The Latest In Refractive Surgical Correction

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Topography Guided Lasik
Topography-Guided Surgery News

• Fort Worth, TX (PREYEWISE EVERYDAY) October 20, 2013

Alcon receives industries first FDA Approval for Topography-guided LASIK

“Alcon, the global leader in eye care industry announced today that the FDA approved the Allegretto Wave Eye-Q 400 Hz Excimer laser system in conjunction with the WaveLight Allegro Topolyzer and topography-guided customized ablation treatment (T-CAT) planning software for topography-guided LASIK. According to the FDA, topography-guided is indicated for patient who are 18 years of age or older for the reduction or elimination of up to -9.0D of spherical equivalent myopia or myopia with astigmatism.

• Freemont, CA (PRWEB) November 07, 2013

“NIDEK, a global leader in laser and diagnostic instrumentation for the eye care industry, announced today that the United States Food & Drug Administration (FDA) has approved its highly innovative Customized Aspheric Treatment Zone (CATz) for the NAVEX Quest; EC-5000 Excimer Laser System, one of the first topography-assisted LASIK procedure.”
Surgical Application of Corneal Topography

- Many methods with individual strengths
  - Placido, slit-scanning, Scheimpflug, monochromatic and color LED topography

- Challenge is to provide more accurate data going into corneal ablation planning

- Goal is to reduce the number of variables going into surgical planning, which drives more accurate outcomes for patients and reduced outliers in a surgeon’s data set
T-CAT Treatment System

Devices Used

ALLEGRO Topolyzer

Treatment Notebook

500 Hz Excimer Laser
THE EMERGENCE OF TOPOGRAPHY-GUIDED LASIK

• Developed to correct higher-order aberrations

• Provides an alternative to the correction of higher-order refractive errors based on aberrometry
  • Not dependent upon pupil size
  • Can be measured reproducibly
  • Unaffected by lenticular opacities and vitreous opacities
  • Accurately measures peripheral corneal irregularities, which are responsible for many visual complaints
• But…corneal topography does not provide information about the refractive state of the eye

• So…the corrective laser ablation profile must be based on refractive data (for low order refractive abnormalities) in addition to topographic information (for high order aberrations)
It Takes a SYSTEM

- Placido topographer
- Calculates height data
- Locates pupil centroid

Calculates mean height profile from 4–8 images

Combines Z2 from MR with Z3 and higher from topography to create shot file

asphere and calculates high-order Zernikes

height profile from 4–8 images
TOPOGRAPHY GUIDED ABLATIONS

• Uses corneal data to customize the ablation profile

• Can use data from:
  • Placido disc

• Can reliably measure highly aberrated topographies that wavefront sensors do not measure

• Goal: normalize the corneal surface rather than customizing the corneal surface
VARIO OVERVIEW

• Calculates height data for areas where mire images are available
• No interpolated data
• No extrapolated data
MEASUREMENT & PUPIL/IRIS DETECTION

- **Placido projection surface**: provides 11 rings, 44 edges, and 22,000 measurement points

- **Infrared light illuminated-picture**: analyzed for registration and centration of ablation at the corneal apex

- **Allegretto Eye-Q laser**: uses the pupil-to-apex centration vector for centration. Does not compensate or control for pupil centroid shift or cyclotorsional rotation.

Iris & pupil circumference using infrared illumination

Pupil diameter and relative position with captured & processed Placido ring
WAVEFRONT VS. TOPOGRAPHY-GUIDED CUSTOM ABLATION

[Image showing pre-topography, eye image, and ablation profiles]
GOOD COMPARE
GOOD COMPARE
BAD COMPARE
FDA Study Outcomes

• Improvement in patient vision symptoms
  • At 12 months, fewer patients reported light sensitivity, difficulty driving at night, reading difficulty, and glare

• Contoura™ Vision outperformed even glasses and contacts
  • 98.4% of patients said they would have the procedure again
  • Post hoc analysis showed post operative UCVA improvement over baseline BSCVA in over 30% of eyes

• Stands alone in refractive precision
  • 92.6% saw 20/20
  • 64.8% saw 20/16
  • 34.4% saw 20/12.5

1. Results from FDA T-CAT-001 clinical study for topography-guided vision correction (with the 400 Hz ALLEGRO® WAVE® Eye-Q Excimer Laser).
Visual Symptoms

Wavefront Optimized

Topo-Guided (Contoura)

Effective Optic Zone Comparison
Visual Symptoms: Preop to 6M, n=244

<table>
<thead>
<tr>
<th>Question</th>
<th>None - Moderate</th>
<th>Marked - Severe</th>
<th>Difference in Marked – Severe</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6M</td>
<td>Baseline</td>
<td>6M</td>
</tr>
<tr>
<td>Light Sensitivity</td>
<td>94.8%</td>
<td>99.6%</td>
<td>5.2%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Difficulty Driving at Night</td>
<td>91.6%</td>
<td>98.0%</td>
<td>8.4%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Reading Difficulty</td>
<td>90.0%</td>
<td>97.5%</td>
<td>10.0%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Double Vision</td>
<td>98.8%</td>
<td>98.4%</td>
<td>1.2%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Fluctuation in Vision</td>
<td>98.4%</td>
<td>100.0%</td>
<td>1.6%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Glare</td>
<td>95.2%</td>
<td>100.0%</td>
<td>4.8%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Halos</td>
<td>96.8%</td>
<td>100.0%</td>
<td>3.2%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Starbursts</td>
<td>96.8%</td>
<td>99.6%</td>
<td>3.2%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Dryness</td>
<td>95.2%</td>
<td>97.5%</td>
<td>4.8%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Pain</td>
<td>99.6%</td>
<td>100.0%</td>
<td>0.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>FBS</td>
<td>99.6%</td>
<td>100.0%</td>
<td>0.4%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Visual Symptoms Summary

• There was a decrease in the proportion of eyes with marked to severe ratings for light sensitivity, difficulty driving at night, reading difficulty, fluctuation in vision, glare, halos, starbursts, dryness and pain after T-CAT LASIK compared to before surgery. Statistical significance was achieved for light sensitivity, difficulty driving at night, reading difficulty and glare.

• Eye dryness was the most commonly reported visual complaint that occurred in the first 3 month postoperative period.

• 98% of subjects indicated that they would have T-CAT LASIK again.

• Visual symptoms and objective visual acuity measurements generally improved with time, through the end of the study (12 months postoperatively).
## Standard Outcomes

### Chart

**Uncorrected Distance Visual Acuity**

141 Eyes at 1 Month Visit

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>Percentage of Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20/12.5</td>
<td>0.7%</td>
</tr>
<tr>
<td>&gt;=20/16</td>
<td>46.8%</td>
</tr>
<tr>
<td>&gt;=20/20</td>
<td>94.3%</td>
</tr>
<tr>
<td>&gt;=20/25</td>
<td>98.6%</td>
</tr>
<tr>
<td>&gt;=20/32</td>
<td>99.3%</td>
</tr>
<tr>
<td>&lt;20/40</td>
<td></td>
</tr>
</tbody>
</table>

### Demographics

- **Eyes analysed (n):** 141 of 141
- **Preop. Parameters:**
  - dUCVA mean/SD:
  - dUCVA range:
  - SE range:
  - Age mean/SD:
  - Age range:
  - Different patients:

### Preoperutive Parameters

- BCDVA from (dec):
- SE from:
- Cyl from:
- Ax from:

### Postoperative Parameters

- UCDVA 1m from:
- UCDVA 3m from:
- BCDVA 1m from:
- BCDVA 3m from:
**Standard Outcomes**

**Chart**
- Type: 01 UCVA
- Visit: 3m
- Color: blue gradient
- 07-08.12
- Scale: 100%
- 01-05
- VA: Distance monocular
- 01-03
- VA Unit: Snellen Foot
- 07
- Lin. Regr.: on
- 07.08
- Gate: 0.5

**Uncorrected Distance Visual Acuity**
- 65 Eyes at 3 Month Visit

**Percentage of Eyes**
- >=20/12.5: 100.0%
- >=20/16: 95.4%
- >=20/20: 100.0%
- >=20/25: 100.0%
- >=20/32: 100.0%
- >20/40: 55.4%

**Demographics**
- Eyes analysed (n): 65 of 141
- Right: 33 (50.8%)
- Left: 32 (46.2%)
- Female: 40 (61.5%)
- Male: 25 (38.5%)
- Age mean/SD: 33.3 ± 3.92
- Age range: 28 to 42

**Preop. Parameters**
- dUCVA mean/SD: 1 ± 0
- dUCVA range: 2 to 0 (1)
- SE mean/SD: -4.87 ± 1.99
- SE range: -9.125 to -1.125
- Cyl mean/SD: 0.75 ± 0.74
- Cyl range: 0 to 3

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Database: EMR with automatic Upload

User: Michael Gordon
Pentacam Elevations are being treated to make a Uniform Cornea
Creation of a uniform cornea by removing HOAs

Pre-op Manifest: -3.00

Measured Treatment: -2.50, -1.00 x 179

Post-op 1 week: plano with 20/15 vision

In this case the patient’s aberrations were masking and offsetting the patient’s astigmatism. Resultant cornea shows no bowtie astigmatism and is very uniform by one week.
Hartmann-shack based wavescan and topography
High definition sensor

• Maximizes Capture Rates
  – High-definition Hartmann-Shack wavefront sensor (five times higher resolution than *WaveScan* system)
  – Fourier reconstruction algorithms using up to 1257 micro-refractions over a 7 mm diameter wavefront
  – 3x dynamic range (vs. *WaveScan* system):
    • Sphere: -16.0 D to +12.0 D, Cylinder: up to +8.0 D
  – Increasing resolution enables¹:
    • Potential to capture more eyes
    • Improved spot quality, reduces spot cross-over effect
    • Greater detection of HOAs
    • Enhanced reconstruction precision
High resolution wavefront sensor enables measurement of challenging eyes.

*New*

system
high-definition
wavefront

*WaveScan* system
wavefront
High Resolution is the Key to Success

*WaveScan* system wavefront

System Model Eye

*New* system high-definition wavefront
Full Gradient Corneal Topography

- New corneal topography technology, non-placido based
  - Reduced sensitivity to misaligned eyes
  - Accurately measures x and y displacement for each spot
  - Integrated on same measurement axis as aberrometer
  - >8.3 mm diameter with central region topography data
Full gradient corneal topography

- Specifications Include:
  - Zonal reconstruction and 8th order Zernike reconstruction
  - Coverage > 8.3 mm*
  - Axial Power Accuracy better than 0.25 D**
  - Axial Power Repeatability < 0.15 D**

Full Topography Design
Keratometry

- Calculated from corneal topography data
- Accurate to within 0.25 D
pupillometry

- Measures pupil diameter under controlled scotopic and photopic lighting conditions
Case 1

• Keratoconus patient
• S/P CXL
• Chief Complaint “Severe ghosting with glasses”
• Manifest -4.00-3.00x152  20/60
• Coma 0.80
Manifest plano -0.50x154 20/35
Coma 0.14
Case 2

- S/P Lasik 1999
- Decentered Ablation
- Manifest +1.50-200x120  20/20
- Coma 0.62
- Debilitating night vision symptoms
Manifest 0.25-0.50x180  20/20

Coma – 0.12
Corneal Inlays

KAMRA

Flexivue

Raindrop
Where the inlay falls within the Patient Spectrum

- Lasik
  - No distance Rx Lasik
  - Too Young for IOL

- IOLs

Ages 20 – 40
Ages 40 – 60
Ages 60+

Near vision loss begins
Raindrop® Near Vision Inlay

- Transparent hydrogel inlay, similar material to a soft contact lens
- Size
  - 2 mm in diameter
  - 30 microns thick, half the thickness of a human hair
- Biocompatible Material
  - Similar refractive index and water content as the cornea
  - Maintains natural nutrient flow within the cornea*
  - Removable

Indications for Use

The Raindrop Near Vision Inlay is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent (MRSE) of +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.
Ideal Patient

• Refraction: +1.00 D to -0.50 D, ≤ 0.75 D Cylinder
• Healthy Ocular Surface
• Good Distance Vision
• Needs at least +1.50 D of Near Add
• Minimum 500 μm thick cornea
• Pupil Size
  – > 3 mm photopic pupil
  – < 7 mm mesopic pupil
How Does It Work?

Gently reshapes the cornea to create a near center that transitions to intermediate* then distance

*Intermediate was not an endpoint in the FDA clinical study.
Simple To Perform (video)
Simple Results: Lines Achieved

<table>
<thead>
<tr>
<th>MEAN CHANGE IN ACUITY</th>
<th>FROM PREOP (LINES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCNVA</td>
<td>+6</td>
</tr>
<tr>
<td>UCIVA</td>
<td>+5</td>
</tr>
<tr>
<td>UCDVA</td>
<td>+4</td>
</tr>
<tr>
<td>UCDVAOU</td>
<td>+3</td>
</tr>
</tbody>
</table>

VISITS
- 1W (N=373)
- 1M (N=371)
- 3M (N=366)
- 6M (N=365)
- 9M (N=364)
- 12M (N=361)
- 18M (N=351)
- 24M (N=344)
Simple Results: Raindrop Eye Results (Monocular)

- **MEAN VISUAL ACUITY (SNELEN)**
  - UCNVA
  - UCIVA
  - UCDVA

- **VISITS**
  - Preop (N=373)
  - 1W (N=373)
  - 1M (N=371)
  - 3M (N=366)
  - 6M (N=365)
  - 9M (N=364)
  - 12M (N=361)
  - 18M (N=351)
  - 24M (N=344)
Simple Results: Binocular Results

MEAN VISUAL ACUITY (SNELEN)

- UCNVAOU
- UCIVAOU
- UCDVAOU

VISITS

Preop (N=373)
1W (N=373)
1M (N=371)
3M (N=366)
6M (N=365)
9M (N=364)
12M (N=361)
18M (N=351)
24M (N=344)
Postop Instructions

• One week of Antibiotics: 4 times a day
• One month of a Strong Steroid: Taper
  – First week 4 times a day
  – Second week 3 times a day
  – Third week 2 times a day
  – Fourth week once a day
• Two additional months of a Weaker Steroid
  – Second month 2 times a day
  – Third month once a day
### Safety Profile* (N = 135)

#### Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ocular Infection</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Lost, misaligned, misplaced flap</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Increased IOP</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>DLK</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Inlay Exchange</td>
<td>5 (3.7%)</td>
</tr>
<tr>
<td>Inlays Removal**</td>
<td>5 (3.7%)</td>
</tr>
<tr>
<td>Iritis</td>
<td>1 (0.7%)</td>
</tr>
</tbody>
</table>

#### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral corneal defect at 1 month or later</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Corneal edema between 1 week and 1 month after surgery</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td>Central corneal haze</td>
<td>12 (8.9%)</td>
</tr>
<tr>
<td>Foreign body sensation at 1 month or later</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Pain at 1 month or later</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Severe dry eye beyond 6 months after surgery</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Herpes zoster</td>
<td>1 (0.7%)</td>
</tr>
</tbody>
</table>

**Reasons for inlay removal:** Dissatisfaction with visual outcome after 3 months postop (2), epithelial ingrowth (1), haze (1), and an individual request (1). All subjects had a BCDVA of 20/20 or better after inlay removal.

*These subjects had surgery performed using the single bend inserter, 3 months of steroids, and a flap depth of 30% or greater with a minimum target of 150 microns thick and a diameter of 8 mm or greater.
**Visual Symptoms**: Glare and Halos

**Preop (N = 135)**
- Glare: 94%
  - Absent: 94%
  - Mild: 3%
  - Moderate: 3%
  - Severe: 3%

**Month 24 (N = 128)**
- Glare: 70%
  - Absent: 70%
  - Mild: 30%

**Halos**
- Absent: 97%
  - Mild: 3%

*These subjects had surgery performed using the single bend inserter, 3 months of steroids, and a flap depth of 30% or greater with a minimum target of 150 microns thick and a diameter of 8 mm or greater.*
Ocular Symptoms*: Dry Eye

**Preop (N = 135)**
- 87% Absent
- 13% Mild

**Month 24 (N = 128)**
- 61% Absent
- 35% Mild
- 4% Severe

*These subjects had surgery performed using the single bend inserter, 3 months of steroids, and a flap depth of 30% or greater with a minimum target of 150 microns thick and a diameter of 8 mm or greater.
KAMRA® Inlay Design

- Inlay improves near vision by extending depth-of-focus
- Central aperture is a hole in the inlay and has no power
- Inlay provides an unobstructed pathway for focused light to reach the retina
Permeability

8,400 micro-perforations (5-11µ)

Pseudo-random pattern

Maximize nutrient flow

Minimize visual symptoms
Extended Depth-of-Focus

• The small aperture design only allows focused central light rays to reach the retina resulting in continuous functional vision without blur zones
At 12 months, patients achieved up to 2.75 diopters of functional depth-of-focus.
Depth-of-Focus Pre-op and Post-op

Pre-op

0.25D of depth of focus

Several Months Post-op

2.50D of depth of focus

AcuTarget HD™ Instrument
**Surgical Procedure**

- **Description:** The recommended procedure is creating a femtosecond laser created pocket in the stroma at a depth of 200-250μm with spot/line setting of ≤ 6x6 or equivalent and implanting the KAMRA inlay.

![Pocket Emmetropic KAMRA (PEK) Diagram]

- **Pocket:** 200-250μm
- **Epithelium**
- **Endothelium**
US IDE - Study Design

• 24 Sites (US, Europe & Asia-Pacific)
• Prospective, non-randomized clinical trial
• Subjects:
  – 507 enrolled and implanted in non-dominant eye
  – Naturally occurring presbyopic emmetropes
  – 45 - 60 years old
  – Spherical equivalent between + 0.50 D to -0.75 D
  – Uncorrected Near VA
    • Worse than 20/40 (0.5), and
    • Better than 20/100 (0.2)
  – Best Corrected Distance VA ≥ 20/20 (1.0) in both eyes
Distance, Intermediate, and Near Visual Acuities: Implanted Eyes

- An average 3 line gain at 12 months was achieved and sustained over the duration of the study
- Achieved results remain stable over the 36 month follow-up
Uncorrected Visual Acuity in the KAMRA® Inlay Eye

• Change between Pre-Op and 36 Months:
  – Mean UCNVA improved 5 lines from J8 to J2
  – Mean UCDVA reduction from 20/18.5 to 20/20
  – Mean MRSE changed from 0.02 + 0.28 D to 0.14 + 0.72 D

*N=153 at 36 months, ≤6x6 group, data on file at AcuFocus™*
Long-Term Results:

Uncorrected Near VA at 5 Years

- UCNVA improved from a mean of J8 to J2 in the inlay eye (IE) between preop and 1 month. This result is maintained out to 5 years.
- Vision in the inlay eye and with both eyes (OU) is unaffected by the progression of presbyopia.
- UCNVA in the untreated other eye (OE) shows an mean loss of 1 line over the same time period.

[Graph showing UCNVA over time]

*Data courtesy of Günther Grabner, MD*
Questions