and satisfaction scores at six months postop.

	WFG LASIK	**WFO LASIK**	***P-value****
†Daily Activities	11.4 ±6.5	10.0 ±4.8	0.43
†Glare	12.0 ±8.3	9.7 ±7.3	0.35
†Halo	11.4 ±7.5	9.1 ±6.2	0.29
Overall visual expectations	2.1 ±1.4	1.3 ±0.6	0.01
If given the opportunity, would have surgery again	1.5 ±1.2	1.1 ±0.2	0.13

- At 6 months postop, 10 out of 22 WFG LASIK patients (45.5%) versus 16 of 21 WFO LASIK patients (76.2%) reported that their vision was much better than expected (scored 1 on a 10-point scale).
- Of those who underwent WFG LASIK, 18 out of 22 patients (81.8%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).
- Of those who underwent WFO LASIK, 20 out of 21 patients (95.2%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).

**t-test, P<0.05 statistically significant*
†Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Figure 3. Comparing WFG vs. WFO over time by repeated measures analysis of variance (RM ANOVA) at each pupil size, p=0.77, 0.90, 0.64, 0.24 at 4mm, 5mm, 6mm, and 7mm respectively.



Initial results show there is no significant difference in RMS HOA when comparing WFG vs. WFO LASIK over time, regardless of pupil size analyzed. There was no significant difference between the two procedures when postoperative visual symptoms were assessed. However, when compared to baseline, halos seemed worse in WFG LASIK. Overall visual expectations appeared to be better in patients who underwent WFO LASIK than WFG LASIK. Association of optical quality after either WFG or WFO treatment to military task performance is still being tested.

TASK 2: Develop, test, and validation of military metrics of visual performance that measure a human observer's ability to detect and discriminate objects of interest within a static or a dynamic sequence of images.

A) Utilize objective target acquisition metrics to predict visual performance. Compare pre- and post-surgical results.

B) Threshold target identification (56 subjects, 12 per group) tested with a 12 alternative forced choice paradigm. Human Perception Lab (HPL)

C) Threshold target detection task (56 subjects, 12 per group) tasked to search and detect vehicle targets in a cluttered environment. HPL

D) Weapons (M16) performance at a rifle range in mesopic conditions. Night Firing Range (NFR)

- **TASK 2- A-D**

Tables 10 and 11 list the current enrollment and follow up rates by Phase at the Night Firing Range (Phase II), and Human Perception Lab (Phase III). Testing occurs preoperatively, at six weeks postoperatively and six months postoperatively. Enrollments are completed for both LASIK and PRK in Phase I. Phase II and Phase III PRK enrollments are complete.

Table 10. Follow up rates at the Night Firing Range (NFR) Phase II

	Preop		**6W**		**6M**	
Phase II NFR	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)
Seen for Visit	14/13	4/4	14/13	4/4	12/10	0
Missed Visit	0	0	0	0	½	0
Total Eligible	14/13	4/4	14/13	4/4	13/12	0
	100%	100%	100%	100%	92.3%/ 83.3%	-

Table 11. Follow up rates at the Human Perception Lab (HPL) Phase III

	Preop		**6W**		**6M**	
Phase III HPL	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)	PRK (O/G)	LASIK (O/G)
Seen for Visit	13/14	12/8	13/14	2/2	8/9	0
Missed Visit	0	0	0	0	0/1	0
Total Eligible	13/14	12/8	13/14	2/2	8/10	0
	100%	100%	100%	100%	100%/ 90%	-

- **TASK 2-D**

(Presented at IMRSS 2013[4] and ASCRS 2013[5])

An initial comparison of military task performance in WFG vs. WFO PRK in terms of visual outcomes and night firing range scores was conducted. Patients with myopia or myopic astigmatism were randomized to undergo either WFG or WFO PRK as previously reported.

Testing pre-operatively and at one month, three months, and six months post-operatively included UDVA, manifest refraction, CDVA, intraocular pressure (IOP), and slit lamp biomicroscopy. Patients were also assessed for complications at each postoperative visit. Marksmanship skill was evaluated with an M16-A4 rifle on a modified range under low light or nighttime conditions preoperatively and at six weeks and six months postoperatively

Participants fired an M16-A4 rifle under the following conditions:

1) iron sight;
2) night vision goggle (monocular) and aiming light; and
3) gun-mounted thermal sight (forward looking infrared).

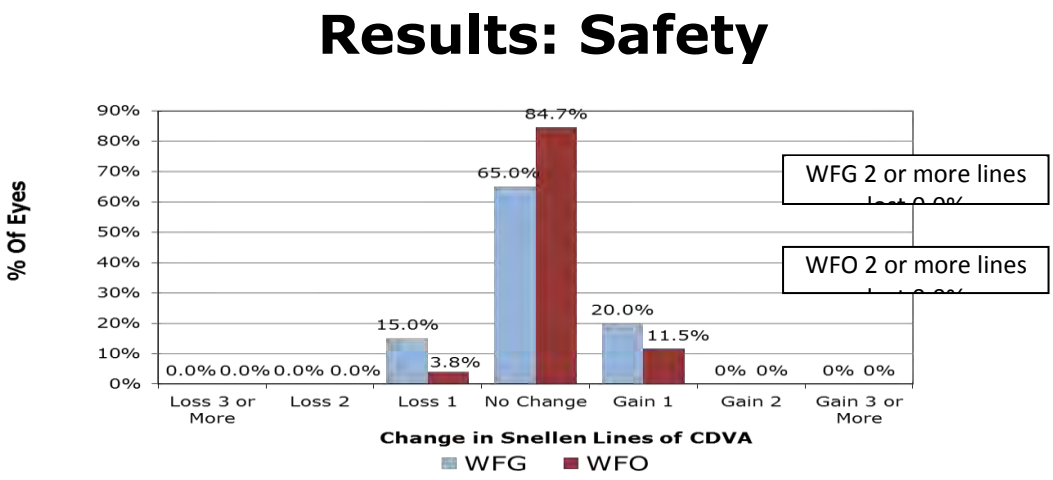
Light levels for condition 1 was low light (simulated dusk) and for conditions 2 and 3, starlight only. Pre- and postoperative firing range scores were compared using Wilcoxon signed-rank test. WFG and WFO PRK were compared in terms of six months visual outcomes using Fisher exact test and six months firing range scores using Mann-Whitney test. A p-value of <0.05 was considered significant.

Table 12 lists the baseline preoperative characteristics of the WFG vs. WFO PRK firing rate sub-group. Results of the sub-group analysis include safety, predictability, and stability as seen in **Figures 4a-d**.

Table 12. Baseline preoperative characteristics

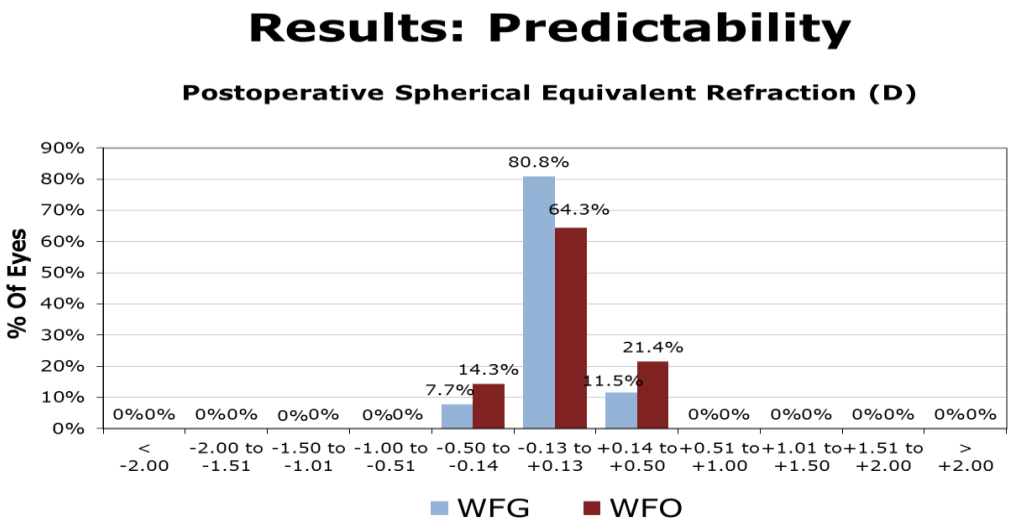
	WFG (n=26) **mean± SD (range)**	**WFO (n=28)** **mean± SD (range)**	***P-value***
Age	31.3 ±6.8 (21 to 43)	31.8 ±6.9 (21 to 51)	0.70
Male/female	10/3	9/5	0.68
UDVA (logMAR)	0.99± 0.30 (0.72 to 1.60)	1.13± 0.26 (0.72 to 1.60)	0.11
Manifest Sph (D)	-2.93± 1.41 (-2.00 to -7.00)	-3.08± 1.06 (-2.00 to -7.00)	0.26
Manifest Cyl (D)	-0.75± 0.51 (0 to -2.00)	-0.66± 0.51 (0 to -3.00)	0.45
MSE (D)	-3.31± 1.41 (-2.00 to -7.00)	-3.41± 1.10 (-2.00 to -7.00)	0.42
CDVA (logMAR)	-0.10± 0.03 (0 to -0.16)	-0.10± 0.04 (0 to -0.12)	0.61
MMC treated (%)	76.9	35.7	0.54

Figure 4a. Safety: WFG vs. WFO PRK



WFG/ WFO	1 month (26/28)	3 months (24/28)	6 months (20/26)
WFG	2 (7.7%)	0 (0%)	0 (0%)
WFO	0 (0%)	0 (0%)	0 (0%)
P-value	0.23	-	-

Figure 4b. Predictability: WFG vs. WFO PRK at six months postop

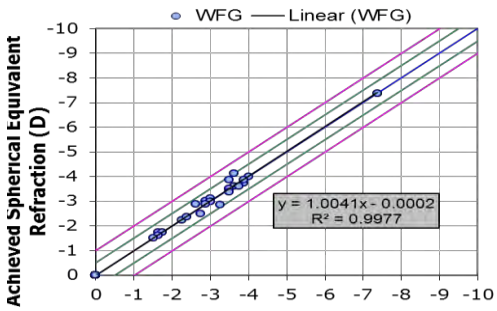


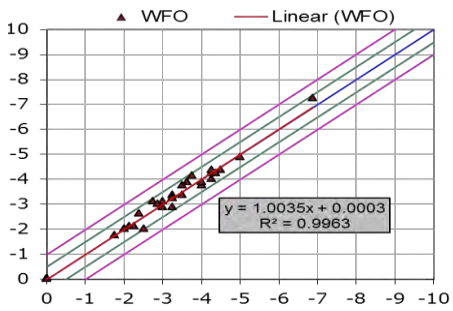
Number (%) of eyes with MSE within ±0.50D

WFG/WFO	1 month (26/28)	3 months (24/28)	6 months (20/26)
WFG	19 (73.1%)	24 (92.3%)	20 (100%)
WFO	20 (71.4%)	26 (92.9%)	26 (100%)
P-value	0.99	0.99	-

Figure 4c. Predictability: WFG vs. WFO PRK at six months postop

Results:



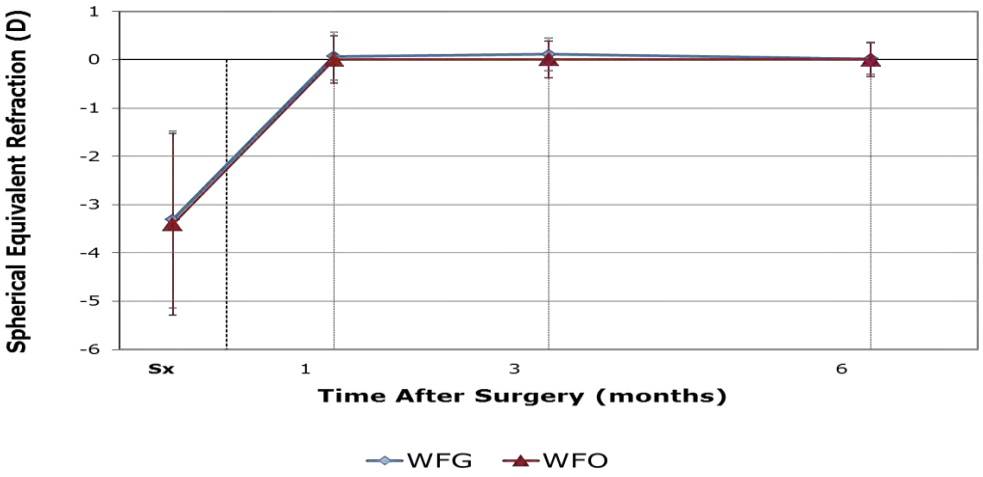


WFG: -3.31±1.41 D

WFO: -3.41±1.10 D

Figure 4d. Stability: WFG vs. WFO PRK at six months postop

Results: Stability



Firing range data under the three conditions (iron sight, night vision, and thermal sight) are listed in **Tables 13-14** and were compiled as a score for accuracy (average distance from target center) and precision (standard deviation). Scores were also compared as a ±5 point change from preop as seen in **Figures 5a-c**.

Table 13. Comparison of six-month postoperative firing range scores between WFG and WFO PRK.

	Iron sight	**Night vision**	**Thermal sight**
WFG PRK	97.3 ±4.1	96.6 ±3.2	94.0 ±4.3
WFO PRK	96.0 ±3.9	95.5 ±4.6	96.3 ±3.8
P-value	0.44	0.82	0.30

Table 14. Pre- and 6-month postoperative firing range scores after WFG and WFO PRK.

		Iron sight	Night vision	Thermal sight
WFG PRK	Preop (with correction)	97.1 ±5.0	92.9 ±6.6	97.2 ±2.9
	6 months (without correction)	97.3 ±4.1	96.6 ±3.1	94.0 ±4.3
	P-value	0.89	0.11	0.18
WFO PRK	Preop (with correction)	94.0 ±7.7	95.4 ±4.5	93.6 ±5.5
	6 months (without correction)	96.0 ±3.9	95.5 ±4.6	96.3 ±3.8
	P-value	0.62	0.48	0.14

Figure 5a. Iron sight: Change in score from preop WFG vs. WFO

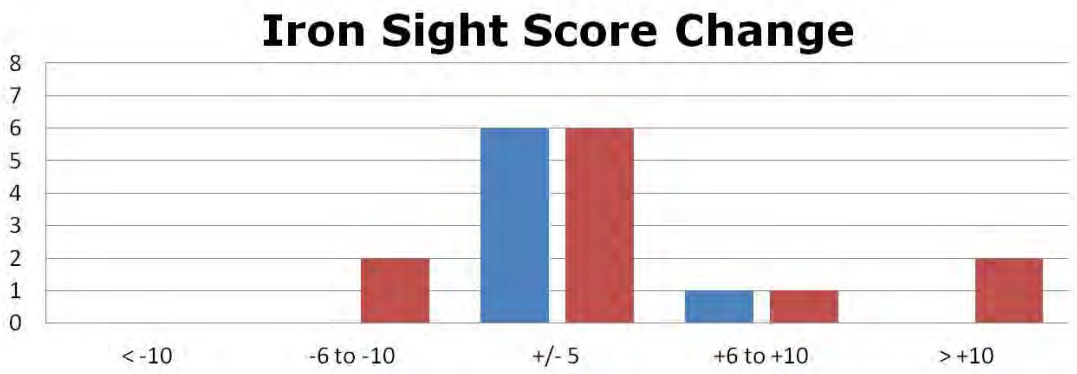


Figure 5b. Night vision: Change in score from preop WFG vs. WFO

Figure 5c. Thermal Sight: Change in score from preop WFG vs. WFO

Results showed there was no significant change within subjects over time in terms of military target task performance. There was also no significant difference in any firing range scores when looking at a loss or gain of > +/-5 points between WFG and WFO PRK. Preliminary analysis showed visual and target task performance outcomes are comparable between WFG and WFO PRK.

TASK 3: Determine efficacy of wavefront guided refractions vs. wavefront optimized refractions; determine efficacy of Intralase femtosecond laser generated LASIK.

A) Conduct six month postoperative evaluation, cycloplegic refraction, contrast sensitivity testing, and measurement of wavefront map/ monochromatic optical aberrations.

B) Comparison preoperative objective measures of optical quality to six month post-operative values, comparison of pre to post refraction

C) Utilize a 2x2 factorial design and 2-way ANOVA to determine if either a main interaction effect exist between the two independent variables. (PRK and LASIK, WFG and WFO)

D) Determine efficacy of ablation pattern on outcome variables

E) Compare efficacy of refractive surgery method

- **TASK 3-A**

(Presented at ARVO 2013[6])

A preliminary comparison of visual acuity and contrast sensitivity results after WFG and WFO LASIK was conducted. CDVA and contrast sensitivity (CS) were evaluated preoperatively and at one, three and six months postoperatively. High and low contrast acuity testing was performed using the Variable Contrast 4-meter Rabin Super Vision Test (Precision Vision, La Salle, IL). Night vision testing was conducted with a back-illuminated 25% contrast acuity chart viewed through a dark green night vision goggle filter (Precision Vision, La Salle, IL). Room illumination and viewing distance (4 meters) were standardized for all measurements. For scoring the 25% contrast with night vision filter and high contrast Super Vision test, a credit of 0.02 logMAR units was calculated for each letter correctly identified. For the low contrast Super Vision test, a credit of 0.05 logCS units was calculated for each letter correctly identified. A RM-ANOVA was used to compare WFO vs. WFG LASIK over time and a p-value <0.05 was considered significant.

This cohorts demographic and baseline analysis is listed in **Table 15** while **Figures 6a-c** represent Super Vision and night vision contrast scores.

Table 15. Demographic data and baseline clinical characteristics.			
	WFG LASIK	WFO LASIK	*P-value**
No. of participants (eyes)	22 (44)	21 (42)	-
Age (years)	32.7 ±8.1	32.0 ±8.0	0.68
Male/Female	16/6	17/4	0.72[†]
Sphere (Diopters)	-3.05 ±1.36	-3.26 ±1.52	0.51
Cylinder (Diopters)	-0.57 ±0.49	-0.69D ±0.67	0.34
MSE (Diopters)	-3.26 ±1.37	-3.60 ±1.54	0.27
Preop UDVA (logMAR)	1.07 ±0.28	1.06 ±0.34	0.87
Central corneal thickness (µm)	561.1±30.1	572.6±34.7	0.11
Ablation depth (µm)	55.4 ±17.0	57.1 ±21.2	0.68

**t-test, P<0.05 statistically significant*
[†]Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Figure 6a. Super Vision High Contrast WFG LASIK and WFO LASIK. Negative shift equals improvement. *Preoperative baseline as covariate

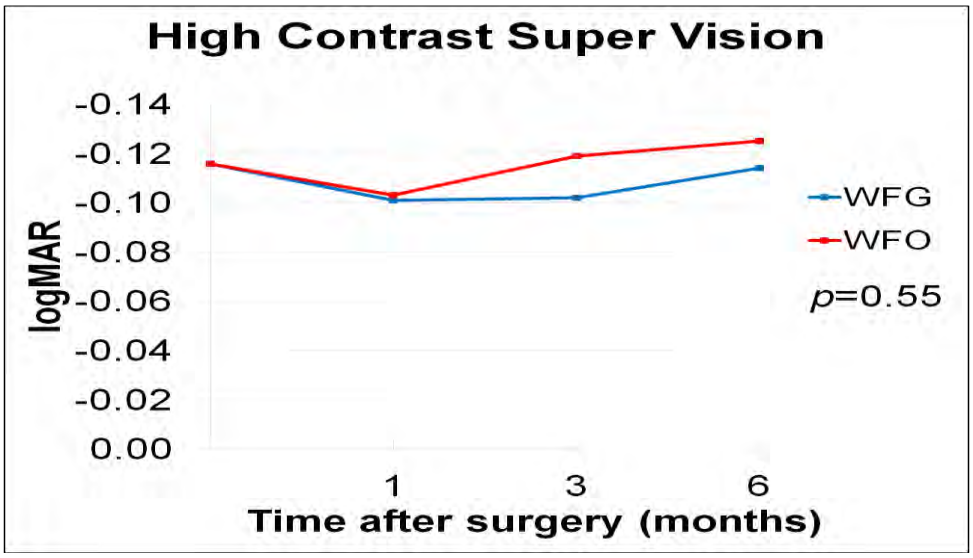


Figure 6b. Super Vision Low Contrast WFG LASIK and WFO LASIK. Positive shift equals improvement. *Preoperative baseline as covariate.

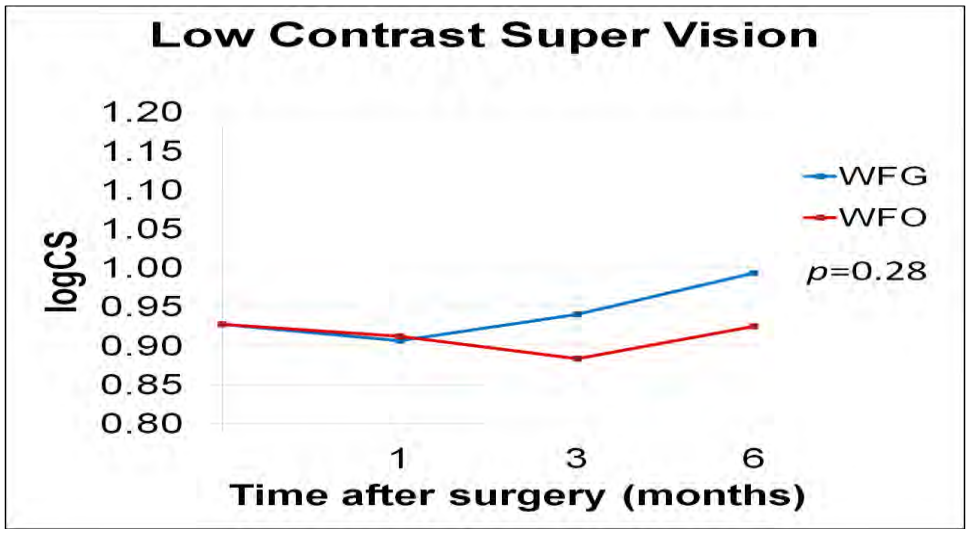
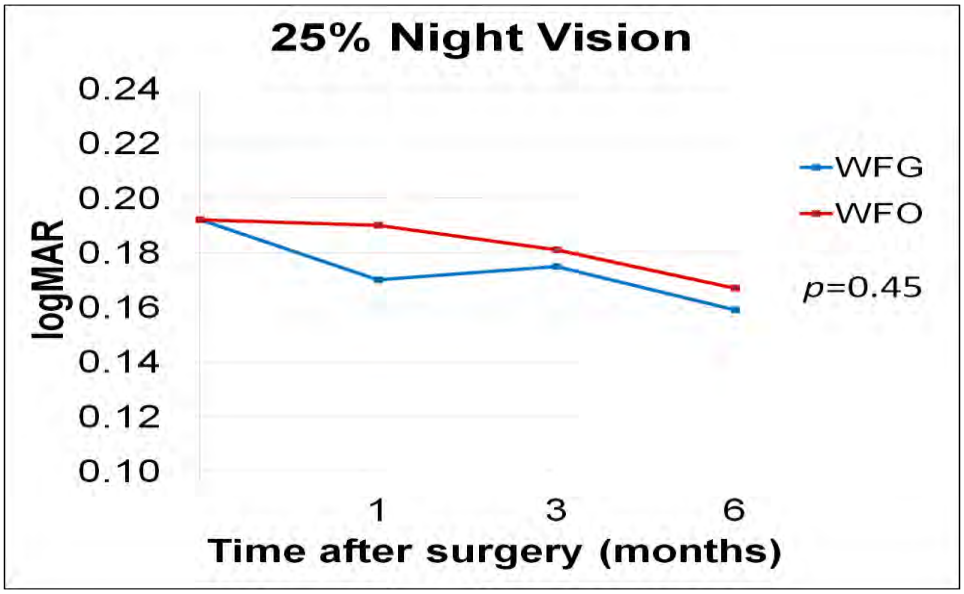


Figure 6c. 25% Night Vision WFG LASIK and WFO LASIK. Negative shift equals improvement. *Preoperative baseline as covariate.



In an initial comparison of WFG and WFO LASIK visual performance on Super Vision test and night vision test shows WFG and WFO LASIK are comparable over time.

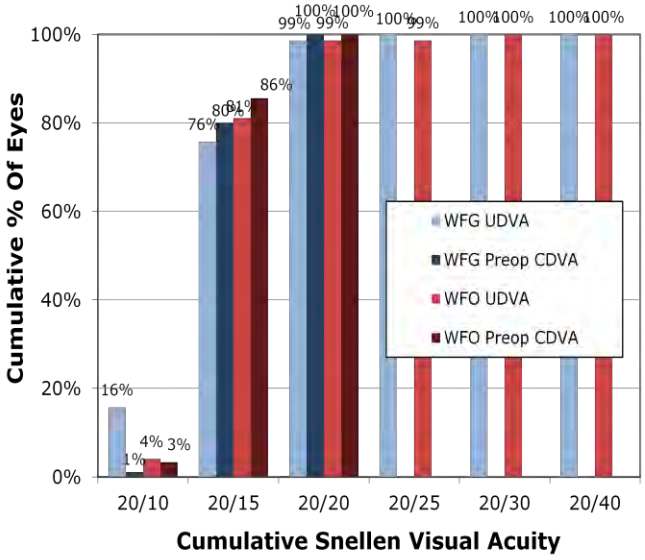
- **TASK 3-B**
  (Presented at ASCRS 2013[7])
  A preliminary analysis of visual outcomes following myopic WFG and WFO PRK using subjective manifest refraction, UDVA and CDVA determined preoperatively and six months postoperatively, generated the baseline demographics in **Table 16**. Visual outcomes are illustrated and described in **Figures 7a-e**.

Table 16. Demographic data and baseline clinical characteristics.

	WFG PRK	WFO PRK	*P-value**
No. of participants	35 (70 eyes)	37 (74 eyes)	-
Age (years)	30.1 ±6.6	30.9 ±6.1	0.43
Male/Female	26/9	26/11	0.80†
Sphere (diopter)	-2.96 ±1.67	-3.07 ±1.53	0.66
Cylinder (diopter)	-0.70 ±0.49	-0.67 ±0.54	0.72
MSE (diopter)	-3.30 ±1.69	-3.41 ±1.62	0.71
Preop UDVA (logMAR)	1.03 ±0.36	1.09 ±0.32	0.27
Mitomycin C use (no. of eyes)	41 (58.6%)	22 (29.7%)	0.001†

*t-test, $P<0.05$ statistically significant
†Fisher exact test, $P<0.05$ statistically significant
MSE, manifest spherical equivalent; UDVA, uncorrected distance visual acuity

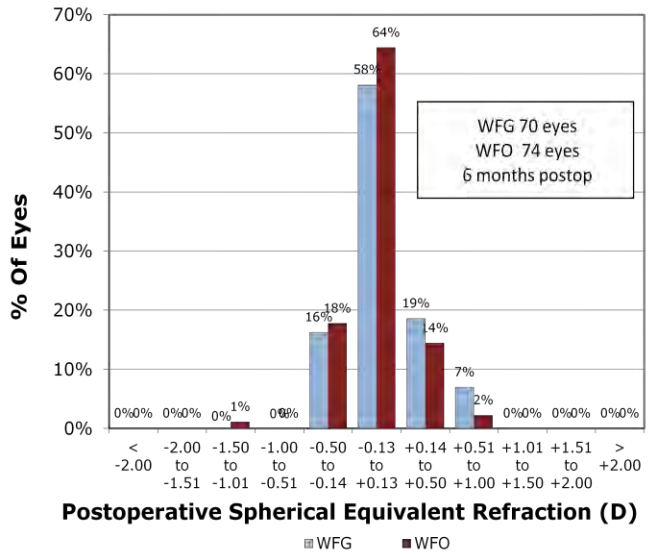
Figure 7a. WFG vs. WFO uncorrected distance visual acuity at six months postop.



❖At 6 months postop, there was no significant difference between WFG and WFO PRK in the number of eyes achieving UDVA of:

- ❖ 20/20 or better: 98.6% WFG vs. 98.6% WFO, P=0.99
- ❖20/15 or better: 75.7% WFG vs. 81.1% WFO, P=0.54

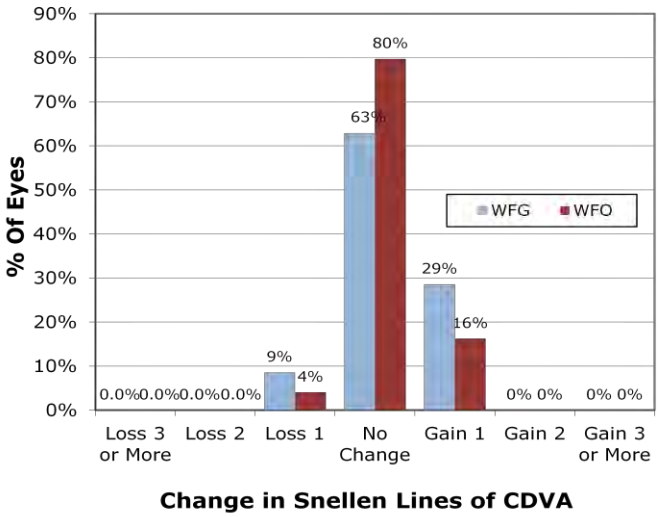
Figure 7b. WFG vs. WFO Spherical equivalent refractive accuracy six months postop.



❖At 6 months postop, there was no significant difference between WFG and WFO PRK in the number of eyes with MSE:

- ❖ ±0.50D: 91.4% WFG vs. 95.9% WFO, *P*=0.32
- ❖ ±1.00D: 100% WFG vs. 98.6%, *P*=0.99

Figure 7c. WFG vs. WFO Change in corrected distance visual acuity at six months postop.



❖At 6 months postop, none in either WFG or WFO lost more than 2 CDVA lines from baseline.

Figure 7d. Spherical equivalent attempted vs. achieved at six months postop

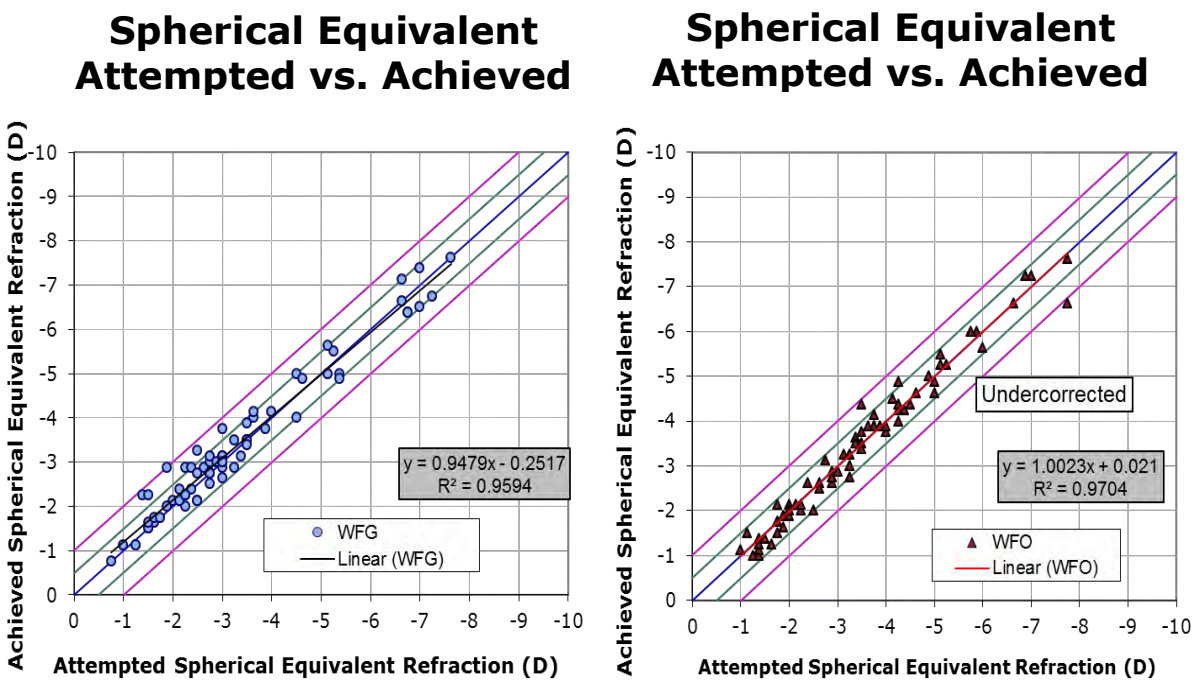
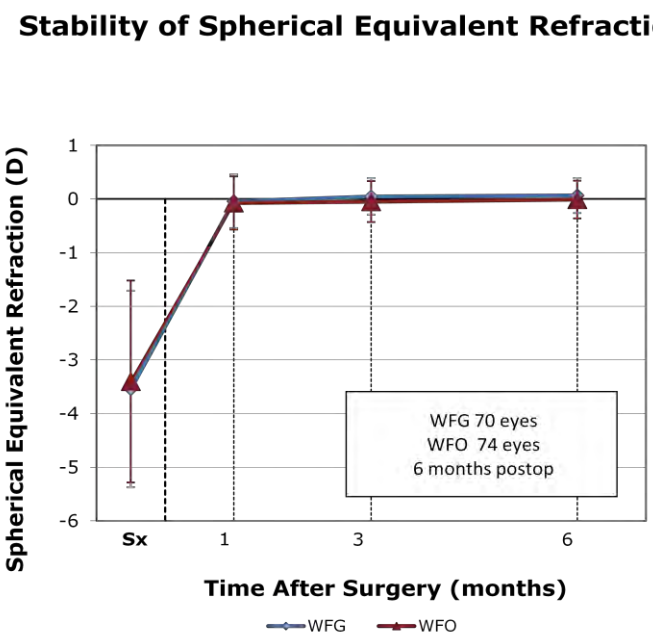


Figure 7e. Stability at six months postop WFG vs. WFO



❖ Change in MSE between 1 and 6 months postop were within ±0.50D in 80.0% WFG and 79.7% WFO (*P*=0.99).

Initial outcome analysis following WFG and WFO PRK are comparably effective, predictable, safe and stable at 6 months after surgery.

- **TASK 3-B**
  (Presented at ASCRS 2013[8])
  An initial review of participant satisfaction and visual symptoms following WFG and WFO LASIK was conducted to help identify factors that can affect quality of life following LASIK in order to improve patient selection, preoperative counseling, and the evaluation and management of quality of vision issues. The cohort analyzed included 31 subjects: (WFG LASIK, n=16); (WFO LASIK, n=15). UDVA and subjective manifest refraction with CDVA were determined preoperatively and at 6 months postoperatively. Satisfaction and visual quality were evaluated using pre- and postoperative questionnaires that were totaled and compared in the following categories:
  - Visual difficulties in performing daily activities
  - Glare
  - Halo
  - In comparison to what you expected before you had surgery, has your overall vision turned out to be:
    Much better than expected (1)----------(10) Much Worse
  - Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:
    Definitely would have surgery (1)----------(10) Definitely would NOT

  Table 17 lists the baseline characteristics in this cohort analyzed. **Tables 18-20** list questionnaire results while **Table 21** lists visual outcomes at six months postop**.**

Table 17. Demographic data and baseline clinical characteristics.

	WFG LASIK	***WFO LASIK***	***P-value****
No. of participants (eyes)	16 (32)	15 (30)	-
Age (years)	30.1 ±7.6	31.9 ±8.7	0.39
Male/Female	11/5	12/3	0.39†
Sphere (Diopters)	-2.64 ±1.12	-3.28 ±1.62	0.08
Cylinder (Diopters)	-0.56 ±0.51	-0.77D ±0.77	0.22
MSE (Diopters)	-2.92 ±0.98	-3.66 ±1.64	0.03
Preop UDVA (logMAR)	1.00 ±0.27	1.05 ±0.38	0.57

t-test, P<0.05 statistically significant
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Table 18. Difference in preoperative vs. 6 month postoperative questionnaire results.

WFG LASIK	*Pre*	*6 M Post*	*P-value**
Daily Activities	10.9±3.7	9.2±2.7	0.17
Glare	12.0±7.0	9.9±6.2	0.28
Halo	7.8±4.1	9.7±6.0	0.14
WFO LASIK	**Pre**	**6 M Post**	***P-value****
Daily Activities	10.2±4.3	8.7±3.9	0.40
Glare	8.0±3.8	8.4±4.8	0.73
Halo	7.1±6.6	7.4±3.1	0.87
t-test, P<0.05 statistically significant **Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.**			

Table 19. Visual symptoms scores at six months postop.

	WFG LASIK	*WFO LASIK*	*P-value**
Daily Activities	9.2±2.7	8.7±3.9	0.49
Glare	9.9±6.2	8.4±4.8	0.12
Halo	9.7±6.0	7.4±3.1	0.39
Repeated measures Analysis of Variance, P<0.05 statistically significant **Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.**			

Table 20. On a 10-point scale, a score of one being the highest, six month expectations and satisfaction scores

	WFG LASIK	*WFO LASIK*	*P-value**
Overall visual expectations	2.0±1.4	1.1±0.5	0.03
If given the opportunity, would have surgery again	1.3±1.0	1.1±0.3	0.37
t-test, P<0.05 statistically significant			

- At 6 months postop, there were 9 out of 16 WFG LASIK patients (56.2%) versus 14 of 15 WFO LASIK patients (93.3%) who reported that their vision was much better than expected (score of 1 on a 10-point scale).
- Of those who underwent WFG LASIK, 14 out of 16 patients (87.5%) responded, if given the chance to do it over, they definitely would have surgery again (score of 1 on a 10-point scale).
- Of those who underwent WFO LASIK, 14 out of 15 patients (93.3%) responded, if given the chance to do it over, they definitely would have surgery again (score 1 on a 10-point scale).

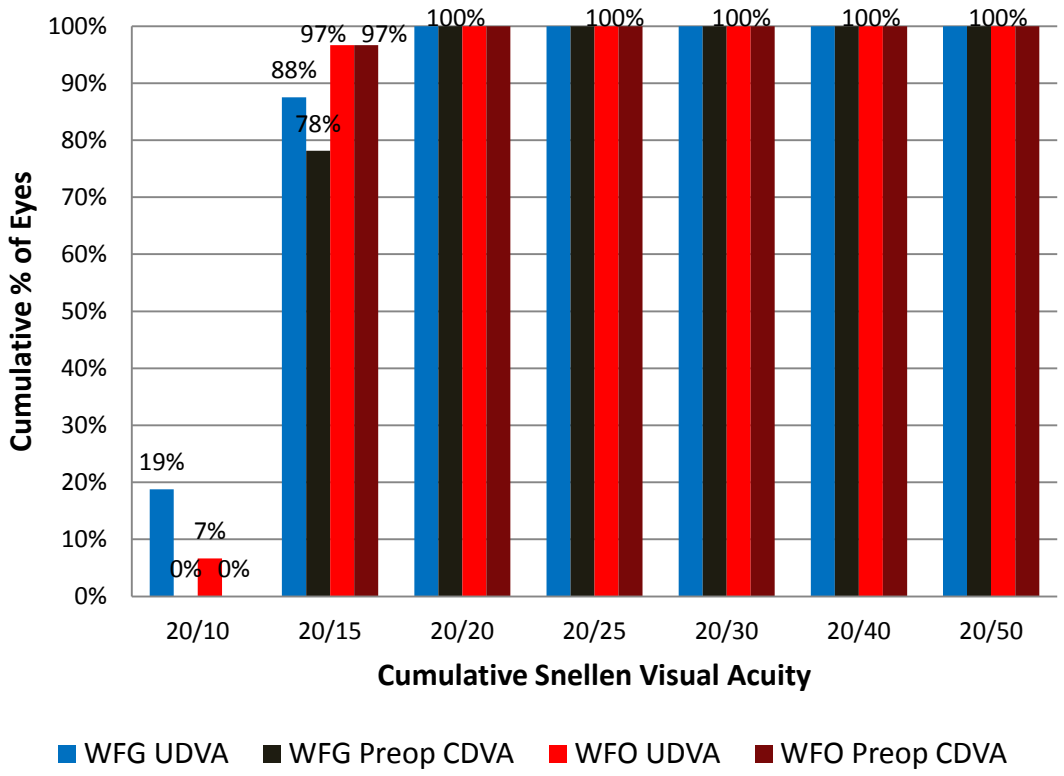
Table 21. Six-month postoperative visual outcomes.

	WFG LASIK	*WFO LASIK*	*P-value**
UDVA (logMAR)	-0.10 ±0.07	-0.08 ±0.06	0.31
CDVA (logMAR)	-0.14 ± 0.08	-0.12 ±0.05	0.33
MSE (Diopters)	0.04 ±0.28	0.03 ±0.23	0.88
t-test, P<0.05 statistically significant ***UDVA- uncorrected distance visual acuity; CDVA- corrected distance visual acuity; MSE- manifest spherical equivalent***			

At 6 months postop, there was no significant difference between WFG and WFO LASIK in the number of eyes achieving UDVA of:

- 20/20 or better: 100% WFG vs. 100% WFO, P=0.99
- 20/15 or better: 87.5% WFG vs. 96.7% WFO, P=0.36

Figure 8. Uncorrected Distance Visual Acuity (UDVA).



Preliminary results show WFG and WFO LASIK are comparable in terms of subjective quality of vision. Of note, more WFO LASIK patients felt their postoperative vision was better than they expected compared to those who underwent WFG LASIK.

KEY RESEARCH ACCOMPLISHMENTS

- A comparison of psychosocial and visual characteristics after 16 WFG and 15 WFO LASIK participants found WFG and WFO LASIK were comparable in terms of subjective quality of vision. More WFO LASIK patients felt their postoperative vision was better than they expected compared to those who underwent WFG LASIK. **(Appendix 2)**

- In a comparison of visual outcomes after WFG and WFO PRK for Myopia in 35 WFG and 37 WFO PRK participants, outcomes following WFG and WFO PRK were comparably effective, predictable, safe and stable at 6 months after surgery. **(Appendix 2)**

- In examining quality of vision and patient satisfaction after WFG and WFO PRK in 35 WFG and 37 WFO PRK participants, a majority of patients who underwent WFG and WFO PRK were highly satisfied with their surgeries. Furthermore, WFG and WFO PRK were comparable in terms of quality of vision and overall patient visual expectation and satisfaction. **(Appendix 2)**

- A comparison of visual and target task performance after WFG and WFO PRK in 26 WFG and 28 WFO participants found the following **(Appendix 3)**:
  - There was no significant change within subjects over time in terms of military task performance.
  - There was no significant difference in any firing range scores when looking at a loss or gain of > +/-5 points between WFG and WFO PRK.
  - Visual and target task performance outcomes are comparable between WFG and WFO PRK.

- A comparison of visual acuity and contrast sensitivity results after 22 WFG and 21 WFO LASIK participants found visual performance on Super Vision test and night vision were comparable between WFG and WFO LASIK over time. **(Appendix 4)**

- A comparison of higher order aberration (HOA) root mean square (RMS) and patient satisfaction of postoperative vision after WFG vs. WFO PRK in a preliminary review of 52 participants (WFG, n=26; WFO, n=26) found there is a significant difference in RMS HOA when comparing WFG vs. WFO PRK over time. Although there was a significant increase in HOA RMS of WFO PRK patients postoperatively, questionnaire results showed no significant difference in daily activities, glare, halo or satisfaction with the procedure when comparing WFG vs. WFO PRK. **(Appendix 4)**

- When comparing HOA RMS and patient satisfaction of postoperative vision after WFG vs. WFO LASIK of 22 WFG and 21 WFO LASIK participants, there is no significant difference in RMS HOA when comparing WFG vs. WFO LASIK over time, regardless of pupil size analyzed. There was no significant difference between the two procedures when postoperative visual symptoms were assessed. However, when compared to baseline, halos seemed worse in WFG LASIK. Overall visual expectations appeared to be better in patients who underwent WFO LASIK than WFG LASIK. **(Appendix 4)**

REPORTABLE OUTCOMES

1. Ryan DS, Peppers L, Sia RK, Mines MJ, Cute D, Stutzman RD, Howard RS, Bower KS. Comparison of Contrast Threshold after Wavefront-guided vs. Wavefront-optimized Photorefractive keratectomy (PRK). May 2012. Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Ft. Lauderdale, Florida

2. Ryan DS , Sia RK, Stutzman RD, Pasternak JF, Peppers L, Eaddy JB, Logan LA, Trudo EW, Bower KS. Patient Satisfaction and Quality of Vision after Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) Photorefractive keratectomy (PRK). May 2013. Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Seattle, Washington.

3. Sia RK, Stutzman RD, Pasternak JF, Ryan DS, Eaddy JB, Logan LA, Peppers L, Trudo EW, Bower KS. Patient Satisfaction and Quality of Vision after Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) LASIK. May 2013. Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Seattle, Washington.

4. Trudo EW, Ryan DS, Sia RK, Stutzman RD, Pasternak JF, Surrett C, Maurer T, Peppers L, Bower KS. Visual and target task performance after Wavefront-guided (WFG) and Wavefront-optimized (WFO) Photorefractive Keratectomy (PRK). January 2013. International Military Refractive Surgery Research Symposium (IMRSS). San Antonio, Texas. *Best paper of the session.*

5. Stutzman RD, Ryan DS, Sia RK, Trudo EW, Pasternak JF, Surrett C, Maurer T, Peppers L, Bower KS. Visual and target task performance after Wavefront-guided (WFG) and Wavefront-optimized (WFO) Photorefractive Keratectomy (PRK). April 2013. American Society of Cataract and Refractive Surgery Annual Meeting, *Special Session: Best of IMRSS*. San Francisco, California.

6. Bower KS, Peppers L, Sia RK, Stutzman RD, Pasternak JF, Ryan DS, Trudo EW. Visual Performance Comparison of Wavefront-optimized and Wavefront-guided Laser in situ keratomileusis (LASIK). May 2013. Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Seattle, Washington.

7. Sia RK, Stutzman RD, Mines MJ, Ryan DS, Trudo EW, Bower KS. Visual Outcomes After Wavefront-Guided and Wavefront-Optimized PRK for Myopia. April 2013. American Society of Cataract and Refractive Surgery Annual Meeting. San Francisco, California.

8. Stutzman RD, Sia RK, Ryan DS, Trudo EW, Mines MJ, Bower KS. Psychosocial and visual characteristics after wavefront-guided and wavefront-optimized LASIK. April 2013. American Society of Cataract and Refractive Surgery Annual Meeting. San Francisco, California.

9. Trudo EW, Ryan DS, Sia RK, Pasternak JF, Mines MJ, Bower KS. Quality of Vision and Patient Satisfaction After Wavefront-Guided and Wavefront-Optimized PRK. April 2013. American Society of Cataract and Refractive Surgery Annual Meeting. San Francisco, California.

10. Peppers L, Sia RK, Mines MJ, Ryan DS, Cute D, Stutzman RD, Bower KS. Visual Performance Comparison of Wavefront-optimized and Wavefront-guided Photorefractive Keratectomy (PRK). May 2012. Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Ft. Lauderdale, Florida.

11. Sia RK, Ryan DS, Stutzman RD, Mines MJ, Cute K, Bower KS. Wavefront-guided vs. Wavefront-optimized PRK: a comparison of simulated keratometric changes after myopic ablation. April 2012. American Society of Cataract and Refractive Surgery Annual Meeting. Chicago, IL.

CONCLUSION

The hypothesis for this study was that WFG surgery would minimize optical aberrations induced by refractive surgery when compared to WFO treatments, thereby minimizing any degradation of objective optical quality following both PRK and LASIK. It was unknown whether such differences would have a meaningful impact on military relevant tasks, however, and thus the importance of this study. Based on the PRK study results to date, WFG surgery is comparable to WFO surgery in terms of safety, efficacy, optical quality and subjective observations. As for

military relevant tasks, WFG vs. WFO PRK is comparable when observing NFR scores. LASIK study results are still under investigation. Ongoing testing in this study will help determine if there is a difference in LASIK firing range performance as well as if there is a difference in target detection and target identification.

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SUPPORTING DATA

None

APPENDICES

Appendix 1 - Current consent form and WRNMMC IRB approval and acknowledgement letters
Appendix 2 - Posters presenting results at the American Society of Cataract and Refractive Surgery Annual Meeting 2013
Appendix 3 - Oral presentations at the 2013 International Military Refractive Surgery Research Symposium and The American Society of Cataract and Refractive Surgery Annual Meeting 2013
Appendix 4 - Posters presenting results at the Annual Research in Vision and Ophthalmology Annual Meeting 2013

Walter Reed National Military Medical Center, Bethesda
IRBNet# 20481-37
IRB Expiration Date: 11 August 2013
Do not sign after this date.

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: COL Richard D. Stutzman, 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. 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 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).

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

Psychosocial and visual characteristics after wavefront-guided and wavefront-optimized LASIK

Richard D. Stutzman[1], Rose K. Sia[2], Denise S. Ryan[2], Edward W. Trudo[2], Michael J. Mines[3], Kraig S. Bower[3]

[1]Ophthalmology Service, Walter Reed National Military Medical Center, Bethesda, MD, USA
[2]U.S. Army Warfighter Refractive Surgery Research Center, Fort Belvoir, VA, USA
[3]The Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD, USA

•The authors have no financial interest in the subject matter of this poster

•This work is supported by U.S. Army Medical Research and Materiel Command grant # W81XWH-09-2-0018.

Disclaimer: The views expressed in this poster are those of the authors and do not reflect the official policy of the Department of the Army/Navy/Air Force, Department of Defense, or the U.S. Government.

Purpose

- Laser refractive surgery has proven enormously positive in terms of improving quality of life for the large majority of patients. [1]
- Results from a quality of life survey can help identify factors that can affect quality of life following LASIK[2] in order to improve patient selection, preoperative counseling, and the evaluation and management of quality of vision issues.
- In this study, we aim to compare patient satisfaction and visual symptoms following myopic wavefront-guided (WFG) and wavefront-optimized (WFO) LASIK.

[1]Solomon KD et al. LASIK World Literature Review: Quality of Life and Patient Satisfaction. Ophthalmology. 2009,116(4): 691-701.
[2]Nichols JJ et al. Sensitivity of the National Eye Institute Refractive Error Quality of Life Instrument to Refractive Surgery Outcomes. Journal of Cataract and Refract Surg. 2005, 31(12):2313-18.

Methods

- This is a prospective study of 31 patients randomized to undergo either wavefront-guided (WFG, n=16) or wavefront-optimized LASIK (WFO, n=15) for myopia or myopic astigmatism.
- Uncorrected visual acuity and subjective manifest refraction with corrected distance visual acuities were determined preoperatively and at 6 months (M) postoperatively.
- Patient satisfaction and visual quality were evaluated using pre- and postoperative questionnaires.

Methods

Surgical Procedure:

- Flaps were created using the Intralase femtosecond laser system (Abbott Medical Optics, Santa Ana, CA).
- WFG LASIK was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Santa Ana, CA) and WFO LASIK was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX).

Postoperative topical medications for both groups included:

- Moxifloxacin 0.5% 4x daily for 1 week
- Prednisolone acetate 0.1% 1 drop every two hours for the first 3 days, then 1 drop 4x daily for 1 week.
- Preservative-free carboxymethylcellulose 0.5%1 drop every hour for the first 2 weeks, then at least every 2 hours or more for 1-3 months.
- Preservative-free ketorolac 0.5% up to 4x daily for 48 hours

Methods

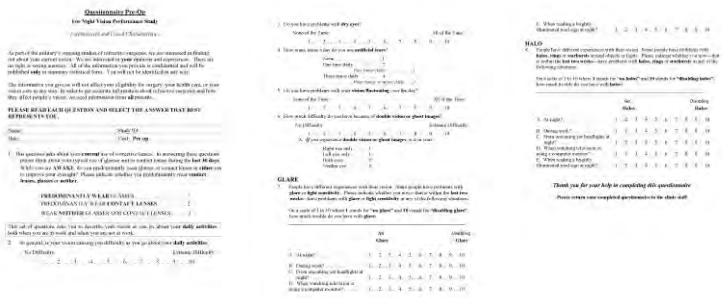
- Pre- and post-operative questionnaire results were totaled and compared in the following categories:
  - Visual difficulties in performing daily activities
  - Glare
  - Halo
  - In comparison to what you expected before you had surgery, has your overall vision turned out to be:

Much better than expected (1)----------(10) Much Worse

  - Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:

Definitely would have surgery (1)----------(10) Definitely would NOT

PRE:



POST:

Results

Table 1. Demographic data and baseline clinical characteristics.

	WFG LASIK	WFO LASIK	*P-value**
No. of participants (eyes)	16 (32)	15 (30)	-
Age (years)	30.1 ±7.6	31.9 ±8.7	0.39
Male/Female	11/5	12/3	0.39†
Sphere (Diopters)	-2.64 ±1.12	-3.28 ±1.62	0.08
Cylinder (Diopters)	-0.56 ±0.51	-0.77D ±0.77	0.22
MSE (Diopters)	-2.92 ±0.98	-3.66 ±1.64	0.03
Preop UDVA (logMAR)	1.00 ±0.27	1.05 ±0.38	0.57

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Results

Table 2. Difference in preop vs. 6M postop questionnaire results.

WFG LASIK	Pre	6 M Post	*P-value**
Daily Activities	10.9±3.7	9.2±2.7	0.17
Glare	12.0±7.0	9.9±6.2	0.28
Halo	7.8±4.1	9.7±6.0	0.14
WFO LASIK	**Pre**	**6 M Post**	***P-value****
Daily Activities	10.2±4.3	8.7±3.9	0.40
Glare	8.0±3.8	8.4±4.8	0.73
Halo	7.1±6.6	7.4±3.1	0.87

**t-test, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Results

Table 3. Visual symptoms scores at six months postop.

	WFG LASIK	WFO LASIK	*P-value**
Daily Activities	9.2±2.7	8.7±3.9	0.49
Glare	9.9±6.2	8.4±4.8	0.12
Halo	9.7±6.0	7.4±3.1	0.39

**Repeated measures Analysis of Variance, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Table 4. Six-month postoperative visual outcomes.

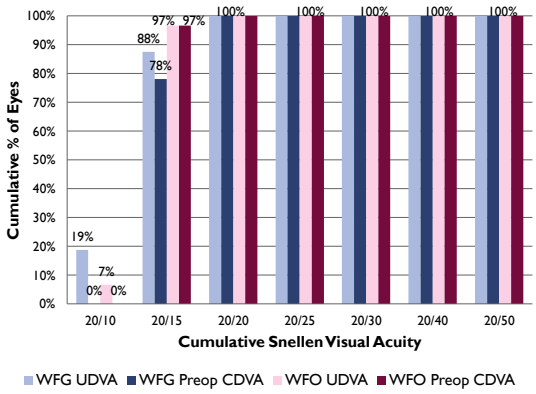
	WFG LASIK	WFO LASIK	*P-value**
UDVA (logMAR)	-0.10 ±0.07	-0.08 ±0.06	0.31
CDVA (logMAR)	-0.14 ± 0.08	-0.12 ±0.05	0.33
MSE (Diopters)	0.04 ±0.28	0.03 ±0.23	0.88

**t-test, P<0.05 statistically significant*
UDVA- uncorrected distance visual acuity; CDVA- corrected distance visual acuity; MSE- manifest spherical equivalent

Results

WFG 32 eyes
WFO 30 eyes
6 months postop

Figure 1. Uncorrected Distance Visual Acuity



At 6 months postop, there was no significant difference between WFG and WFO LASIK in the number of eyes achieving UDVA of:

- 20/20 or better: 100% WFG vs. 100% WFO, P=0.99
- 20/15 or better: 87.5% WFG vs. 96.7% WFO, P=0.36

Results

Table 5. On a 10-point scale, a score of one being the highest, 6M expectations and satisfaction scores

	WFG LASIK	WFO LASIK	*P-value**
Overall visual expectations	2.0±1.4	1.1±0.5	0.03
If given the opportunity, would have surgery again	1.3±1.0	1.1±0.3	0.37

**t-test, P<0.05 statistically significant*

- At 6 months postop, there were 9 out of 16 WFG LASIK patients (56.2%) versus 14 of 15 WFO LASIK patients (93.3%) who reported that their vision was much better than expected (score of 1 on a 10-point scale).
- Of those who underwent WFG LASIK, 14 out of 16 patients (87.5%) responded, if given the chance to do it over, they definitely would have surgery again (score of 1 on a 10-point scale).
- Of those who underwent WFO LASIK, 14 out of 15 patients (93.3%) responded, if given the chance to do it over, they definitely would have surgery again (score 1 on a 10-point scale).

Conclusion

- WFG and WFO LASIK were comparable in terms of subjective quality of vision. More WFO LASIK patients felt their postoperative vision was better than they expected compared to those who underwent WFG LASIK.

Visual Outcomes After Wavefront-Guided and Wavefront-Optimized PRK for Myopia

Rose K. Sia[1], Richard D. Stutzman[2], Michael J. Mines[3], Denise S. Ryan[1], Edward W. Trudo[1], Kraig S. Bower[3]

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The authors have no financial interest in the subject matter of this poster.
This work is supported by U.S. Army Medical Research and Materiel Command Grant # W81XWH-09-2-0018.

Disclaimer: The views expressed in this poster are those of the authors and do not reflect the official policy of the Department of the Army/Navy/Air Force, Department of Defense, or the U.S. Government.

Purpose

- To compare visual outcomes following myopic wavefront-guided (WFG) and wavefront-optimized (WFO) photorefractive keratectomy (PRK).
- Off label use: This presentation discusses the off-label use of the Allegretto Wavelight and the VISX Star S4 CustomVue for PRK.

Methods

- This is a prospective study of patients with myopia or myopic astigmatism randomized to undergo either WFG or WFO PRK.
- 72 patients aged 21 or older were randomized to undergo either WFG or WFO PRK for myopia or myopic astigmatism.
- Subjective manifest refraction, uncorrected and corrected distance visual acuities were determined preoperatively and at 6 months postoperatively.

Methods

Surgical Procedure:

- The corneal epithelium was removed using a rotary brush (Amoils, Innovative Excimer Solutions, Toronto, Canada)
- Surface ablation was performed using either the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Santa Ana, CA) for WFG PRK or the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX) for WFO PRK.
- Prophylactic use of mitomycin C (MMC) was based on the study sites' standard operating procedures.
- For all WFG treatments, MMC was used on eyes with central ablation depth of greater than 49.5 microns or cylinder >1.25D.
- For all WFO treatments, MMC was used on eyes with central ablation depth of greater than 75 microns.

Methods

- Postoperative topical medications for both groups included:
  - Moxifloxacin 0.5% 4x daily for 1 week or until complete re-epithelialization
  - Fluorometholone 0.1% 4x daily for 4 weeks followed by a 6-week taper
  - Preservative-free carboxymethylcellulose 0.5% 4 to 8 times daily for 2 weeks then as needed
  - Preservative-free ketorolac 0.5% up to 4x daily for 48 hours
- Fisher exact test was done to compare visual outcomes and a P value of <0.05 was considered statistically significant.

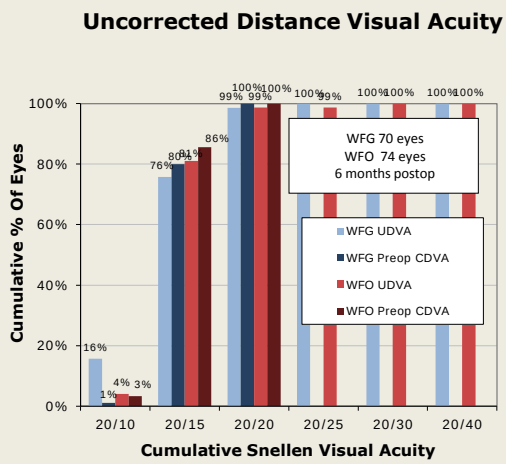
Results

Table 1. Demographic data and baseline clinical characteristics.

	WFG PRK	WFO PRK	*P-value**
No. of participants	35 (70 eyes)	37 (74 eyes)	-
Age (years)	30.1 ±6.6	30.9 ±6.1	0.43
Male/Female	26/9	26/11	0.80†
Sphere (diopter)	-2.96 ±1.67	-3.07 ±1.53	0.66
Cylinder (diopter)	-0.70 ±0.49	-0.67 ±0.54	0.72
MSE (diopter)	-3.30 ±1.69	-3.41 ±1.62	0.71
Preop UDVA (logMAR)	1.03 ±0.36	1.09 ±0.32	0.27
Mitomycin C use (no. of eyes)	41 (58.6%)	22 (29.7%)	0.001†

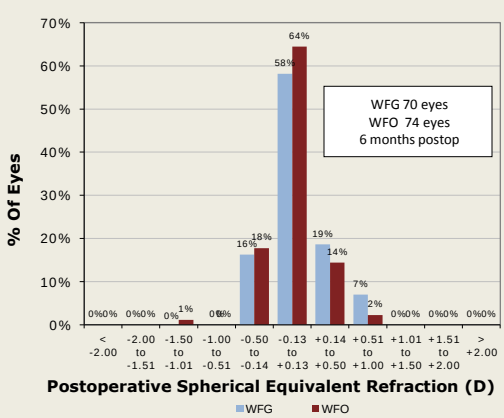
*t-test, P<0.05 statistically significant
†Fisher exact test, P<0.05 statistically significant
MSE, manifest spherical equivalent; UDVA, uncorrected distance visual acuity

Results



- At 6 months postop, there was no significant difference between WFG and WFO PRK in the number of eyes achieving UDVA of:
  - 20/20 or better: 98.6% WFG vs. 98.6% WFO, P=0.99
  - 20/15 or better: 75.7% WFG vs. 81.1% WFO, P=0.54

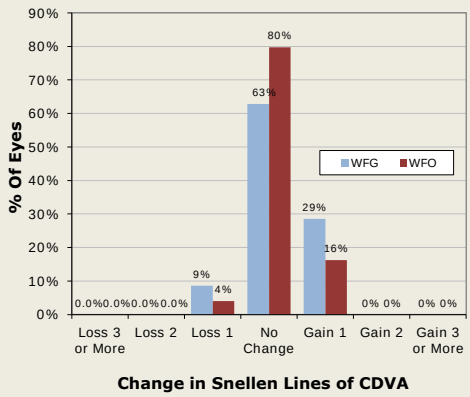
Results



- At 6 months postop, there was no significant difference between WFG and WFO PRK in the number of eyes with MSE:
  - ±0.50D: 91.4% WFG vs. 95.9% WFO, P=0.32
  - ±1.00D: 100% WFG vs. 98.6%, P=0.99

Results

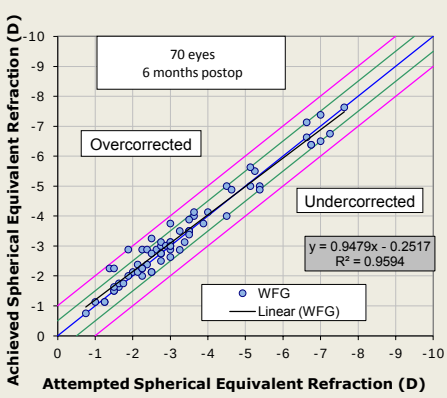
Change in Corrected Distance Visual Acuity



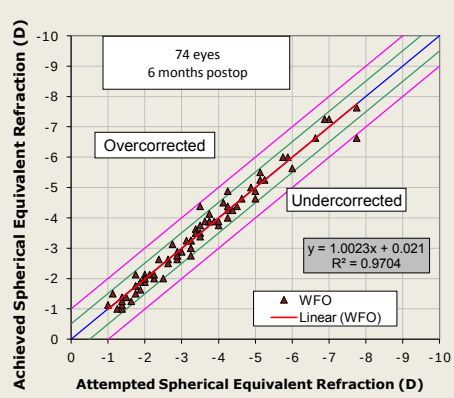
❖At 6 months postop, none in either WFG or WFO lost more than 2 CDVA lines from baseline.

Results

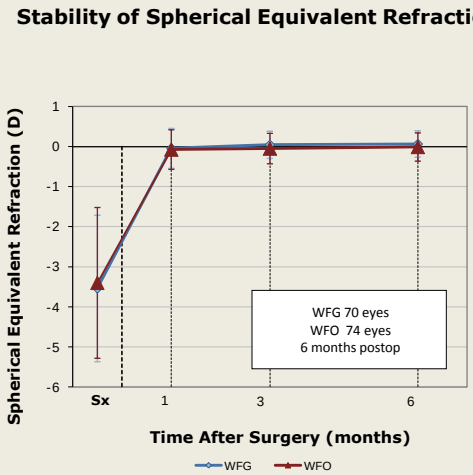
Spherical Equivalent Attempted vs. Achieved (WFG)



Spherical Equivalent Attempted vs. Achieved (WFO)



Results



❖ Change in MSE between 1 and 6 months postop were within ±0.50D in 80.0% WFG and 79.7% WFO (P=0.99).

Conclusion

- Outcomes following WFG and WFO PRK were comparably effective, predictable, safe and stable at 6 months after surgery.
- Additional assessment of optical quality and visual performance after WFG and WFO PRK are underway.

QUALITY OF VISION AND PATIENT SATISFACTION AFTER WAVEFRONT-GUIDED AND WAVEFRONT-OPTIMIZED PRK

Edward W. Trudo[1], Denise S. Ryan[1], Rose K. Sia[1], Joseph F. Pasternak[2], Michael J. Mines[3], Kraig S. Bower[3]

[1]U.S. Army Warfighter Refractive Surgery Research Center at Fort Belvoir, Fort Belvoir, VA, USA

[2]Walter Reed National Military Medical Center, Bethesda, MD, USA

[3]The Wilmer Eye Institute, Johns Hopkins University, Baltimore, MD, USA

The authors have no financial interest in the subject matter of this poster.
This work is supported by U.S. Army Medical Research and Materiel Command grant # W81XWH-09-2-0018.

Disclaimer: The views expressed in this poster are those of the authors and do not reflect the official policy of the Department of the Army/Navy/Air Force, Department of Defense, or the U.S. Government.

Purpose

- To evaluate quality of vision and patient satisfaction following myopic wavefront-guided (WFG) and wavefront-optimized (WFO) photorefractive keratectomy (PRK).
- Off label use: This presentation discusses the off-label use of the Allegretto Wavelight and the VISX Star S4 CustomVue for PRK.

Methods

- This is a prospective study of patients with myopia or myopic astigmatism randomized to undergo either WFG or WFO PRK. WFG PRK was performed using VISX STAR S4 Excimer Laser and WFO PRK with Allegretto Wave Eye Q Excimer Laser System.
- Subjective manifest refraction, uncorrected and corrected distance visual acuities were determined preoperatively and at 6 months postoperatively.
- A questionnaire that focused on general satisfaction and visual quality was given pre- and postoperatively.

Methods

Surgical Procedure:

- A rotary brush (Amoils, Innovative Excimer Solutions, Toronto, Canada) was used to remove the corneal epithelium.
- Surface ablation was performed using either the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Santa Ana, CA) for WFG PRK or the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX) for WFO PRK.
- Prophylactic use of mitomycin C (MMC) was based on the study sites' standard operating procedures.
- For all WFG PRK treatments, MMC was used on eyes with central ablation depth of greater than 49.5 microns or cylinder >1.25D.
- For all WFO PRK treatments, MMC was used on eyes with central ablation depth of greater than 75 microns.

Methods

- Postoperative topical medications for both groups included:
  - Moxifloxacin 0.5% 4x daily for 1 week or until complete re-epithelialization
  - Fluorometholone 0.1% 4x daily for 4 weeks followed by a 6-week taper
  - Preservative-free carboxymethylcellulose 0.5% 4 to 8 times daily for 2 weeks then as needed
  - Preservative-free ketorolac 0.5% up to 4x daily for 48 hours

Methods

- The total preoperative and postoperative scores of the following categories were determined:
  - Visual difficulties in performing daily activities
  - Glare
  - Halo
  - In comparison to what you expected before you had surgery, has your overall vision turned out to be:

  Much better than expected (1)----------(10) Much Worse

  - Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:

  Definitely would have surgery (1)----------(10) Definitely would NOT

- Student t-test was used to compare visual symptoms and overall patient satisfaction before and after surgery. Repeated measures analysis of variance was used to compare outcomes of WFG and WFO PRK. A *P* value of <0.05 was considered statistically significant.

Results

Table 1. Demographic data and baseline clinical characteristics.

	WFG PRK	WFO PRK	*P-value**
No. of participants	35 (70 eyes)	37 (74 eyes)	-
Age (years)	30.1 ±6.6	30.9 ±6.1	0.43
Male/Female	26/9	26/11	0.80†
Sphere (diopter)	-2.96 ±1.67	-3.07 ±1.53	0.66
Cylinder (diopter)	-0.70 ±0.49	-0.67 ±0.54	0.72
MSE (diopter)	-3.30 ±1.69	-3.41 ±1.62	0.71
Preop UDVA (logMAR)	1.03 ±0.36	1.09 ±0.32	0.27
Mitomycin C use (no. of eyes)	41 (58.6%)	22 (29.7%)	0.001†

*t-test, P<0.05 statistically significant
†Fisher exact test
MSE, manifest spherical equivalent; UDVA, uncorrected distance visual acuity

Results

Table 2. Difference in preop vs. 6 months postop questionnaire results.

WFG PRK	Preop	6 mos. postop	*P-value**
Daily Activities	10.7 ±5.2	10.4 ±4.1	0.79
Glare	11.3 ±8.3	9.9 ±5.9	0.40
Halo	7.1 ±3.0	8.9 ±6.0	0.06
WFO PRK			
Daily Activities	10.1 ±4.1	9.8 ±4.5	0.75
Glare	9.6 ±7.0	7.8 ±3.1	0.08
Halo	7.3 ±4.9	6.6 ±2.2	0.40

**t-test, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Results

Table 3. Six-month postoperative visual symptoms scores.

	WFG PRK	WFO PRK	*P-value**
Daily Activities	10.4 ±4.1	9.8 ±4.5	0.51
Glare	9.9 ±5.9	7.8 ±3.1	0.11
Halo	8.9 ±6.0	6.6 ±2.2	0.21

**Repeated measures Analysis of Variance, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Table 4. Six-month postoperative visual outcomes.

	WFG PRK	WFO PRK	*P-value**
UDVA (logMAR)	-0.10 ±0.07	-0.08 ±0.06	0.31
CDVA (logMAR)	-0.14 ± 0.08	-0.12 ±0.05	0.33
MSE (Diopters)	0.04 ±0.28	0.03 ±0.23	0.88

**t-test, P<0.05 statistically significant*
UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; MSE, manifest spherical equivalent

Results

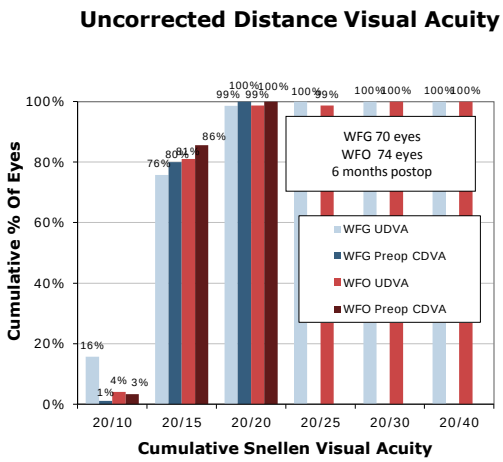
Table 4. On a 10-point scale, score of 1 being the highest, patient expectations and satisfaction scores at 6 months postoperatively.

	WFG PRK	WFO PRK	*P-value**
Overall visual expectations	1.6 ±1.0	1.6 ±1.0	0.98
If given the opportunity, would have surgery again	1.2 ±0.8	1.2 ±0.5	0.94

**t-test, P<0.05 statistically significant*

- At 6 months postop, vision was rated much better than expected (score of 1 on a 10-point scale) in 22 out of 35 patients who underwent WFG PRK (62.9%) versus 24 of 37 patients who underwent WFO PRK (64.9%).
- Of the 35 patients who underwent WFG PRK, 32 (91.4%) responded, if given the chance to do it over, they definitely would have surgery again (score of 1 on a 10-point scale).
- Of the 37 patients who underwent WFO PRK, 32 (86.5%) responded, if given the chance to do it over, they definitely would have surgery again (score 1 on a 10-point scale).

Results



❖At 6 months postop, there was no significant difference between WFG and WFO PRK in the number of eyes achieving UDVA of:

- ❖ 20/20 or better: 98.6% WFG vs. 98.6% WFO, *P*=0.99
- ❖20/15 or better: 75.7% WFG vs. 81.1% WFO, *P*=0.54

Conclusion

- Majority of patients who underwent WFG and WFO PRK were highly satisfied with their surgeries.
- WFG and WFO PRK were comparable in terms of quality of vision and overall patient visual expectation and satisfaction.

Visual and target task performance after Wavefront-guided (WFG) and Wavefront-optimized (WFO) Photorefractive Keratectomy (PRK)

COL Mark F. Torres

2013 International Military Refractive Surgery Research Symposium

Authors: Trudo EW, Ryan DS, Sia RK, Stutzman RD, Pasternak JF, Surrett C, Maurer T, Peppers L, Bower KS

Financial Disclosure

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Disclaimer

- The views expressed in this presentation are those of the author and do not reflect the official policy of the Department of Army/Navy/Air Force, Department of Defense or U.S. Government.

Off-Label Use

- This presentation discusses the off-label use of the Allegretto Wavelight and the VISX Star S4 CustomVue for photorefractive keratectomy (PRK).

Walter Reed National Military Medical Center

Fort Belvoir Community Hospital

Background

- This is part of an ongoing prospective study in collaboration with the U.S. Army Warfighter Refractive Surgery Research Center at Fort Belvoir, Walter Reed National Military Medical Center and the Night Vision and Electronic and Sensors Directorate.
- Study participants and physicians select treatment: PRK or LASIK. WFG vs. WFO treatment modality is randomized. The study is being conducted in three phases :
- Phase 1 (112 patients) – subjective visual performance and objective optical quality (includes contrast sensitivity, wavefront analysis, and contrast threshold testing)
- Phase 2 (56 patients) – In addition to subjective visual performance and objective optical quality, participants will also be tested on military task performance at the night firing range (NVESD)
- Phase 3 (56 patients) – In addition to subjective visual performance and objective optical quality, participants will be tested on performance prediction modeling using target detection and identification at the human perception lab (NVESD)

Purpose

- The objective of this study is to compare military task performance in WFG vs. WFO PRK in terms of visual outcomes and night firing range scores.

Methods

- Patients with myopia or myopic astigmatism were randomized to undergo either WFG or WFO PRK. WFG patients were treated after wavescan capture using the VISX Star S4 CustomVue (Abbott Medical Optics). WFO patients were treated on the Wavelight Allegretto Wave Eye-Q (Alcon Surgical).
- Epithelial removal was performed with the Amoils epithelial scrubber (Innova Inc).
- Testing pre-operatively and at 1 month, 3 months, and 6 months post-operatively included uncorrected distance visual acuity (UDVA), manifest refraction, corrected distance visual acuity (CDVA), IOP, and slit lamp biomicroscopy. Patients were also assessed for complications at each postoperative visit.

Methods

- Marksmanship skill was evaluated with an M16-A4 rifle on a modified range under low light or nighttime conditions preoperatively and at 6 weeks and 6 months postoperatively .

Methods

Participants fired an M16-A4 rifle under the following conditions:

- ❖1) iron sight;
- ❖2) night vision goggle (monocular) and aiming light; and
- ❖3) gun-mounted thermal sight (forward looking infrared).

Light levels for condition 1 was low light (simulated dusk) and for conditions 2 and 3, starlight only.

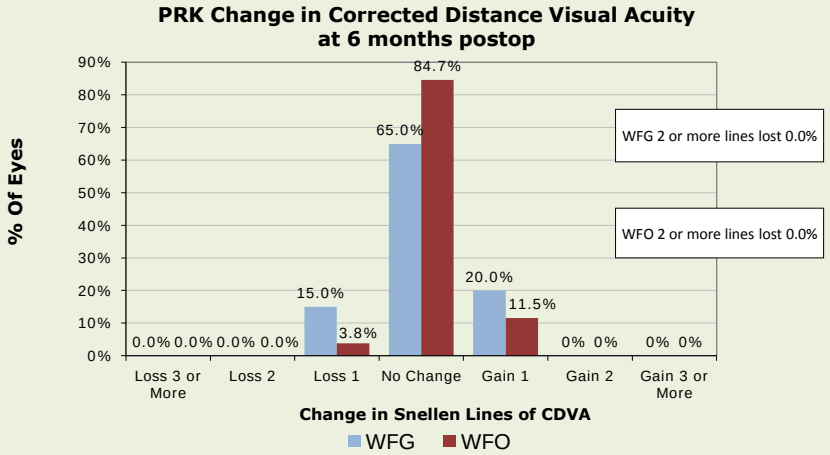
Methods

- Pre- and postoperative firing range scores were compared using Wilcoxon signed-rank test. WFG and WFO PRK were compared in terms of 6 months visual outcomes using Fisher exact test and 6 months firing range scores using Mann-Whitney test. A p-value of <0.05 was considered significant.

Results: Baseline preoperative characteristics

	WFG (n=26) **mean**± SD (range)	WFO (n=28) **mean**± SD (range)	***P-value***
Age	31.3 ±6.8 (21 to 43)	31.8 ±6.9 (21 to 51)	0.70
Male/female	10/3	9/5	0.68
UDVA (logMAR)	0.99± 0.30 (0.72 to 1.60)	1.13± 0.26 (0.72 to 1.60)	0.11
Manifest Sph (D)	-2.93± 1.41 (-2.00 to -7.00)	-3.08± 1.06 (-2.00 to -7.00)	0.26
Manifest Cyl (D)	-0.75± 0.51 (0 to -2.00)	-0.66± 0.51 (0 to -3.00)	0.45
MSE (D)	-3.31± 1.41 (-2.00 to -7.00)	-3.41± 1.10 (-2.00 to -7.00)	0.42
CDVA (logMAR)	-0.10± 0.03 (0 to -0.16)	-0.10± 0.04 (0 to -0.12)	0.61
MMC treated (%)	76.9	35.7	0.54

Results: Safety

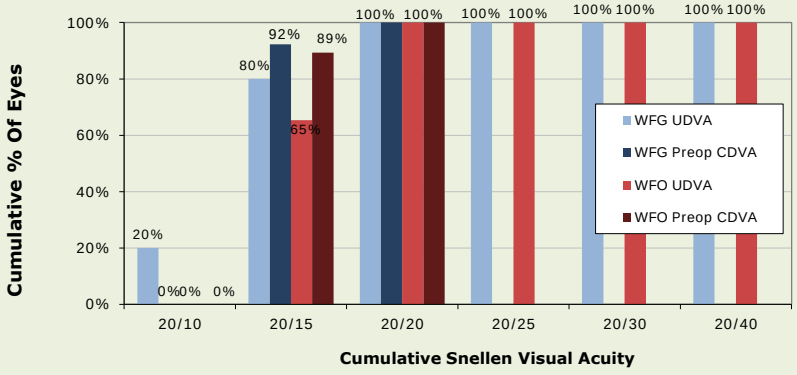


Number (%) of eyes losing two or more CDVA lines

WFG/ WFO	1 month (26/28)	3 months (24/28)	6 months (20/26)
WFG	2 (7.7%)	0 (0%)	0 (0%)
WFO	0 (0%)	0 (0%)	0 (0%)
P-value	0.23	-	-

Results: Efficacy

PRK Uncorrected Distance Visual Acuity preop and at 6 months postop

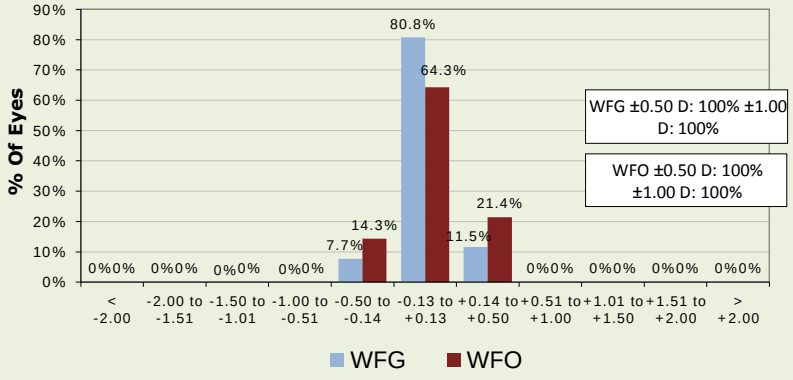


Number (%) of eyes achieving UDVA 20/15 or better

WFG/ WFO	1 month (26/28)	3 months (24/28)	6 months (20/26)
WFG	5 (19.2%)	16 (61.5%)	16 (80.0%)
WFO	6 (21.4%)	15 (53.6%)	17 (65.4%)
P-value	0.99	0.59	0.34

Results: Predictability

Postoperative Spherical Equivalent Refraction (D)

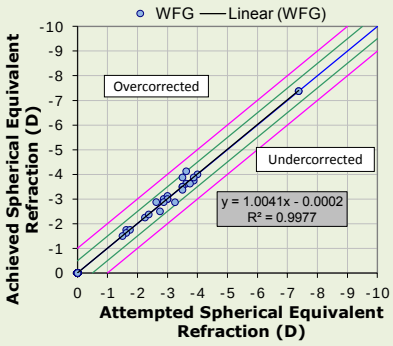


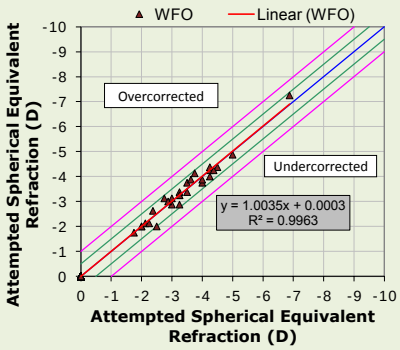
Number (%) of eyes with MSE within ±0.50D

WFG/WFO	1 month (26/28)	3 months (24/28)	6 months (20/26)
WFG	19 (73.1%)	24 (92.3%)	26 (100%)
WFO	20 (71.4%)	26 (92.9%)	28 (100%)
P-value	0.99	0.99	-

Results: Predictability

PRK Spherical Equivalent
Attempted vs. Achieved at 6 months postop



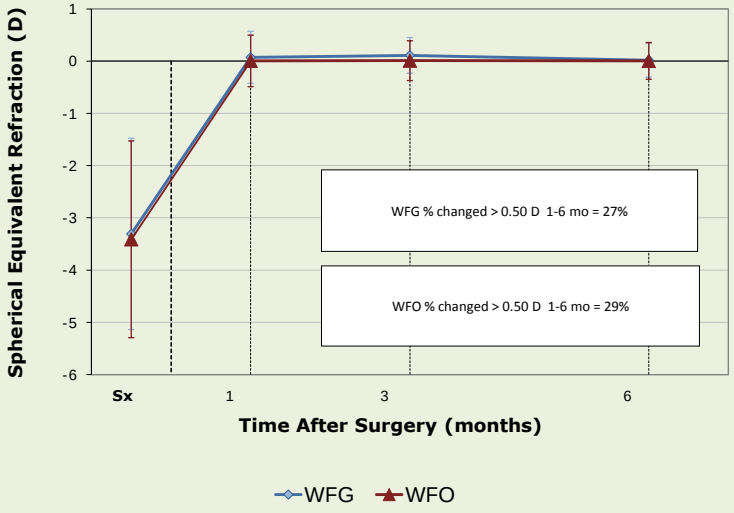


WFG: -3.31±1.41 D
range: -1.50 to -7.38 D

WFO: -3.41±1.10 D
range: -1.75 to -6.88 D

Results: Stability

PRK Stability of Spherical Equivalent Refraction



Results: Military task performance

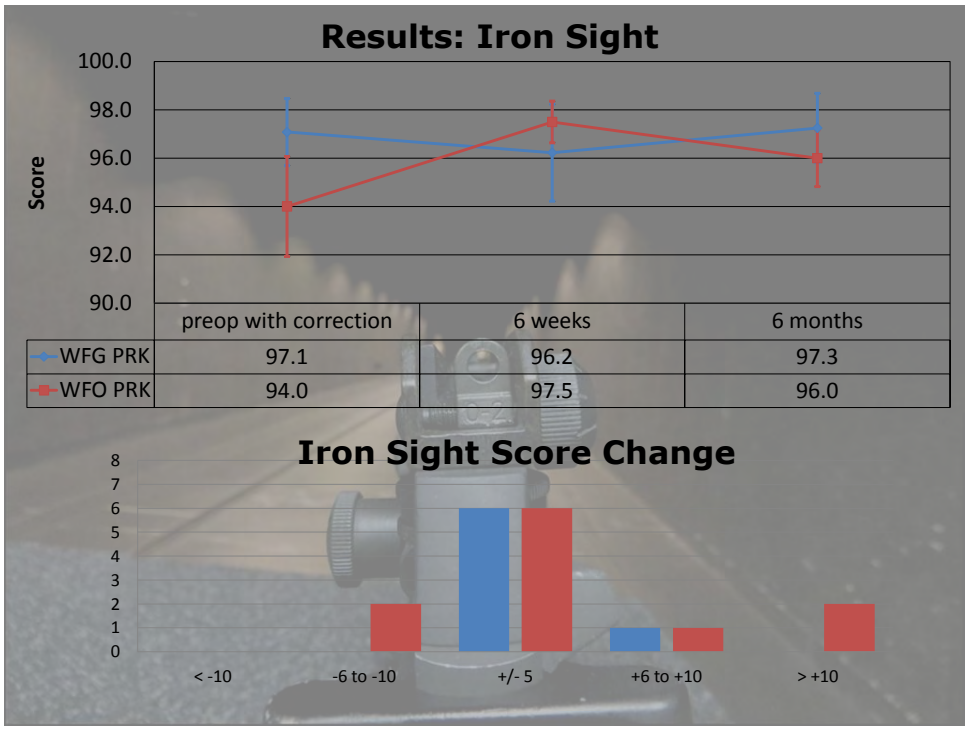
Table 1. Comparison of six-month postoperative firing range scores between WFG and WFO PRK.

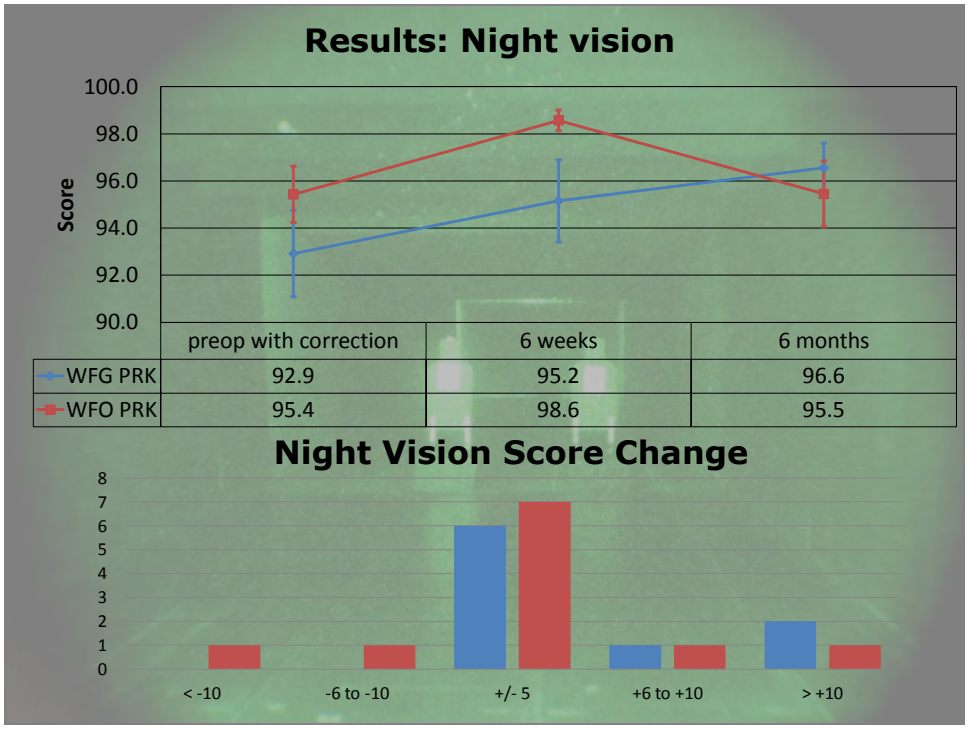
	Iron sight	Night vision	Thermal sight
WFG PRK	97.3 ±4.1	96.6 ±3.2	94.0 ±4.3
WFO PRK	96.0 ±3.9	95.5 ±4.6	96.3 ±3.8
P-value	0.44	0.82	0.30

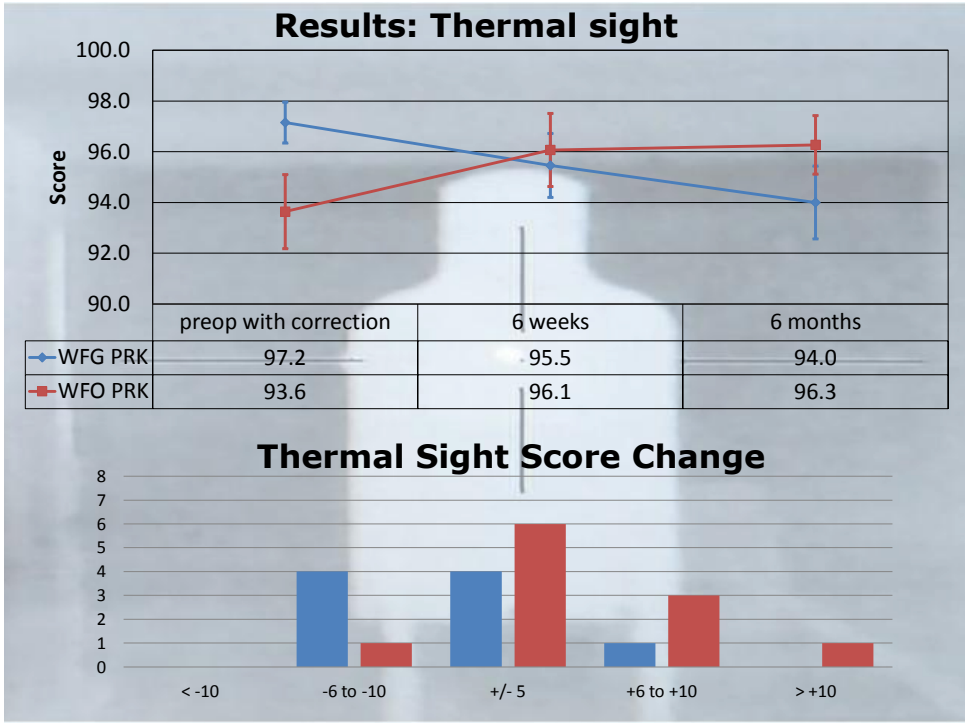
Results

Table 2. Pre- and 6-month postoperative firing range scores after WFG and WFO PRK.

		Iron sight	Night vision	Thermal sight
WFG PRK	Preop (with correction)	97.1 ±5.0	92.9 ±6.6	97.2 ±2.9
	6 months (without correction)	97.3 ±4.1	96.6 ±3.1	94.0 ±4.3
	P-value	0.89	0.11	0.18
WFO PRK	Preop (with correction)	94.0 ±7.7	95.4 ±4.5	93.6 ±5.5
	6 months (without correction)	96.0 ±3.9	95.5 ±4.6	96.3 ±3.8
	P-value	0.62	0.48	0.14


Results: Iron Sight
Score
100.0
98.0
96.0
94.0
92.0
90.0
preop with correction
6 weeks
6 months
WFG PRK 97.1 96.2 97.3
WFO PRK 94.0 97.5 96.0
Iron Sight Score Change
8
7
6
5
4
3
2
1
0
< -10
-6 to -10
+/- 5
+6 to +10
> +10


Results: Night vision
Score
100.0
98.0
96.0
94.0
92.0
90.0
preop with correction
6 weeks
6 months
WFG PRK 92.9 95.2 96.6
WFO PRK 95.4 98.6 95.5
Night Vision Score Change
8
7
6
5
4
3
2
1
0
< -10
-6 to -10
+/- 5
+6 to +10
> +10



Conclusions

- There was no significant change within subjects over time in terms of military task performance.
- There was no significant difference in any firing range scores when looking at a loss or gain of > +/-5 points between WFG and WFO PRK.
- Visual and target task performance outcomes are comparable between WFG and WFO PRK.

Visual Performance Comparison of Wavefront-optimized and Wavefront-guided Laser in-situ keratomileusis (LASIK)

ARVO Program
Number 3125
Board #D0060

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INTRODUCTION

Visual demands in the military are unique, as operations occur not only in adverse environments with varying lighting conditions such as night, rain, smoke or fog but also involve the use of different devices including night vision goggles and protective masks.[1] Although laser refractive surgery has greatly contributed to reducing soldiers' dependence on optical corrections such as spectacles and contact lenses, it has also been associated with various visual disturbances including glare, halos and starbursts as well as reduced contrast sensitivity following the procedure.[2-4] Significant loss of visual performance after refractive surgery may potentially have an impact on military tasks performed under low light settings.

The advent of customization in corneal laser surgery has improved optical and visual outcomes of refractive surgery procedures.[5-6] Wavefront-guided (WFG) laser treatments measure and treat not only lower order aberrations, but also higher order aberrations. Treatments are patterned based on the individual ablation profile of each eye.[7] 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.[8] WFO ablations add peripheral treatment to minimize spherical aberration, the principal high order aberration generated by the surgery.

In this study, we evaluated visual performance using night vision and Super Vision tests that were designed for quantifying exceptional levels of and/or subtle decrements in vision.

PURPOSE

To compare visual acuity and contrast sensitivity results after wavefront-guided and wavefront-optimized LASIK.

METHODS

This is a prospective study of patients aged 21 or older with myopia or myopic astigmatism randomized to undergo either WFG or WFO LASIK. Best corrected visual acuity (VA) and contrast sensitivity (CS) were evaluated preoperatively and at 1, 3 and 6 months postoperatively. High and low contrast acuity testing was performed using the Variable Contrast 4-meter Rabin Super Vision Test (Precision Vision, La Salle, IL). Night vision testing was conducted with a back-illuminated 25% contrast acuity chart viewed through a dark green night vision goggle filter (Precision Vision, La Salle, IL). Room illumination and viewing distance (4 meters) were standardized for all measurements. For the 25% contrast with night vision filter and high contrast Super Vision test, a credit of 0.02 logMAR units was calculated for each letter correctly identified. For the low contrast Super Vision test, a credit of 0.05 logCS units was calculated for each letter correctly identified. A repeated measures analysis of variance (RM-ANOVA) was used to compare WFO vs. WFG LASIK over time and a p-value <0.05 was considered significant.

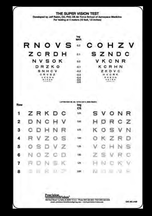

Figure 1. Variable Contrast Rabin Super Vision Test (Precision Vision, La Salle, IL). High contrast VA ranges from 20/32 to 20/5 (0.1 log MAR per row). Letter CS (20/25 letter size) log CS values range from 0.25 to 2.00; (0.25 log CS per row; 0.05 log CS per letter).

Figure 2. Low Contrast 25% SLOAN Logarithmic Visual Acuity Chart with Night Vision Goggle Filter (Precision Vision, La Salle, IL)

LASIK. A superior-hinged flap was created using a femtosecond laser system (Intralase, Abbott Medical Optics, Sta. Ana, CA). WFG photoablation was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Sta. Ana, CA) while WFO photoablation was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX). Postoperative medications regimen was the same for both groups and included: topical moxifloxacin 0.5%, one drop four times daily for one week; Prednisolone acetate 1.0%, one drop every two hours for the first three days, then one drop four times daily for one week; carboxymethylcellulose 0.5%, one drop four to eight times daily for two weeks and then as needed; topical ketorolac tromethamine 0.4%, one drop up to four times daily for the first 48 hours after surgery as needed.

RESULTS

Table 1. Demographic data and baseline clinical characteristics.

	WFG LASIK	WFO LASIK	*P-value**
No. of participants (eyes)	22 (44)	21 (42)	-
Age (years)	32.7 ±8.1	32.0 ±8.0	0.68
Male/Female	16/6	17/4	0.72†
Sphere (Diopters)	-3.05 ±1.36	-3.26 ±1.52	0.51
Cylinder (Diopters)	-0.57 ±0.49	-0.69D ±0.67	0.34
MSE (Diopters)	-3.26 ±1.37	-3.60 ±1.54	0.27
Preop UDVA (logMAR)	1.07 ±0.28	1.06 ±0.34	0.87
Central corneal thickness (µm)	561.1±30.1	572.6±34.7	0.11
Ablation depth (µm)	55.4 ±17.0	57.1 ±21.2	0.68

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

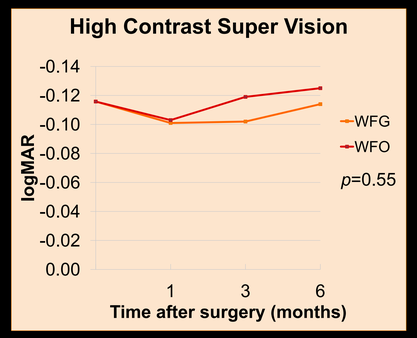

Figure 3. Super Vision High Contrast WFG LASIK and WFO LASIK. Negative shift equals improvement. *Preoperative baseline as covariate.

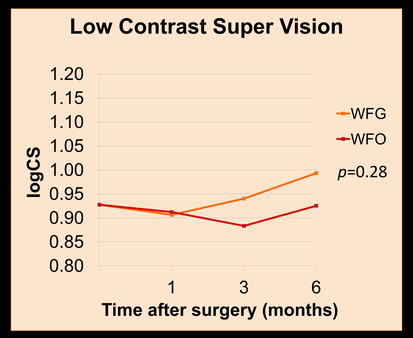

Figure 4. Super Vision Low Contrast WFG LASIK and WFO LASIK. Positive shift equals improvement. *Preoperative baseline as covariate.

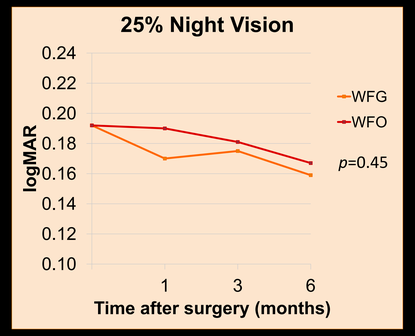

Figure 5. 25% Night Vision WFG LASIK and WFO LASIK. Negative shift equals improvement. *Preoperative baseline as covariate.

CONCLUSION

Visual performance on Super Vision test and night vision were comparable between WFG and WFO LASIK over time. Ongoing testing in this study will determine military task performance after WFG or WFO treatment.

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Patient Satisfaction and Quality of Vision after Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) Photorefractive keratectomy (PRK)

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ARVO Program Number 3135
Board # D0070

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.[1] Refractive surgery decreases 2nd order aberrations, but it increases the magnitude of higher-order aberrations (HOA). HOAs have been correlated with increased visual symptoms such as glare, halos and starbursts.[2,3]

Technological advances have reduced the amount of optical aberrations induced by refractive surgery, resulting in improvements in postoperative quality of vision.[4-6] 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.[7] 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.[8] Our current report supplements the few published studies that directly compared outcomes of these technologies.[9-10]

PURPOSE

To compare higher order aberration (HOA) root mean square (RMS) and patient satisfaction of postoperative vision after WFG vs. WFO PRK.

METHODS

Participants in this prospective study, aged 21 or older with myopia or myopic astigmatism, were randomized to undergo either WFG or WFO PRK. Subjective manifest refraction and uncorrected and corrected distance visual acuities were determined preoperatively and at 6 months postoperatively. The Complete Ophthalmic Analysis System (COAS, Abbott Medical Optics, Sta. Ana, CA) was used to measure wavefront aberrations. All measurements were done on natural pupils under mesopic light conditions. No dilating or cycloplegic drugs were used. Four different pupil sizes (4, 5, 6, and 7mm) were used for RMS HOA analysis. A repeated measures analysis of variance (RM-ANOVA) was used to compare WFG vs. WFO PRK HOA RMS at each pupil size over time. A p-value <0.05 was considered statistically significant.

Participants responded to a questionnaire preoperatively and 6 months postoperatively. Subjective visual quality in terms of 1) visual difficulties in performing daily activities; 2) glare and 3) halo were assessed and total scores of each category were calculated. Patient satisfaction was also evaluated:

•In comparison to what you expected before you had surgery, has your overall vision turned out to be:
Much better than expected (1)----------(10) Much Worse

•Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:
Definitely would have surgery (1)----------(10) Definitely would NOT

PRK. Epithelial removal was performed with the Amoils epithelial scrubber (Innovative Excimer Inc, Toronto, Ont). WFG photoablation was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Sta. Ana, CA) while WFO photoablation was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX). Postoperative medications regimen was the same for both groups.

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RESULTS

Table 1. Demographic data and baseline clinical characteristics.

	WFG PRK	WFO PRK	*P-value**
No. of participants (eyes)	26 (52)	26 (52)	-
Age (years)	30.0 ±7.0	29.9 ±5.6	0.90
Male/Female	19/7	18/8	0.50†
Sphere (Diopters)	-3.13 ±1.87	-3.00±1.69	0.70
Cylinder (Diopters)	-0.70 ±0.49	-0.65D ±0.54	0.60
MSE (Diopters)	-3.49 ±1.88	-3.32 ±1.79	0.66
Preop UDVA (logMAR)	1.07 ±0.38	1.04 ±0.34	0.76
Central corneal thickness (µm)	547.0 ±33.2	553.5 ±36.6	0.34
Ablation depth (µm)	56.3 ±23.9	51.6 ±23.4	0.31
Mitomycin C treated (%)	57.7	23.1	0.001†

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Table 2. Difference in WFG vs. WFO PRK preoperative and postop questionnaire results.

Preoperatively	WFG	WFO	*P-value**
Daily Activities	11.50±5.65	10.72±4.56	*0.59*
Glare	12.27±9.33	10.27±8.03	*0.41*
Halo	7.08±3.06	7.85±5.67	*0.55*
6 Month Post	**WFG**	**WFO**	***P-value****
Daily Activities	10.73±4.57	9.65±3.87	*0.36*
Glare	9.85±6.42	7.77±2.75	*0.14*
Halo	8.88±6.57	6.46±2.02	*0.08*

*t-test was used to compare patient satisfaction of postoperative vision, *P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

Table 3. Vision and overall expectation and satisfaction scores at six months postop.

	WFG PRK	WFO PRK	*P-value**
MSE (Diopters)	0.09 ±0.38	-0.02 ±0.31	0.09
Postop UDVA (logMAR)	-0.11 ±0.09	-0.10 ± 0.07	0.74
Expectations: Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.			
Overall visual expectations	1.81 ±1.13	1.65 ±1.02	0.61
If given the opportunity, would have surgery again	1.27 ±0.87	1.19 ±0.57	0.71

•At 6 months postop, 14out of 26 WFG PRK patients (53.8%) versus 16 of 26 WFO PRK patients (61.5%) reported that their vision was much better than expected (scored 1 on a 10-point scale).

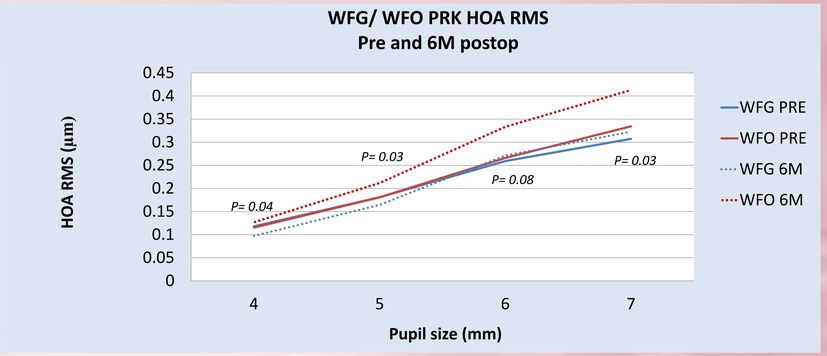
•Of those who underwent WFG PRK, 23 out of 26 patients (88.5%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).

• Of those who underwent WFO PRK, 23 out of 26 patients (88.5%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).

**t-test, P<0.05 statistically significant*

RESULTS CONTINUED

Figure 1. Comparison of WFG vs. WFO PRK higher order aberrations (HOA) root mean square (RMS) at each pupil size.



CONCLUSION

Results show there is a significant difference in RMS HOA when comparing WFG vs. WFO PRK over time. Although there was a significant increase in HOA RMS of WFO PRK patients postoperatively, questionnaire results showed no significant difference in daily activities, glare, halo or satisfaction with the procedure when comparing WFG vs. WFO PRK. Ongoing testing in this study will determine if either WFG or WFO generated optical quality affects military task performance.

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Patient Satisfaction and Quality of Vision after Wavefront-guided (WFG) vs. Wavefront-optimized (WFO) LASIK

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INTRODUCTION

Laser in-situ keratomileusis (LASIK) has been shown to be safe and effective in correcting myopia.[1] However, with conventional LASIK, it tends to induce higher order aberrations (HOAs)[2] which have been correlated with increased visual symptoms such as glare, halos and starbursts.[3,4] Advances in excimer laser ablation profiles have been developed to potentially provide better quality of vision in patients over conventional laser platforms.[5-7] Two widely used approaches today are wavefront–guided (WFG) treatments which are pattern based on the individual ablation profile of each eye and wavefront optimized (WFO) treatments which are preprogrammed ablation profiles pattern based on population analysis while taking some ocular variables into account.[8] Our current report supplements the few published studies that directly compared outcomes of these technologies.[8-11]

PURPOSE

To compare higher order aberration (HOA) root mean square (RMS) and patient satisfaction of postoperative vision after WFG vs. WFO LASIK.

METHODS

This is a prospective study of patients aged 21 or older with myopia or myopic astigmatism randomized to undergo either WFG or WFO LASIK. Subjective manifest refraction and uncorrected and corrected distance visual acuities were determined preoperatively and at 6 months postoperatively. Wavefront aberrations were measured using the Complete Ophthalmic Analysis System (COAS, Abbott Medical Optics, Sta. Ana, CA). All measurements were done on natural pupils without the use of any dilating or cycloplegic drugs under mesopic light conditions. RMS HOA was determined at four different pupil sizes (4, 5, 6, and 7mm). Participants responded to questionnaires preoperatively and at the 6-month postoperative visit. Subjective visual quality in terms of 1) visual difficulties in performing daily activities; 2) glare and 3) halo were assessed and total scores of each category were calculated. Patient satisfaction was also evaluated:

•In comparison to what you expected before you had surgery, has your overall vision turned out to be:

Much better than expected (1)----------(10) Much Worse

•Thinking about your vision during the last two weeks, if you had it to do over, would you have the surgery today:

Definitely would have surgery (1)----------(10) Definitely would NOT

LASIK. A superior-hinged flap was created using a femtosecond laser system (Intralase, Abbott Medical Optics, Sta. Ana, CA). WFG photoablation was performed using the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Santa Ana, CA) while WFO photoablation was performed using the Allegretto Wave Excimer Laser System (Alcon Surgical, Fort Worth, TX). Postoperative medications regimen was the same for both groups and included: topical moxifloxacin 0.5%, one drop four times daily for one week; Prednisolone acetate 1.0%, 1 drop every two hours for the first three days, then one drop four times daily for one week; carboxymethylcellulose 0.5%, one drop four to eight times daily for two weeks and then as needed; topical ketorolac tromethamine 0.4%, one drop up to four times daily for the first 48 hours after surgery as needed.

RESULTS

Table 1. Demographic data and baseline clinical characteristics.

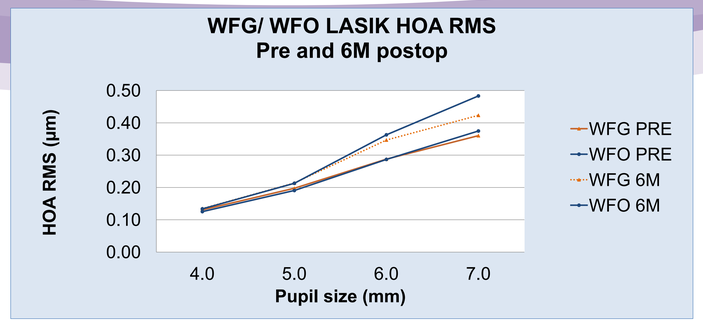
	WFG LASIK	WFO LASIK	*P-value**
No. of participants (eyes)	22 (44)	21 (42)	-
Age (years)	32.7 ±8.1	32.0 ±8.0	0.68
Male/Female	16/6	17/4	0.72†
Sphere (Diopters)	-3.05 ±1.36	-3.26 ±1.52	0.51
Cylinder (Diopters)	-0.57 ±0.49	-0.69D ±0.67	0.34
MSE (Diopters)	-3.26 ±1.37	-3.60 ±1.54	0.27
Preop UDVA (logMAR)	1.07 ±0.28	1.06 ±0.34	0.87
Central corneal thickness (µm)	561.1±30.1	572.6±34.7	0.11
Ablation depth (µm)	55.4 ±17.0	57.1 ±21.2	0.68

**t-test, P<0.05 statistically significant*
†Fisher exact test
MSE- manifest spherical equivalent; UDVA- uncorrected distance visual acuity

Table 2. Difference in preop vs. 6months postop questionnaire results.

WFG LASIK	Pre	6 M Post	*P-value**
Daily Activities	10.1 ±3.7	9.9 ±4.0	0.88
Glare	11.8 ±6.9	12.0 ±8.3	0.94
Halo	8.3 ±4.1	11.4 ±7.5	0.03
WFO LASIK	**Pre**	**6 M Post**	***P-value****
Daily Activities	9.9 ±4.3	9.8 ±4.9	0.95
Glare	8.9 ±6.1	9.7 ±7.3	0.70
Halo	6.8 ±5.6	8.5 ±5.6	0.29

**t-test, P<0.05 statistically significant*
Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.



- Comparing WFG vs. WFO over time by repeated measures analysis of variance (RM ANOVA) at each pupil size, p=0.77, 0.90, 0.64, 0.24 at 4mm, 5mm, 6mm, and 7mm respectively.

Table 3. Visual symptoms, overall expectation and satisfaction scores at six months postop.

	WFG LASIK	WFO LASIK	*P-value**
†Daily Activities	11.4 ±6.5	10.0 ±4.8	0.43
†Glare	12.0 ±8.3	9.7 ±7.3	0.35
†Halo	11.4 ±7.5	9.1 ±6.2	0.29
Overall visual expectations	2.1 ±1.4	1.3 ±0.6	0.01
If given the opportunity, would have surgery again	1.5 ±1.2	1.1 ±0.2	0.13

**t-test, P<0.05 statistically significant*
†Total score under each category ranged from 5 (no symptoms) to 50 (severe, disabling symptoms); scores are presented as mean ± standard deviation.

- At 6 months postop, 10 out of 22 WFG LASIK patients (45.5%) versus 16 of 21 WFO LASIK patients (76.2%) reported that their vision was much better than expected (scored 1 on a 10-point scale).
- Of those who underwent WFG LASIK, 18 out of 22 patients (81.8%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).
- Of those who underwent WFO LASIK, 20 out of 21 patients (95.2%) responded, if given the chance to do it over, they definitely would have surgery again (scored 1 on a 10-point scale).

CONCLUSION

Results showed there is no significant difference in RMS HOA when comparing WFG vs. WFO LASIK over time, regardless of pupil size analyzed. There was no significant difference between the two procedures when postoperative visual symptoms were assessed. However, when compared to baseline, halos seemed worse in WFG LASIK. Overall visual expectations appeared to be better in patients who underwent WFO LASIK than WFG LASIK. Association of optical quality after either WFG or WFO treatment to military task performance is currently being investigated.

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