January 26-29 2006
Atlantis Hotel, Paradise Island, Bahamas
Wavefront Outcomes

Steve Schallhorn, MD
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Quality of Vision Assessment

**Subjective**
- Questionnaires

**Objective**
- BCVA
- Contrast sensitivity
- Glare testing
- Low light vision
- Performance based
Contrast Sensitivity

Measure acuity (cpd) at a set contrast level

Measure contrast at a set cpd

Spatial Frequency cycles/degree
## Conv LASIK vs PRK Preop

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(&lt;-3.0D)</td>
<td>(-3.0 to -5.5D)</td>
<td>(&gt;5.5D)</td>
</tr>
<tr>
<td><strong>PRK (747 patients)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSE</td>
<td>-1.79</td>
<td>-3.76</td>
<td>-6.22</td>
</tr>
<tr>
<td>n (eyes)</td>
<td>720</td>
<td>604</td>
<td>151</td>
</tr>
<tr>
<td><strong>LASIK (635 patients)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MSE</td>
<td>-2.02</td>
<td>-3.90</td>
<td>-6.20</td>
</tr>
<tr>
<td>n (eyes)</td>
<td>360</td>
<td>613</td>
<td>298</td>
</tr>
</tbody>
</table>
Wavefront Guided LASIK
### Matched Analysis: 3 mos.

<table>
<thead>
<tr>
<th></th>
<th>Conv LASIK (n=500)</th>
<th>WFG LASIK (n=170)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MSE</strong></td>
<td>+0.01 ± 0.42</td>
<td>-0.16 ± 0.33</td>
</tr>
<tr>
<td><strong>UCVA 20/20+</strong></td>
<td>91%</td>
<td>93%</td>
</tr>
<tr>
<td>± 0.5D</td>
<td>84%</td>
<td>90%</td>
</tr>
</tbody>
</table>
**Custom vs Conventional (3 mo) Change in BCVA**

- **Conventional**
  - n=500
  - No Change: +0.05
  - Gain 1: +0.02

- **Custom**
  - n=170
  - Loss >2
  - Loss 2
  - Loss 1
  - No Change
  - Gain 1
  - Gain 2

*significantly different, \( t_{(0.05)} \), p=0.02

**Change in Lines of Vision**
Custom vs Conventional (3 mo)
Change in 5% CA

Conventional
n=500

Custom
n=170

*significantly different, t(0.05), p<<0.01
Significantly more complaints after surgery

Conv LASIK (6 Mo) (-29%)

Significantly less complaints after surgery

WFG LASIK (3 Mo)
Change in HOA

% of Eyes

WFG LASIK

Conventional LASIK

More higher order aberrations after surgery

Change in Higher Order Aberrations (µ)

6mm pupil
Comparison of Induced Aberrations

- HOA RMS
- Sph Ab (z12)
- HOA RMS-z12

Conventional vs WFG

* p<0.001

6mm pupil
WFG-LASIK Induced HO RMS as a Function of Pre-op Levels

WFG-LASIK

\[ y = -0.70x + 0.25 \]

\[ R^2 = 0.27 \]

6mm pupil
Conclusions – WFG LASIK

• More predictable
  – Fewer retreatments

• Better quality of vision
  – Better contrast acuity
  – Better night vision
  – Fewer symptoms
  – Less induction of HOA

• Clearly an improvement
WFG-PRK vs. WFG-LASIK

Steve Schallhorn, MD
Naval Medical Center San Diego
2 Surgeons
89 Patients (43 PRK / 48 LASIK)
Investigational Device Exemption
Amoils Brush or Hansatome/IntraLase
VISX Star S4 / WaveScan 3.62
Bilateral Treatment
No Nomogram Adjustment
## WFG-LASIK v WFG-PRK Preop Characteristics

<table>
<thead>
<tr>
<th>Randomized Comparison</th>
<th>WFG-LASIK (n=96 eyes)</th>
<th>WFG-PRK (n=86 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>32 ± 7 (22 to 51)</td>
<td>30 ± 7 (21 to 47)</td>
</tr>
<tr>
<td>Sph</td>
<td>-2.85 (-1.00 to -5.25)</td>
<td>-2.71 (-1.00 to -5.25)</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.78 (0.00 to -2.50)</td>
<td>-0.75 (0.00 to -2.50)</td>
</tr>
<tr>
<td>MSE</td>
<td>-3.24 (-1.00 to -5.75)</td>
<td>-3.09 (-1.25 to -5.50)</td>
</tr>
</tbody>
</table>
WFG-LASIK
\[ y = 0.95x + 0.24 \]
\[ R^2 = 0.93 \]
n = 96

WFG-PRK
\[ y = 0.97x + 0.05 \]
\[ R^2 = 0.91 \]
n = 86
## Clinical Results: 3 Months

<table>
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<tr>
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<th>WFG-LASIK (n=96)</th>
<th>WFG-PRK (n=86)</th>
</tr>
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<tbody>
<tr>
<td><strong>MSE</strong></td>
<td>+0.09 ± 0.33</td>
<td>-0.06 ± 0.36</td>
</tr>
<tr>
<td>± 0.50 D</td>
<td>90%</td>
<td>87%</td>
</tr>
<tr>
<td>± 0.25 D</td>
<td>68%</td>
<td>71%</td>
</tr>
</tbody>
</table>
UCVA: 3 Months

- **LASIK** (n=96):
  - 20/12.5: 34%
  - 20/16: 93%
  - 20/20: 98%
  - 20/25: 87%
  - 20/40:

- **PRK** (n=86):
  - 20/12.5: 37%
  - 20/16: 77%
  - 20/20: 87%
  - 20/25: 87%
  - 20/40:
20/16 UCVA

- **1 wk**
  - LASIK: 73%
  - PRK: 13%

- **1 mo**
  - LASIK: 89%
  - PRK: 58%

- **3 mo**
  - LASIK: 93%
  - PRK: 77%
Change in BCVA: 3 Months

WFG-LASIK (n=60)

WFG-PRK (n=56)

Change in Lines of Vision

Better Acuity
Change in 5% CA: 3 Months

WFG-LASIK (n=96)

WFG-PRK (n=86)

Change in Lines of Vision

Better Acuity

0.01

0.02
Change in 25% CA: 3 Months

WFG-LASIK (n=96)

WFG-PRK (n=86)

*significantly different, p<0.001
Change in HOA: 3 Months

% of Eyes

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

WFG PRK

WFG LASIK

Increased HOA after surgery

Change in Higher Order Aberrations (µ)

0.03µ*

0.08µ

*significantly different, p<0.05

6mm pupil
Conclusions – WFG PRK

- Better UCVA for LASIK
- Same nomogram
- PRK induces less HOA
  - Particularly coma
  - Differences may be due to type of keratome
- Results are preliminary
Influence of Flap Creation
Methods

- 2 Surgeons
- 1 Excimer
  - **VISX Star S4 CustomVue (ver 3.07)**
- 2 flap techniques
  - Mechanical (Hansatome & Amadeus)
  - Femtosecond (Intralase)
- 2 treatment modes
  - Immediate treatment (Flap/Treat)
  - Staged treatment (Flap/Wait/Treat)
- Endpoints
  - Flap characteristics
  - Refractive and visual outcome
  - Questionnaire
  - Wavefront aberrations
## Demographic Information

<table>
<thead>
<tr>
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<th>Mechanical (n = 252)</th>
<th>Femtosecond (n = 200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>33 ± 7 (21 to 54)</td>
<td>34 ± 8 (21 to 53)</td>
</tr>
<tr>
<td>Sph</td>
<td>-2.79 (-0.50 to -6.00)</td>
<td>-2.64 (-0.75 to -6.00)</td>
</tr>
<tr>
<td>Cyl</td>
<td>-0.70 (0.00 to -3.00)</td>
<td>-0.73 (0.00 to -2.50)</td>
</tr>
<tr>
<td>MSE</td>
<td>-3.14 (-1.00 to -6.25)</td>
<td>-3.00 (-1.00 to -6.38)</td>
</tr>
</tbody>
</table>
Day 1 Subjective Symptoms

FBS

Photophobia
Clinical Results – 1 Day

Mechanical (n=252)

Femtosecond (n=200)

UCVA

P=0.01
Clinical Results – 1 Week

Mechanical (n=252)
-0.15 ± 0.36
85%

Femtosecond (n=200)
-0.09 ± 0.34
90%

MSE ± 0.50 D

UCVA

P<0.001

56% 77%
Clinical Results – 1 Month

Mechanical (n=242)
-0.08 ± 0.37
90%

Femtosecond (n=198)
-0.03 ± 0.32
93%

MSE
± 0.50 D

UCVA
ns

20/12.5
20/16
20/20
20/25
20/40

73%
81%

90%
Clinical Results – 3 Month

**MSE ± 0.50 D**

**Mechanical**
(n=235)

-0.13 ± 0.34

90%

**Femtosecond**
(n=196)

-0.10 ± 0.35

89%

**UCVA**

- 20/12.5
- 20/16
- 20/20
- 20/25
- 20/40

80% 83%
Attempted vs Achieved (MSE)  
3 Months

Mechanical:
\[ y = 0.94x + 0.06 \]
\[ R^2 = 0.92 \]

Femtosecond:
\[ y = 0.95x + 0.06 \]
\[ R^2 = 0.93 \]
Change in BCVA – 3 Month

Mean Difference:
-0.05 LM (gain)
-0.05 LM (gain)

ns

Mechanical (n=235)
Femtosecond (n=196)
Change in 5% CA – 1 Month

Mean Difference:
+0.02 LM (loss)
-0.01 LM (gain)

P=0.03

Loss >=2:
10% 7%

Mechanical (n=242)
Femtosecond (n=198)
Change in 5% CA – 3 Month

Mean Difference:
+0.01 LM (loss)
-0.02 LM (gain) *

P=0.01

Loss >=2:
6% 3%

Mechanical (n=235)
Femtosecond (n=196)
Change in 25% CA – 3 Month

Mean Difference:
+0.01 LM (loss)
-0.03 LM (gain) *

P<0.001

Loss >=2:
5%
1%

Loss >2
Loss 2
Loss 1
No Chg
Gain 1
Gain 2
Gain >2

Mechanical (n=231)
IntraLase (n=186)
Change in Sph Ab – 3 Months

Mean Difference:
+0.09 ± 0.09
+0.07 ± 0.08

p=0.02

6mm pupil
Conclusion

Femtosecond laser

- Less flap variability
- Early FBS & photophobia
- Faster visual recovery
- Similar nomo adjustment
- Improved contrast acuity
- Differences in HOA
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