MEMORANDUM FOR SGVT
ATTN: CAPT DONOVAN REED

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled *Retrospective Analysis of the Post-Operative Changes in Higher Order Aberrations: A Comparison of the EX500 to the Allegretto and VISX S4 Laser in Refractive Surgery* presented at/published to *Journal of Military Medicine and San Antonio Military Health Systems and Universities Research Forum, 16 June 17* in accordance with MDWI 41-108, has been approved and assigned local file #17229.

2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

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4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

Warrior Medics – Mission Ready – Patient Focused
PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON THE PUBLISHING

1. The author must complete page one of this form:
   a. In Section 2, add the funding source for your study (e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SGS &M), SGF R&D;
      Trans-Nursing Research Program (TNSR); Defense Medical Research & Development Program (DMRDP); NIH, Congressionally Directed
      Medical Research Program (CDMRP); Grants, etc.)
   b. In Section 2, there may be funding available for journal costs, if your department is paying for
      figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form. If you need publication funding support.

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3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type
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     is reported to the 59 CRD/ICC. All medical research or technical information publications/presentations must be reported to the Defense Technical
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11. The Joint Ethics Regulation (JER) DoD 5000.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their
     interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal
     ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings,
     publications/presentations, disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc.
     The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in
     block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISS/JAC legal office for an ethics review. To
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     If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation
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40-401 IP:
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### PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO CLINICAL RESEARCH  2. FROM (Author's Name, Rank, Grade, Office Symbol)
   Donovan Reed, Capt, O-3, 959 CSPS

3. OM/GHSE STUDENT
   X YES  NO

4. PROTOCOL NUMBER
   201500993H

5. PROTOCOL TITLE
   (Note: For each new release of medical research or technical information as a publication/presentation, a new 69 MDW Form 3309 must be submitted for review and approval)
   Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the Ex500 to the Allegretto and Vixx lasers.

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED
   Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the Ex500 to the Allegretto and Vixx lasers.

7. FUNDING RECEIVED FOR THIS STUDY?  YES  NO  FUNDING SOURCE

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES?  YES  NO

9. IS THIS MATERIAL CLASSIFIED?  YES  NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC?  YES  NO
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   Military Medicine

   11b. PUBLISHED ABSTRACT (List intended journal.)

   11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)
   San Antonio Military Health Systems and Universities Research Forum; 16 Jun 17

   11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, city, state, and date of meeting.)
   San Antonio Military Health Systems and Universities Research Forum; 16 Jun 17

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13. EXPECTED DATE WHEN YOU WILL NEED THE ORD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
   NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).
   DATE
   1 June 2017

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)
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15. DUTY PHONE/PAGER NUMBER
   210-292-2554

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

   LAST NAME, FIRST NAME AND M.I.  GRADE/RANK  SQUADRON/GROUP/OFFICE SYMBOL  INSTITUTION (If not 59 MDW)
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      O-3/Capt  CSPS 959
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      O-5/CDR
      59 TRS
   d. Townley, James R.
      O-5/Lt Col
      59 TRS
   e. Caldwell, Michael C.
      O-5/Lt Col
      59 TRS

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19. AUTHOR'S PRINTED NAME, RANK, GRADE
   Donovan Reed, Capt, O-3

20. DATE
   04 Apr 2017

21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE
   Brett Davies, Maj, APD

22. APPROVING AUTHORITY'S SIGNATURE

23. DATE
   11 Apr 2017

69 MDW FORM 3309, 20160828
Previous editions are obsolete.
The poster presentation, article and oral presentation are approved.

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Once added, presentations are approved and cleared for public release.
Retrospective analysis of the post-operative changes in higher order aberrations: A comparison of the WaveLight® EX500 to the VISX® S4 laser in refractive surgery

Donovan Reed MD, Doug Apsey OD, Walter Steigleman MD, Matthew Caldwell MD, J. Richard Townley MD

Wilford Hall Ambulatory Surgical Center (WHASC)

Disclaimer

• The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Air Force, the Department of the Army or the Department of Defense or the U.S. Government

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Introduction

- PRK & LASIK reduce spherical and cylindrical defocus
  - Aberrations of the cornea are insufficient to characterize the entire visual quality of an eye.

- Measurement of the entirety of ocular aberrations is the most definitive means to establish the true effect of refractive surgery on image quality and visual performance.¹

- PRK and LASIK increase wavefront aberrations and alter the comparative contributions of coma- and spherical-like higher order aberrations often inherent to the natural eye.²

- RMS wavefront error as a metric of global image quality³

- Moshirfar et al. demonstrated both the VISX® CustomVue and WaveLight® Allegretto systems perform equally in terms of visual acuity, safety, and predictability in both PRK and LASIK⁴,⁵
  - Higher-order and spherical aberrations during photorefractive keratectomy, not statistically significant⁴
Purpose

- Future advancements in refractive surgery
- Investigate the utility of the current excimer lasers employed by the DoD in terms of induced aberrations to maximize refractive treatment.
- The impact on post-operative higher order aberrations between the currently available DoD laser platforms
  - Offer insight as to which provides the best overall image quality following refractive surgery in the active duty and DoD beneficiary population

Methods

- Retrospective analysis
- Pre and post-operative changes in higher order aberrations following refractive surgery with the WaveLight® EX500 Excimer Laser System (Alcon, Fort Worth, TX) and the VISX® Star S4 IR Excimer Laser System (Abbott Medical Optics, Santa Ana, CA)
- RMS
  - Pentacam
Inclusion Criteria

• Active duty military or DoD beneficiaries who had refractive surgery at the Joint Warfighter Refractive Surgery Center and:
  – were 21 years of age or older
  – had PRK or LASIK refractive surgery
  – completed a 3 month follow-up visit

Exclusion Criteria

• Subjects who do not meet the inclusion criteria listed
• Subjects who previously had refractive surgery
• Patients who did not have follow-up data
• Pregnant women or incompetent adults
Methods

- Matching
- SPSS statistics
  - Student’s T-test
  - Regression analysis: preoperative SE
    - Larger refractive errors = larger ablations

Results

<table>
<thead>
<tr>
<th></th>
<th>PRK</th>
<th>LASIK</th>
</tr>
</thead>
<tbody>
<tr>
<td>VISX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at Surgery (Mean)</td>
<td>29.4</td>
<td>31.5</td>
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<tr>
<td>Gender (Total)</td>
<td>74M 26F</td>
<td>16M 6F</td>
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<tr>
<td>PreOp MSE</td>
<td>-3.33</td>
<td>-2.73</td>
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<tr>
<td>Total Eyes</td>
<td>100</td>
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<tr>
<td>EX500</td>
<td></td>
<td></td>
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<tr>
<td>Age at Surgery (Mean)</td>
<td>29.1</td>
<td>30.2</td>
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<tr>
<td>Gender (Total)</td>
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<td>16M 6F</td>
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<tr>
<td>PreOp MSE</td>
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<td>-4.38</td>
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<tr>
<td>Total Eyes</td>
<td>96</td>
<td>22</td>
</tr>
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</table>

Table 1: Patient Demographics
Results

<table>
<thead>
<tr>
<th></th>
<th>Mean Δ RMS</th>
<th>SD</th>
<th>p-Value (T-test)</th>
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</thead>
<tbody>
<tr>
<td>PRK</td>
<td></td>
<td></td>
<td>0.431</td>
</tr>
<tr>
<td>VISX®</td>
<td>0.00122</td>
<td>0.02583</td>
<td></td>
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<tr>
<td>EX500</td>
<td>0.004323</td>
<td>0.02916</td>
<td></td>
</tr>
<tr>
<td>LASIK</td>
<td></td>
<td></td>
<td>0.295</td>
</tr>
<tr>
<td>VISX</td>
<td>0.00841</td>
<td>0.03011</td>
<td></td>
</tr>
<tr>
<td>EX500</td>
<td>0.0174</td>
<td>0.02417</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Change in RMS statistics

Results

<table>
<thead>
<tr>
<th></th>
<th>PRK</th>
<th></th>
<th>LASIK</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b</td>
<td>p</td>
<td>b</td>
<td>p</td>
</tr>
<tr>
<td>PreOp MSE</td>
<td>-0.001</td>
<td>0.551</td>
<td>-0.003</td>
<td>0.161</td>
</tr>
<tr>
<td>Laser (EX500 w</td>
<td>0.003</td>
<td>0.433</td>
<td>0.004</td>
<td>0.670</td>
</tr>
<tr>
<td>VISX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Regression Analysis concerning pre-operative refractive error for both LASIK and PRK
Figure 1: Change in RMS data for PRK between the VISX© and WaveLight© EX500 Lasers. p-value is 0.431

Figure 2: Change in RMS data for PRK between the VISX© and WaveLight© EX500 Lasers. p-value is 0.295
Discussion

• No statistically significant difference
  – Adjusting for preoperative refractive error
• Observations:
  – LASIK higher pre-operative MSE in EX500
  – VISX laser lower induced RMS values
  – 2-4x higher in each category for EX500
    • Moshirfar et al.
• Power

Limitations

• Design
• Sample size
• Generalizability
• Clinical significance
Recommendations

• Further investigation of visual outcomes
• Additional factors
  – Cost
  – Patient characteristics
  – Surgeon preference

References


Introduction

Both photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) effectively reduce spherical and cylindrical defocus, the key lower order optical aberrations contributing to decreased visual acuity. Aberrations of the cornea are insufficient to characterize the entire visual quality of an eye. Measurement of the entire ocular aberrations is the most definitive means to establish the true effect of refractive surgery on image quality and visual performance.

Both PRK and LASIK have been demonstrated to improve wavefront aberrations of the cornea and alter the comparative contributions of coma- and spherical-like higher order aberrations often inherent to the natural eye.

Previous studies have utilized the root-mean-square (RMS) wavefront error as a metric of global image quality, thus effectively isolating different aberration orders contributing to post-operative vision. Manfris et al. demonstrated both the VISX CustomVue and WaveLight Allegretto systems perform equally in terms of visual acuity, safety, and predictability in both PRK and LASIK refractive surgery procedures. Both platforms induce a comparable degree of higher-order and spherical aberrations during photorefractive keratectomy, though no statistically significant difference in terms of the RMS of higher-order optical aberrations was demonstrated.

As future advancements in refractive surgery are being directed toward customized ablation to correct not only lower-order aberrations, but also higher-order aberrations specific to the individual eye, it is important to investigate the utility of the current excimer lasers employed by the DoD in terms of induced aberrations to maximize refractive treatment. The impact on post-operative higher order aberrations between the currently available DoD laser platforms was investigated to offer insight as to which provides the best overall image quality following refractive surgery in the active duty and DoD beneficiary population.

Methods

A retrospective analysis was performed to evaluate the pre and post-operative changes in higher order aberrations following refractive surgery with the WaveLight EX500 Excimer Laser System (Alcon, Fort Worth, TX) and the VISX Star S4 IR Excimer Laser System (Abbott Medical Optics, Santa Ana, CA) by evaluating the RMS value of the higher order corneal aberrations post-operatively.

Inclusion Criteria:
- Active duty military or DoD beneficiaries who had refractive surgery at the Joint Warfighter Refractive Surgery Center and;
- were 21 years of age or older
- had PRK or LASIK refractive surgery
- completed a 3 month follow-up visit

Exclusion Criteria:
- Subjects who do not meet the inclusion criteria listed
- Subjects who previously had refractive surgery
- Patients who did not have follow-up data
- Pregnant women, or incompetent adults

Patient demographics were matched to avoid bias. Utilizing SPSS statistics software, the mean change in RMS values between the two lasers and refractive surgery procedures were determined. A student's t-test was performed to compare the root mean square of the higher order aberrations of the subjects' corneas from the lasers being studied. A regression analysis was performed to adjust for postoperative SE, as larger refractive errors often require larger ablations, which could ultimately affect the amount of higher order aberrations post-operatively.

Results

<table>
<thead>
<tr>
<th>Table 1: Patient demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Surgery</td>
</tr>
<tr>
<td>21</td>
</tr>
</tbody>
</table>

Figure 1: Change in RMS data for PRK between the VISX® and WaveLight® EX500 lasers. P-value of 0.001.

Discussion

The results suggest no statistically significant difference concerning induced higher order aberrations between the two laser platforms albeit LASIK or PRK. After adjusting for preoperative refractive error there was still no statistically significant difference. This is despite the fact patients who received LASIK did have a significantly higher pre-operative SE in the EX500 group. It is likely the statistical significance of this study was hindered by the power, given the relatively small sample size. For instance, every value calculated demonstrated the VISX laser to have lower induced RMS values. Additionally, the induced higher order aberrations by the EX500 were two to four times higher in each category. These findings coincide with the study performed by Manfris et al.

Additional limitations of the study include its design and the generalizability of the study, as the Department of Defense population may be significantly different from the commercial refractive surgery population in terms of overall health and refractive error.

The level at which induced higher order aberrations reach clinical significance is debatable and it is difficult to quantify subjective reports of visual disturbances. Therefore, it remains a challenge to determine whether statistically significant differences in higher order aberrations have a clinically significant impact on visual outcomes. Further investigation of visual outcomes between the two laser platforms should be investigated before determining superiority in terms of visual image quality and post-operatively. Additional factors such as cost, availability, patient characteristics, and surgery preferences should be taken into consideration determining the most appropriate laser to utilize for refractive surgery.

References

1. Donovan Reed MD, Doug Apsey OD, Walter Steigleman MD, Matthew Caldwell MD, J. Richard Townley MD
2. Wilford Hall Ambulatory Surgical Center (WHASC)