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CONTOURA® VISION

# Understanding the Concept of Topography-Guided LASIK and the Refractive Postoperative Patient*

Overview for Referring Optometrists and Staff

## LASIK – Laser in situ Keratomileusis

- First LASIK was performed 25 year ago; more than 16 million cases performed to date
- One of the most common surgical procedures performed, also one of the most successful with 2% growth per year; 2nd only to Cataract Surgery at 4-5% growth per year
- Outcome: 90.8% 20/20 or better; 99.5% 20/40 or better–Uncorrected Distance Visual Acuity(UDVA)
  - Largest collection of global samplings of published outcomes; landmark study*

*JCRS 2016.07.017 Sandoval et al

## LASIK – Wavefront vs Topography

- Wavefront-optimized or - guided (2nd Generation LASIK)
  - Designed to limit the induction of positive spherical aberration *without* specifically targeting the preexisting patterns of Higher Order Aberrations (HOAs)
  - Treatment of periphery with greater pulses than to center
  - Maintains prolate shape of cornea.
- Topography-guided (3rd Generation LASIK)
  - Designed to treat spherocylindric refractive errors ( ie lower – order aberrations(LOAs)) *PLUS* the irregularities of the corneal elevation (HOAs) to reshape cornea into ideal curve and achieve planar wavefront cornea
  - DOES NOT attempt to correct aberrations from the crystalline lens or other ocular structures like wavefront-optimized or - guided profiles

## LASIK – Laser in situ Keratomileusis

- ***So Why Topography-Guided LASIK?***
- *Better Outcomes* - associated with full line better of UDVA than conventional LASIK
  - Is surpassing wavefront-guided /wavefront-optimized
- *Safety and effectiveness* – overall rate of loss of 2 or more lines of corrected distance visual acuity(CDVA) was <1% (0.61%) with conventional LASIK
  - Loss of CDVA: Hyperopia (5.00D) and Astigmatism (1 to 4D)
  - Overall rate of loss of CDVA less with Topography-guided ablation… eye tracking, astigmatic alignment, nomograms incorporating personalized (corneal) measurements….

## LASIK – Laser in situ Keratomileusis

- ***So Why Topography-Guided LASIK?***
- Secondary goal to be able to retreat those patients:
  - with less than satisfactory refractive surgery outcomes
  - complicated cornea surface whether postsurgical corneal transplants (DALK … Deep Anterior Lamellar Keratoplasty) or patients with irregular astigmatism (eg. Cross linked patients, CXL)
  - bioptics – pseudophakic patients with "upgraded" Intraocular Lenses (Toric, Presbyopic…) who need "fine tuning" with LASIK

## LASIK – Laser in situ Keratomileusis

- Topography-guided LASIK Benefits…
  - *better outcomes* because
    - better contrast sensitivity
    - lower induction of Higher Order Aberrations (HOAs), and
    - smaller amount of tissue ablation
  - important in treating subset of postop LASIK patients who may be dissatisfied because of side effects: glare, halos, starbursts, and reduced contrast sensitivity.
  - Custom personalized profiles developed to overcome undesirable postop symptoms in addition to treatment of refractive error

*JCRS 2016.06.035 Jain et. Al.

## Contoura® Vision LASIK Patient Inclusion Criteria

- For the reduction or elimination of up to -9.00 D of spherical equivalent myopia or myopia with astigmatism, with up to -8.00 D of spherical component and up to -3.00 D of astigmatic component at the spectacle plane
- In patients age 18+ and documented stable manifest refraction (0.5 D or less of preoperative spherical equivalent shift over one year prior to surgery)
- Please refer to FDA Labeling for complete list of patient contraindications

## Topography-Guided LASIK

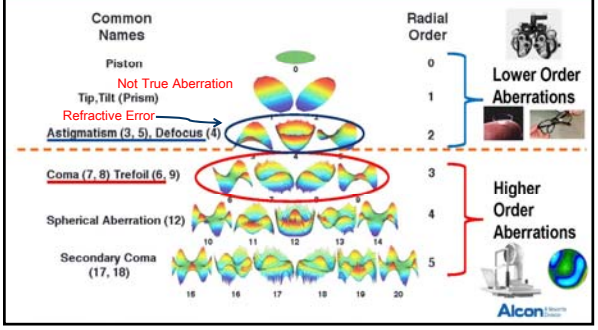
Key Points to remember:

- Topographic measurements for corneal surface can measure significant number of points, including periphery where most aberrations occur.
- Corneal topography is unaffected by pupil size, accommodative status (which itself can induce spherical refractive error and HOAs), and centroid shifts or internal optical components such as lens changes unlike wavefront guided LASIK
- Topographic algorithms must be combined with measurements obtained from manifest refractions unlike wavefront analyzers

## What and How data is obtained for Contoura® Vision Surgery

- Using the placido-disk based topographer, Topolyzer VARIO, a series of consistent and reproducible maps are obtained that provide accurate height data of the irregularities of the anterior cornea
  - The data can be directly input into the laser for calculation in the patient's treatment plan
- 22,000 data points are captured on the surface of the cornea, as compared to the one data point with manifest refraction
- Limiting factors in accurate capture are tear film and exposure of the ocular surface to be measured but is only an issue in a small minority of patients

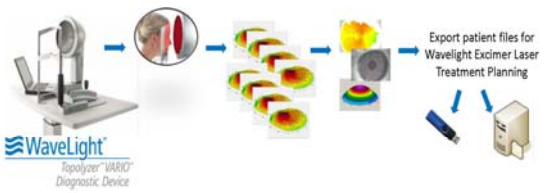
## Zernike Pyramid




## Contoura® Vision

*Topography Guided LASIK OVERVIEW*

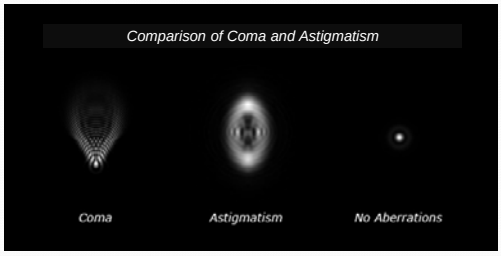
CONTOURA® VISION



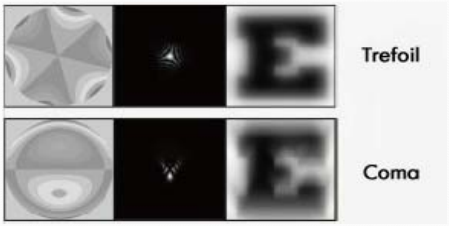

## What irregularities are measured by the VARIO?

- The irregularities (**Higher Order Aberrations**) that are measured can have a great effect on your patient's vision but are not captured in the manifest (**subjective**) refraction of the virgin eye
  - The most common Higher Order Aberrations that affect Lower Order Cylinder are:
    - **Coma** (light is entering a pupil that is off-axis as it traverses in and is very detrimental to the patient's vision – causing a comet-like tail on lights)
      - This aberration can also make the manifest refraction challenging when trying to accurately acquire the cylindrical component
    - **Trefoil** (light is scattered by a tri-lobed elevation typically in the periphery that induces glare and halo)

HOA of Coma and and LOA of Astigmatism

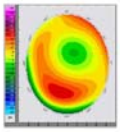



HOA of Trefoil vs Coma

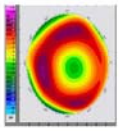



## Aberrations that impact 2nd Order Astigmatism

- Coma (3rd Order)
  - Has an axis and is centrally located on the cornea
  - Patients with coma often manifest a different cylinder in the phoropter to compensate



- Trefoil (3rd Order)
  - Is located peripherally on the cornea
  - Can affect coma
  - Patients with trefoil often see glare and halo around lights especially at night



## LASIK – Laser in situ Keratomileusis

- Contrast Sensitivity
  - sensitive performance index of the functional quality of vision after refractive surgery, assesses effect of
    - light scattering
    - optical aberrations
    - defocus
- Induced changes in contrast sensitivity function correlates with increases in HOAs (Coma, Trefoid, and to some extent Spherical aberration) which are directly related to increased amounts of tissue ablation.
- Topography-guided LASIK achieving better contrast sensitivity through mechanism of decreasing HOAs and tissue ablation

*JCRS 2016.06.035 Jain et. Al.

## LASIK – Laser in situ Keratomileusis

- LESS corneal ablation (~ 20microns vs wavefront) can save tissue
  - increase the candidates for LASIK
  - magnitude of correctable refractive error
- Removal of less tissue achieves more prolate shape of cornea
- Treatment is centered on corneal apex rather than pupil center and hence addresses angle kappa issues(decentration of ablation).

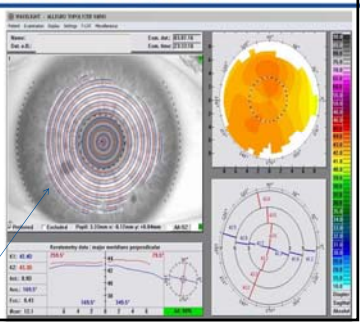
*JCRS 2016.06.035 Jain et. Al.

## What other information does the VARIO provide?

- True keratometry at 3mm
- Accurate corneal astigmatism
- Pupil and corneal diameters
- Pupil location, shape and location of corneal vertex
- Diagram of regularity/irregularity of corneal astigmatism

*The VARIO does not measure the posterior surface of the cornea and cannot provide pachymetry measurements of the cornea.*

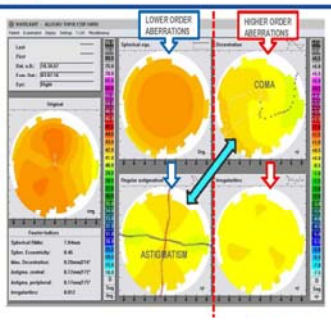
*Scheimpflug vs Placido*



## Fourier display of the Topolyzer VARIO

FOURIER Display is quite helpful in analyzing the eye

- Separates an individual map into 4 parts - LOA (2 maps on left) to HOA (2 maps on right)
- The interaction of Coma (upper right...aka. Decentration) and Regular Astigmatism (lower left) will help explain why the VARIO measured Astigmatism varies from phoropter derived Manifest
  - May add to the magnitude of manifest astigmatism
  - May counteract the magnitude of manifest astigmatism
  - Axis will commonly differ from the manifest astigmatism




## Why do these Higher Order Aberrations matter?

- Traditionally – the manifest (subjective) refraction has driven the ablation for LASIK surgery patients
- With Contoura™ Vision – a more physiologic approach may be best for your patient, meaning that the laser will be driven by the manifest refraction in combination with height data of aberrations that can affect the magnitude and axis of astigmatism as measured in the phoropter


## Clinically, what does Contoura® Vision offer your patients?

- The ability to provide treatments in increments less than 0.25D
- A treatment that both maintains asphericity while providing a normalized cornea
- Correction of both lower and higher order aberrations on the cornea from an accurate measurement taken from the highest refractive power of the eye
- Some patients achieve improvement of contrast and visual acuity beyond 20/20
- Reduction of common postoperative symptoms associated with LASIK surgery[1]

[1]Stulting RD, Farid BS; T-CAT Study Group. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. J Cataract Refract Surg. 2016;42(1):11-18. Study description: Prospective, nonrandomized, multicenter study of 249 eyes with myopia (up to -8D) or myopic astigmatism of 6.0 D or less. Outcome measures included manifest refraction, UCVA, CDVA and visual

## What could be expected postoperatively from Contoura® Vision

- Upon chart review, it is to be expected that the manifest refraction may not be directly input into the laser (as was common in the past). If aberrations exist on the cornea that could adversely affect the subjective manifest refraction, these are taken into account with Topography-Guided Ablations.
- Typically analyze at 3 months for best postoperative data
- Study data shows at 12 months, a decrease in....
  - Complaints of glare
  - Light sensitivity
  - Difficulty driving at night
  - Reading difficulty
- Patient satisfaction rates higher than LASIK studies of the past
  - 98.4% of patients said they would have it again!
- Improved sharpness and clarity (contrast sensitivity) of the patient

## Contoura® Vision Sets a New Standard in LASIK Outcomes

*It redefined Quantity of Vision*[1]

| | | | |
|---|---|---|---|
| 20/12.5 | UCVA | 34.4% | of all eyes in the study[1] |
| 20/16 | UCVA | 64.8% | |
| 20/20 | UCVA | 92.6% | |
| +1 line | BSCVA | 40.4% | |

**Post-op symptoms at 12 months**[2]

| | |
|---|---|
| Light sensitivity | 5.2% decrease |
| Difficulty driving at night | 8.0% decrease |
| Reading difficulty | 8.7% decrease |
| Complaints of glare | 4.8% decrease |
| Halos | 3.2% decrease |
| Starbursts | 2.8% decrease |

Remember First Slide 90.8% > 20/20 with First Generation Conventional LASIK, incremental but important especially including reduction of PostOp Symptoms.

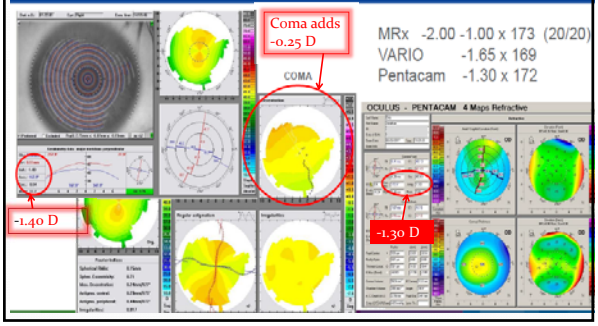
*Improved symptoms typically associated with LASIK*[1]

[1]Stulting RD, Farid BS; T-CAT Study Group. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. J Cataract Refract Surg. 2016;42(1):11-18. Study description: Prospective, nonrandomized, multicenter study of 249 eyes with myopia (up to -8D) or myopic astigmatism of 6.0 D or less. Outcome measures included manifest refraction, UCVA, CDVA and visual symptoms up to 12 months.

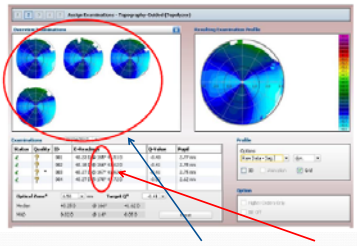
## Contoura® Vision Sets a New Standard in LASIK Outcomes

## Case Study Example

## Case Study – 36 yr old male
## VARIO Measured Cylinder Higher than Manifest Cylinder




## Planning Treatment at EX500



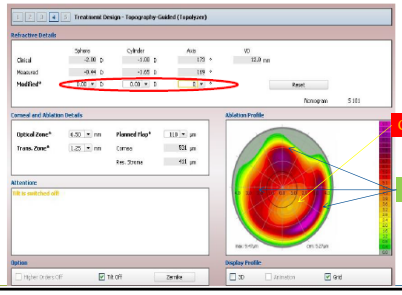
Raw Data Sagittal View of Measurement Maps

- Allows best view of central cornea
- Do quick review for consistency
- Do quick review of axis consistency
- Go forward >>>>>

Best Quality Scans then Axis : 169° Manifest Astigmatism: 173 °

## 36 yr male – OD - Planning

Zero Out Modified Refraction
- Allows view of HOA measured by VARIO and added to the Treatment

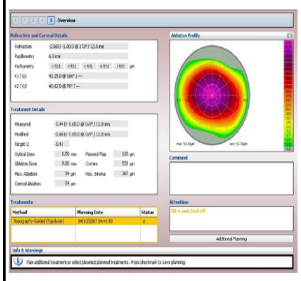



## Planning Surgery OD – 36 yr male

| | | Sphere | Cylinder | Axis |
|---|---|---|---|---|
| Non-nomogram adjusted Manifest Refraction | Clinical | -2.00 D | -1.00 D | 173 ° |
| | Measured | -0.44 D | -1.65 D | 169 ° |
| Actual EX500 Laser Treatment | Modified* | -1.68 | -1.65 | 169 ° |

- Achieve SEQ equality between Clinical and Modified Rx
  - Take half of the difference in the Manifest and Measured Cylinders
    **1.65 – 1.00 = 0.65** **0.65 ÷ 2 = 0.325**
  - In this case – subtract it from the Sphere to achieve SEQ balance
    **2.00 – 0.32 = 1.68** - the new sphere is -1.68
- Use the Cylinder and Axis of the measured Rx from VARIO

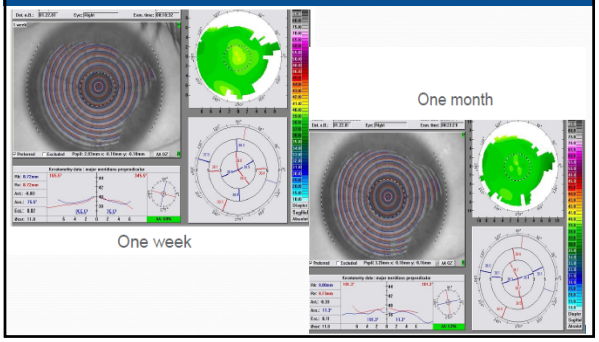
## Treatment OD – 36 yr male



MRx -2.00 -1.00 x 173°
Treatment -1.68 -1.65 x 169°

- 1 day Post-op 20/25
- 1 week Post-op 20/20
- 1 month Post-op 20/15
- 2 month Post-op 20/15+

## Postop Progress




Thank You.....