5th International Congress of Wavefront Sensing & Optimized Refractive Corrections

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WaveFront Guided
LASIK vs. PRK

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Why WFG Surface Ablation?

- Microkeratome can induce aberrations
- WFG produces better outcomes
- Early reports suggest better outcome with surface ablation
WF Guided LASIK/PRK Study

- IDE Study of 375 patients at 2 sites:
  - NMCSD — 250 subjects randomized between PRK and LASIK
  - WHMC — 125 subjects, PRK only

- Primary Goals:
  - Prospective study of WFG-PRK
  - Compare WFG-PRK (investigational) to WFG-LASIK (FDA-approved)
Enrollment Criteria
(Nomogram Adjustment Group)

- Navy/AF personnel or dependents
- Healthy eyes
- Stable refraction
- At least 270 microns stroma remaining
- PRK Fellow Eyes receive conventional Tx
- Up to -6 MSE, up to 3D of astigmatism
Demographics

- 2 sites: NMCSD and WHMC
- 75 patients treated (149 eyes)
- Average age: 31.7 ± 7.3 yrs (22 to 48)
- Gender: Male 54 (72%)
  Female 21 (28%)
Surgical Procedures

- VISX Star S4 with CustomVue
- No Nomogram adjustment made
- Standard Temp and Humidity
- Standard Post-Op meds
- PRK: Amoils Brush and BCL
- LASIK: Hansatome
Clinical Endpoints

<table>
<thead>
<tr>
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<th>Pre-Op*</th>
<th>1 Month</th>
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<tbody>
<tr>
<td></td>
<td>All Eyes</td>
<td>wPRK (n=50)</td>
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<tr>
<td></td>
<td>(n=149)</td>
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<tr>
<td>MRSE</td>
<td>-2.98</td>
<td>-0.33</td>
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<tr>
<td></td>
<td>(-0.75 to -6.00)</td>
<td>± 0.36</td>
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<td>UCVA 20/20+</td>
<td>0%</td>
<td>68%</td>
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<tr>
<td>BCVA Loss &gt; 2 Lines</td>
<td>--</td>
<td>0%</td>
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*Pre-Op values were not statistically significantly different between groups.
Attempted vs Achieved (MSE)

WFG-PRK (n=50)

\[ y = 1.04x - 0.44 \]
Attempted vs Achieved (MSE)  
1 Month: WFG-LASIK (n=48)

\[ y = -0.91x + 0.25 \]
Quality of Vision Testing

Questionnaire
Habitual Correction, Glare and Halos, Activities, Dry Eyes, Fluctuating Vision, Double/Ghosting, Satisfaction

Night Driving Simulator
Subjects with -5 to -6 MRSE

5%
Contrast Acuity (photopic)

25%
Contrast Acuity (mesopic)
Best Corrected Visual Acuity

WFG PRK (n=50)
PRK (n=49)
WFG LASIK (n=50)
25% Contrast Acuity

- WFG PRK (n=49)
- PRK (n=48)
- WFG LASIK (n=48)

Gain categories:
- Gain > 2
- Gain 2
- Gain 1
- No Change
- Loss 1
- Loss 2
- Loss > 2
Change in HOA

WFG PRK (n=23)

Conventional PRK (n=22)

More higher order aberrations after surgery

Change in Higher Order Aberrations (µ)
Change in HOA

% of Eyes

Change in Higher Order Aberrations (µ)

WFG PRK (n=23)

WFG LASIK PRK (n=50)

-0.3 -0.2 -0.1 0 0.1 0.2 0.3 0.4 0.5

0% 10% 20% 30% 40%

WFG PRK

WFG LASIK

.03µm

.06µm
Change in Higher Order Aberrations (µ)

% of Eyes

-0.3 -0.2 -0.1 0 0.1 0.2 0.3 0.4 0.5 0.6

WFG LASIK

Conventional LASIK

0.06µ 0.16µ

0%

10%

20%

30%

40%
Conclusions

• A nomogram adjustment is required for WFG PRK
• WFG treatments induce fewer aberrations

What’s next...

• Treat the Primary Cohort (200 subjects)