OUTCOMES OF CUSTOM PRK AND IntraLASIK IN THE U.S. NAVY

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Navy Refractive Surgery Center, San Diego

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Pursuing optimal visual correction for the Warfighter

- **Overview** -

**Comparative data to be discussed:**

- **PRK**: WFG vs Conventional
- **Keratome**: Mechanical vs femtosecond
- **Custom**: WFG-PRK vs WFG-IntraLASIK
PRK: Wavefront-Guided -vs- Conventional
- **Why Surface Ablation?** -

- **Anatomical Limits:**
  - Refraction
  - Corneal thickness

- **Patient Request/Occupation:**
  - Special Ops, divers, firefighters
  - Naval Aviators (LASIK is disqualifying)

- **Improved Quality of Vision...???
  - Conv-LASIK associated with decreased 5% LCVA, increased Sph Abs & night vision complaints (vs Conv-PRK)
- **DATASETS** -

- Two matched groups:
  - Wavefront guided (WFG) PRK
    - First evaluation of WFG PRK at NMCSD
    - Investigational Device Exemption (IDE) with FDA
  - Conventional (Conv) PRK (Aviation Retention Study)
## - SURGICAL TECHNIQUES -

<table>
<thead>
<tr>
<th></th>
<th>WFG PRK</th>
<th>Conv PRK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample Size (eyes)</strong></td>
<td>267</td>
<td>1042</td>
</tr>
<tr>
<td><strong>Ablation Pattern</strong></td>
<td>Wavefront guided</td>
<td>Manifest refraction</td>
</tr>
<tr>
<td><strong>Derivation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Software</strong></td>
<td>VISX CustomVue 3.65</td>
<td>VISX Star S3</td>
</tr>
<tr>
<td><strong>Optical Zone</strong></td>
<td>6 mm</td>
<td>6.5 mm</td>
</tr>
<tr>
<td><strong>Transition Zone</strong></td>
<td></td>
<td>8 mm</td>
</tr>
<tr>
<td><strong>Epithelial Removal</strong></td>
<td>Amoils brush</td>
<td></td>
</tr>
<tr>
<td><strong>Bandage Contact Lens</strong></td>
<td>3-to-5 days</td>
<td></td>
</tr>
<tr>
<td><strong>Topical Steroid</strong></td>
<td>2-month taper</td>
<td></td>
</tr>
</tbody>
</table>
- DISTRIBUTION OF TREATMENTS -

Refractive Error (MSE)

WFG (n=267 eyes, mean age=31)

Conv (n=1042 eyes, mean age=34)
<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WFG</strong></td>
<td>-2.90 ± 1.23</td>
<td>-0.24 ± 0.35</td>
<td>-0.11 ± 0.31</td>
<td>-0.05 ± 0.28</td>
</tr>
<tr>
<td></td>
<td>(-0.8 to -5.9)</td>
<td>(-1.6 to +0.9)</td>
<td>(-1.1 to +1.0)</td>
<td>(-1.2 to +0.9)</td>
</tr>
<tr>
<td><strong>Conv</strong></td>
<td>-2.95 ± 1.28</td>
<td>+0.03 ± 0.49</td>
<td>0.00 ± 0.44</td>
<td>-0.04 ± 0.40</td>
</tr>
<tr>
<td></td>
<td>(-1.0 to -6.4)</td>
<td>(-1.7 to +2.8)</td>
<td>(-1.7 to +2.4)</td>
<td>(-2.0 to +1.8)</td>
</tr>
</tbody>
</table>

**- MANIFEST SPH. EQUIVALENT -**

MSE ± SD, (range)
**MSE DISTRIBUTION: 6m**

WFG is *more* predictable \( (F=2.31, p<0.001) \)
- MSE Predicability -
Percentage of eyes within ±0.5 D of emmetropia

Months Post-op

<table>
<thead>
<tr>
<th>Months</th>
<th>WFG</th>
<th>Conv</th>
</tr>
</thead>
<tbody>
<tr>
<td>1M</td>
<td>84%</td>
<td>80%</td>
</tr>
<tr>
<td>3M</td>
<td>89%</td>
<td>83%</td>
</tr>
<tr>
<td>6M</td>
<td>94%</td>
<td>85%</td>
</tr>
</tbody>
</table>
- **Uncorrected Acuity (UCVA)** -

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20/12 or better</td>
<td>20/20 or better</td>
<td>20/12 or better</td>
</tr>
<tr>
<td><strong>WFG</strong></td>
<td>14%</td>
<td>44%</td>
<td>55%</td>
</tr>
<tr>
<td><strong>Conv</strong></td>
<td>25%</td>
<td>46%</td>
<td>48%</td>
</tr>
</tbody>
</table>

On average, **WFG** MSE is slightly myopic @ 1M; **Conv** MSE is very slightly hyperopic.

Both groups progress close to emmetropia by 3M post-op.
**Preop BCVA - Postop UCVA: 6m**

*WFG* provides better results (Chi² = 43.1, p<0.001)

**Mean ± SD**
- **WFG**: +0.1 ± 1.1
- **Conv**: -0.3 ± 1.1

(t=12, p<0.01)

**UCVA < BCVA**
- **WFG**: 20%
- **Conv**: 33%

**UCVA > BCVA**
- **WFG**: 38%
- **Conv**: 23%

*Change of ≥1 lines*
### Best Corrected Visual Acuity - 20/20 or Better

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td>WFG</td>
<td>99.3%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Conv</td>
<td>98.3%</td>
<td>99.9%</td>
<td>100%</td>
</tr>
</tbody>
</table>

BCVA LogMAR $\leq 0.04$
**- CHANGE IN BCVA: 6m -**

WFG provides better results (Chi²=70.2, p<0.001)

- **Mean ± SD**
  - **WFG**: +0.6 ± 0.6
  - **Conv**: +0.2 ± 0.8

*(t=20, p<0.01)*

- **Lost ≥1 Line**
  - **WFG**: 4%
  - **Conv**: 19%

- **Gained ≥1 Line**
  - **WFG**: 55%
  - **Conv**: 34%
- CHANGE IN 5% LCVA: 6m -

WFG provides better results than Conv

Lost ≥ 2 Lines
WFG = 2%
Conv = 6%

Gained ≥2 Lines
WFG = 14%
Conv = 17%

Mean ± SD
WFG: +0.6 ± 1.0
Conv: +0.4 ± 1.2
(t=3.8, p<0.01)

Improvement

LCVA = low contrast visual acuity

Chi² = 17.2, p<0.009
- Sample: 25 Subjects
- Excimer Laser: VISX
- Randomized PRK:
  Conv performed in one eye,
  WFG in other
- CHANGE IN HOA RMS -
(6m PostOp – PreOp)

Mean Change HOA RMS

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean Change</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WFG</td>
<td>0.04</td>
<td>0.045</td>
</tr>
<tr>
<td>Conv</td>
<td>0.09</td>
<td></td>
</tr>
</tbody>
</table>

Change in HOA RMS (microns)
**- CHANGE IN SPH AB -**

*(6m PostOp – PreOp)*

<table>
<thead>
<tr>
<th></th>
<th>WFG-PRK</th>
<th>Conv-PRK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Change Sph Ab</td>
<td>0.08</td>
<td>0.13</td>
</tr>
</tbody>
</table>

*(p = 0.07)*

**Change in Sph Ab (microns)**

- Decreased Sph Ab
- Increased Sph Ab
**- Mean Change in Aberrations -**

*(1 and 6m PostOp – PreOp)*

<table>
<thead>
<tr>
<th></th>
<th>Coma</th>
<th>Sph Ab</th>
<th>2nd Astig</th>
<th>Trefoil</th>
<th>HOA RMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1M</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WFG</td>
<td>0.002</td>
<td>-0.004</td>
<td>0.05</td>
<td>0.0004</td>
<td>0.04</td>
</tr>
<tr>
<td>Conv</td>
<td>0.05</td>
<td>0.07</td>
<td>0.06</td>
<td>0.03</td>
<td>0.11</td>
</tr>
<tr>
<td><strong>6M</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WFG</td>
<td>0.03</td>
<td>0.08</td>
<td>0.01</td>
<td>-0.01</td>
<td>0.04</td>
</tr>
<tr>
<td>Conv</td>
<td>0.05</td>
<td>0.13</td>
<td>0.02</td>
<td>0.007</td>
<td>0.09</td>
</tr>
</tbody>
</table>

**Bottom-line:** **WFG** induced less aberrations in **ALL** cases

*More negative = Decreased Aberrations (microns)*

*Significant Difference*
- **CONCLUSIONS** -

• **Compared to Conv PRK, WFG PRK is:**
  – Slower to recover: MSE and UCVA

• **However, by 3 months WFG PRK has:**
  – Greater refractive precision
  – Better correctable vision
  – Better uncorrected vision
  – Better contrast acuity
  – Less loss of BCVA & LCVA
  – Less induction of HOAs
KERATOME:
M E C H A N I C A L - v s - F E M T OSECOND
- **METHODS** -

- **2 Surgeons**
- **1 Excimer: VISX CustomVue (ver 3.07)**
- **3 Keratomes:**
  - **Mechanical:** Amadeus & Hansatome
  - **Femtosecond:** IntraLase
- **Endpoints:**
  - Refractive and visual outcomes
  - Flap results, questionnaire & HOA
    - Data not presented
### DEMOGRAPHICS

<table>
<thead>
<tr>
<th></th>
<th>Mechanical</th>
<th>Eyes n = 197</th>
<th>Femtosecond</th>
<th>Eyes n = 199</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>32 (21 to 54)</td>
<td></td>
<td>33 (22 to 53)</td>
<td></td>
</tr>
<tr>
<td><strong>Sph</strong></td>
<td>-2.84 (-0.75 to -6.00)</td>
<td></td>
<td>-2.64 (-0.75 to -6.00)</td>
<td></td>
</tr>
<tr>
<td><strong>Cyl</strong></td>
<td>-0.68 (0.00 to -3.00)</td>
<td></td>
<td>-0.73 (0.00 to -2.50)</td>
<td></td>
</tr>
<tr>
<td><strong>MSE</strong></td>
<td>-3.18 (-1.00 to -6.25)</td>
<td></td>
<td>-3.01 (-1.00 to -6.38)</td>
<td></td>
</tr>
</tbody>
</table>
- Uncorrected Acuity: 1 Day -

<table>
<thead>
<tr>
<th></th>
<th>Mechanical</th>
<th>Femtosecond</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>-0.01 ± 0.12</td>
<td>-0.08 ± 0.10</td>
</tr>
</tbody>
</table>

(LogMAR)

p<0.001
## Uncorrected Acuity: 1M

<table>
<thead>
<tr>
<th>Method</th>
<th>Mean ± SD</th>
<th>(LogMAR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td>-0.01 ± 0.35</td>
<td></td>
</tr>
<tr>
<td>(n=169)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femtosecond</td>
<td>-0.03 ± 0.32</td>
<td></td>
</tr>
<tr>
<td>(n=192)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Mechanical (n=169)**
  - 20/12.5: 75% 81%
  - 20/16: 81%
  - 20/20: 81%
  - 20/25: 81%
  - 20/40: 81%

- **Femtosecond (n=192)**
  - 20/12.5: 81%
  - 20/16: 81%
  - 20/20: 81%
  - 20/25: 81%
  - 20/40: 81%

**ns**
- Change in BCVA: 1M -

Mean Difference:
Mech -0.03 LM (gain)
Femto -0.04 LM (gain)

Mechanical (n=169)
Femtosecond (n=190)
- CHANGE IN 5% LCVA: 1M -

Femto provides better results

Mean Difference:
Mech +0.04 LM (loss)
Femto -0.01 LM (gain)

p<0.001

Mechanical (n=169)
Femtosecond (n=192)
- CHANGE IN 25% LCVA (Mesopic): 1M -

Femto provides better results

Mean Difference:
Mech +0.02 LM (loss)
Femto 0.00 LM (no chg)

Mechanical (n=167)
Femtosecond (n=184)
p=0.01
- **CONCLUSIONS** -

- Compared to mechanical keratome, femtosecond laser provides...
  - Faster visual recovery
  - Improved low contrast acuity
  - More predictable flap (depth accuracy & precision)
    - Data not shown
CUSTOM:
WFG-PRK -vs- WFG-IntraLASIK
- **DATASETS** -

- **Two Centers**
  - NRSC San Diego (USN)
  - WHMC (USAF)
- **VISX Star S4 CustomVue 3.65**
- **Investigational Device Exemption (IDE) with FDA**
- **Subjects randomly assigned**
  - WFG-PRK
  - WFG-IntraLASIK
- **Bilateral treatment**
- **No nomogram adjustment**
<table>
<thead>
<tr>
<th><strong>Surgical Techniques</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WFG-PRK</strong></td>
</tr>
<tr>
<td>Sample Size (eyes)</td>
</tr>
<tr>
<td>Ablation Pattern</td>
</tr>
<tr>
<td>Software</td>
</tr>
<tr>
<td>Optical Zone</td>
</tr>
<tr>
<td>Transition Zone</td>
</tr>
<tr>
<td>Epithelial Removal</td>
</tr>
<tr>
<td>Microkeratome</td>
</tr>
<tr>
<td>Topical Steroid</td>
</tr>
</tbody>
</table>
**- DISTRIBUTION OF TREATMENTS -**

Refractive Error (MSE)

- **WFG PRK** (n=267 eyes, mean age=31)
- **WFG LASIK** (n=290 eyes, mean age=34)
## MANIFEST SPH. EQUIVALENT

<table>
<thead>
<tr>
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<th>Pre-op</th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
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<tbody>
<tr>
<td><strong>WFG-PRK</strong></td>
<td>-2.90 ± 1.23</td>
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<td>-0.05 ± 0.28</td>
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<td></td>
<td>(-0.8 to -5.9)</td>
<td>(-1.6 to +0.9)</td>
<td>(-1.1 to +1.0)</td>
<td>(-1.2 to +0.9)</td>
</tr>
<tr>
<td><strong>WFG-LASIK</strong></td>
<td>-3.11 ± 1.29</td>
<td>+0.03 ± 0.30</td>
<td>-0.01 ± 0.31</td>
<td>-0.01 ± 0.30</td>
</tr>
<tr>
<td></td>
<td>(-1.0 to -6.4)</td>
<td>(-1.1 to +1.0)</td>
<td>(-0.9 to +1.5)</td>
<td>(-0.8 to +1.3)</td>
</tr>
</tbody>
</table>

MSE ± SD, (range)
- MSE DISTRIBUTION: 6m -

Difference is insignificant (F=0.90, p=0.82)

Mean ± SD

**WFG PRK** -0.05 D ± 0.28

**WFG LASIK** -0.01 D ± 0.30

Difference is insignificant (F=0.90, p=0.82)
- MSE Predicability -

Percentage of eyes within ±0.5 D of emmetropia

![Bar chart showing percentage of eyes within ±0.5 D of emmetropia for different months post-op with labels 'WFG PRK' and 'WFG LASIK'.]
### Uncorrected Acuity (UCVA)

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td>WFG-PRK</td>
<td>14% 20/12 or better</td>
<td>44% 20/12 or better</td>
<td>55% 20/12 or better</td>
</tr>
<tr>
<td></td>
<td>80% 20/20 or better</td>
<td>93% 20/20 or better</td>
<td>95% 20/20 or better</td>
</tr>
<tr>
<td>WFG-LASIK</td>
<td>36% 20/12 or better</td>
<td>39% 20/12 or better</td>
<td>40% 20/20 or better</td>
</tr>
<tr>
<td></td>
<td>96% 20/20 or better</td>
<td>96% 20/20 or better</td>
<td>96% 20/20 or better</td>
</tr>
</tbody>
</table>

On average, **WFG-PRK** MSE is slightly myopic @ 1M; **WFG-LASIK** MSE is emmetropic.

Both groups progress close to emmetropia by 3M post-op.
- PreOP BCVA - PostOP UCVA: 6m -

Difference in distributions is insignificant (Chi², p>0.1)

Mean ± SD

WFG-PRK
+0.1 ± 1.1

WFG-LASIK
+0.0 ± 0.9

UCVA < BCVA*
PRK = 20%
LASIK = 19%

UCVA > BCVA*
PRK = 38%
LASIK = 30%

Change in Lines of Acuity

* Change of ≥1 lines
**Best Corrected Visual Acuity - 20/20 or Better**

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td>WFG-PRK</td>
<td>99.3%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>WFG-LASIK</td>
<td>98.3%</td>
<td>99.9%</td>
<td>100%</td>
</tr>
</tbody>
</table>

BCVA LogMAR ≤ 0.04
**- CHANGE IN BCVA: 6m -**

Difference in distributions is insignificant (Chi², p>0.1)

**Mean ± SD**

- **WFG-PRK**
  - +0.6 ± 0.6

- **WFG-LASIK**
  - +0.5 ± 0.5

**Lost ≥1 Line**

- **PRK** = 4%
- **LASIK** = 3%

**Gained ≥1 Line**

- **PRK** = 55%
- **LASIK** = 49%

**Change in Lines of Acuity**
- Quality of Vision -
**- CHANGE IN 5% LCVA: 6m -**

**WFG-PRK** provides better results ($\text{Chi}^2$, $p=0.05$)

\[ \text{Mean} \pm \text{SD} \]

- **WFG-PRK**: +0.6 ± 1.0
- **WFG-LASIK**: +0.2 ± 0.9

Lost ≥ 2 Lines
- **PRK**: 2%
- **LASIK**: 2%

Gained ≥2 Lines
- **PRK**: 14%
- **LASIK**: 8%

**LCVA** = low contrast visual acuity
- HIGHER ORDER ABERRATIONS -
- **CHANGE IN HOA RMS** -
(6m PostOp – PreOp)

<table>
<thead>
<tr>
<th>WFG-LASIK</th>
<th>WFG-PRK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Change HOA RMS</td>
<td>n = 125</td>
</tr>
<tr>
<td>WFG-LASIK</td>
<td>0.05</td>
</tr>
<tr>
<td>WFG-PRK</td>
<td>0.05</td>
</tr>
</tbody>
</table>

**Change in HOA RMS (microns)**
- CHANGE IN SPH AB -
(6m PostOp – PreOp)

- Decreased Sph Ab
- Increased Sph Ab

Mean Change Sph Ab

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Mean Change</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>WFG-LASIK</td>
<td>0.08</td>
<td>125</td>
</tr>
<tr>
<td>WFG-PRK</td>
<td>0.10</td>
<td>198</td>
</tr>
</tbody>
</table>

(p = NS)
# Mean Change in Aberrations -

(1 AND 6m PostOp – PreOp)

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coma</td>
<td>Sph Ab</td>
</tr>
<tr>
<td>WFG-PRK</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>WFG-LASIK</td>
<td>0.05</td>
<td>0.07</td>
</tr>
</tbody>
</table>

More negative = **Decreased Aberrations** (microns)

* Significant Difference
- CONCLUSIONS -

• WFG-IntraLASIK
  – Faster visual recovery: MSE and UCVA

• WFG-PRK
  – Better 5% LCVA (~2 letters = real world significance??)

• No difference (@ 6 m post-op):
  – Refractive accuracy & precision
  – Best corrected vision
  – Uncorrected vision (although WFG-PRK may have >% @ 20/12.5)
  – Induction of HOAs
Questions?

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