Customized laser cornea remodeling:
Theory and clinical practice

MEACO 09

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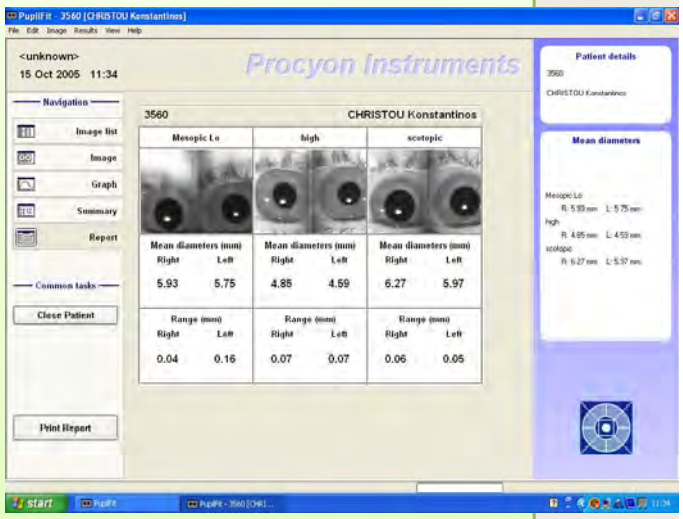
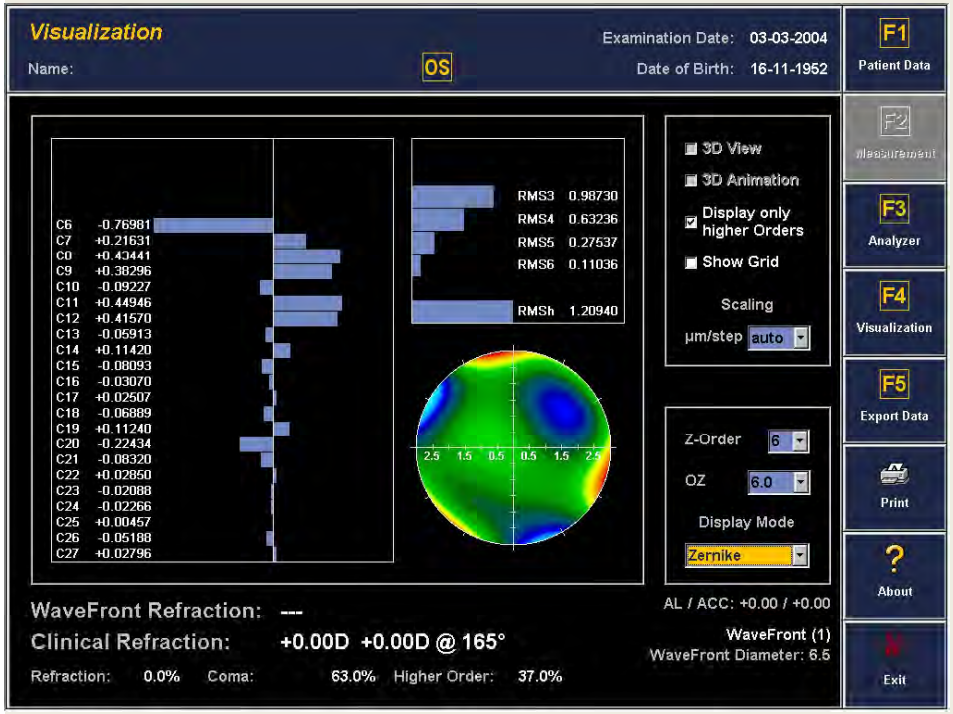
www.brilliantvision.com

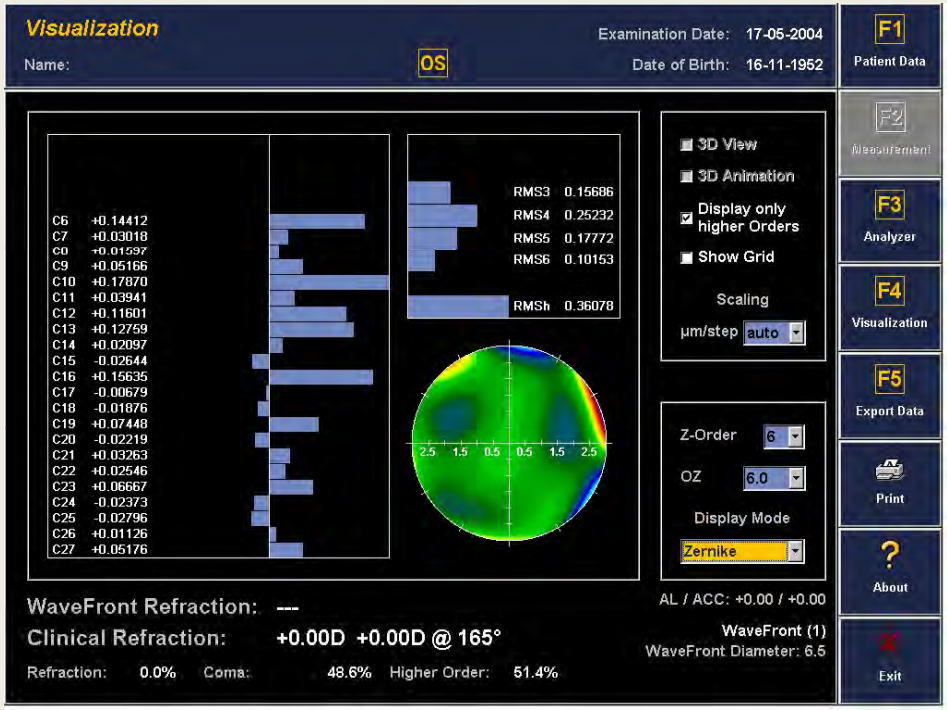
Define customised in 2008?

- Wavefront guided?
- Topography guided?
- Wavefront-optimised?
- Asphericity adjustment?
- Adjustment to pupil size?
- Adjustment to angle kappa?
- Customised flap (Intralase)?
- Customizing cornea biomechanics with cross-linking?



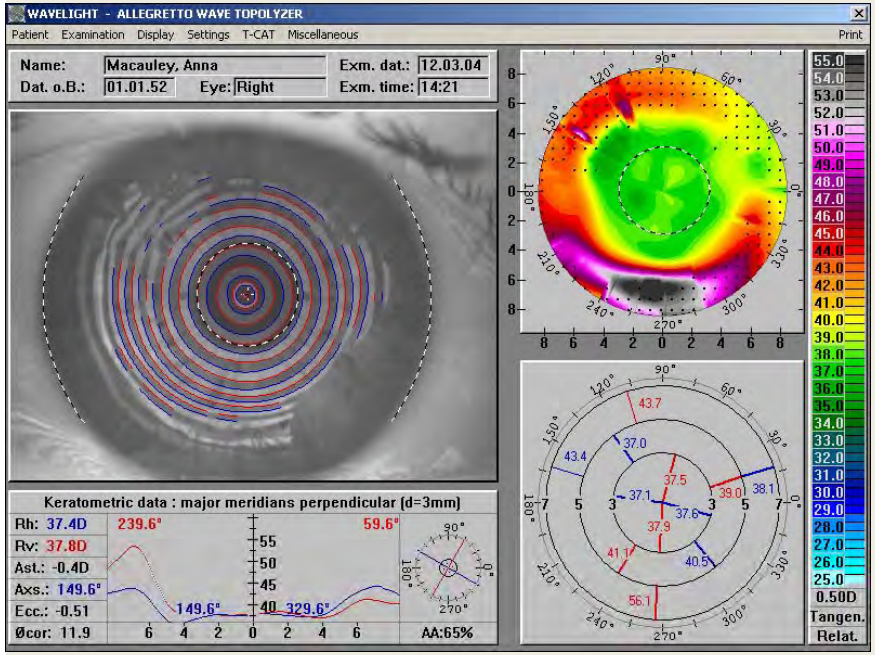
Same pt other eye RMSH improved from 1,2 to 0.36 (!) LCS improved from C3 to C7 (!)

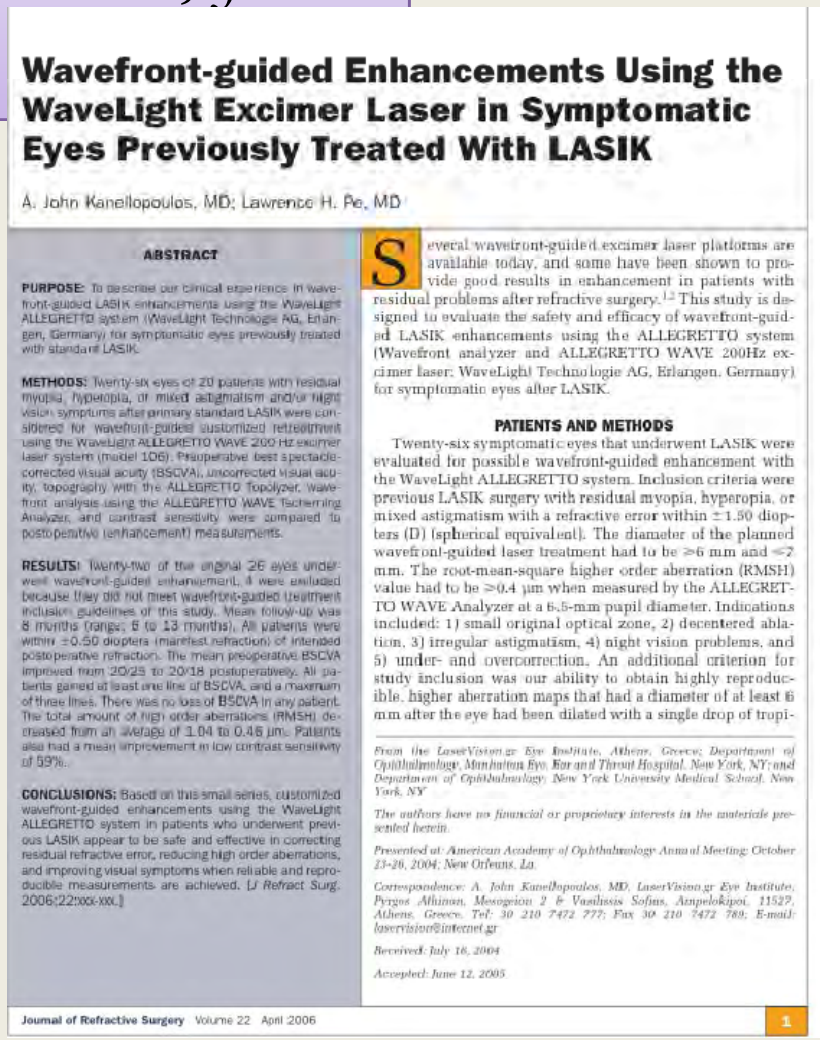




Wavefront guided results:

Kanellopoulos et al, AAO 2004, JRS May 2006





Wavefront-guided Enhancements Using the WaveLight Excimer Laser in Symptomatic Eyes Previously Treated With LASIK

A. John Kanellopoulos, MD; Lawrence H. Pe, MD

ABSTRACT

PURPOSE: To describe our clinical experience in wavefront-guided LASIK enhancements using the WaveLight ALLEGRETTO system (WaveLight Technologie AG, Erlangen, Germany) for symptomatic eyes previously treated with standard LASIK.

METHODS: Twenty-six eyes of 20 patients with residual myopia, hyperopia, or mixed astigmatism and/or night vision symptoms after primary standard LASIK were considered for wavefront-guided customized retreatment using the WaveLight ALLEGRETTO WAVE 200 Hz excimer laser system (model 105). Preoperative best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity, topography with the ALLEGRETTO Topolyzer, wavefront analysis using the ALLEGRETTO WAVE Tscherning Analyzer, and contrast sensitivity were compared to postoperative (enhancement) measurements.

RESULTS: Twenty-two of the original 26 eyes underwent wavefront-guided enhancement. 4 were excluded because they did not meet wavefront-guided treatment inclusion guidelines of this study. Mean follow-up was 8 months (range, 6 to 13 months). All patients were within ±0.50 diopters (manifest refraction) of intended postoperative refraction. The mean preoperative BSCVA improved from 20/25 to 20/18 postoperatively. All patients gained at least one line of BSCVA, and a maximum of three lines. There was no loss of BSCVA in any patient. The total amount of high order aberrations (RMSH) decreased from an average of 1.04 to 0.46 µm. Patients also had a mean improvement in low contrast sensitivity of 59%.

CONCLUSIONS: Based on this small series, customized wavefront-guided enhancements using the WaveLight ALLEGRETTO system in patients who underwent previous LASIK appear to be safe and effective in correcting residual refractive error, reducing high order aberrations, and improving visual symptoms when reliable and reproducible measurements are achieved. [*J Refract Surg.* 2006;22:xxx-xxx.]

Several wavefront-guided excimer laser platforms are available today, and some have been shown to provide good results in enhancement in patients with residual problems after refractive surgery.[1,2] This study is designed to evaluate the safety and efficacy of wavefront-guided LASIK enhancements using the ALLEGRETTO system (Wavefront analyzer and ALLEGRETTO WAVE 200Hz excimer laser; WaveLight Technologie AG, Erlangen, Germany) for symptomatic eyes after LASIK.

PATIENTS AND METHODS

Twenty-six symptomatic eyes that underwent LASIK were evaluated for possible wavefront-guided enhancement with the WaveLight ALLEGRETTO system. Inclusion criteria were previous LASIK surgery with residual myopia, hyperopia, or mixed astigmatism with a refractive error within ±1.50 diopters (D) (spherical equivalent). The diameter of the planned wavefront-guided laser treatment had to be ≥6 mm and ≤7 mm. The root-mean-square higher order aberration (RMSH) value had to be ≥0.4 µm when measured by the ALLEGRETTO WAVE Analyzer at a 6.5-mm pupil diameter. Indications included: 1) small original optical zone, 2) decentered ablation, 3) irregular astigmatism, 4) night vision problems, and 5) under- and overcorrection. An additional criterion for study inclusion was our ability to obtain highly reproducible, higher aberration maps that had a diameter of at least 6 mm after the eye had been dilated with a single drop of tropi-

From the LaserVision.gr Eye Institute, Athens, Greece; Department of Ophthalmology, Manhattan Eye, Ear and Throat Hospital, New York, NY; and Department of Ophthalmology, New York University Medical School, New York, NY.

The authors have no financial or proprietary interests in the materials presented herein.

Presented at: American Academy of Ophthalmology Annual Meeting; October 23-26, 2004; New Orleans, La.

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Accepted: June 12, 2005

Accommodation

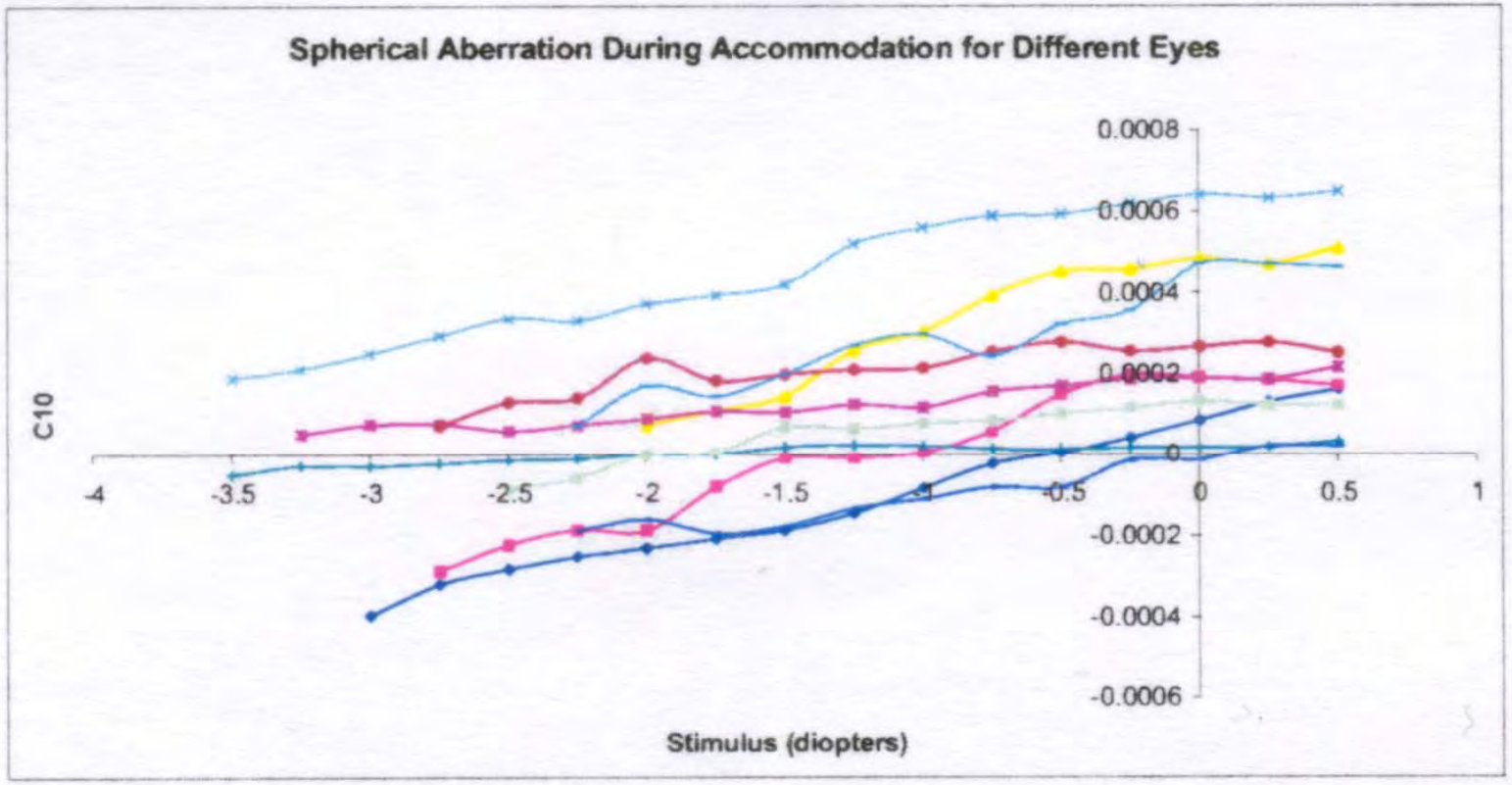
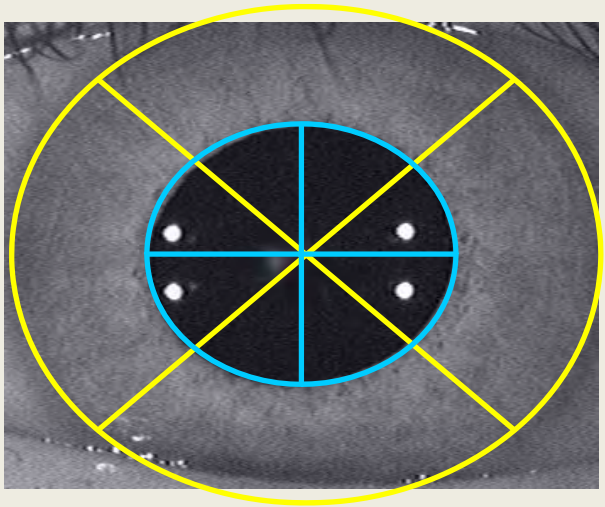


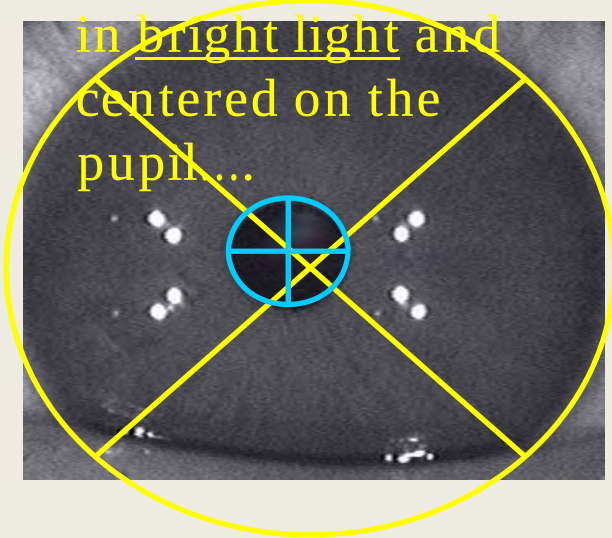
Fig 10 Overall spherical aberration becomes more negative as the eye accommodates.

Center of pupil change with dilation(mydriasis)

Donnenfeld E. J Refract Surg. 2004 Sep-Oct;20(5):S593-6.



If the wavefront is captured in <u>dim light</u> *and* referenced to the pupil center... **<u>Accurate before surgery</u>**

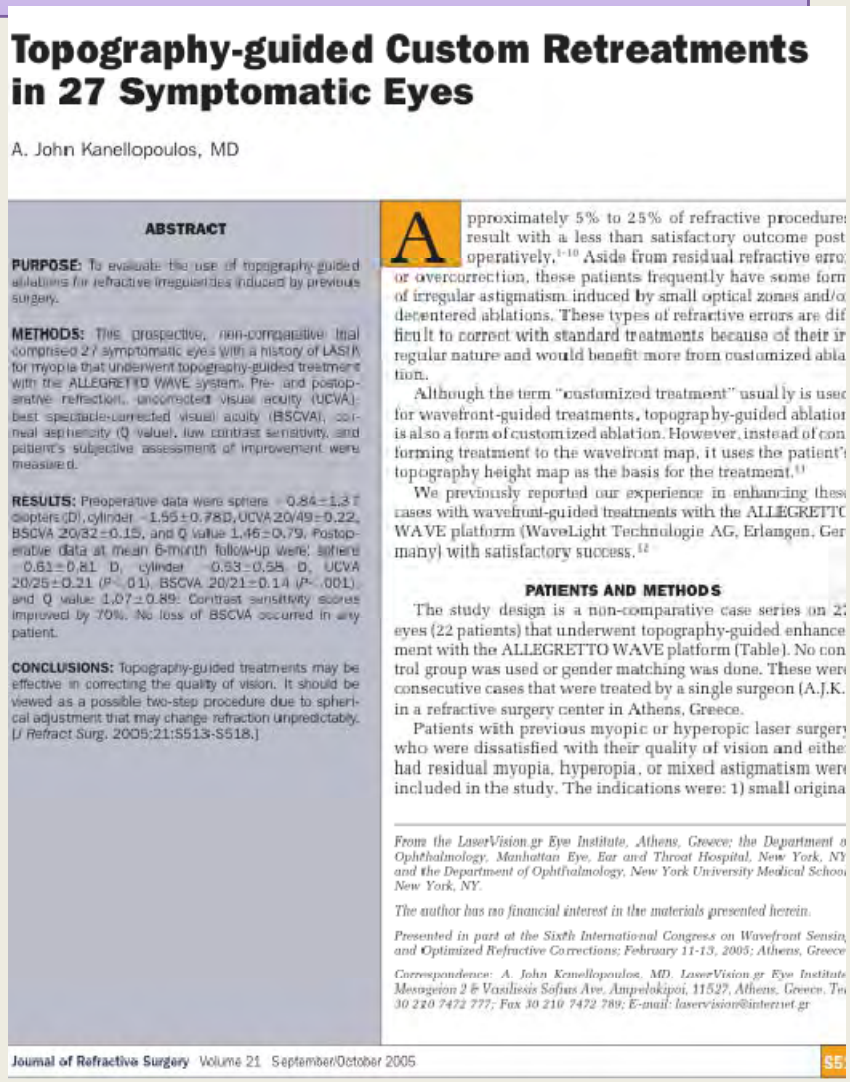


Your wavefront ablation will be applied to the wrong area.

Here, a **260 micron shift** in pupil center is seen!

Topography-guided

JRS Sept/Oct 2005



Topography-guided Custom Retreatments in 27 Symptomatic Eyes

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ABSTRACT

PURPOSE: To evaluate the use of topography-guided ablations for refractive irregularities induced by previous surgery.

METHODS: This prospective, non-comparative trial comprised 27 symptomatic eyes with a history of LASIK for myopia that underwent topography-guided treatment with the ALLEGRETTO WAVE system. Pre- and postoperative refraction, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), corneal asphericity (Q value), low contrast sensitivity, and patient's subjective assessment of improvement were measured.

RESULTS: Preoperative data were sphere −0.84±1.31 diopters (D), cylinder −1.55±0.78D, UCVA 20/49±0.22, BSCVA 20/32±0.15, and Q value 1.46±0.79. Postoperative data at mean 6-month follow-up were: sphere −0.61±0.81 D, cylinder −0.53±0.55 D, UCVA 20/25±0.21 ($P<.01$), BSCVA 20/21±0.14 ($P<.001$), and Q value 1.07±0.89. Contrast sensitivity scores improved by 70%. No loss of BSCVA occurred in any patient.

CONCLUSIONS: Topography-guided treatments may be effective in correcting the quality of vision. It should be viewed as a possible two-step procedure due to spherical adjustment that may change refraction unpredictably. [*J Refract Surg.* 2005;21:S513-S518.]

Approximately 5% to 25% of refractive procedures result with a less than satisfactory outcome postoperatively.[1-10] Aside from residual refractive error or overcorrection, these patients frequently have some form of irregular astigmatism induced by small optical zones and/or decentered ablations. These types of refractive errors are difficult to correct with standard treatments because of their irregular nature and would benefit more from customized ablation.

Although the term "customized treatment" usually is used for wavefront-guided treatments, topography-guided ablation is also a form of customized ablation. However, instead of conforming treatment to the wavefront map, it uses the patient's topography height map as the basis for the treatment.[11]

We previously reported our experience in enhancing these cases with wavefront-guided treatments with the ALLEGRETTO WAVE platform (WaveLight Technologie AG, Erlangen, Germany) with satisfactory success.[12]

PATIENTS AND METHODS

The study design is a non-comparative case series on 27 eyes (22 patients) that underwent topography-guided enhancement with the ALLEGRETTO WAVE platform (Table). No control group was used or gender matching was done. These were consecutive cases that were treated by a single surgeon (A.J.K.) in a refractive surgery center in Athens, Greece.

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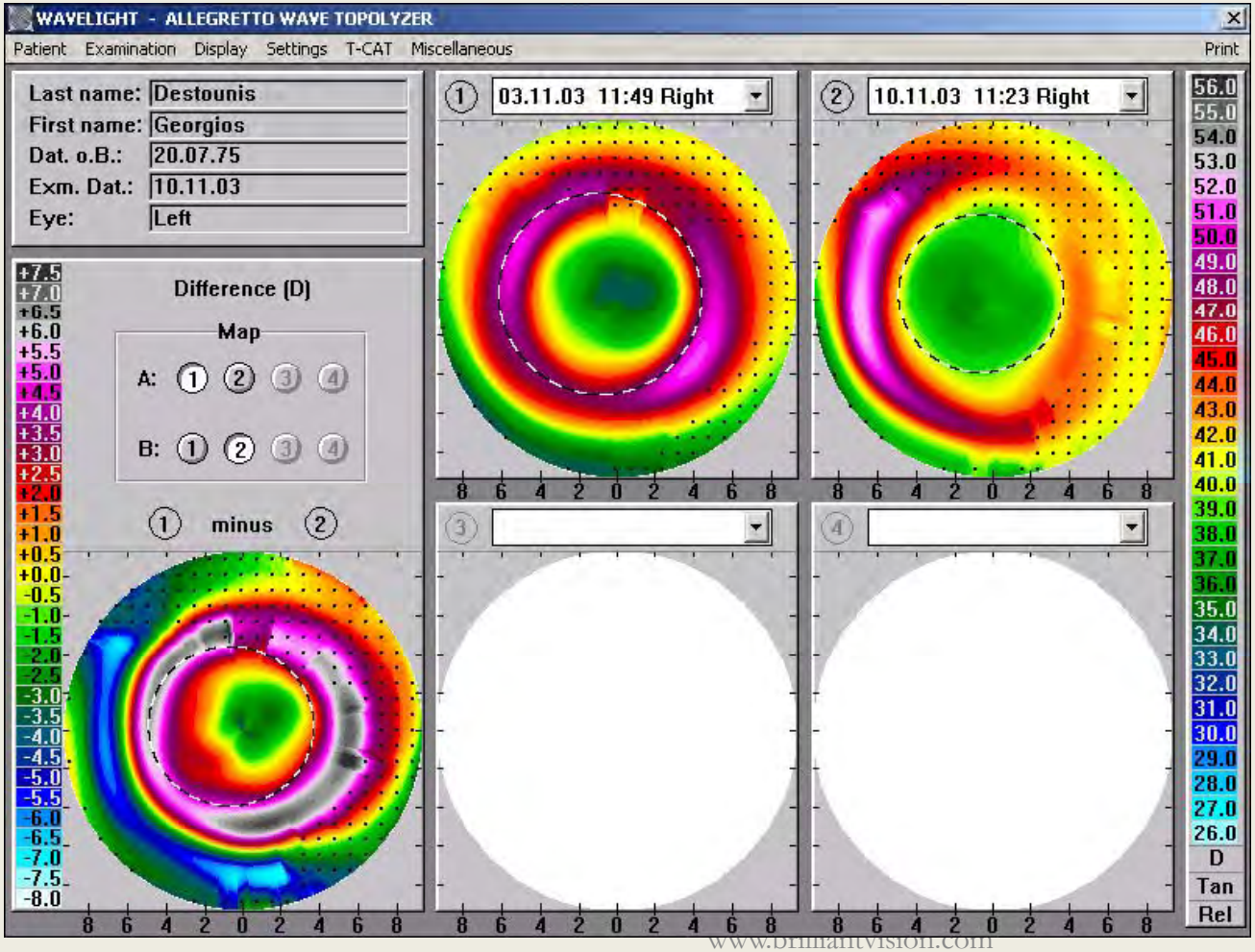
Enlarging myopic optical zone:

Initially -10, 505μ LASIK: 4,5mmOZ, 125μ flap M2->plano ^BCVA 2 lines, but night halosTopo-guided Tx to enlarge OZ to6mm and adjusting Q value to -1,46Initially halos gone,

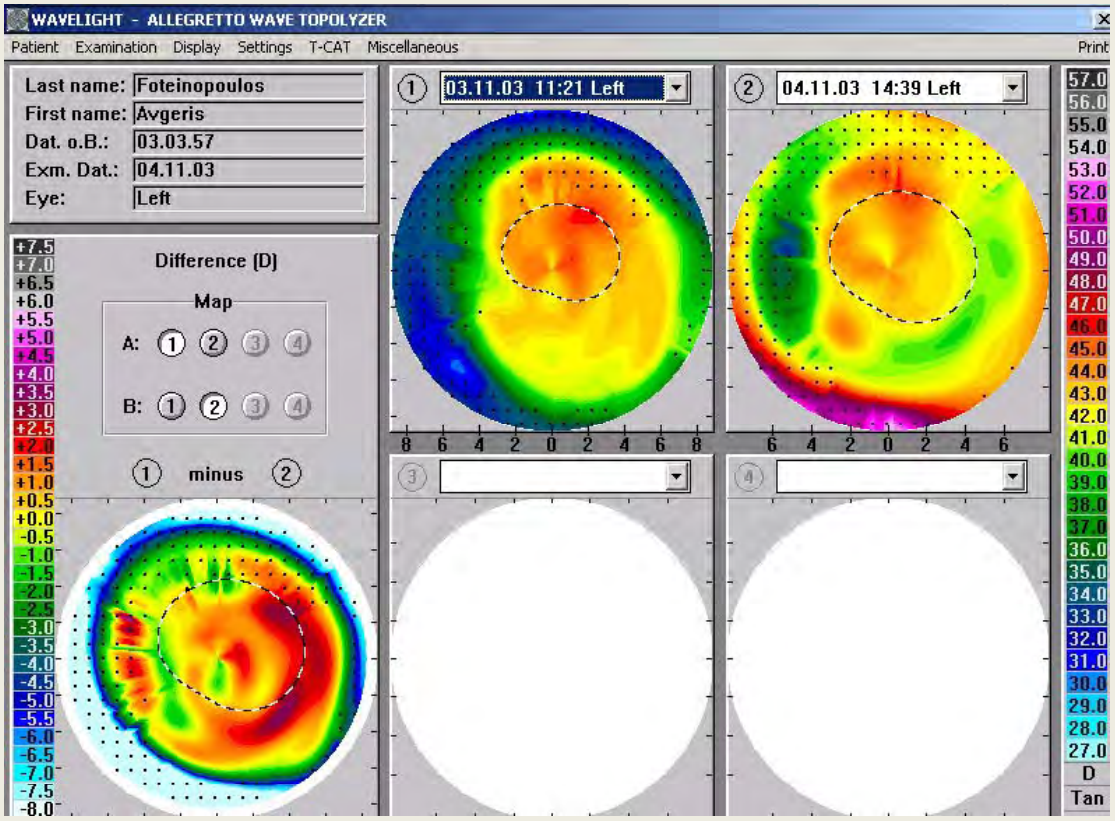


Refraction: -1.25!

Post-trauma irregular astigmatism

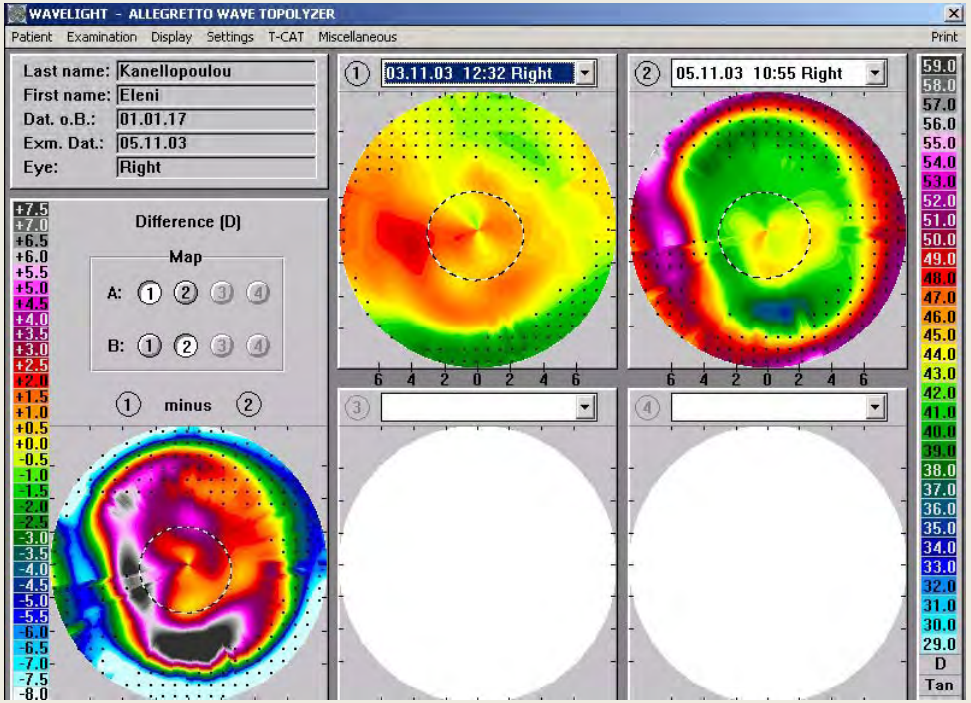
Old K perf, s/p CE, IOL,s/p LASIK for +2.00 now -1,50 -250 160 irregularBCVA 20/40+
Topo-guided, Q adjustment to -0.3

Postop: UCVA 20/30, BCVA 20/25

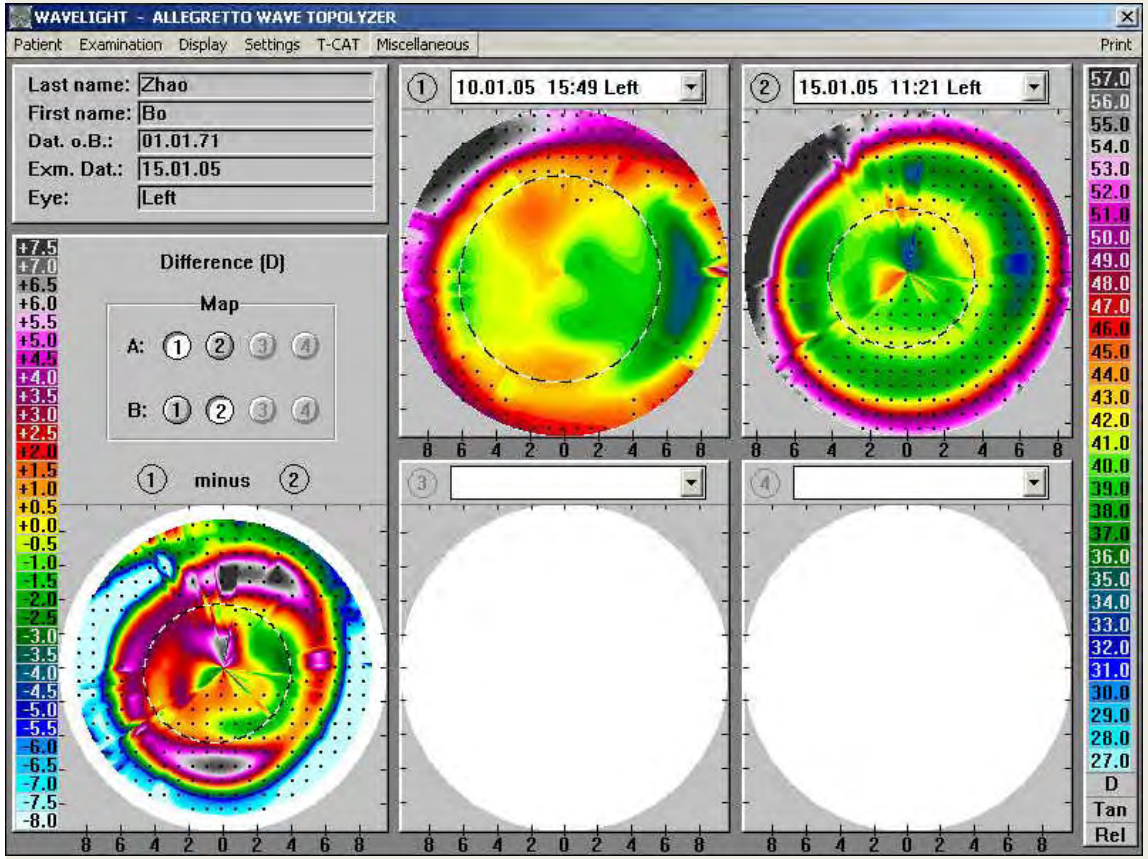


Post-surgery irregular astigmatism

Complicated CE-Aphakia-Artisan IOL-in an old LASIK pt
P -350 90 BCVA 20/60
Postop +0.50-0.50 90 UCVA 20/25

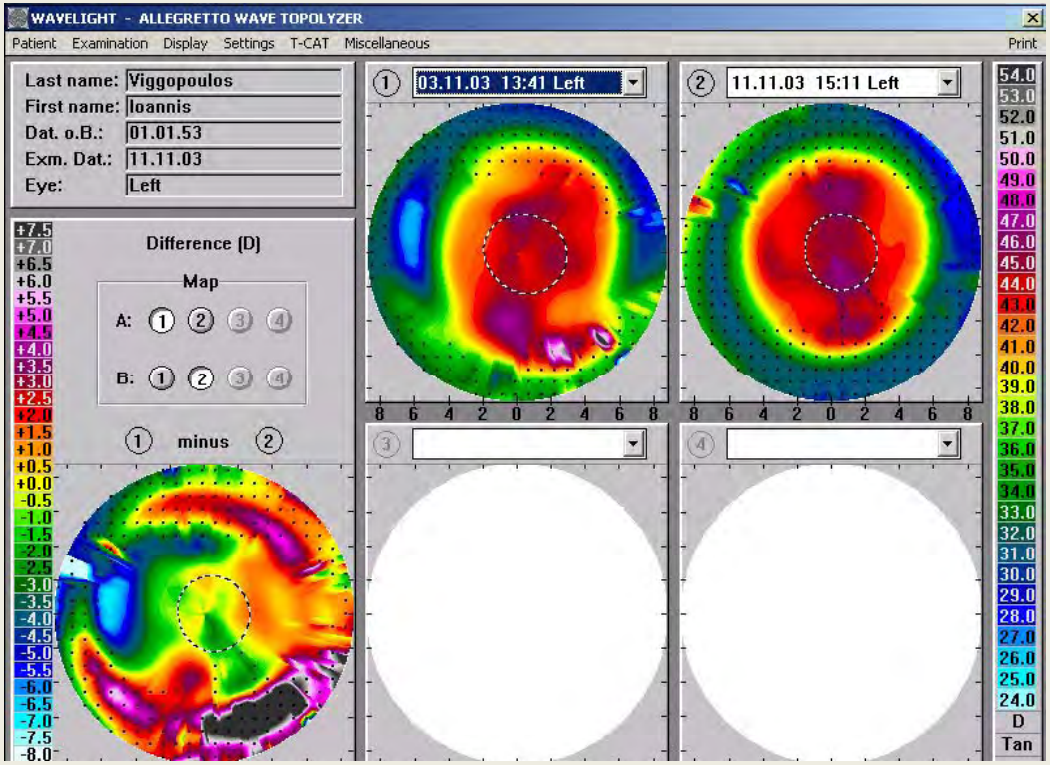


Re-centering OZ,
smoothing irregularities (Loss of K sliver in recuts)



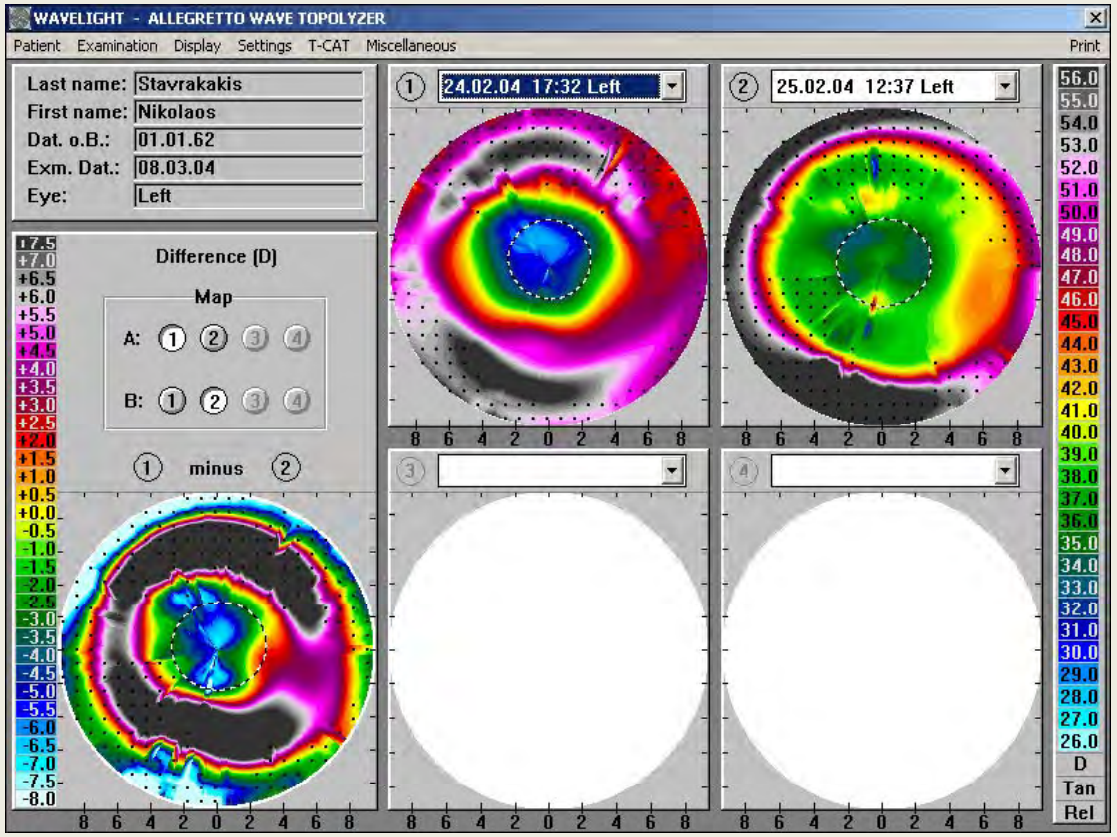
Centering optical zone-hyperopia

Initially: +3.50 -3.00 180, post LASIK:+1.00-1.25 70 UCV
20/40 BCVA 20/25 pTOPOG: plano -0.25 UCVA 20/20



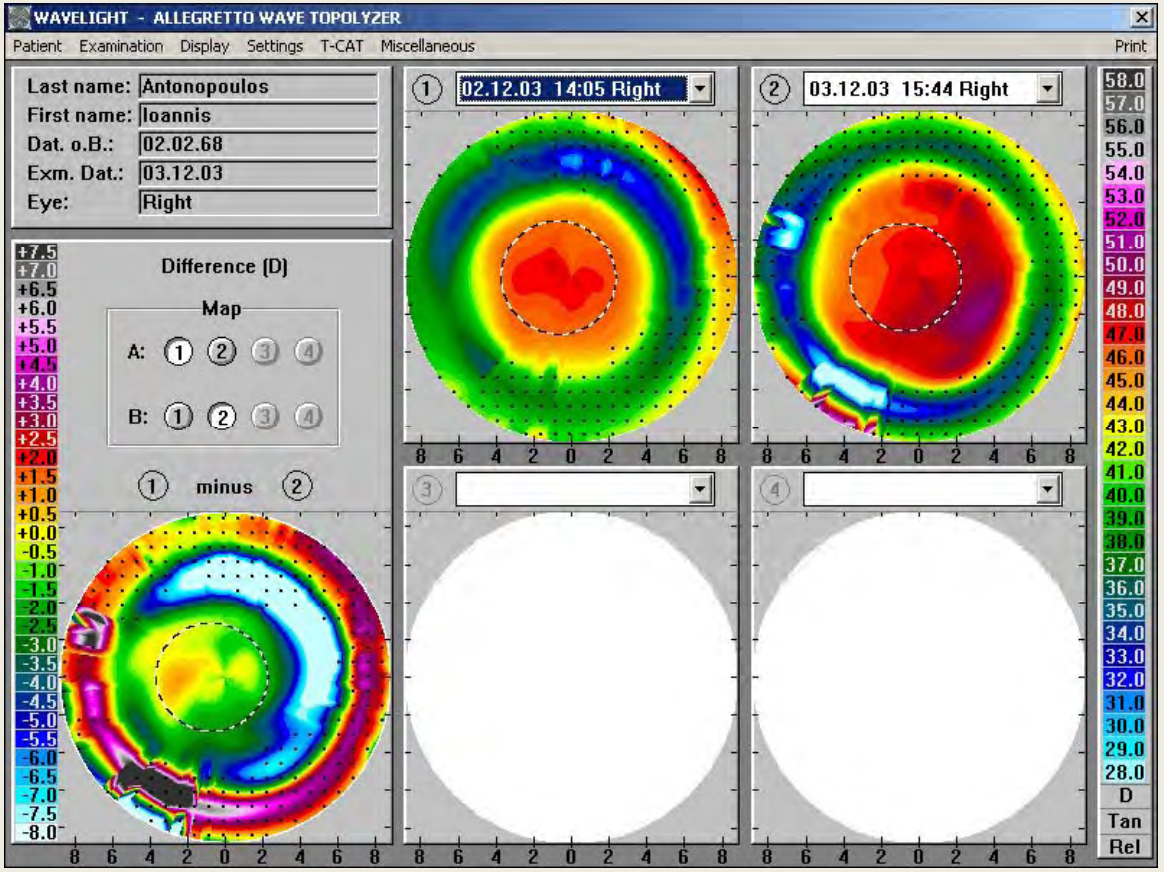
Enlarging optical zone-RK

10 year post-RK, Post-LASIK: +2,50 -1,50Cyl, debilitating night vision. P topo-guided -0.50 -0.50 marked improvement



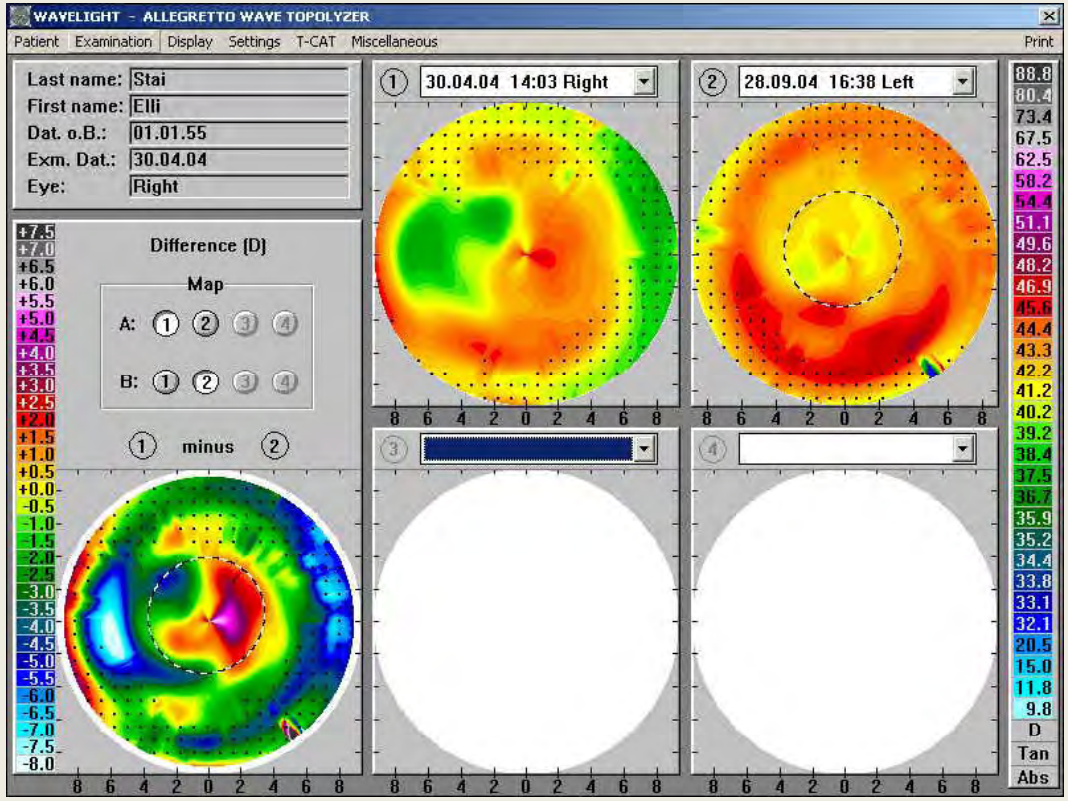
Enlarging optical zone- Hyperopia

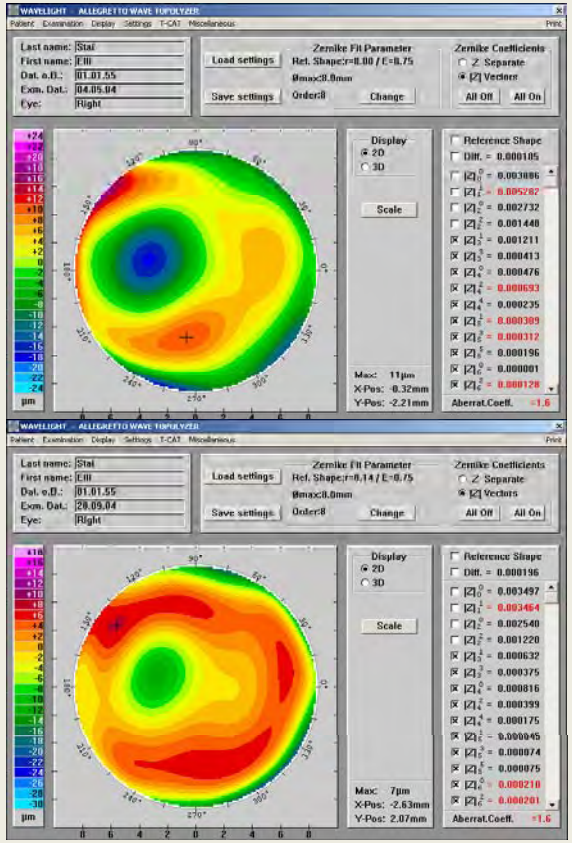
S/p LASIK for +4.50, now +1.00 and night vision down C3, s/p topo-guided CS=C7



Post-keratitis irregular astigmatism

Patient with old severe Cornea ulcer and paracentral flattening
-3.50-2.00 irregular cyl UCVA 20/200 to 20/25
BSCVA from 20/40- to 20/25





Topo-guided with the Wavelight-platform (Kanellopoulos-JRS Sept05)

- 8 high quality topographies

Adjustment for:

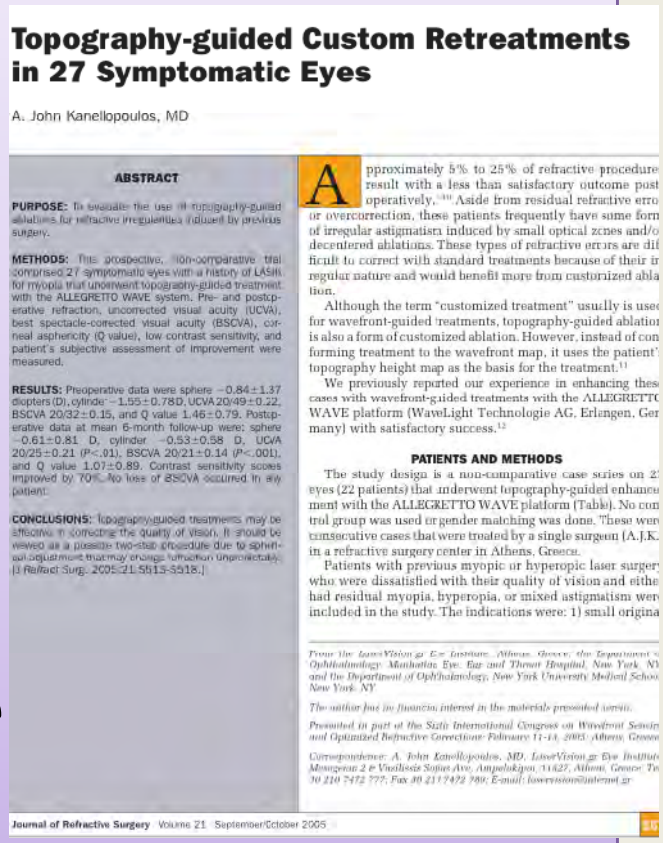
1-sphere

2-Cylinder

3-Axis

4-Q value (asphericity)

Standard angle-kappa adjustme



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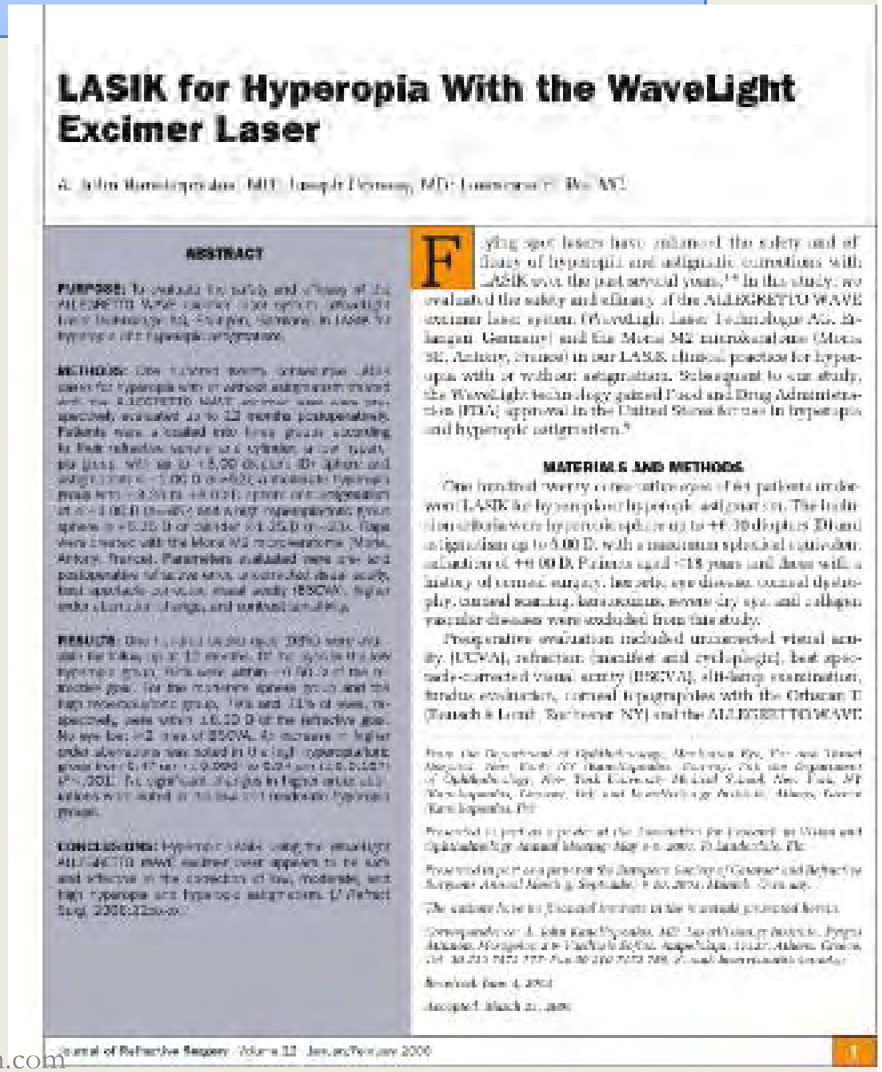
Hyperopia-standard treatment Kanellopoulos-JRS 2006

Initial topography guided Hyperopic and Hyperopic Astigmatism LASIK
Experience with the WaveLight ALLEGRETTO WAVE
excimer laser in 120 Consecutive Eyes

ARVO 2006-JRS 2006



LASIK for Hyperopia With the WaveLight Excimer Laser

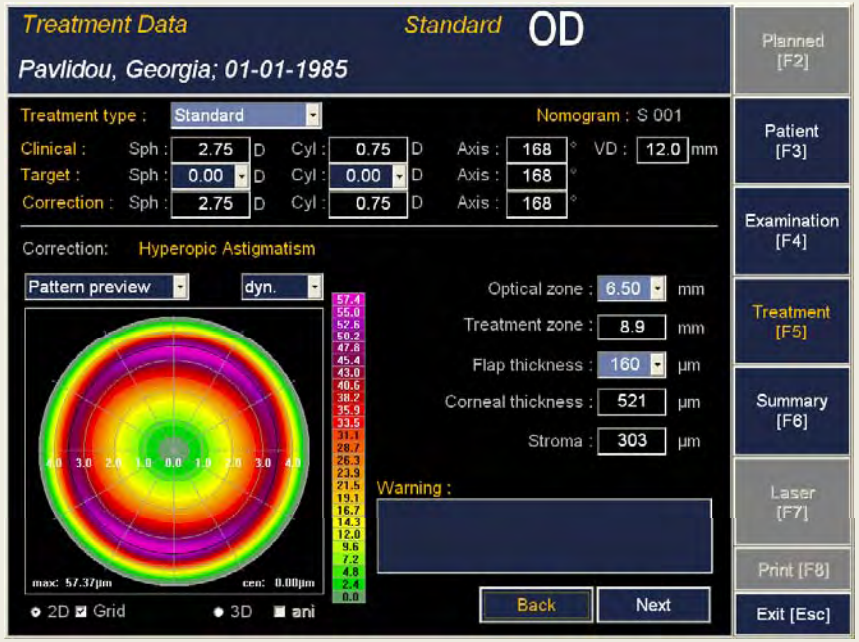
ABSTRACT

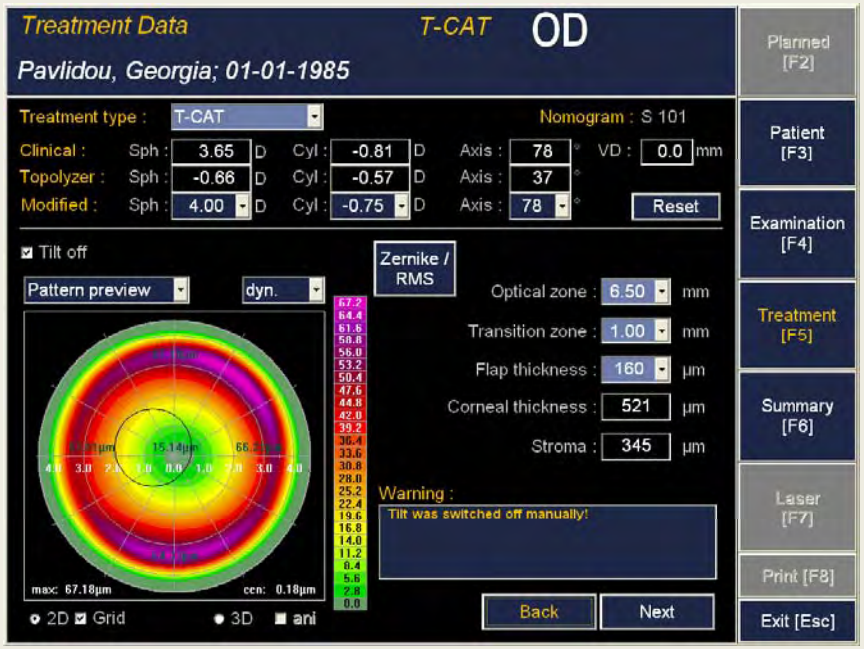
MATERIALS AND METHODS

Is Angle kappa significant in hyperopes?

- **Measurement of angle kappa with synoptophore and Orbscan II in a normal population**
- Hikmet Basmak, MD[1]; Afsun Sahin, MD[2]; Nilgun Yildirim, MD[3]; Thanos D. Papakostas, MD[4,5]; and A. John Kanellopoulos, MD[4,5] 2007 J Refract Surg-in
- There is a significant correlation between positive refractive errors and large positive angle kappa values. Refractive surgeons must take into account angle kappa especially in hyperopic patients in order to avoid complications related to decent ration of ablation zone.

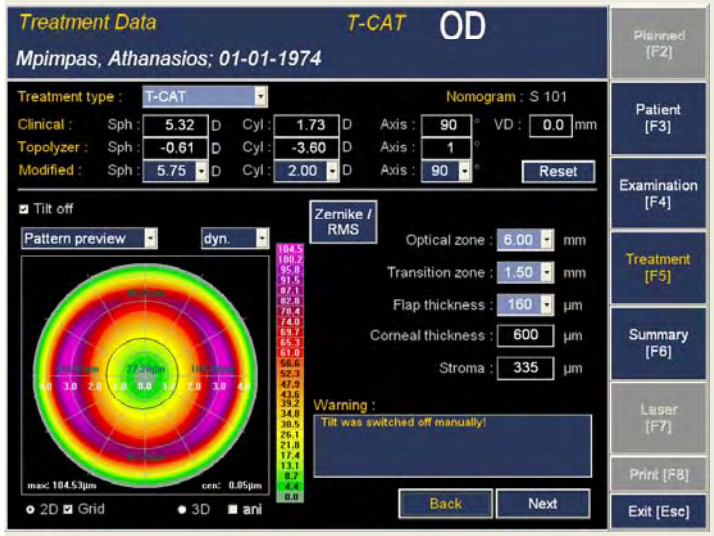
Angle kappa adjustment topo-link

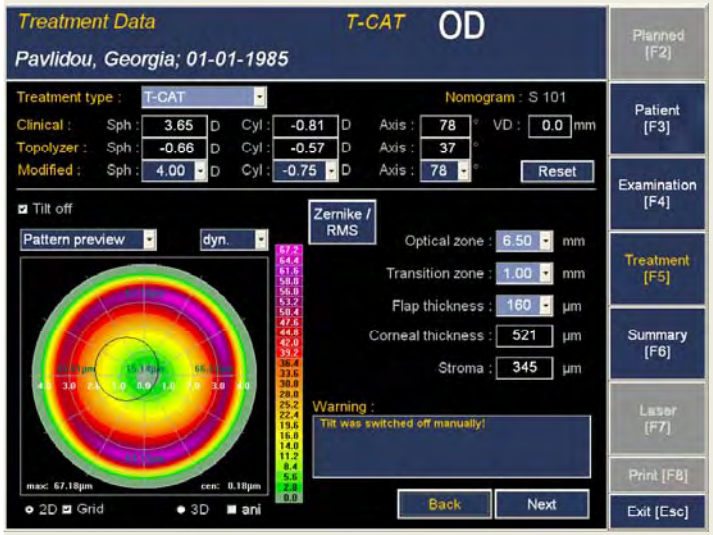


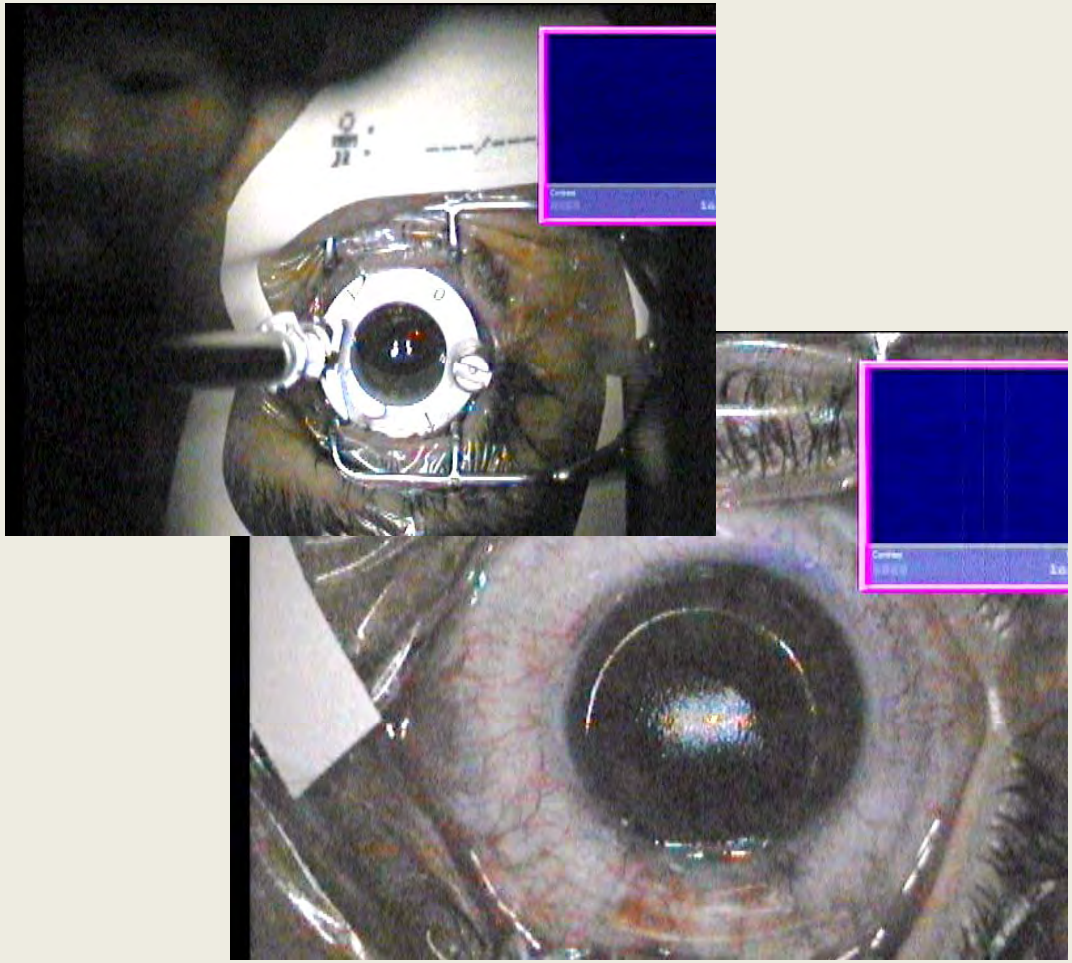


These figures depict the same planned excimer profile for the correction of hyperopic astigmatism on the left: centered on the pupillary center and on the right :adjusted by topography to take into consideration and adjust for angle kappa

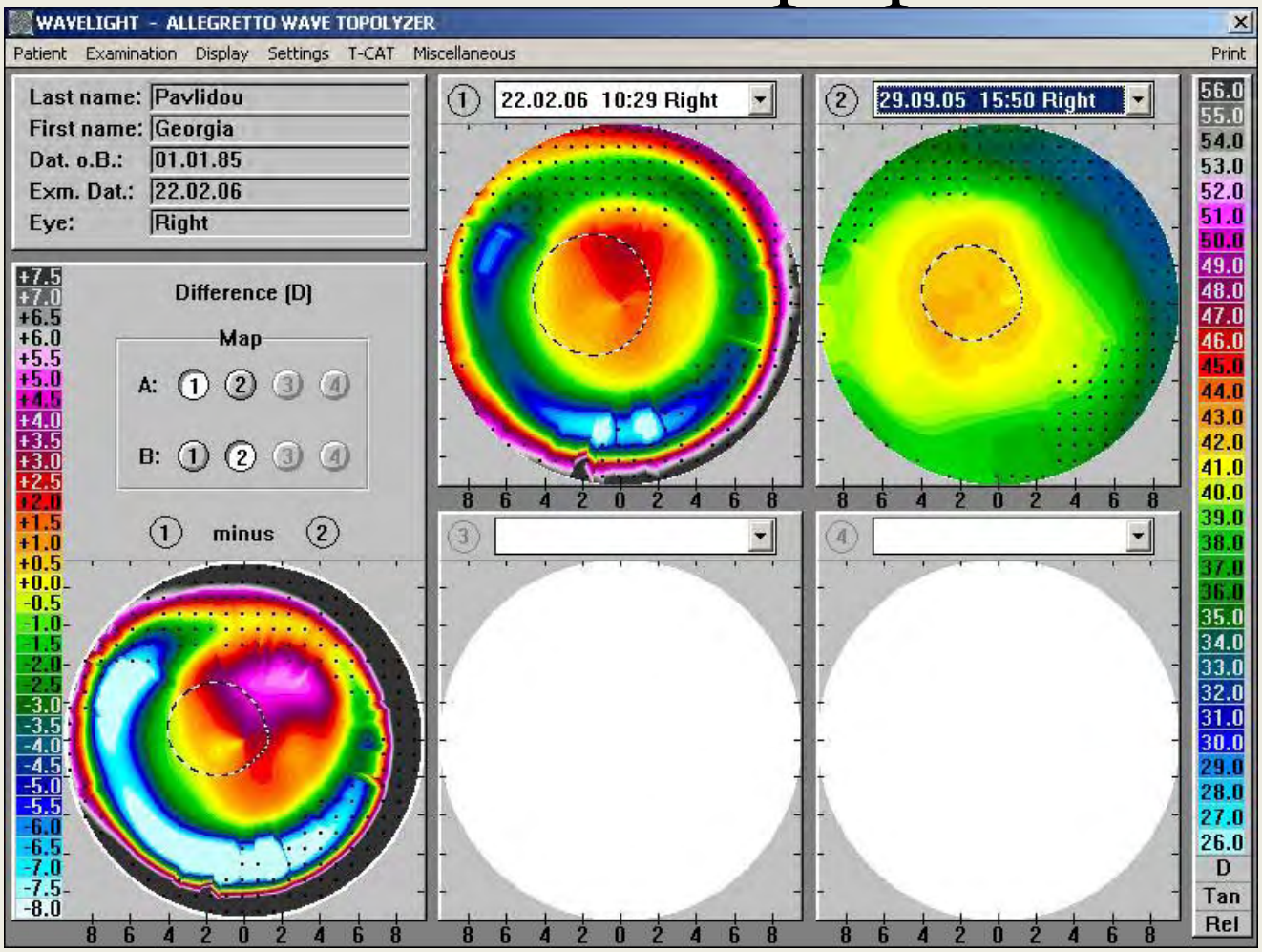
LASIK flap needs to be de-centered as well to accommodate Challenging for surgeon, Intralase?

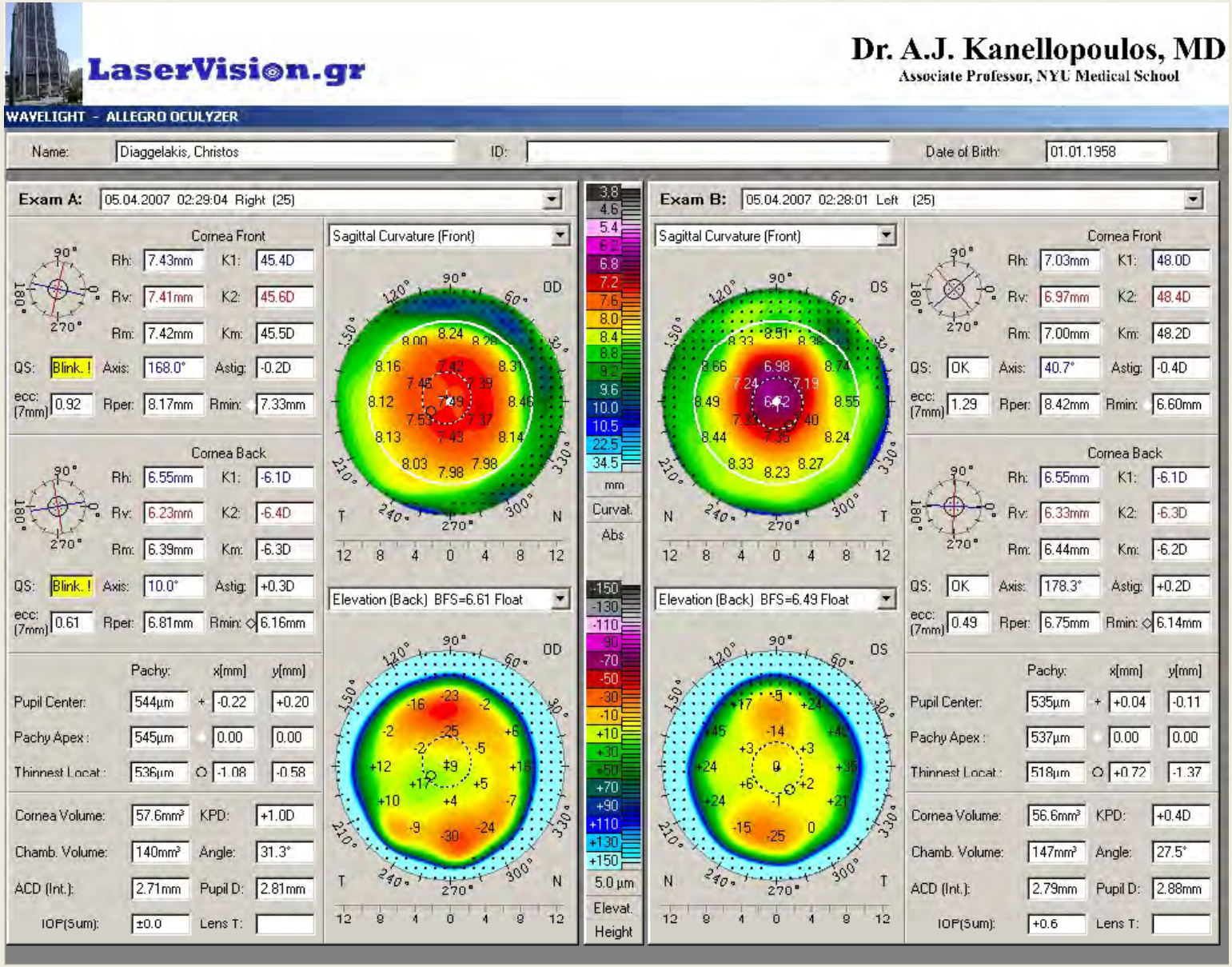




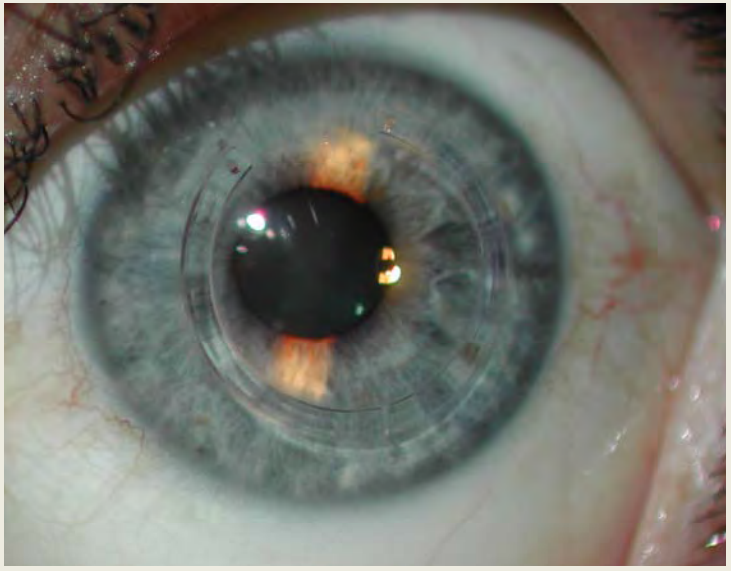


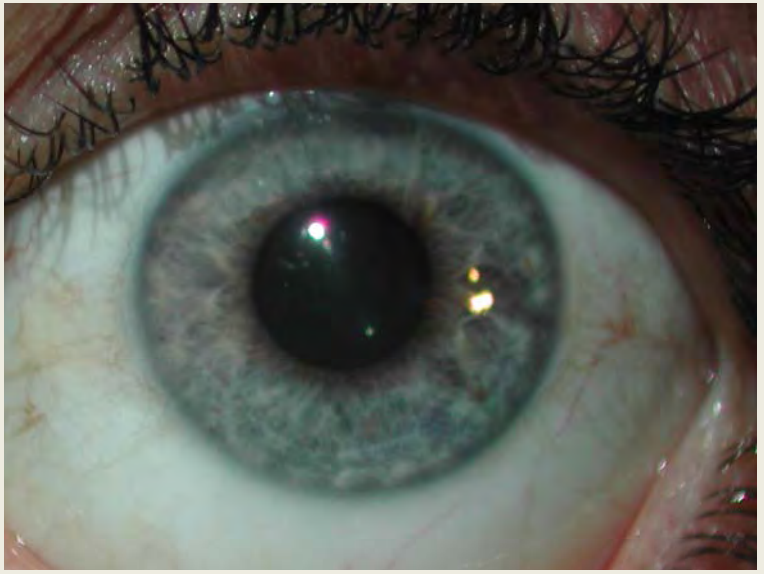
Treatment axis is centered on the visual axis and not pupil center




LaserVision.gr
Dr. A.J. Kanellopoulos, MD
Associate Professor, NYU Medical School
WAVELIGHT - ALLEGRO OCULYZER
Name: Diaggelakis, Christos
ID:
Date of Birth: 01.01.1958
Exam A: 05.04.2007 02:29:04 Right (25)
Exam B: 05.04.2007 02:28:01 Left (25)
Cornea Front
Cornea Back
Sagittal Curvature (Front)
Elevation (Back) BFS=6.61 Float
Elevation (Back) BFS=6.49 Float
Rh: 7.43mm K1: 45.4D
Rv: 7.41mm K2: 45.6D
Rm: 7.42mm Km: 45.5D
QS: Blink. ! Axis: 168.0° Astig: -0.2D
ecc: (7mm) 0.92 Rper: 8.17mm Rmin: 7.33mm
Rh: 6.55mm K1: -6.1D
Rv: 6.23mm K2: -6.4D
Rm: 6.39mm Km: -6.3D
QS: Blink. ! Axis: 10.0° Astig: +0.3D
ecc: (7mm) 0.61 Rper: 6.81mm Rmin: 6.16mm
Pachy: x[mm] y[mm]
Pupil Center: 544µm + -0.22 +0.20
Pachy Apex: 545µm 0.00 0.00
Thinnest Locat.: 536µm -1.08 -0.58
Cornea Volume: 57.6mm³ KPD: +1.0D
Chamb. Volume: 140mm³ Angle: 31.3°
ACD (Int.): 2.71mm Pupil D: 2.81mm
IOP(Sum): ±0.0 Lens T:
Rh: 7.03mm K1: 48.0D
Rv: 6.97mm K2: 48.4D
Rm: 7.00mm Km: 48.2D
QS: OK Axis: 40.7° Astig: -0.4D
ecc: (7mm) 1.29 Rper: 8.42mm Rmin: 6.60mm
Rh: 6.55mm K1: -6.1D
Rv: 6.33mm K2: -6.3D
Rm: 6.44mm Km: -6.2D
QS: OK Axis: 178.3° Astig: +0.2D
ecc: (7mm) 0.49 Rper: 6.75mm Rmin: 6.14mm
Pachy: x[mm] y[mm]
Pupil Center: 535µm + +0.04 -0.11
Pachy Apex: 537µm 0.00 0.00
Thinnest Locat.: 518µm +0.72 -1.37
Cornea Volume: 56.6mm³ KPD: +0.4D
Chamb. Volume: 147mm³ Angle: 27.5°
ACD (Int.): 2.79mm Pupil D: 2.88mm
IOP(Sum): +0.6 Lens T:
mm
Curvat.
Abs
5.0 µm
Elevat.
Height

Keratoconus post LASIK: UCVA 20/400, removal of INTACS and then UVA. Post-op to 20/80





Post-LASIK Ectasia

Dear Editor:

I report a patient who had post-LASIK ectasia and was managed in a novel fashion, without keratoplasty.

A 29-year-old male underwent uniocular LASIK 38 months ago. Little detail was available from the patient and the surgeon. His original uncorrected visual acuity (UCVA) before LASIK was 20/80, and his spectacle-corrected visual acuity (BSCVA) was 20/20 with refraction of sphere being −2.00−175×85. Initially after the LASIK procedure, the patient reported that vision was good. During the following months, vision in that eye deteriorated. The original LASIK surgeon diagnosed ectasia and recommended the placement of Intacs (Addition Technology, Des Plaines, IL). After Intacs placement, his vision did not improve, and the patient developed severe night vision halos.

The treating LASIK surgeon then recommended penetrating keratoplasty (PK) as the next step, and the patient came for a second opinion for PK. 11 months after the original LASIK procedure and 3 months after Intacs implantation. Corneal topography is shown in Figure 1 (available at http://aaojournal.org); the central corneal thickness was 410 μm, and the endothelial cell count was 2750 cells/mm^2 (Conan, Boston, MA). I discussed with the patient the following:

1. The poor long-term experience with Intacs in post-LASIK ectasia that I have reported.[1]
2. The benefits and risks of PK.
3. Combined ultraviolet radiation and riboflavin treatment to achieve collagen cross-linking and biomechanical stabilization of the ectasia.

After informed consent was given, I removed the Intacs. Two weeks later, I treated the ectatic cornea with a single application of combined ultraviolet radiation and riboflavin treatment to achieve collagen cross-linking at 3 mW/cm^2 for 30 minutes (KeraCure, Priavision, Menlo Park, CA) combined with the use of 0.1% riboflavin ophthalmic solution in 20% dextran T-500.

The treatment was performed after 20% alcohol-assisted epithelial removal. The riboflavin solution was then applied for approximately 2 minutes to soak the stromal bed and protect the iris, crystalline lens, and retina from the ultraviolet A irradiation, and then 1 drop every 2 minutes for a total of 30 minutes. A bandage contact lens was placed onto the cornea for 5 days and the patient treated with topical ofloxacin 1% (Ocuflox, Allergan, Irvine, CA) and prednisolone acetate 1% (Predforte, Allergan) 4 times a day for 10 days.

At 3 months, his UCVA improved from 20/400 to 20/70 and his BSCVA from 20/200 to 20/40. Refraction changed from −4.50−4.50×120 to −4.00−3.50×115, and corneal topography changed as seen in Figure 1. The stability of these parameters and the corneal topography between months 1 and 3 of this treatment encouraged me to proceed with topography-guided photorefractive keratectomy (PRK) to reduce the irregular astigmatism and try to provide the patient with a visual acuity not requiring the use of spectacles or a soft contact lens.

The corneal thickness at that point of 420 μm enabled a PRK of his full spectacle correction with a topography-guided customized ablation on top of the LASIK flap (T-CAT software, Wavelight excimer laser, Wavelight, Erlangen, Germany). At the first post-PRK month, UCVA was 20/20 and BSCVA 20/20, with a refraction of +0.50−0.50×160. There was no corneal endothelium count change. It is now 24 months after the operation and the patient enjoys UCVA of 20/20, although there are some mild night vision problems. Postoperative corneal topography is shown on Figure 1.

The most frequent management for post-LASIK ectasia has been PK.[2] Previous reports of the use of combined ultraviolet radiation and riboflavin treatment to achieve collagen cross-linking mention a slowing down of keratoconus.[3] We have reported the management of extreme cornea irregularity with topography-guided ablations.[4] This is the first report of management of post-LASIK ectasia with combined ultraviolet radiation and riboflavin treatment to achieve collagen cross-linking followed by customized PRK for visual rehabilitation. The apparent corneal stabilization, along with the successful visual rehabilitation, suggests that this approach may have a wider application as an alternative to therapeutic PK.[5]

Larger comparative studies and longer follow-up are obviously necessary to validate the long-term efficacy of this combined ultraviolet radiation and riboflavin treatment followed by a surface excimer laser treatment. Nevertheless, the refractive and topographic stability for 2 years appears to validate this minimally invasive treatment of iatrogenic keratectasia and leads me to believe that it may have an even wider application in the near future.

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Athens, Greece

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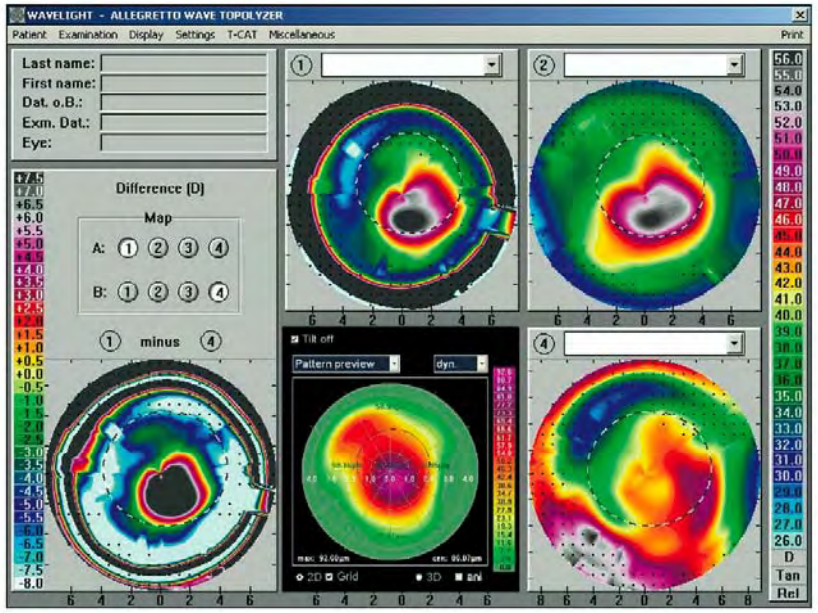
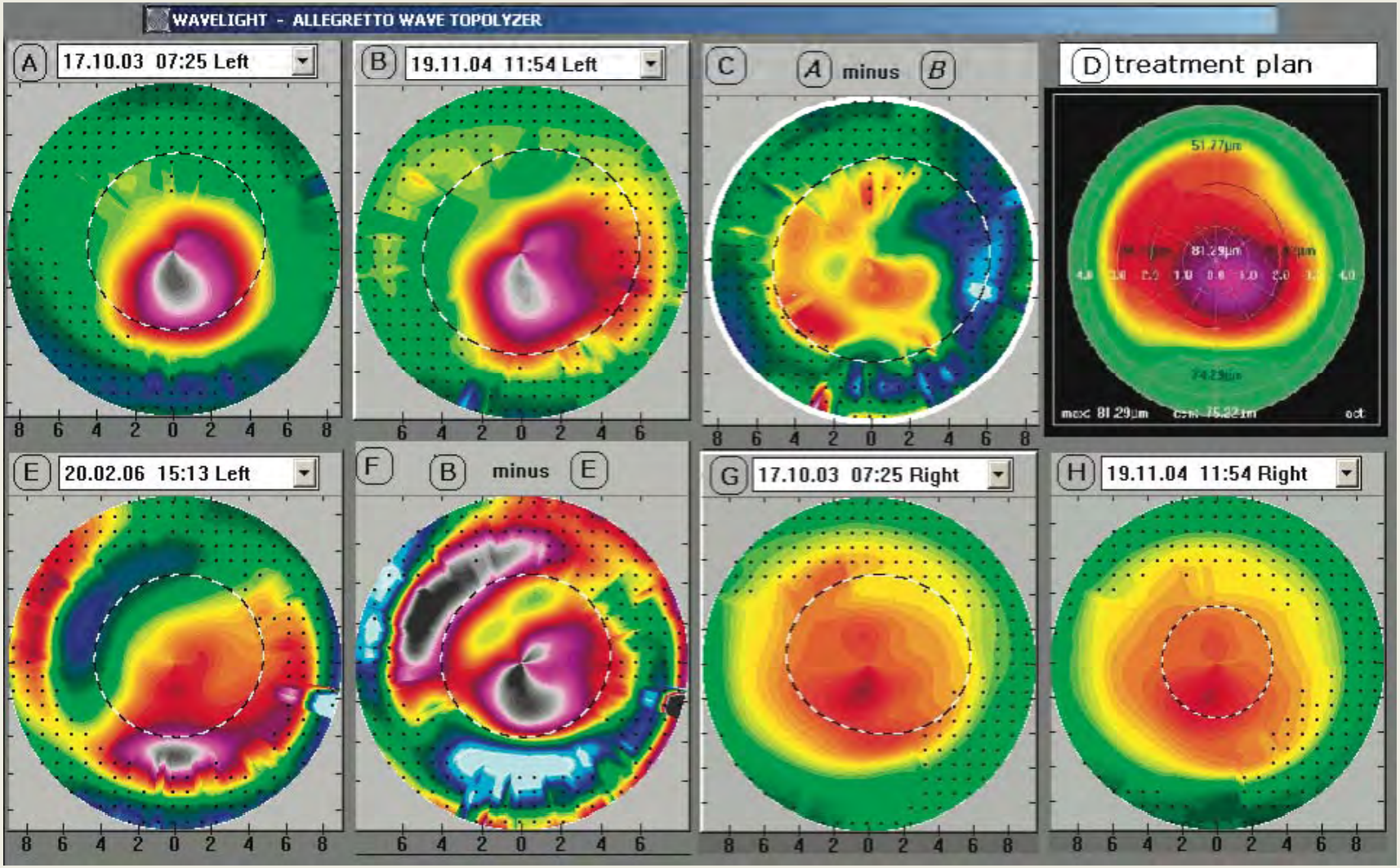
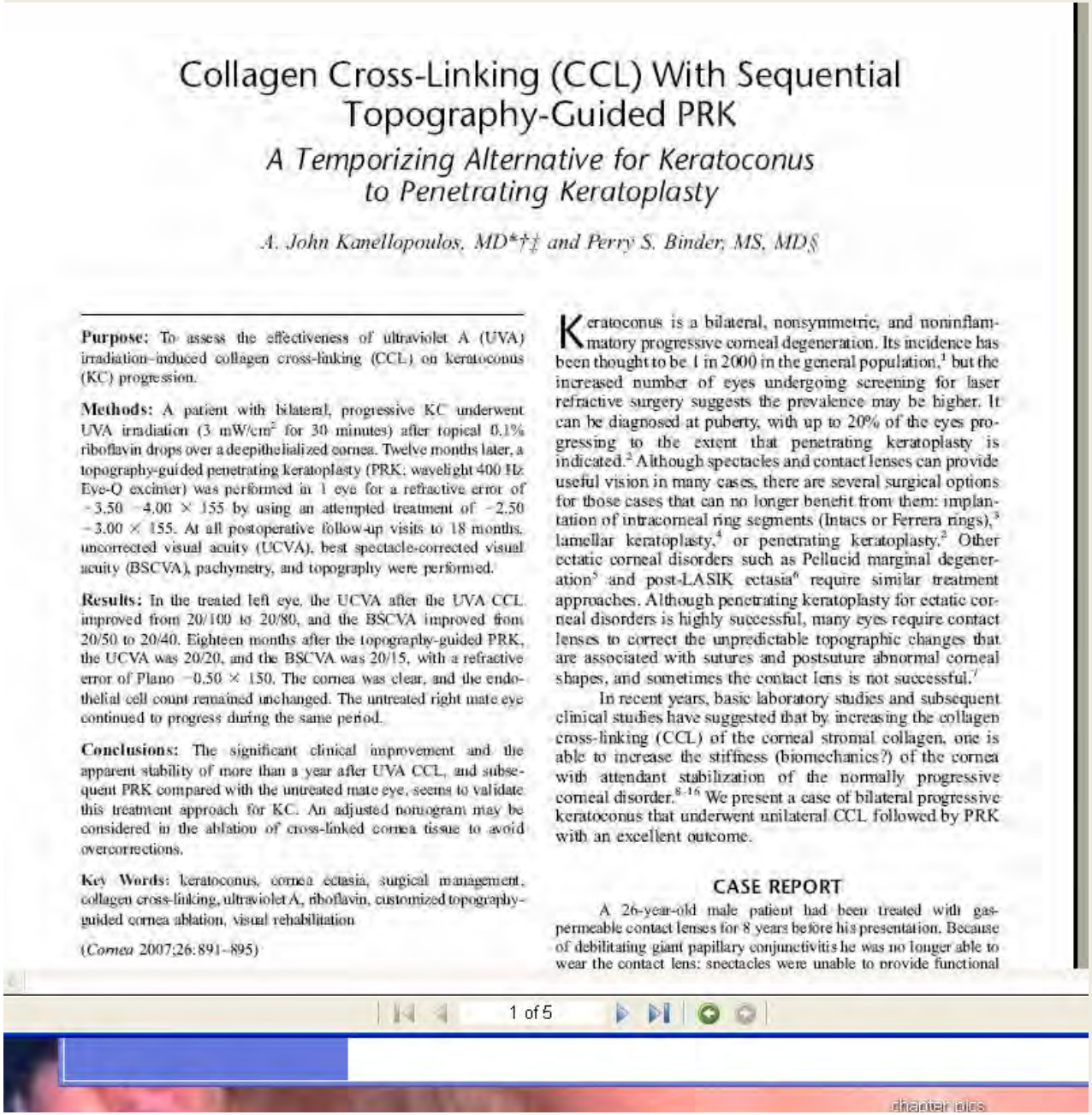


Figure 1. Display of topographies. **1**, Corneal topography of this case when first seen by the authors, with central cornea ectasia and midperiphery flattening as an effect of the Intacs that were present. At this point, best spectacle-corrected visual acuity (BSCVA) is 20/200. **2**, Corneal topography 2 months after the removal of Intacs and 1 month after combined ultraviolet radiation and riboflavin treatment to achieve collagen cross-linking. The central steepening is still present, and the effect of the Intacs removal relative to the previous image is appreciated mostly at the midperiphery, which appears steeper now. At this point, BSCVA is 20/200. **Bottom center**, An estimated corneal topographic ablation pattern as a laser treatment plan of the topography-guided procedure. It is notable that this ablation pattern is highly irregular, with a deeper ablation plan just inferior to and right of the center, which matches, however, the central cornea irregularity in the previous topographies. **4**, Corneal topography 6 months after topography-guided photorefractive keratectomy. The central cornea appears more regular and much flatter. At this point, BSCVA and UCVA are 20/20$^-$. **Bottom left**, Comparison map depicting the result of subtraction of corneal topography 4 (final result) from corneal topography 1 (state of the complication when we encountered it). Impressively, the difference resembles the topography-guided ablation pattern (bottom center), demonstrating effectively the specificity of this treatment in reducing the pathogenic cornea irregularity, which, we theorize, contributed to the drastic improvement in BSCVA.

keratoconus

27 y/o left eye is treated and the right observed over 3 years





Collagen Cross-Linking (CCL) With Sequential Topography-Guided PRK

A Temporizing Alternative for Keratoconus to Penetrating Keratoplasty

A. John Kanellopoulos, MD†‡ and Perry S. Binder, MS, MD§*

Purpose: To assess the effectiveness of ultraviolet A (UVA) irradiation–induced collagen cross-linking (CCL) on keratoconus (KC) progression.

Methods: A patient with bilateral, progressive KC underwent UVA irradiation (3 mW/cm^2 for 30 minutes) after topical 0.1% riboflavin drops over a deepithelialized cornea. Twelve months later, a topography-guided penetrating keratoplasty (PRK; wavelight 400 Hz Eye-Q excimer) was performed in 1 eye for a refractive error of −3.50 −4.00 × 155 by using an attempted treatment of −2.50 −3.00 × 155. At all postoperative follow-up visits to 18 months, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), pachymetry, and topography were performed.

Results: In the treated left eye, the UCVA after the UVA CCL improved from 20/100 to 20/80, and the BSCVA improved from 20/50 to 20/40. Eighteen months after the topography-guided PRK, the UCVA was 20/20, and the BSCVA was 20/15, with a refractive error of Plano −0.50 × 150. The cornea was clear, and the endothelial cell count remained unchanged. The untreated right mate eye continued to progress during the same period.

Conclusions: The significant clinical improvement and the apparent stability of more than a year after UVA CCL, and subsequent PRK compared with the untreated mate eye, seems to validate this treatment approach for KC. An adjusted nomogram may be considered in the ablation of cross-linked cornea tissue to avoid overcorrections.

Key Words: keratoconus, cornea ectasia, surgical management, collagen cross-linking, ultraviolet A, riboflavin, customized topography-guided cornea ablation, visual rehabilitation

(*Cornea* 2007;26:891–895)

Keratoconus is a bilateral, nonsymmetric, and noninflammatory progressive corneal degeneration. Its incidence has been thought to be 1 in 2000 in the general population,[1] but the increased number of eyes undergoing screening for laser refractive surgery suggests the prevalence may be higher. It can be diagnosed at puberty, with up to 20% of the eyes progressing to the extent that penetrating keratoplasty is indicated.[2] Although spectacles and contact lenses can provide useful vision in many cases, there are several surgical options for those cases that can no longer benefit from them: implantation of intracorneal ring segments (Intacs or Ferrera rings),[3] lamellar keratoplasty,[4] or penetrating keratoplasty.[2] Other ectatic corneal disorders such as Pellucid marginal degeneration[5] and post-LASIK ectasia[6] require similar treatment approaches. Although penetrating keratoplasty for ectatic corneal disorders is highly successful, many eyes require contact lenses to correct the unpredictable topographic changes that are associated with sutures and postsuture abnormal corneal shapes, and sometimes the contact lens is not successful.[7]

In recent years, basic laboratory studies and subsequent clinical studies have suggested that by increasing the collagen cross-linking (CCL) of the corneal stromal collagen, one is able to increase the stiffness (biomechanics?) of the cornea with attendant stabilization of the normally progressive corneal disorder.[8–16] We present a case of bilateral progressive keratoconus that underwent unilateral CCL followed by PRK with an excellent outcome.

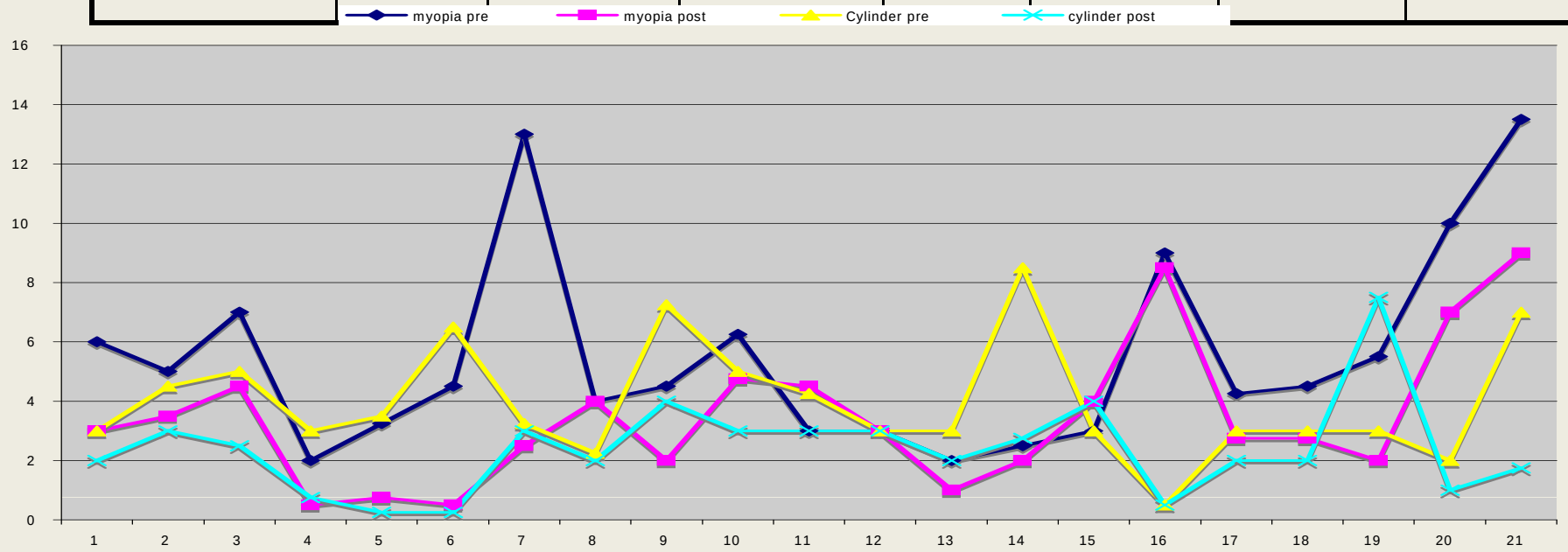
CASE REPORT

A 26-year-old male patient had been treated with gas-permeable contact lenses for 8 years before his presentation. Because of debilitating giant papillary conjunctivitis he was no longer able to wear the contact lens; spectacles were unable to provide functional

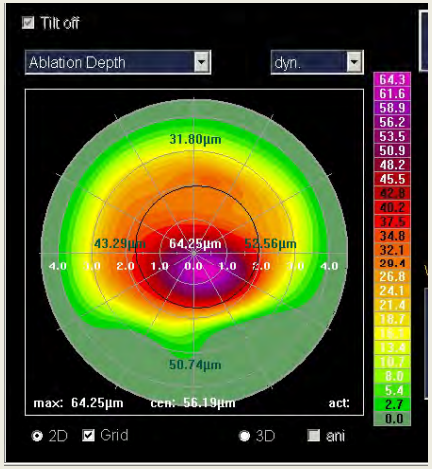
J Cornea
August
2007

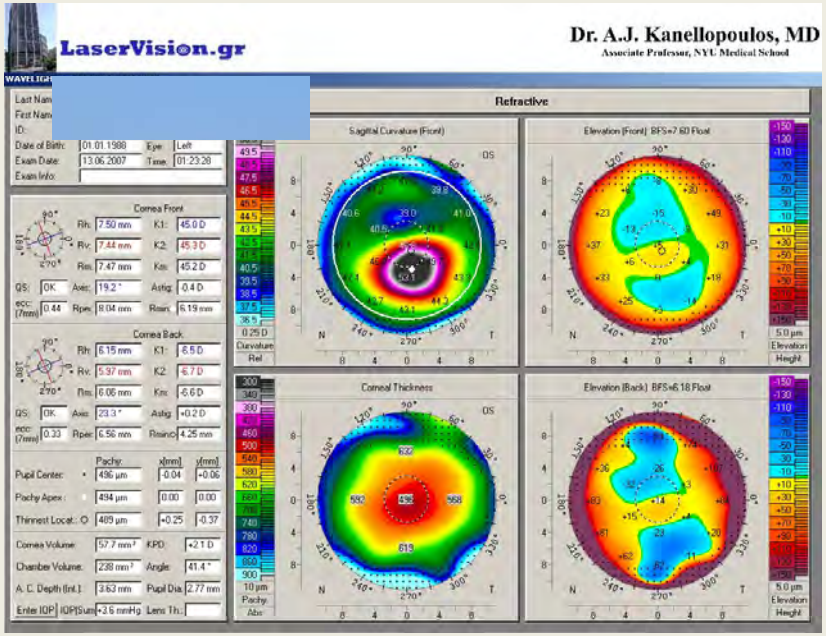
Cumulative average data

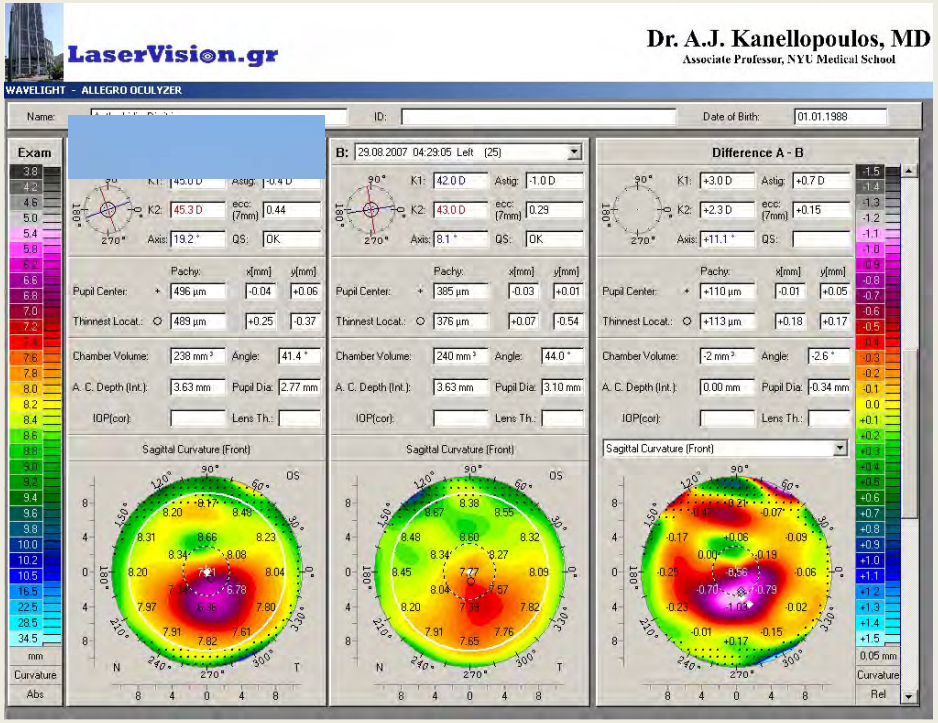
	pach	steep K	BSCVA	myopia	cyl	ECC	comp
pre	448	51.5	0.5	2.5	4.5	2850	
12m Post op	397	46	0.7	1.5	2.5	2850	6 cases haze



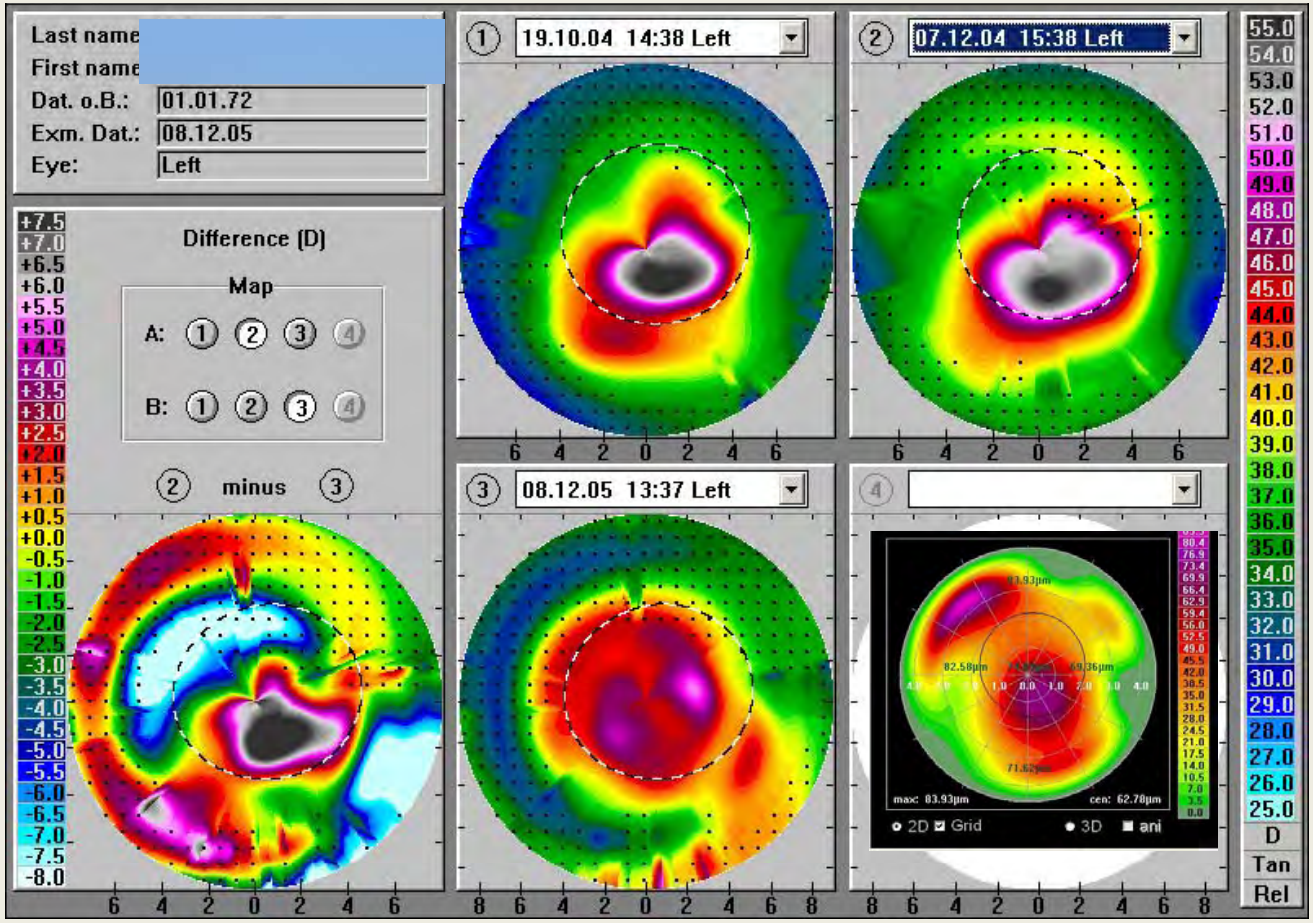
A 24 y/o pilot
Pre: UCVA 20/200
-4.5 -1.50 X 180 20/30
2 months post: UCVA 20/20
-0.25 -0.75 X34







16 months after the CCL
A partial custom PRK



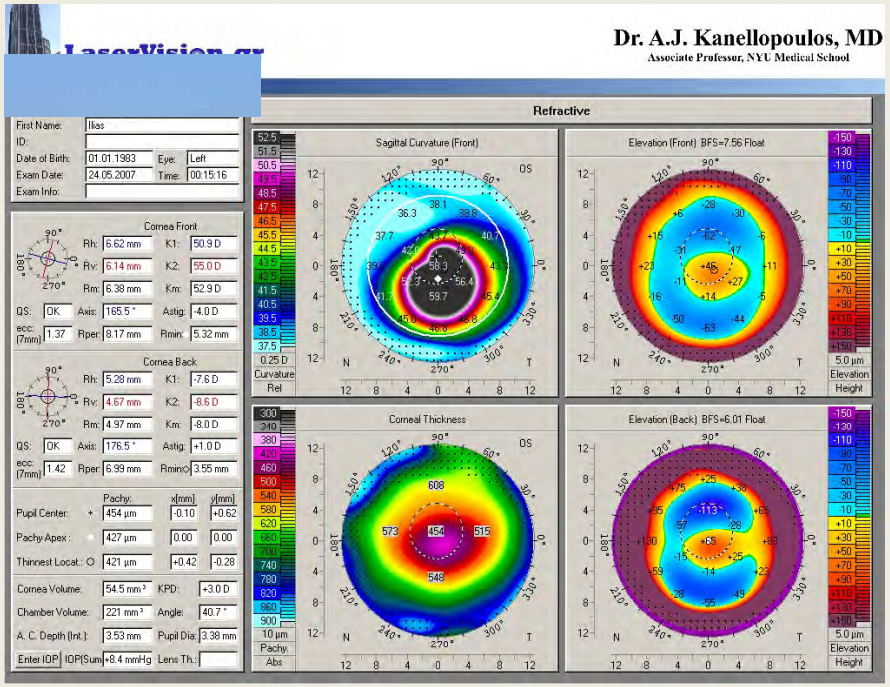
An argument against PK?

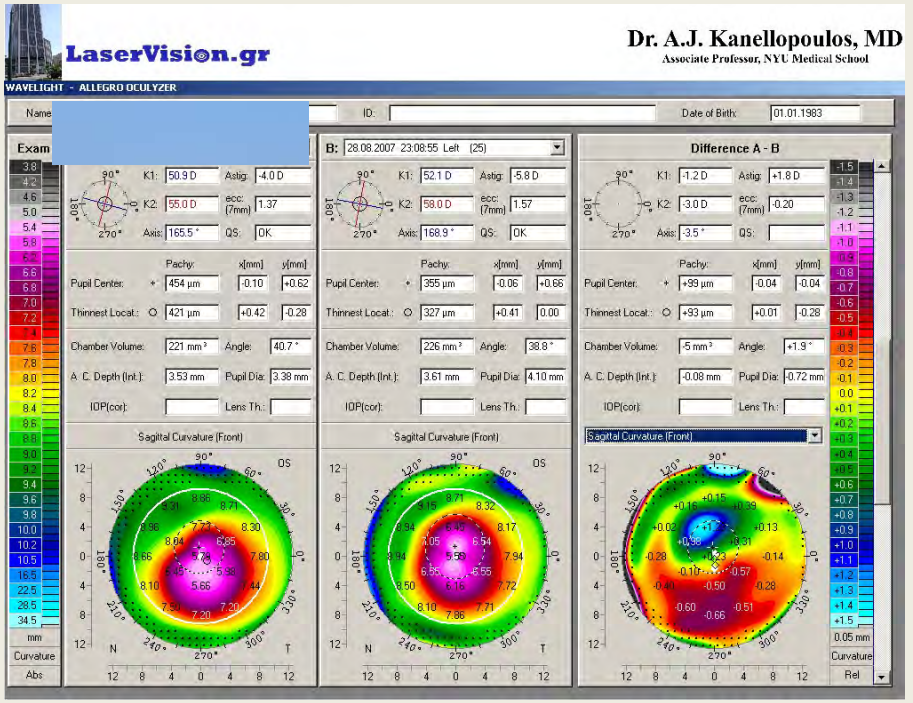
Pre: UCVA: CF

-10.50 -3.5 X170 20/50

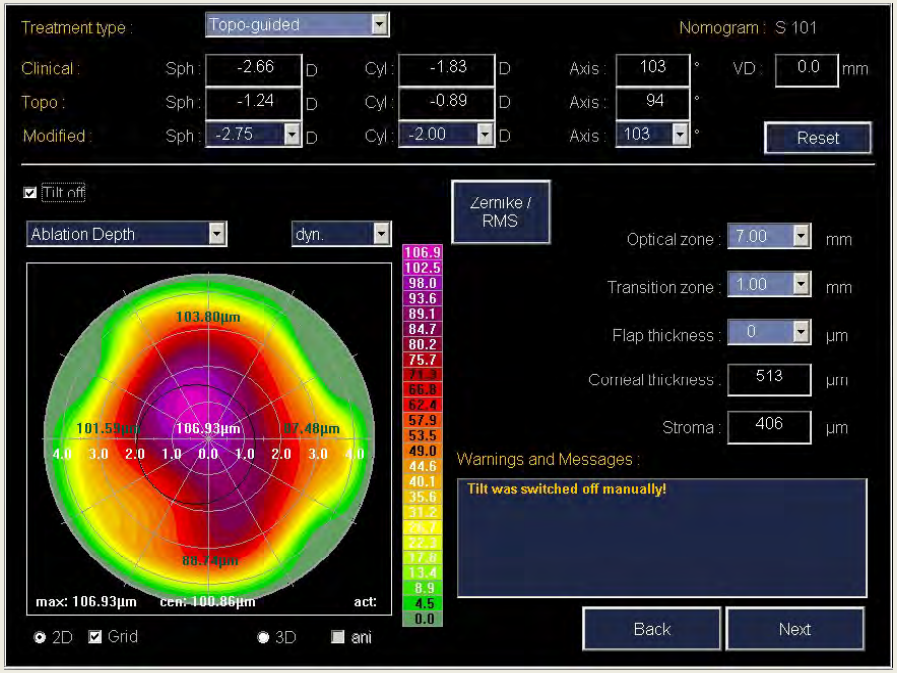
Post: UCVA 20/400

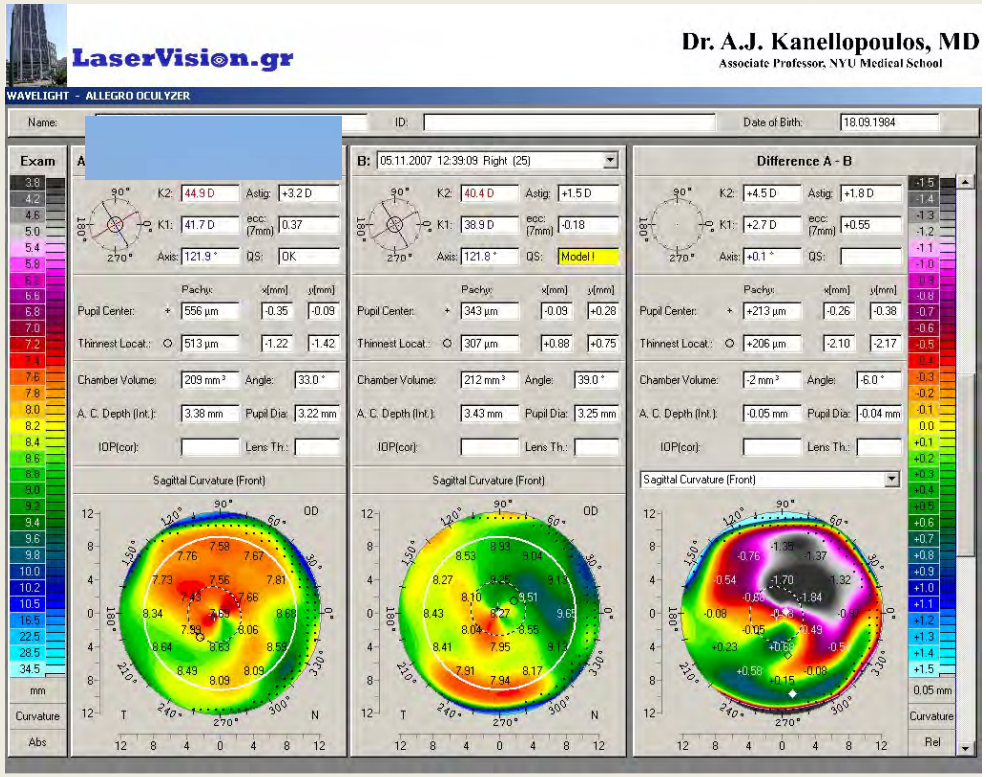
-9 -1.50 X75 20/25 uses SCL -7D





Custom partial PRK and CCL
0.1% riboflavin + 7mW/cm2 X 15minutes





Conclusions

- Today's highly customized ablation tools offer visual rehabilitation in a broad range of corneas: regular to highly irregular.
- In our experience the Alcon/Wavelight topography guided platform has been very effective in predictably offering cornea normalization and enhanced visual function