

Utilizing the latest Refractive Technologies in Classic LASIK



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www.brilliantvision.com



My Background

- Harvard Medical School-Cornea Fellow
- Cornell University-Cornea Fellow
- Medical Director- TLC Laser Eye Centers
- Director of Refractive Surgery, NYU Medical School, NY
- Laservision.gr Eye Institute, Athens, Greece
- Over 11000 Lasik procedures

Experience-Excimer Lasers

- Summit- Apex plus
- VISX-S2 and S3
- Lasersight
- Nidek
- Alcon-Ladarvision
- B&L: Technolas 217
- Wavelight: Allegretto-Wave

Key specifications that are important for the clinician:



- - the frequency of the flying spot treatment is 200 Hz
- - the spot size is 0.9 mm;
- - its active eye-tracking system involves an infrared camera and three individual illumination modules to sense the eye movement (by fixing on the pupillary reflex) with a detection frequency of 250 Hz and a reaction time 6 to 8 msec
- Maintenance issues

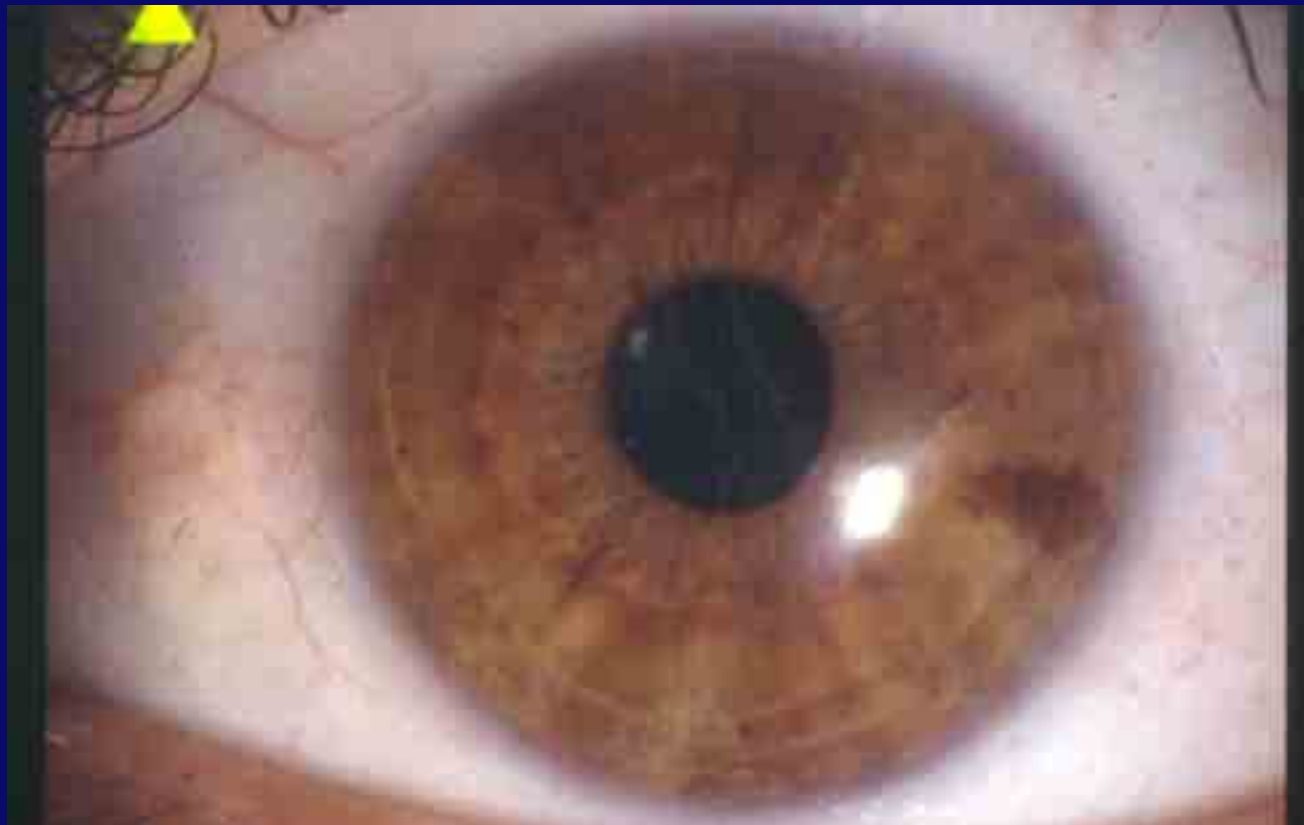
Experience-Microkeratomes

- B&L: ACS
- B&L: Hansatome
- Alcon:SKBM
- Moria:LSK
- Allergan: Amadeus
- Moria: One use
- Moria: M2 and M2 single use

Ideal MK specs:

- Good suction
- Smooth cut
- Reproducible flap size and thickness
- Low abrasion rate
- “Comfortable” for the pt
- Able to address extreme K’s

One of the initial LASIK cases,
1993



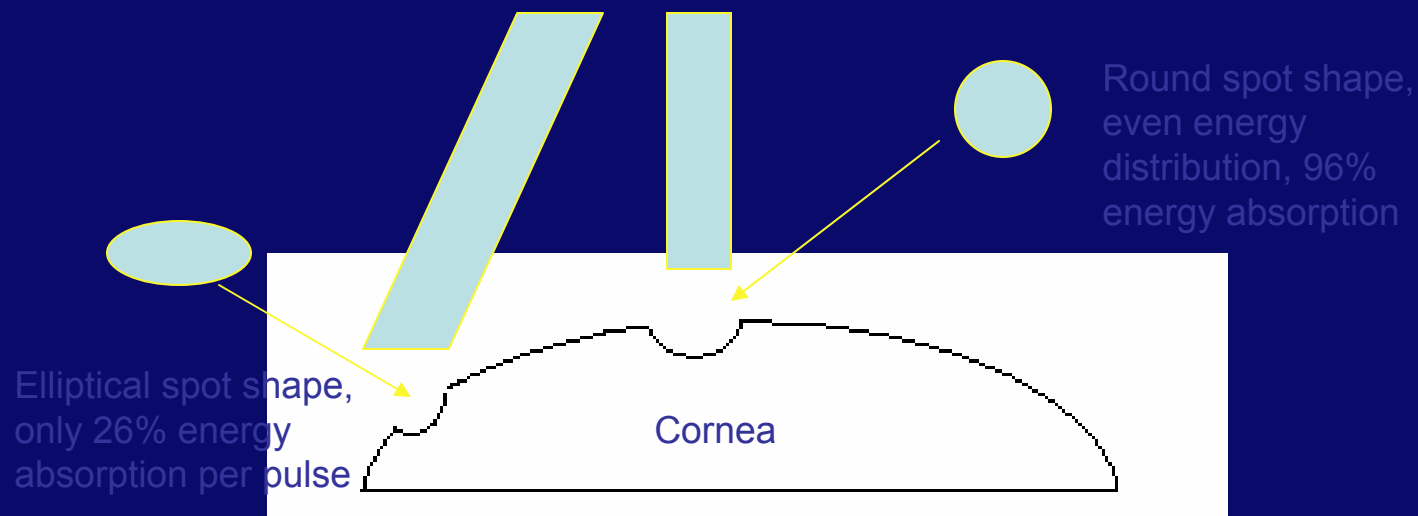
Common problem with standard LASIK:

“goasting”

(large pupils, de-centered/small diameter ablations
etc)



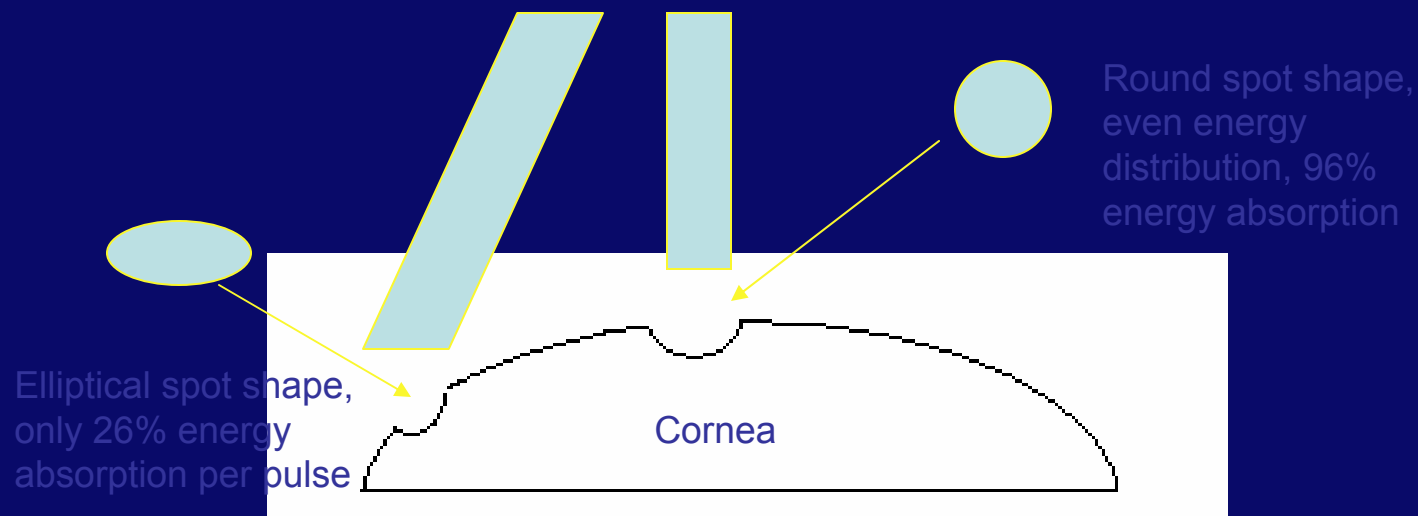
Effects of Corneal Curvature on Ablation Profile



The ALLEGRETTO Wave compensates for the reduced energy absorption in the periphery with more spots!

Result: True, large optical zone and ability to create prolate cornea shape.

Effects of Corneal Curvature on Ablation Profile

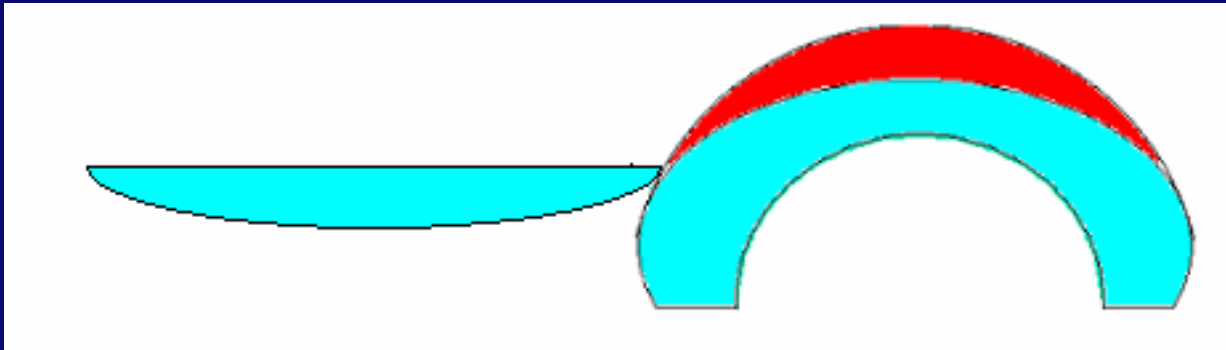


The ALLEGRETTO Wave compensates for the reduced energy absorption in the periphery with more spots!

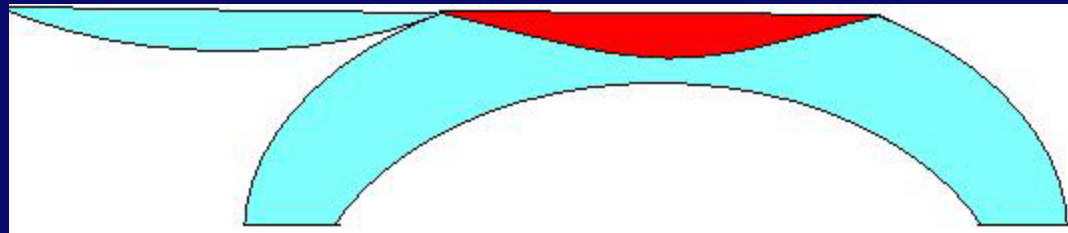
Result: True, large optical zone and ability to create prolate cornea shape.

Prolate Ablation

Prolate Cornea Shape



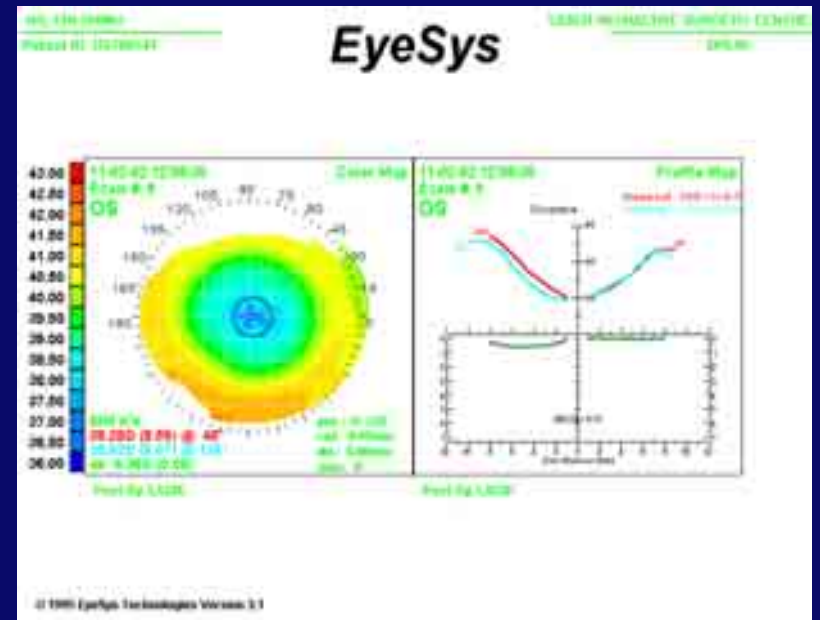
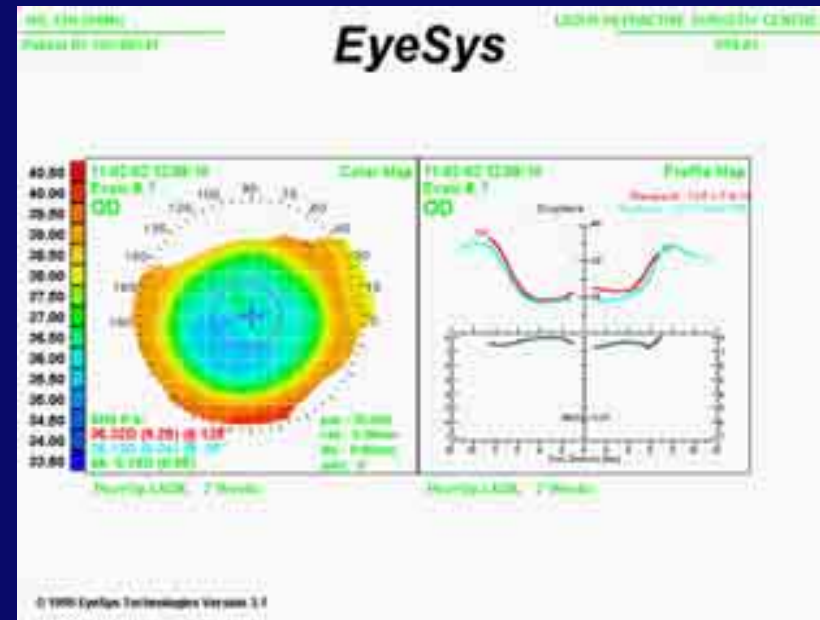
Prolate Cornea Shape with the ALLEGRETTO Wave



Oblate cornea shape with other refractive laser systems

-7D myopia corrected in same pt

- One eye (top) with the Allegretto-Wave
- The other eye (bottom) with the Technolas 217z



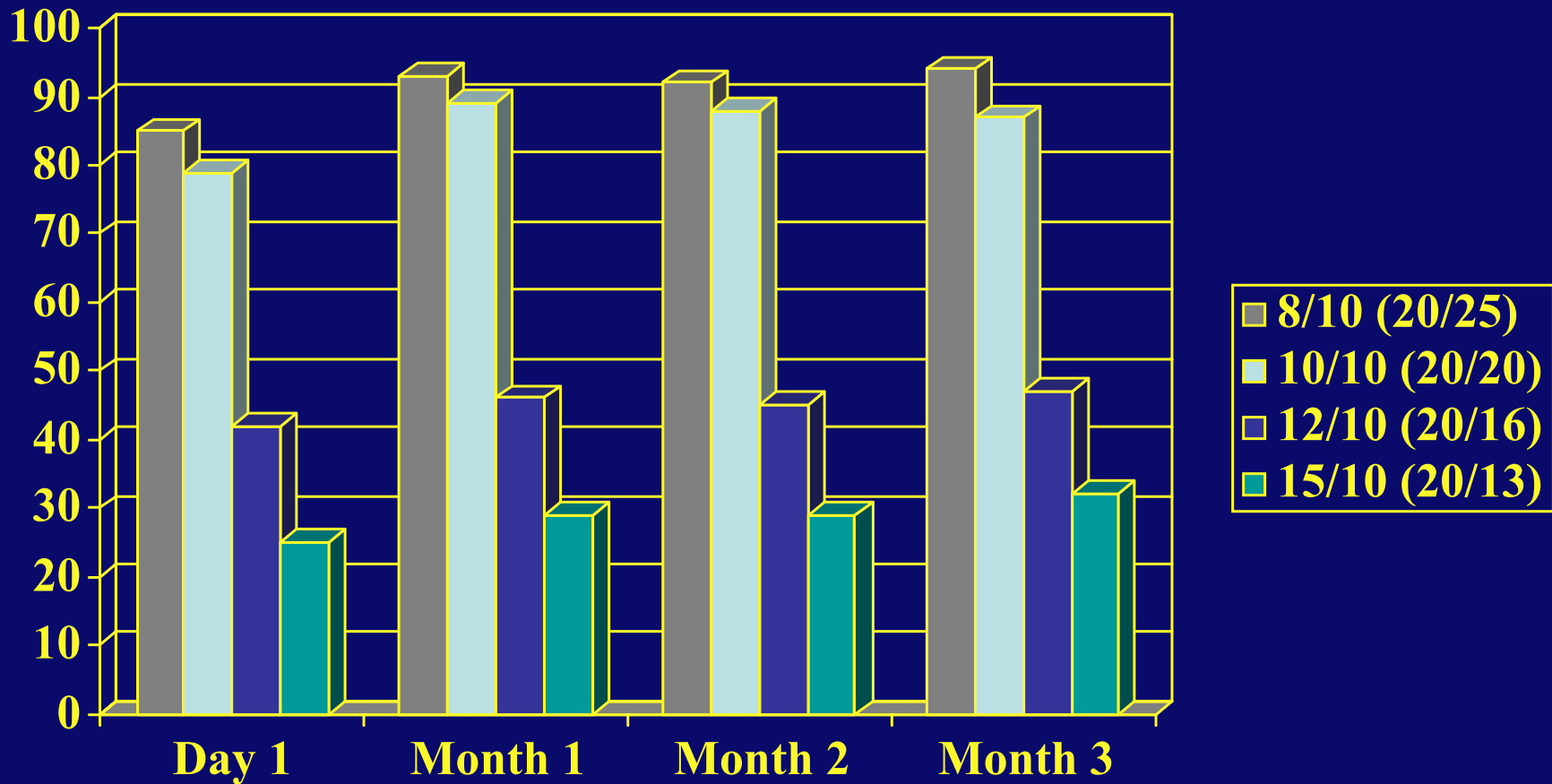
QuickTime™ and a DV/DVCPRO - NTSC decompressor are needed to see this picture.

Results Initial classic LASIK 520 cases:

(presented originally at the winter ESCRS meeting in Barcelona, Spain 2.2002)

- Mean values: The mean pre-operative sphere was -4.75 D (-1.00 to -12.50) and the cylinder -1.25 (-0.25 to -3.75)
- UCVA improved from 20/200 to 20/25. At 3 months 87% of the eyes were 20/20, 47% 20/15 and 32% 20/10. 100% of eye were within +/- 1D at 3 months.

Results-stability

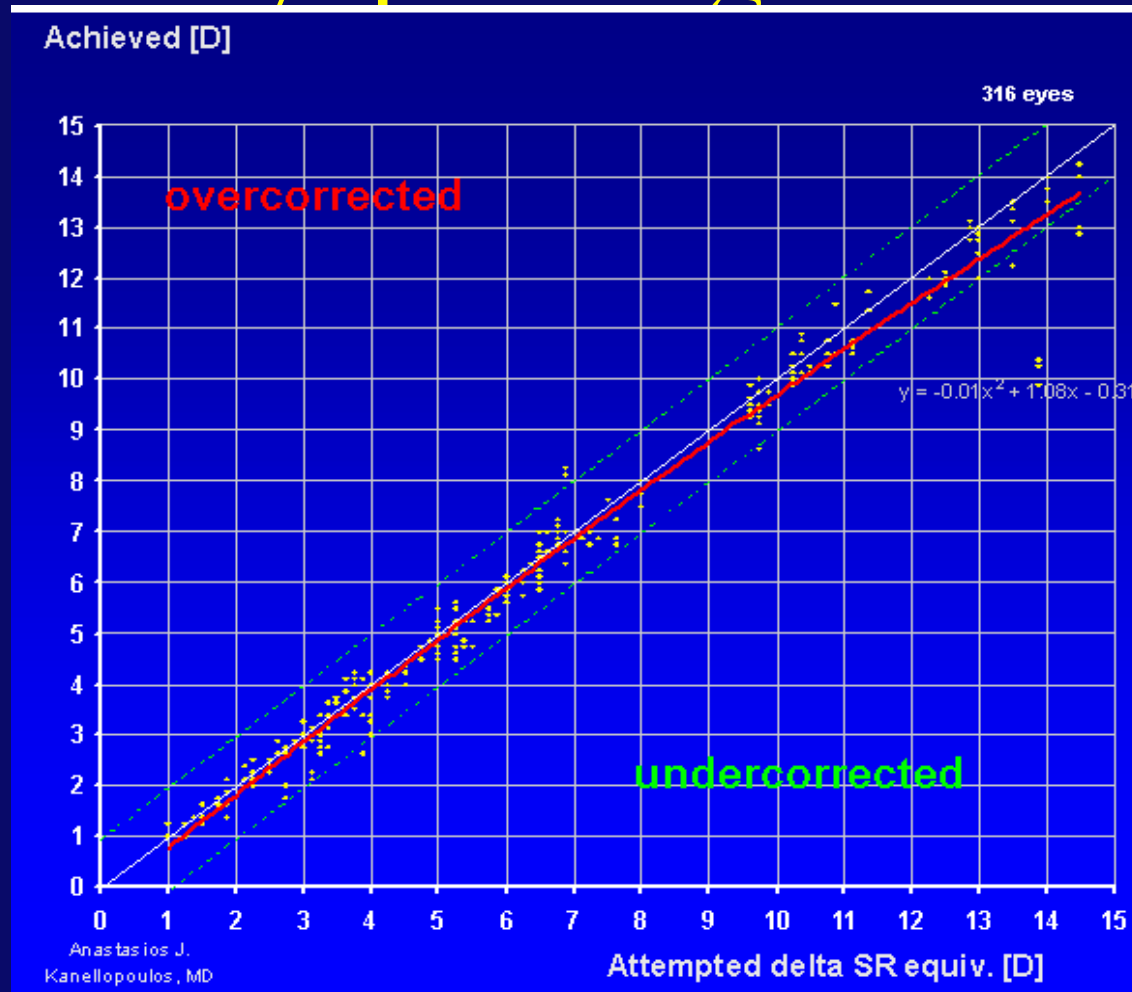


Results:

“standard”-prolate LASIK

- Wavefront analysis showed a postoperative increase in coma of only 35% (mean coma of 6% pre-op to 9% post-op)
- 37% of eyes gained at least 1 line of BCVA
- No complications were noted in this limited group

Results in 520 consecutive cases myopic astigmatism



Hyperopic LASIK with the Allegretto-Wave and the M2

AAO 2003



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Clinical Associate Professor NYU, New York



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The author(s) acknowledge no financial interest in the subject matter of this presentation.



Purpose of Study

- To evaluate the safety, efficacy and accuracy of hyperopic LASIK
- To determine the spherical nomogram adjustment
- To evaluate the wavefront pre- and post-operatively

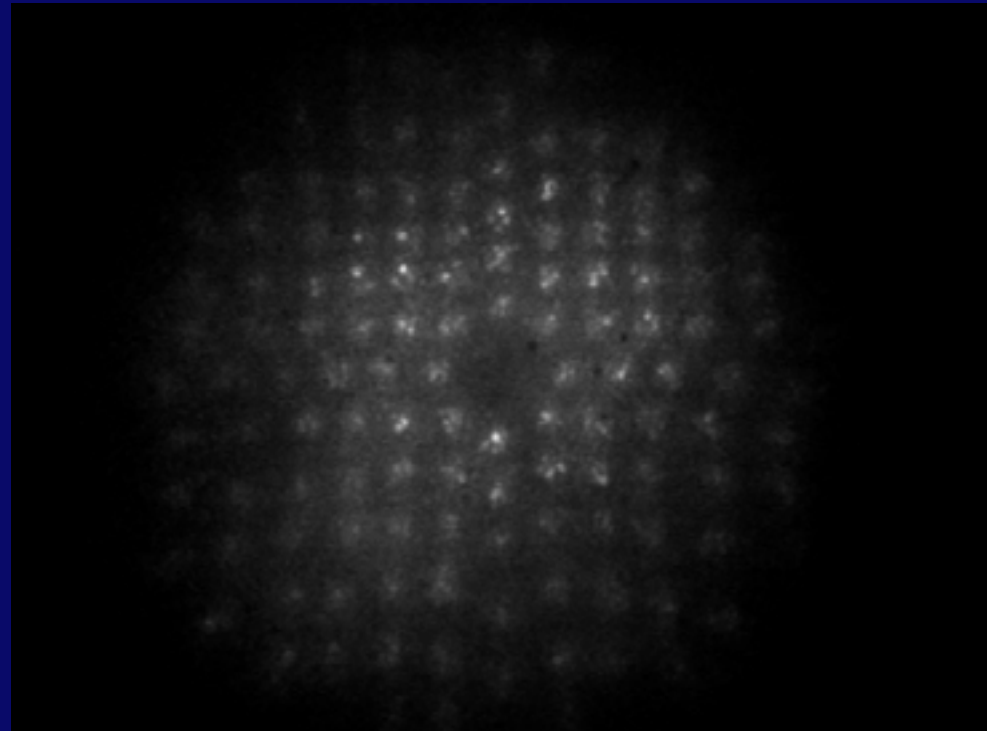
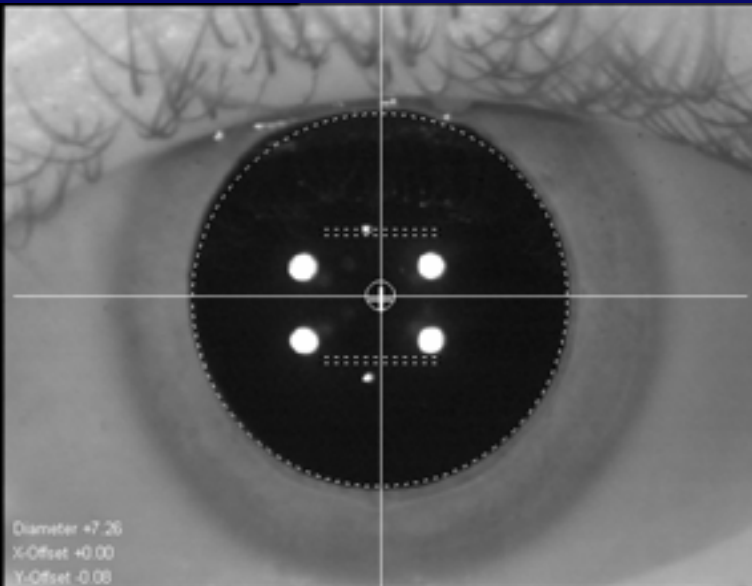


Method

- 120 consecutive eyes, underwent LASIK for hyperopia or hyperopic astigmatism OZ: 6.5-9.
- We evaluated pre- and post-operatively: refractive error, UCVA and BCVA,
- high order aberrations at pre-op, 1 month, 3 months, 6 months and 1 year.
- These data are standard, non-wavefront guided treatments.

Method

- WaveFront evaluated prior to surgery
- Dilated pupil to 7mm (not cycloplegic, 1 drop Mydriacyl 1%)
- Pre-op, Day 1, Week 1, month 1 and Month 3 Data



Results:

- **Results:** Mean values: The pre-op sphere was + 2.25 D (+1.00 to +6.50) and the cylinder -1.25 (0 to -3.75)
- UCVA improved from 20/100 to 20/25.
- At 6 months 88% of the eyes were 20/20, 17% 20/15. 100% of eye were within +/- 0.75D of the refractive goal at 6 months. and 1 year

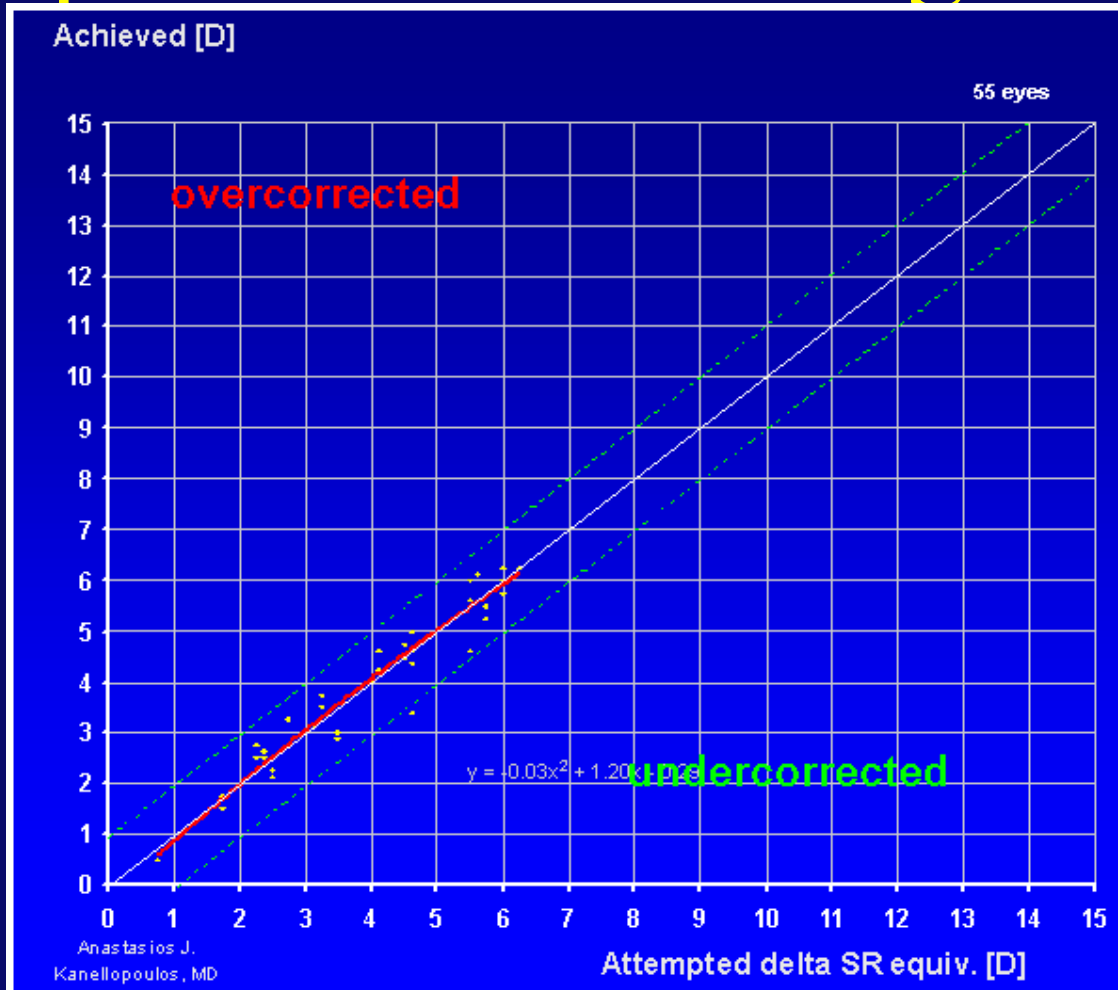
Results:

- RMSH increased by 45%. 47% of eyes gained at least 1 line of BCVA.
- No complications were noted in this limited group.
- There was a mean +0.32 regression in the spherical correction noted between the 1st month

Results at 12 months

120 consecutive cases

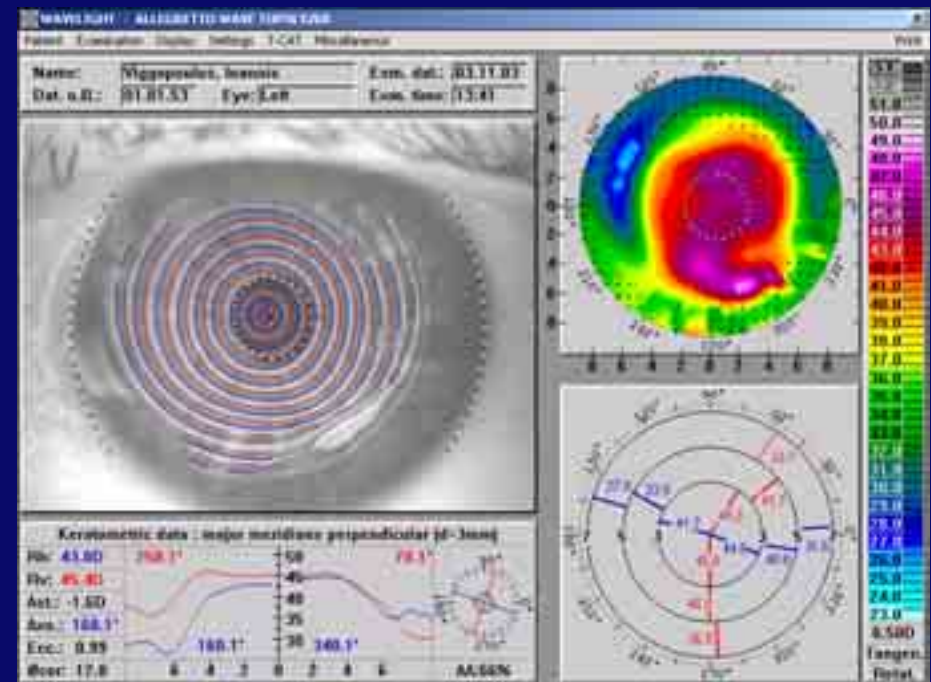
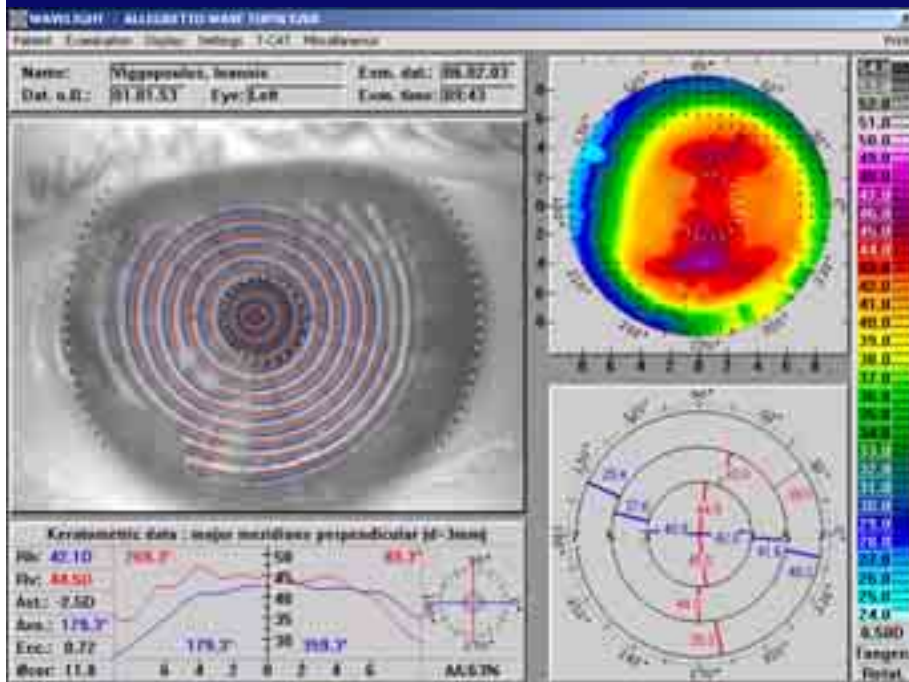
hyperopia and mixed astigmatism



Results: Safety 12 months

QuickTime™ and a TIFF (Uncompressed) decompressor are needed to see this picture.

Case example: +3.50 -3.00 180



Case example:

Pre-op RE:

+2.00 -6.00 x 167 and

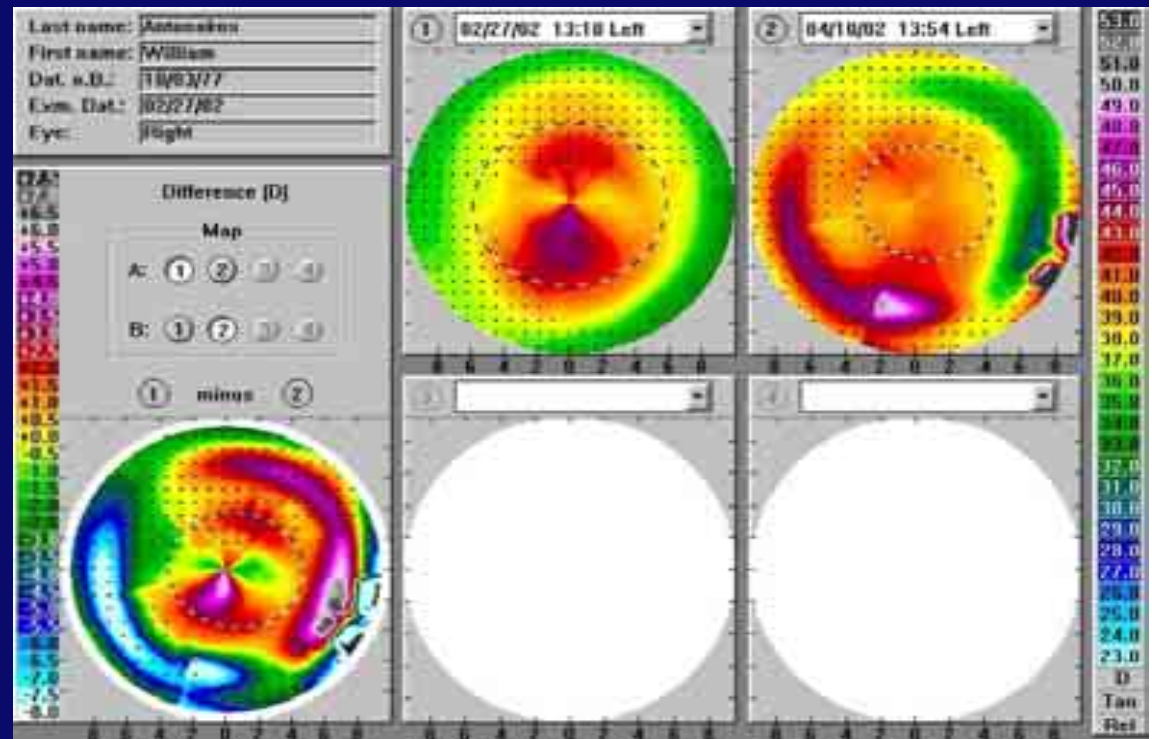
BCVA 6/10

3m post “standard”

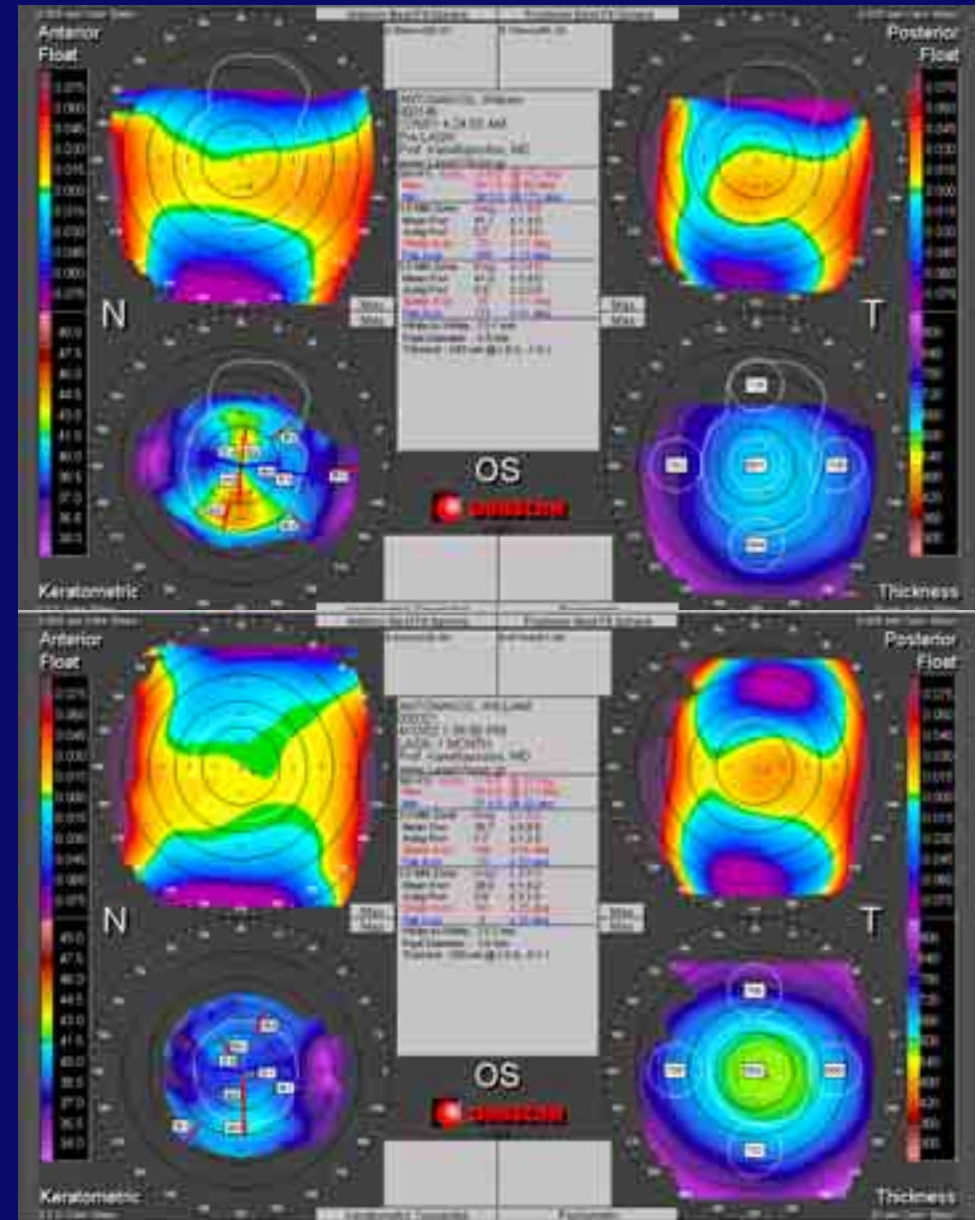
LASIK :+0.50 -0.50 x 19

UCVA 9/10

In topographic terms all of the cylinder corrected, of importance the effective ablation zone on topography is exactly the one planned with the laser: 6.5mm



Same patient:
Orbscan measurements:
pre-op above and post-
op below



Conclusion

Hyperopic LASIK utilizing the ALLEGRETTO-WAVE excimer laser and the M2 microkeratome appears to be safe and effective in the correction of hyperopia and hyperopic astigmatism.

- It has demonstrated in our clinical practice the ability to induce little higher order aberrations

Conclusion

Refraction appears to stable at 12 months

- The postoperative results at day one were very impressive, possibly deriving from the smooth ablation pattern of corneal stroma bed and/or the smooth microkeratome pass.
- Very significant improvement in BCVA postoperatively

Placement of the keratome



Folding of flap, even moisture on stromal bed

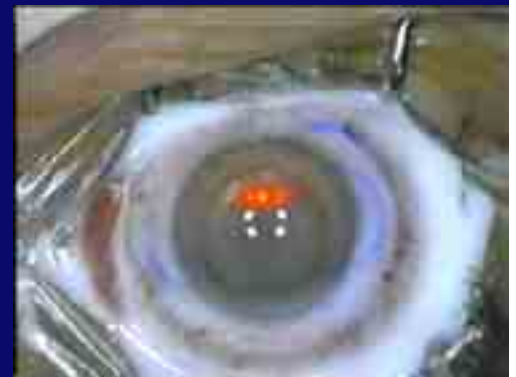


My technique

- Irrigation very important
- “Squeeze” out excess fluid and

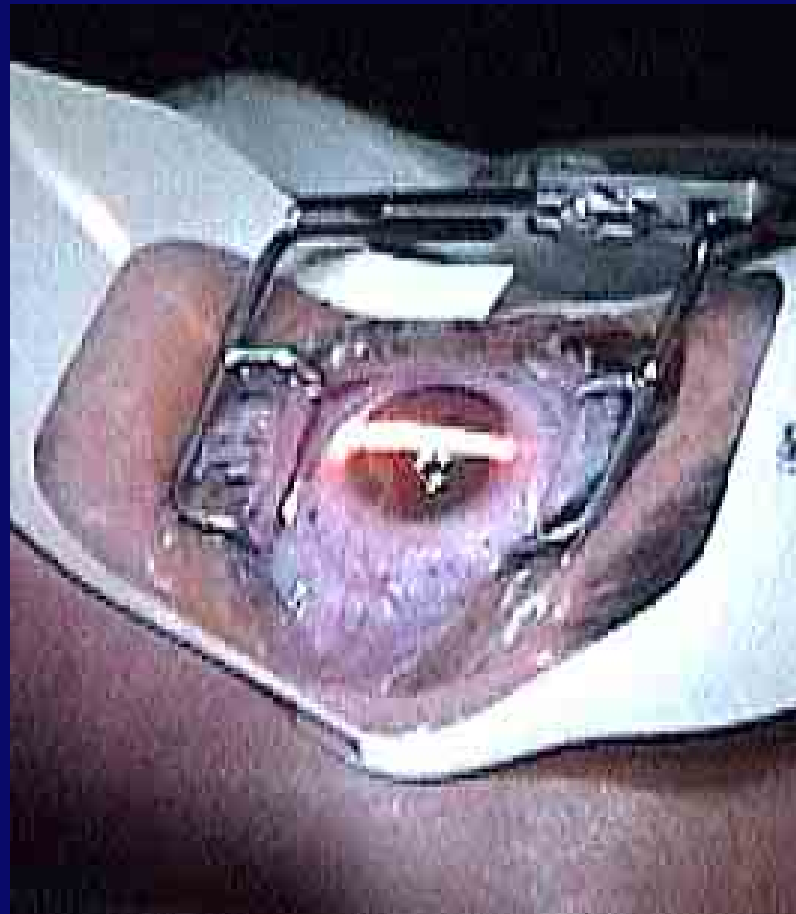
Striae with moist Weck-cell

- “milky” drop (predforte 1%) to delineate gutter width, centration and striae



2' observation interval

Flap is evaluated with build-in slit-lamp



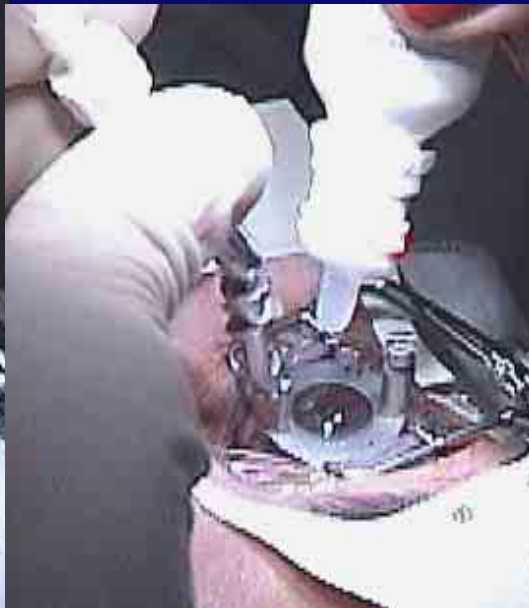
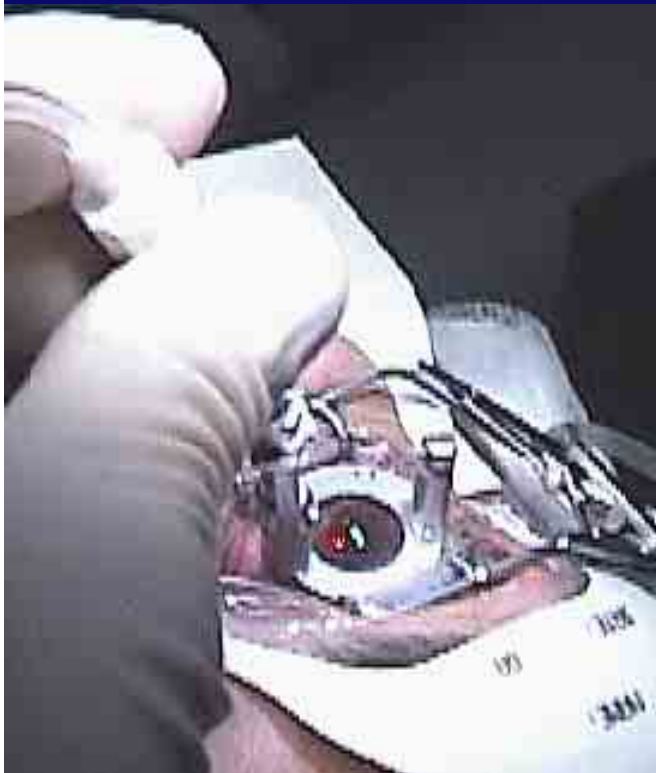
My technique

- **1 Drop of Alcaine**
- Betadine scrub and drape eyelids
- Aspirating speculum
- Lubricate blade and rotating parts with Alcaine!!!



Placement of the M2

Push down until good suction, then lift



Microkeratome pass

Observe patient anxiety and “squeeze”



My technique

- Fold flap onto itself to minimize

Dehydration and exposure
(minimal manipulation)

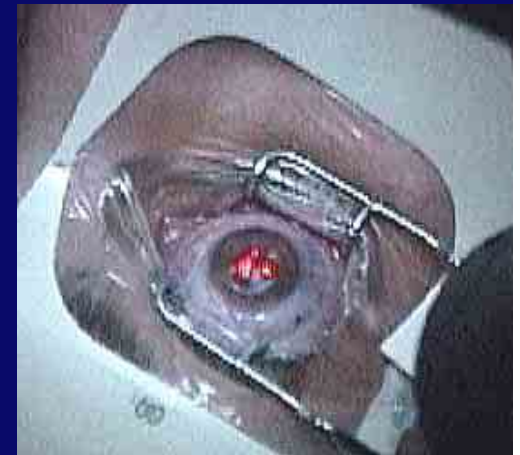
- Even bed hydration –very dry technique (hinge $\frac{1}{2}$ most moist)



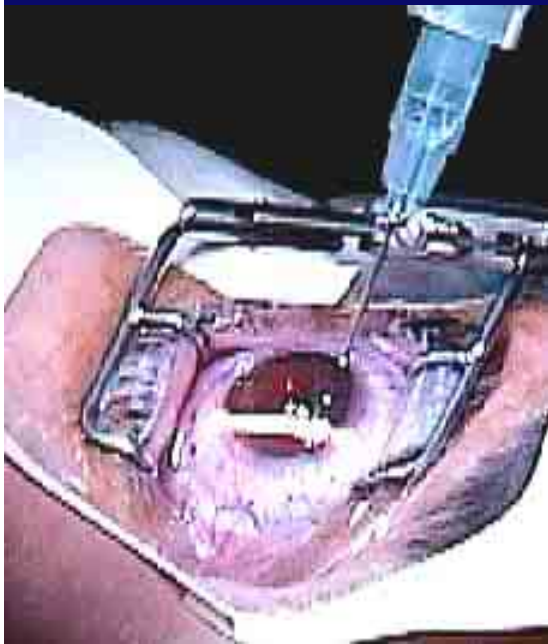
ABLATION:
Check parameters! (last
chance to avoid error)

Intraoperative moisture
eq if needed

PTK	DEPTH	DIA	WaveFront
LASIK	-2.54	-0.32	0° 6.5mm
	SPH	CYL	AXIS
Treatment active			
ArF	N2	READY	center
			E 69 V 83



Irrigation of flap and careful wipe (remove fluid from interface)

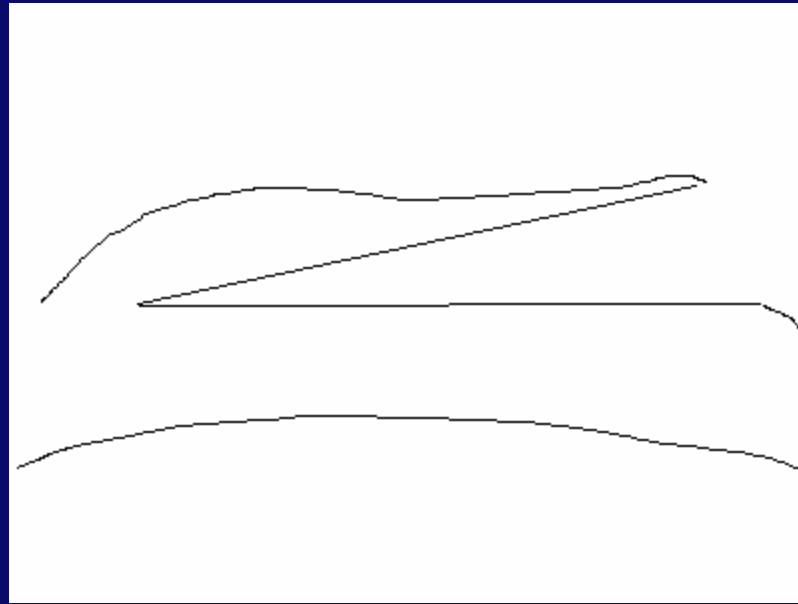


My technique

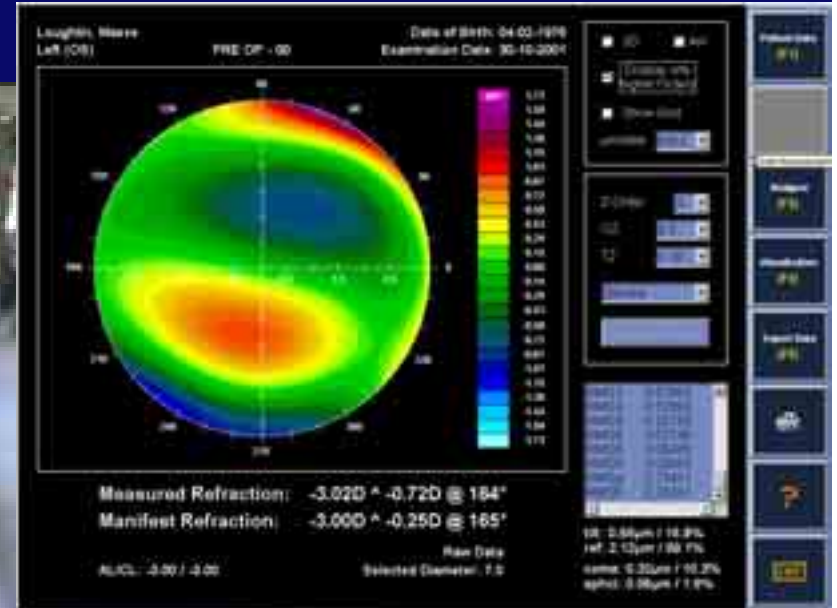
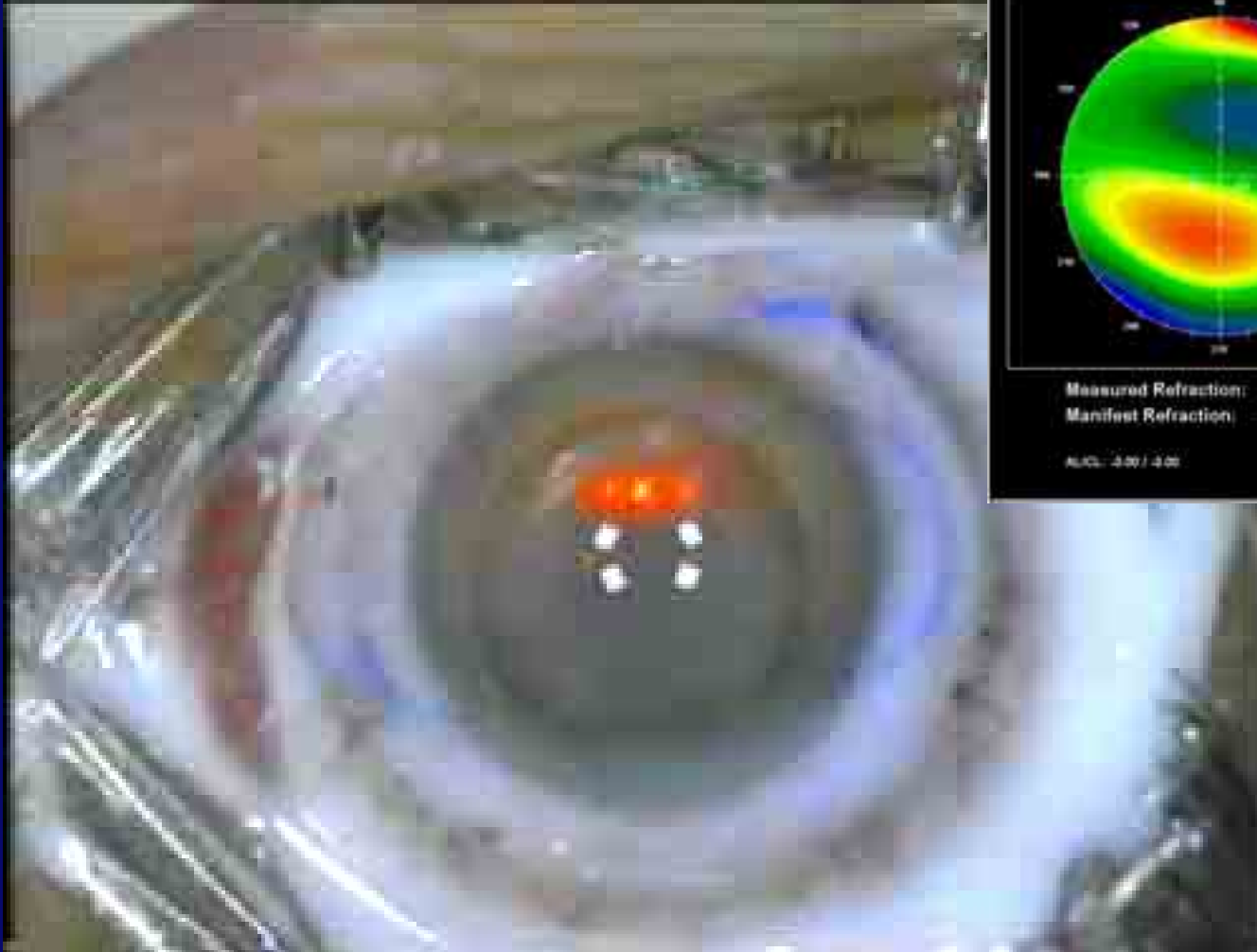
- Irrigation very important
- “Squeeze” out excess fluid and Striae with moist Weck-cell
- Suspension-opaque drop (predforte 1%) to delineate gutter width, centration and possible striae



Attempt to compensate for irregular hydration state of the flap during the procedure (excimer, procedure speed)



Is the flap back in place?



1' observation interval

Flap is evaluated with build-in slit-lamp



Why Wavefront?

- Necessary tool in today's refractive practice
- Large (usually light-colored) pupils
- High astigmatism
- Enhancements (decentrations)
- “Enhancing” monovision

Purpose of Study

- To evaluate the safety, efficacy and accuracy of wavefront-guided LASIK
- To determine the spherical nomogram adjustment
- To evaluate the wavefront pre- and post-operatively

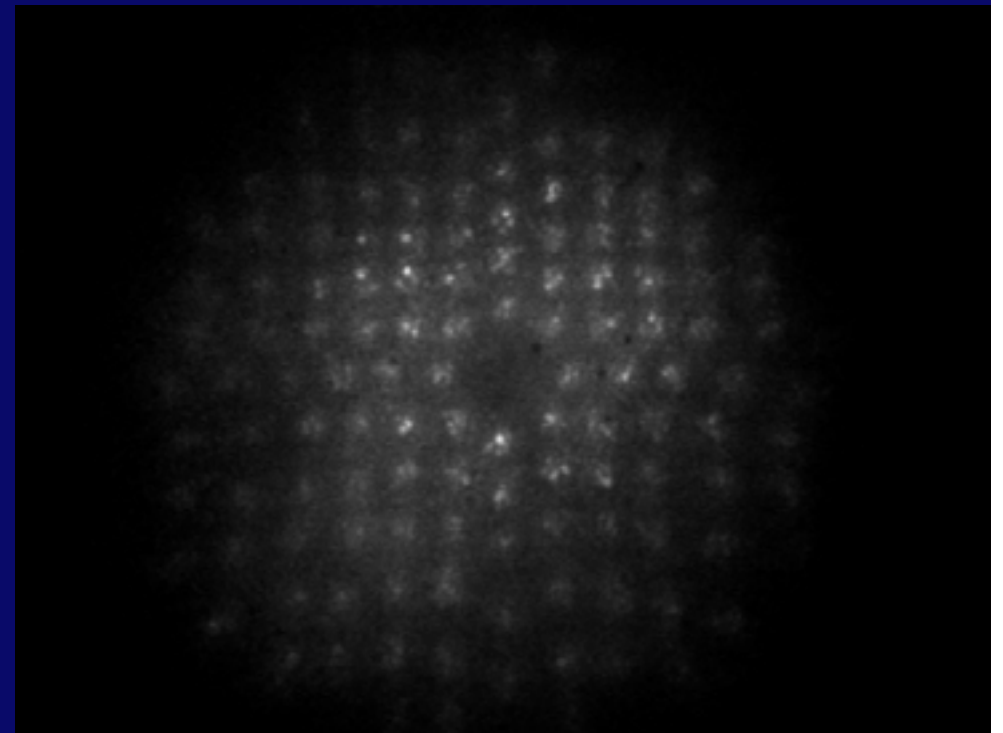
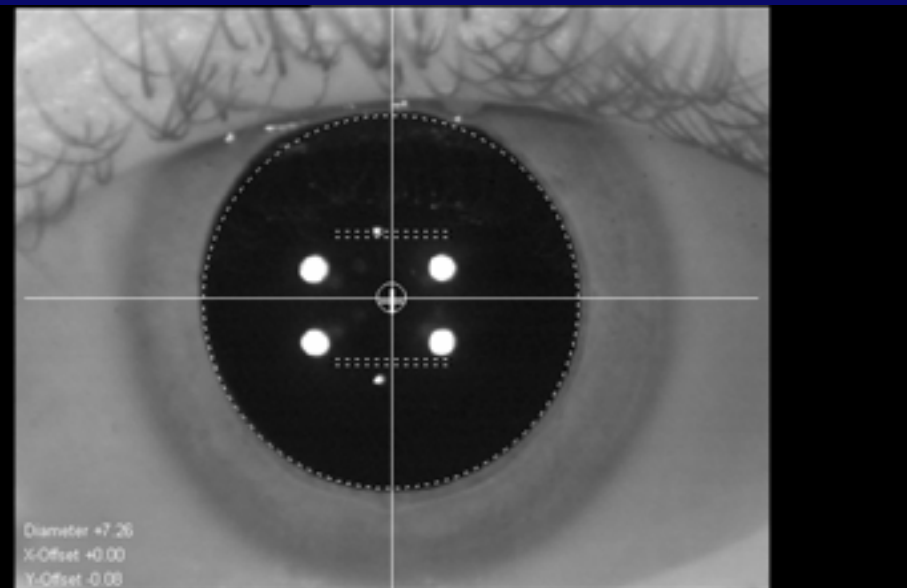


Method

- 105 consecutive cases treated
- Refractive errors: -0.52 to -6.75 D
- Average refraction: -3.80 D
- Astigmatism: 0.00 to -3.75 D
- Average astigmatism: -0.85 D
- Average age: 29.5 yrs

Method

- WaveFront evaluated prior to surgery (4 scans)
- Dilated pupil to 7mm (not cycloplegic, 1 drop Mydriacyl 1%)
- Pre-op, Day 1, Week 1, month 1 and Month 3 Data



Ten pearls in my technique

- Wavefront monitoring essential for refractive surgery
- Pt expectations
- Understand the technology (surgeon-staff)
- Aberration indices that REALLY matter
- Preoperative measurements RE
- Preoperative planning mesopic-scotopic pupil
- Preoperative wave evaluation #, quality
- Wavefront-guided OZ
- Preoperative LASIK planning
- Consistent flap, tracker, excimer energy

Conclusion

- WaveFront-guided LASIK with the ALLEGRETTO-WAVE (a 0.9mm flying-spot and 200Hz) and the M2 appears to be safe and very effective for correction of myopic astigmatism
- It has demonstrated in our clinical practice the ability to significantly reduce higher order aberrations

Conclusion

- Improving the quality of vision (Contrast sensitivity)
- The postoperative results at day one were very impressive, possibly deriving from the smooth ablation pattern of corneal stroma bed and/or the smooth microkeratome pass.
- Very significant improvement in BCVA postoperatively

Wavefront-guided retreat in symptomatic LASIK

eyes

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Co-workers

- John Agapitos, OD
- Mary Chalikia, OD
- Marianthi Chriridou, O.D.

- Part of a Wavelight study with:
Prof. Theo Seiler, M.D., Ph.D.,
Michael Mrochen, Ph.D.,
Arthur Cummings, M.D.,
Matthias Maus, M.D.

Methods:

- 26 consecutive symptomatic eyes p LASIK
- Pre-, and post-operative refraction,
- Total and high order aberrations (RMSH), cornea and flap thickness,
- Low contrast sensitivity (LCS) and possible complications. Follow-up was 3-7 months (4.5)
- Pupil size

Inclusion Criteria

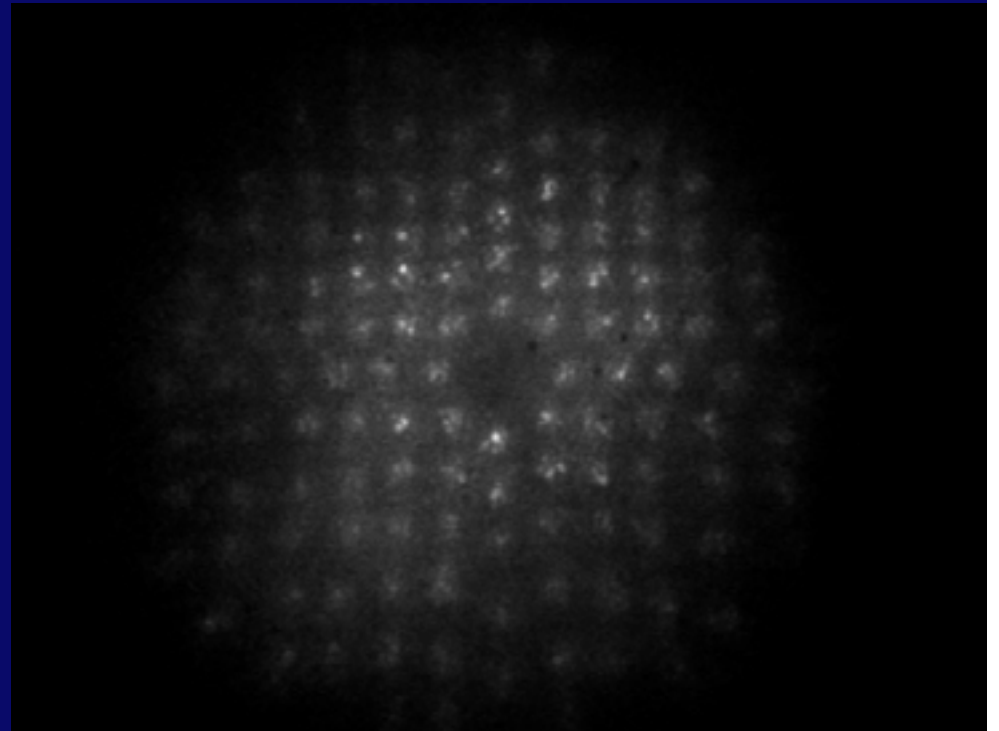
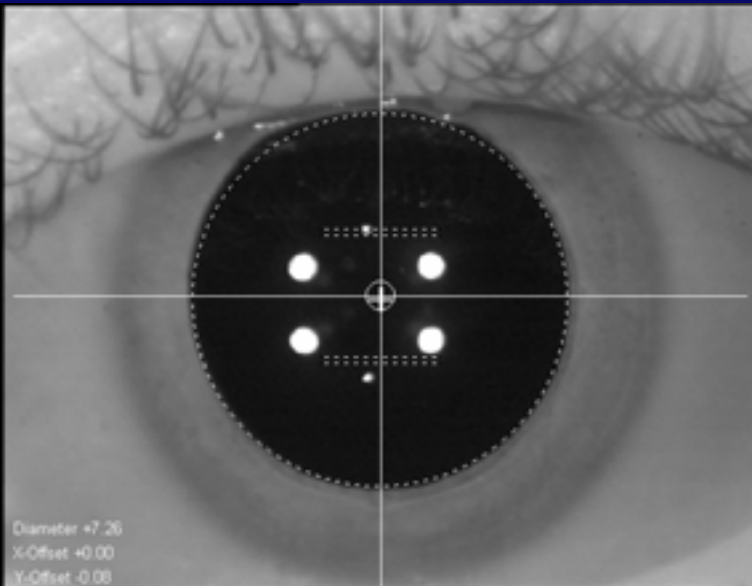
- RE within +/-1.50.
- W-G treatment had to be ≥ 6 mm OZ
- RMSH $\geq 0,4$ at 6mm pupil
- At least one of the below indications:
small OZ, decentered ablation, irregular astigmatism, night vision problems, under- or over- correction

Surgical technique

- All cases re-lift
- Intra-operative subtraction pachymetry
- Treated 6, 6.5 and 7mm Ozs
- Utilized the average of 4 reproducible WFs

Method

- WaveFront evaluated prior to surgery
- Dilated pupil to 7mm (not cycloplegic, 1 drop Mydriacyl 1%)
- Pre-op, Day 1, Week 1, month 1 and Month 3 Data



Results:

22 eyes treated

The mean values were:

RE: sphere: $-0,92\text{D}$ (plano to -1.50)
cylinder: -0.85D (0 to $-1,75$).

UCVA improved from 20/25 to 20/18.

There was no loss of BCVA in any case.

The RMSH decreased from 0.62 to 0.25.

LCS improved by 55%.

Sample study cases

- 45 y/o male s/p LASIK for -5
- OD : plano, BCVA 20/25+, LCS C4
- OS: -0.50, BCVA 20/25+ LCS C5
- WG enhancement OU, 6.5mm OZ
- Post-op:
 - OD UCVA 20/20, LCS C6
 - OS UCVA 20/20, LCS C5

Visualization

preOP - 01

Examination Date: 27-03-2003

Name: RAGKOS, Ilias

OD

Date of Birth: 01-01-0196

F1

Patient Data

F2

WaveFront Refr

F3

Analyzer

F4

Visualization

F5

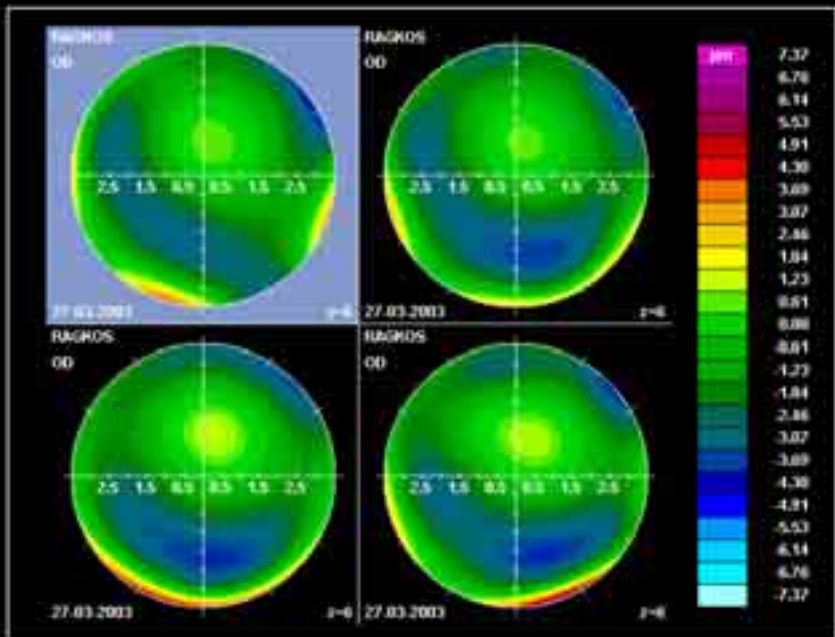
Export Data

?

About

X

Exit

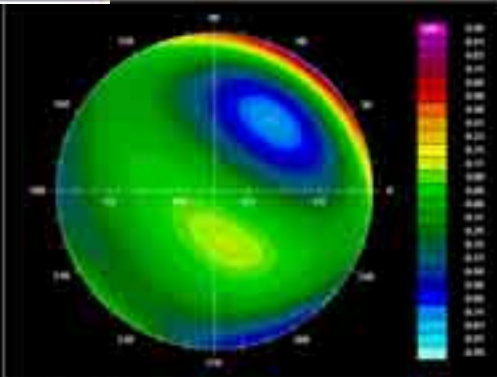


3D View
 3D Animation
 Display only higher Orders
 Show Grid
 Scaling
 um/step

Z-Order:
 OZ:
 Display Mode

WaveFront Refraction: --- AL / ACC: +0.00 / +0.00
 Clinical Refraction: +0.00D +0.00D @ ...° WaveFront (1)
 Refraction: 0.0% Coma: 59.1% Higher Order: 40.9% WaveFront Diameter: 7.0

preOP, 961 00001 - 01 Examination Date: 27-03-2003
 OD Date of Birth: 01-01-0196



3D View
 3D Animation
 Display only higher Orders
 Show Grid
 Scaling
 um/step

Z-Order:
 OZ:
 Display Mode

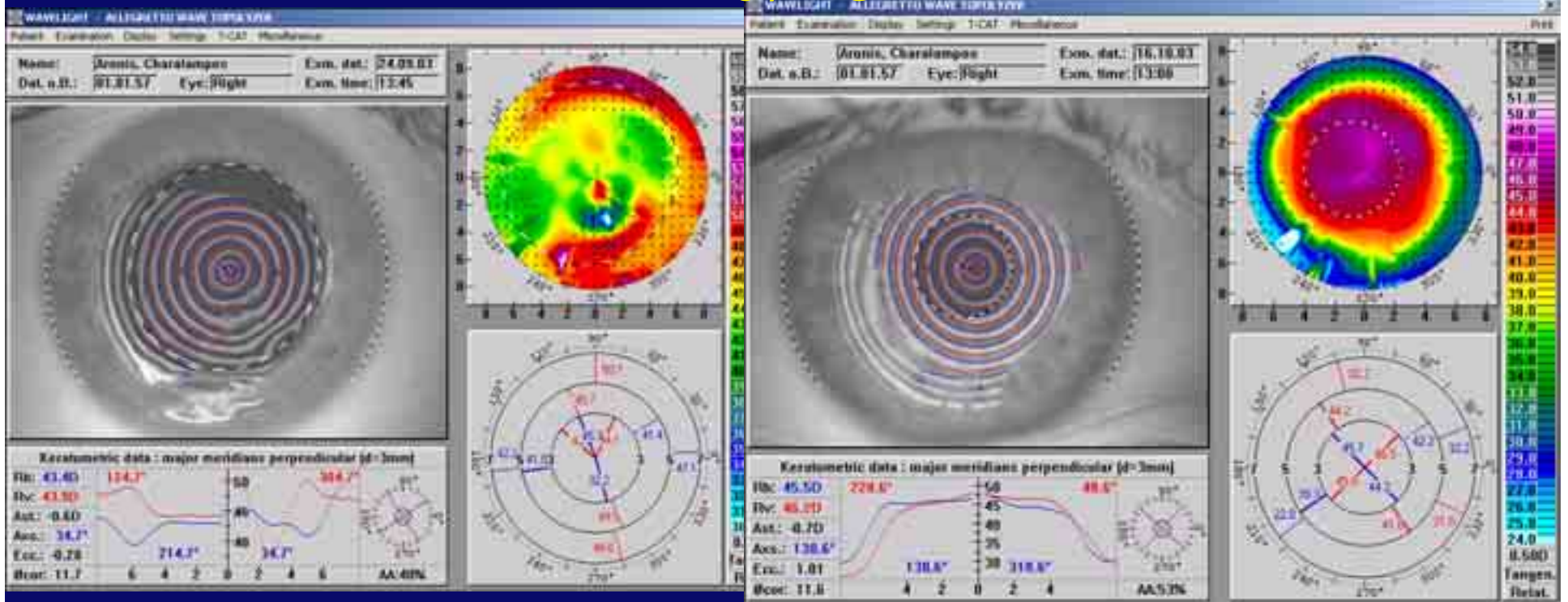
WaveFront Refraction: --- AL / ACC: +0.20 / +0.75
 Clinical Refraction: +0.50D -0.50D @ 40° WaveFront (1)
 Refraction: 0.0% Coma: 87.0% Higher Order: 44.0% WaveFront Diameter: 4.9

F1 Patient Data
 F2 WaveFront Refr
 F3 Analyzer
 F4 Visualization
 F5 Export Data
 ? About
 X Exit

Original +0.50 -2.50

OD: +1.50 -1.75 30

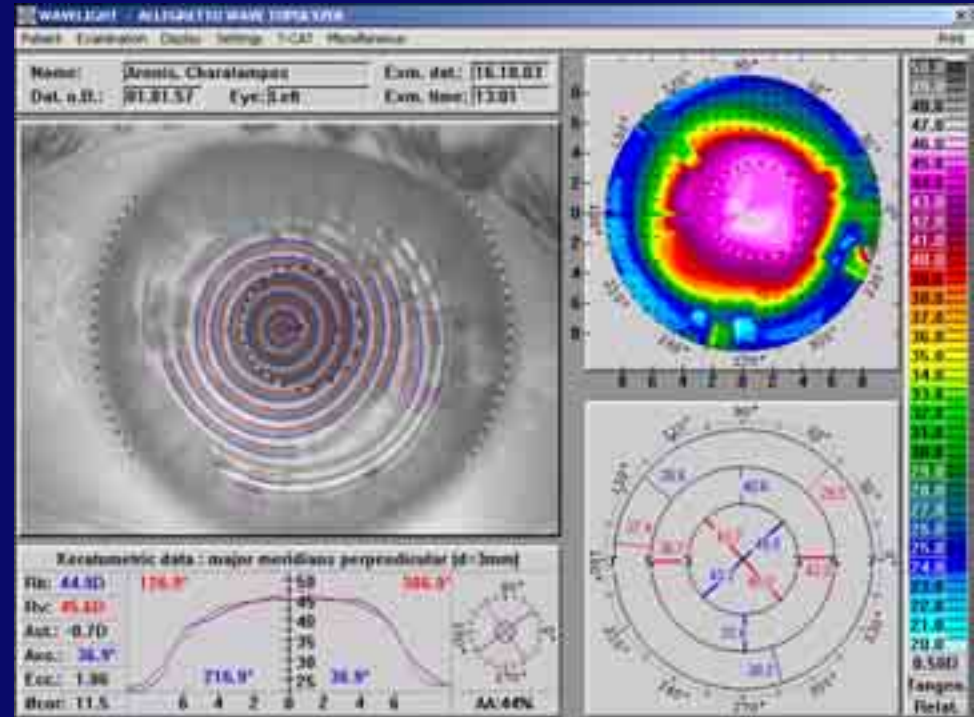
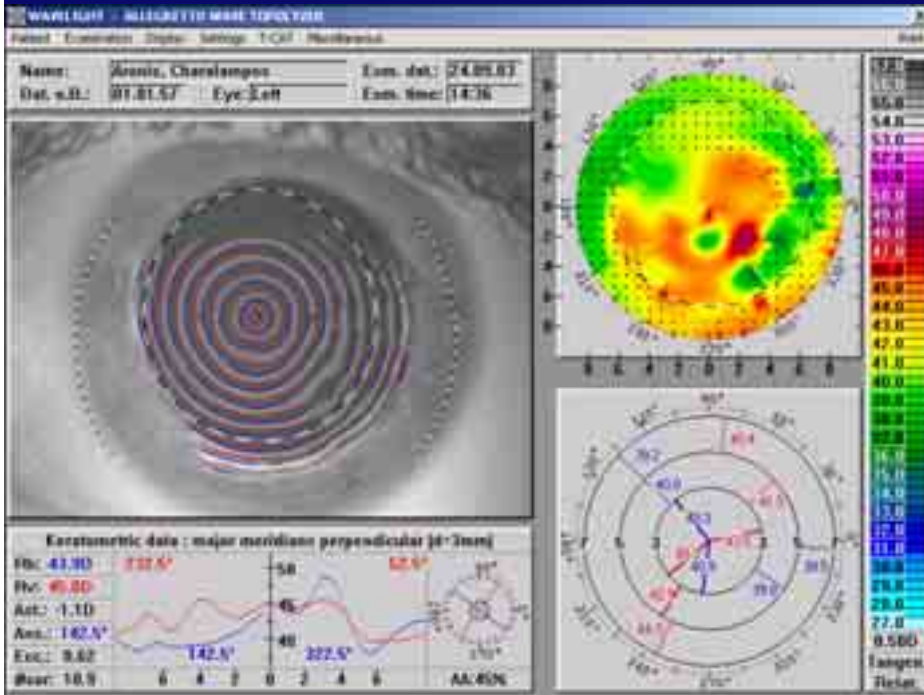
IRREGULAR BCVA 20/60 to 20/25



Original +1.00 -3.00

OS: +1.75-175 130

IRREGULAR BCVA 20/50 to 20/25



QuickTime™ and a DV - PAL decompressor are needed to see this picture.

Conclusion

- WaveFront-guided LASIK with the ALLEGRETTO-WAVE (a 0.9mm flying-spot and 200Hz) and the M2 appears to be safe and very effective for correction of myopic astigmatism
- It has demonstrated in our clinical practice the ability to significantly reduce higher order aberrations

Conclusion

- Improving the quality of vision (Contrast sensitivity)
- The postoperative results at day one were very impressive, possibly deriving from the smooth ablation pattern of corneal stroma bed and/or the smooth microkeratome pass.
- Very significant improvement in BCVA postoperatively

Wavefront-Guided Enhancements

Improving higher-order aberrations and contrast sensitivity in symptomatic post-LASIK eyes.

BY A. JOHN KANELLOPOULOS, MD

I recently participated in a multicenter study designed to evaluate the safety and efficacy of wavefront-guided LASIK enhancements using the Allegretto Wave system (WaveLight Technology AG, Erlangen, Germany) for symptomatic post-LASIK eyes. The other investigators and I have extensive experience using this system for standard and wavefront-guided primary LASIK, and we have presented these findings during the last 2 years. WaveLight Technology AG organized the current study in order to elucidate further the ability of its wavefront analyzer and of wavefront-guided treatments with its excimer laser to correct aberrations in post-LASIK patients.

SUBJECTS

One inclusion criterion was myopia, hyperopia, or mixed astigmatism with a refractive error within a 1.50 D (spherical equivalent). Additionally, the diameter of wavefront-guided laser treatment had to be greater than or equal to 6 mm with an RMSH value (measurement of total higher-order aberrations) of at least 0.4 mm when measured by the wavefront analyzer at a 6-mm pupil diameter. Subjects had to present with at least one of the following five clinical indications: (1) small, original optical zone, (2) decentered ablation, (3) irregular astigmatism, (4) night vision problems, and (5) under- or over-correction. An additional criterion for study inclusion was our ability to obtain four highly reproducible, higher-order-aberration maps that had a diameter of at least 6 mm after the eye had been dilated with a single drop of tropicamide 1% but undergone no cycloplegia.

METHODOLOGY

The study was conducted at four individual centers by investigators Theo Seiler, MD, PhD and Michael Mrochen, PhD, at the University of Zurich in Switzerland; Arthur Cummings, MD, at a center in Dublin, Ireland;

Matthias Mias, MD, at a center in Cologne, Germany; and me at the Laservision Eye Institute in Athens, Greece. Joachim Loeffler, a consultant for WaveLight Technology AG, coordinated the study.

Preoperative evaluations of each subject included UCVA, BCVA with manifest refraction, cycloplegic refraction measurements of scotopic pupil size (Cohort Pupillometer; OASIS Medical, Inc., Glendora, CA), topography, and simulated Ks calculated with both the Orbscan topographer (Bausch & Lomb, Rochester, NY) and the Allegretto Wave system's topographer. When performing measurements with the Allegretto Wave system's wavefront analyzer, we strictly adhered to the study's requirements on diameter. We obtained pachymetry readings by means of both ultrasound and the Orbscan topographer. The data for the operative record included the targeted postoperative refraction.

The Allegretto Wave system's wavefront analyzer averaged together four highly reproducible maps of each subject's higher-order aberrations and used this information for

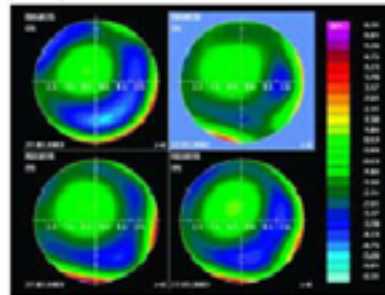


Figure 1. The author obtained higher-order aberration maps of an unhappy post-LASIK patient's left eye.

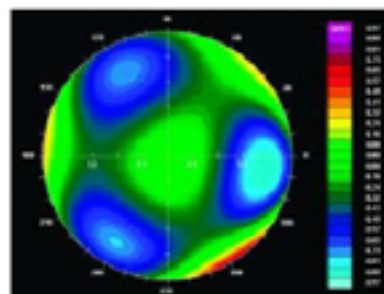


Figure 2. The higher-order aberration map shows the results of a wavefront-guided enhancement procedure on a 6.5 mm optical zone. The RMSH value decreased from 0.75 to 0.23 mm, the patient's low-contrast sensitivity improved 150%, and he gained three lines of BCVA in addition to improving subjectively.

the laser treatments. We could only alter the wavefront treatment's diameter, which had to be between 6 and 7 mm, and the amount of the sphere corrected. The system's software currently does not allow manual changes in the amount and axis of astigmatism because the averaged higher-order aberration maps predetermine this information.

All cases involved lifting (but never cutting) the original LASIK flap, at which time we measured the flap diameter and thickness. We obtained pachymetry measurements preoperatively after lifting the flap, and intraoperatively, and we calculated the flap thickness by subtraction pachymetry. We measure (the subject's) contrast sensitivity under mesopic conditions and using low-contrast materials, and their glare preoperatively by means of the CSV-1000 (VectorVision, Ancaman, OH), and we noted any intraoperative complications on the subject's chart.

Postoperatively, we recorded each subject's UCVA, manifest refraction, cycloplegic refraction, low-contrast sensitivity, topography (calculated with both the Allegretto Wave system's topographer and Orbscan topographer), wavefront measurements, and postoperative complications (if any).

RESULTS

The study included 72 eyes of the 36 patients we evaluated, all of whom were symptomatic with other night vision problems or mesopic and photopic ghosting. One of the four patients excluded did not possess the amount of residual corneal thickness necessary for retreatment (we generally require a total corneal stroma of 400 μ m and a total stromal bed stroma of ≥ 200 μ m). We excluded these other

patients because of our inability to obtain reproducible wavefront maps and our subsequent decision not to proceed with wavefront-guided treatment for these subjects.

The follow-up period averaged 4 months (ranging from 3 to 7 months). Of the 22 eyes included, the average preoperative amount of sphere was -0.92 D (ranging from plano to -1.50 D) and the mean amount of cylinder was -0.85 D (ranging from 0 to -1.75 D). The mean preoperative BCVA was 20/25, and this figure improved to a mean of 20/18 postoperatively. Not only did no patient lose any lines of BCVA, all patients gained at least one line and a maximum of three lines of BCVA. The total amount of higher-order aberrations, as measured by the parameter RMSH, decreased from an average of 0.62 to 0.25 mm. Also, patients experienced a mean improvement in low-contrast sensitivity of 53% (Figures 1 and 2).

CONCLUSION

Although my fellow investigators and I found the pre- and postoperative measurement process to be laborious, we determined the enhancement procedure to be easy overall. The real reward of our work has been our patients' extremely high level of satisfaction, owing to the improvement in their visual symptoms. With regard to quality of night vision, I should note that, according to patients' subjective responses, 21 of the 22 eyes corrected had significantly improved, and one had improved mildly. Wavefront measurements and our measurements of these patients' low-contrast sensitivities indicated significant clinical improvement in all eyes. None of the patients demonstrated the need for further enhancement during the study's brief follow-up period.

My fellow investigators and I feel that these results strongly suggest that wavefront-guided LASIK retreatment with the Allegretto Wave system appears to be safe and effective for the correction of residual refractive error, and we attribute the enhancement of visual function to the significant improvement of subjects' higher-order aberrations and low-contrast sensitivity. We have found that the Allegretto Wave system's wavefront analyzer and excimer laser enabled us to predictably measure and treat most symptomatic post-LASIK patients. ■

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Thank You



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