Wavefront-guided LASIK with Alcon’s CustomCornea®

Ronald R. Krueger, MD
&
The CustomCornea® Study Group

Wavefront-guided LASIK correction with the LADARVision® 4000 System is limited by U.S. Federal Law to investigational use within the United States for treatment of myopic astigmatism, hyperopia, hyperopic astigmatism, and mixed astigmatism.
CustomCornea® Study Group

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- Waterloo, Canada
- Cleveland, OH
- Orlando, FL
- New Orleans, LA
- Los Angeles, CA
Wavefront-Guided CustomCornea® LADARVision®4000 System Correction

LADARVision®4000 Excimer Laser System
- Closed-loop laser radar tracking
- Flying small spot (0.8 mm) Gaussian beam
- 6.5mm optic zone with 1.25mm blend (9mm total zone)
- REGISTRATION

LADARWave™ CustomCornea® Wavefront System
- H-S wavefront sensor
- Low order (defocus) and higher-order aberrations
- Large instantaneous dynamic range
- Auto fogging eliminates accommodation effects
- REGISTRATION
What is Registration?

Capture, Match and Treat in desired position
Capture

Centration - captured prior to wavefront measurement

Snap shot of eye (frozen video image)

Desired position defined (natural pupil center)
Capture

**Wavefront** - composite of 5 individual measurements taken and reconstructed in the defined position established **during centration**
Match

Wavefront to Laser - wavefront data exported from LADARWave and transferred to the LADARVision laser
**Match**

**Wavefront to Eye** - linear and limbus reticles are aligned to place the ablation profile on exact position at which the wavefront was captured
**Treat Laser - LADARVision® 4000** System applies ablation to the exact defined position on the eye.

**Space-stabilized interface:**
- Closed loop eye tracking
- Register wavefront position
- Cyclotorsion compensation
- Hinge masked from ablation
- Ablation grid position
FDA PreMarket Approval of Custom Cornea

October 18, 2002

(Up to -7.0 D with 0.5 D cyl)
(W sph & cyl w/in +/- 1.0 D)
Case Report

- GR, 38yo, male
- Wants the potential for “better than 20/20 vision”
- UCVA 20/200 OU
- MR: OD –2.75 sph  20/20
  OS –2.75 –0.50 x 7°  20/20
- CR: OD –2.50 sph  20/20
  OS –2.25 –0.75 x 4°  20/20
- Pupils: 3.5mm/ 5mm
- Pachs: OD 552µm   OS 540µm
Surgery - 1st Commercial Patient

- LASIK OU - Moria M2 130µm
- Laser setting: OD –2.28 –0.31x 153°
  OS –1.78 –0.66x 4.7°

Treatment optical zone: 6.5mm, 1.25mm blend zone

- 1 Day Postop
  - UCVA 20/20 OU
“I have never seen so well, even with CLs”

UCVA 20/15 OU
LADAR Wave Aberrations (4 days)

**Refraction from Wavefront**

<table>
<thead>
<tr>
<th>Sphere</th>
<th>-2.34 Dioplers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cylinder</td>
<td>-0.33 Dioplers</td>
</tr>
<tr>
<td>Axis</td>
<td>153 Degrees</td>
</tr>
<tr>
<td>Match</td>
<td>84%</td>
</tr>
<tr>
<td>Diameter</td>
<td>6.50 mm</td>
</tr>
</tbody>
</table>

**Aberrations**

| Defocus          | 3.42            |
| Astigmatism      | 0.25            |
| Coma             | 0.35            |
| Spherical Aber   | -0.07 µm        |
| Other            | 0.45            |

**RMS (microns)**

<table>
<thead>
<tr>
<th>Total Aberrations</th>
<th>High Order Aberrations</th>
</tr>
</thead>
<tbody>
<tr>
<td>RMS = 3.49 µm</td>
<td>RMS = 0.69 µm</td>
</tr>
</tbody>
</table>

**WR OD**

-2.34 – 0.33 x 153

**Coma** = 0.35 µm

**Sph Aber** = -0.07 µm

**Other terms** = 0.45 µm

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**Refraction from Wavefront**

<table>
<thead>
<tr>
<th>Sphere</th>
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<tbody>
<tr>
<td>Cylinder</td>
<td>-0.38 Dioplers</td>
</tr>
<tr>
<td>Axis</td>
<td>171 Degrees</td>
</tr>
<tr>
<td>Match</td>
<td>52%</td>
</tr>
<tr>
<td>Diameter</td>
<td>6.50 mm</td>
</tr>
</tbody>
</table>

**Aberrations**

| Defocus          | 0.86            |
| Astigmatism      | 0.29            |
| Coma             | 0.26            |
| Spherical Aber   | 0.20            |
| Other            | 0.37            |

**RMS (microns)**

<table>
<thead>
<tr>
<th>Total Aberrations</th>
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<tr>
<td>RMS = 1.84 µm</td>
<td>RMS = 0.59 µm</td>
</tr>
</tbody>
</table>

**WR OD**

-0.05 – 0.38 x 171

**Coma** = 0.26 µm

**Sph Aber** = 0.20 µm

**Other terms** = 0.37 µm
2 Weeks Postop

- UCVA 20/15 OU
- MR OD pl sph 20/15
  OS pl sph 20/15
- CR OD +0.25sph 20/15
  OS +0.50sph 20/15
- Ks OD 41.75x42.00 @90°
  OS 41.50x41.75 @90°
LADARWave Aberrations (2 wks)

<table>
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<th>Aberrations</th>
<th>RMS(microns)</th>
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<tr>
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<tr>
<td>Sphere</td>
<td>Defocus</td>
<td>0.78</td>
</tr>
<tr>
<td>Cylinder</td>
<td>Astigmatism</td>
<td>0.15</td>
</tr>
<tr>
<td>Axis</td>
<td>Coma</td>
<td>0.30</td>
</tr>
<tr>
<td>Match</td>
<td>Spherical Aberration</td>
<td>0.28</td>
</tr>
<tr>
<td>Diameter</td>
<td>Other</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Coma = 0.35 µm,
Sph Aber = -0.07 µm
Other terms = 0.45 µm

Coma = 0.30 µm (mean 0.96)
Sph Aber = 0.28 µm (mean 1.27)
Other terms = 0.31 µm (mean 0.67)

Mean values after conventional treatment
Myopic LASIK Study Overview

- Treatment **algorithm refined** to compensate for slight undercorrection observed in initial group used to support the FDA approval (received 10/18/02)

- 147 myopic eyes treated with refined algorithm currently under investigation
  - Results showed improved outcomes

- Pre-operative Refractive Parameters
  - Sphere: $-2.62 \pm 1.17D$ 0 to -5.50D
  - Cylinder: $-0.76 \pm 0.63D$ 0 to -2.50D
  - Sph Equiv: $-3.00 \pm 1.16D$ -0.50 to -5.50D
UCVA 6M

- **All Eyes (n=147)**
  - 20/16 or better: 68%
  - 20/20 or better: 71%
  - 20/25 or better: 91%

- **Sphere (n=49)**
  - 20/16 or better: 91%
  - 20/20 or better: 92%
  - 20/25 or better: 99%
Accuracy of MRSE 6M

Mean MRSE -0.03D at 6M for all eyes

- All Eyes (n=147)
- Sphere (n=49)
BCVA 6M

Preop All Eyes (n=147)

6M All Eyes (n=147)

- 20/12.5 or better: 21%
- 20/16 or better: 44%
- 20/20 or better: 93%

- 20/12.5 or better: 99%
- 20/16 or better: 99%
- 20/20 or better: 99%
Contrast Sensitivity 6M

* % of eyes with a significant change from preop

* (>0.3 log (>2 levels) at 2 or more spatial frequencies)
# Change in Symptoms Preop to 6M

<table>
<thead>
<tr>
<th>Condition</th>
<th>Significantly Better (+2 from Preop)</th>
<th>±1 from Preop</th>
<th>Significantly Worse (-2 from Preop)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glare</td>
<td>10.9%</td>
<td>89.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Halos</td>
<td>12.2%</td>
<td>87.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Night Driving Difficulty</td>
<td>10.9%</td>
<td>87.7%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Blurring of Vision</td>
<td>14.3%</td>
<td>85.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Fluctuation of Vision</td>
<td>10.2%</td>
<td>89.8%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Change in Aberrations from Preop

- Initial CustomCornea Spherical Myopia (n=139) 6 M
- Refined CustomCornea Myopia (n=147) 6 M
- Conventional Spherical Myopia (n=50) 6 M

* Statistically Significant (p<0.05)

Difference Initial CustomCornea® vs. Conventional

%
Optical analysis suggests that the benefit of the lower higher-order aberrations after wavefront-guided surgery corresponds to approximately 0.2D of defocus.

Wavefront-Guided Higher-Order Aberrations: Initial CustomCornea®

Conventional Higher-Order Aberrations
Reduction in Aberrations From Preop Initial CustomCornea® 6M (n=139)  | Refined CustomCornea® 6M (n=147)  | Conventional 6M (n=50)
---|---|---
All HOA  | 38%  | 36%  | 14%
Spherical Aberration  | 45%  | 48%  | 10%
Case Example #1 - OD

- 2 previous procedures with last being decentered
- Key RMS data for 3.25 mm pupil:

<table>
<thead>
<tr>
<th></th>
<th>Preop</th>
<th>1 wk Post</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coma</td>
<td>1.48</td>
<td>0.15</td>
<td>- 90%</td>
</tr>
<tr>
<td>SA</td>
<td>0.62</td>
<td>0.13</td>
<td>- 79%</td>
</tr>
</tbody>
</table>

- Patient reports significant improvement in previous severe glare, halos and double vision/ghosting
Initial Complex CustomCornea® Treatments

Patient #1 - preop
Initial Complex CustomCornea® Treatments

Patient #1 -
1 Week
Case Example #2 - OD

- 2 previous procedures
- Large amount of secondary astigmatism present with corresponding interesting wavefront profile
Initial Complex CustomCornea® Treatments

RMS Values by Order

RMS (µm)

Order

Pre-Op
Post-Op

0.2
0.4
0.6
0.8
1.0
1.2
1.4
1.6
1.8

0
2
3
4
5
6
7
8
Initial Complex CustomCornea® Treatments

4th Order Aberrations

RMS (microns)

Pre-Op
Post-Op

Sph Ab
Sec Ast
Teta
Initial Complex CustomCornea® Treatments

• At 1 week, vision fluctuating but very happy overall
• Patient reports improvement in previous symptoms of glare, halos and double vision / ghosting
• UCVA 1 line better than preop BCVA at 1 week
What do you need to perform a true CustomCornea® correction?

Technology Requirements

<table>
<thead>
<tr>
<th>Tracker</th>
<th>Closed-loop tracker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small spot</td>
<td>True spot with Gaussian profile</td>
</tr>
<tr>
<td>Wavefront</td>
<td>Robust enough to measure symptomatic eyes</td>
</tr>
<tr>
<td>Link</td>
<td>True registration between image at wavefront and image at laser</td>
</tr>
</tbody>
</table>
Summary

- Optimal wavefront-guided outcomes require registration
  - Capture, Match, Treat

- Excellent results to date for CustomCornea® myopic eyes
  - Excellent visual acuity and more gain / less loss of mesopic contrast sensitivity for the myopic eyes

- Higher-order aberrations for CustomCornea® eyes:
  - Continue to show reduction from preop in a higher percentage of eyes than conventional treatment
  - Overall increase in magnitude remains small and significantly less than conventional
  - No significant change from preop in spherical aberration for refined CustomCornea® treatment

- Promising results for the initial complex treatments
2nd CCF Commercial Custom Cornea Case Report

- CR, 28yo, female, general surgery resident
- Wants good vision without glasses or CL
- UCVA CF OU
- MR: OD –7.75 sph  20/20
  OS –6.50 –0.50 x 35°  20/20
- CR: OD –6.75 -0.50x 45° 20/20
  OS –5.50 –1.25 x 136°  20/20
Surgery

- LASIK OU - Moria M2 130µm
- Laser set: OD –7.05 –0.94x 174.3°
  OS –5.90 –1.04x 163.6°
Treatment optical zone: 6.5mm, 1.25mm blend zone

- 1 Day Postop
  - UCVA 20/20 OU
1 Week Postop

- UCVA 20/15 OU
- MR OD pl sph 20/15
  OS pl +0.50x 105° 20/15
Pre vs Postop OD

Coma = 0.60 µm,
Sph Aber = -0.08 µm
Other terms = 0.18 µm

Coma = 0.45 µm (mean 0.96)
Sph Aber = 0.41 µm (mean 1.27)
Other terms = 0.43 µm (mean 0.67)

Mean values after conventional treatment
Pre vs Postop OS

Coma = 0.62 µm,
Sph Aber = -0.07 µm
Other terms = 0.41 µm

Coma = 0.27 µm  (mean 0.96)
Sph Aber = 0.32 µm  (mean 1.27)
Other terms = 0.40 µm  (mean 0.67)

Mean values after conventional treatment
Thank You!
Custom Cornea = 20/happy