Lessons from a 2 decade journey through customizing ablations and cornea biomechanics with CXL (CXL plus part I)

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International Society of Refractive Surgery
A Partner of the American Academy of Ophthalmology

New York University School of Medicine

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Financial interests (D) consultant for:

- AJKMD events
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- Allergan
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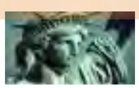

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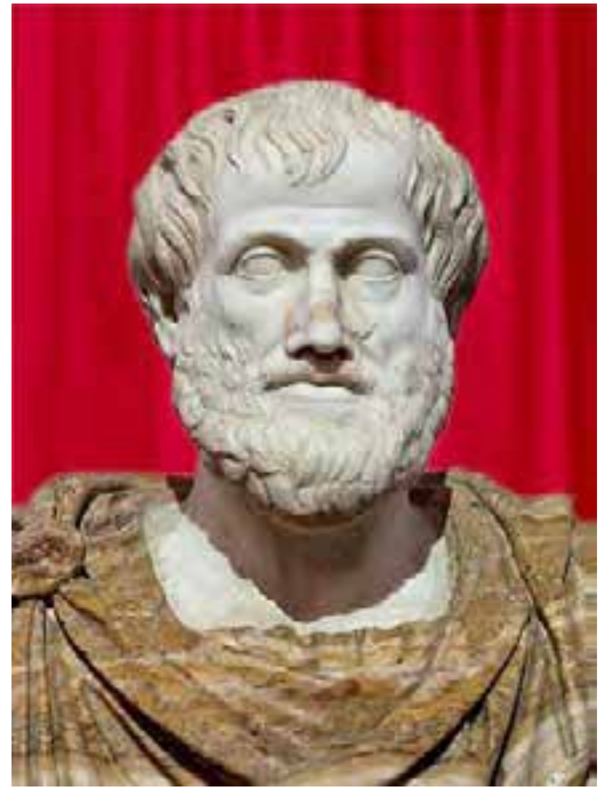
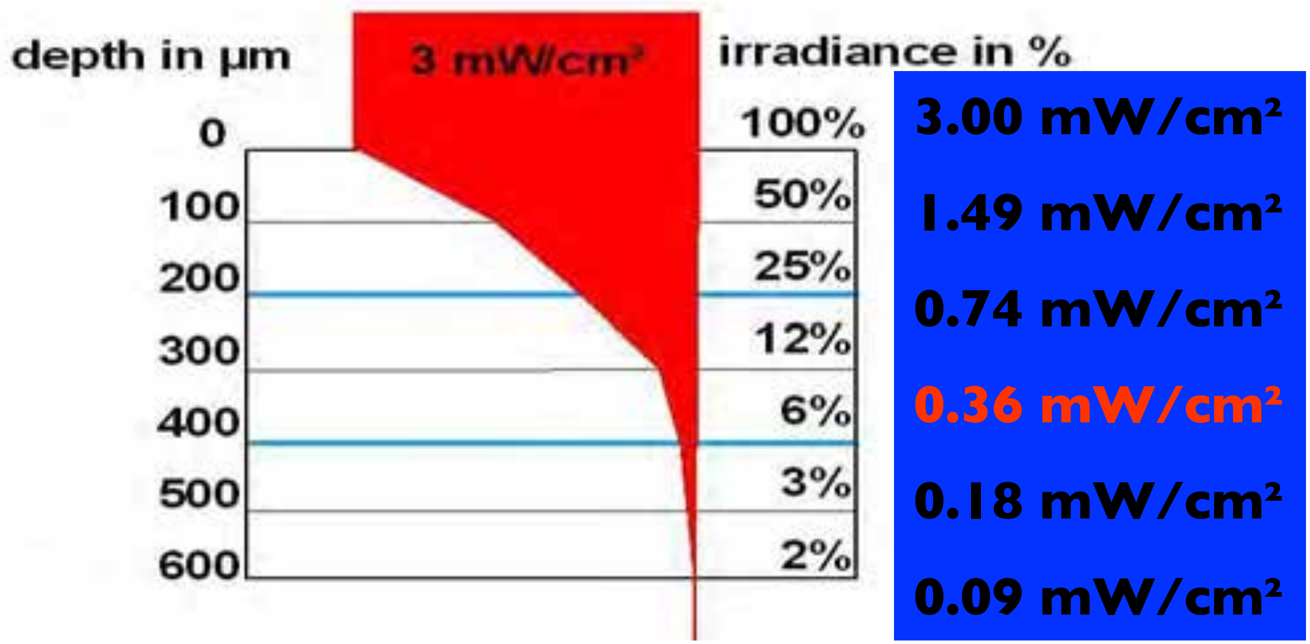
For the things we have to learn before we can do, we learn by doing.

— Aristotle



CXL efficacy and safety
Decrease of UV-intensity

courtesy E. Spoel MD



Our Athens team's CXL contributions:

- Applying topo-guided PRK in CXLed ectatic corneas **2004**
- Combining same-day CXL with topo-guided reshaping of irregular corneas Athens Protocol: **2005**
- Higher fluence: **2006 (6mW, 10mW)**
- Intra-stromal treatments through femto-pocket: **2007**
- LASIK+CXL(Xtra): **2008** (ESCRS)
- LASIK Xtra for hyperopia: **2011** (ASCRS)
- PiXL CXL corneal differentials: **2013** (AAO)
- CXL in Boston Kpro (Cornea resistance to melt)
- Athens Protocol with PiXL CXL **2015**
- **TMR:** Topography-modified refraction **2016**

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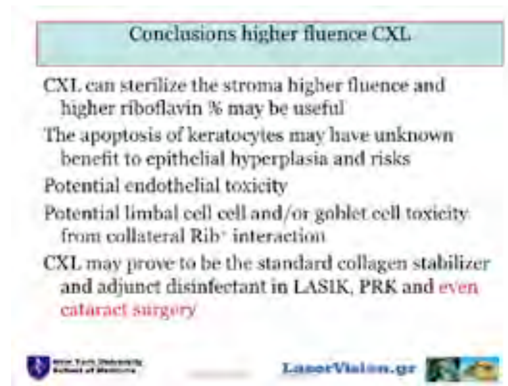
- LASIK combined with CXL
- CXL or bullus keratopathy
- In-pocket CXL
- The Athens Protocol

Zurich 2011



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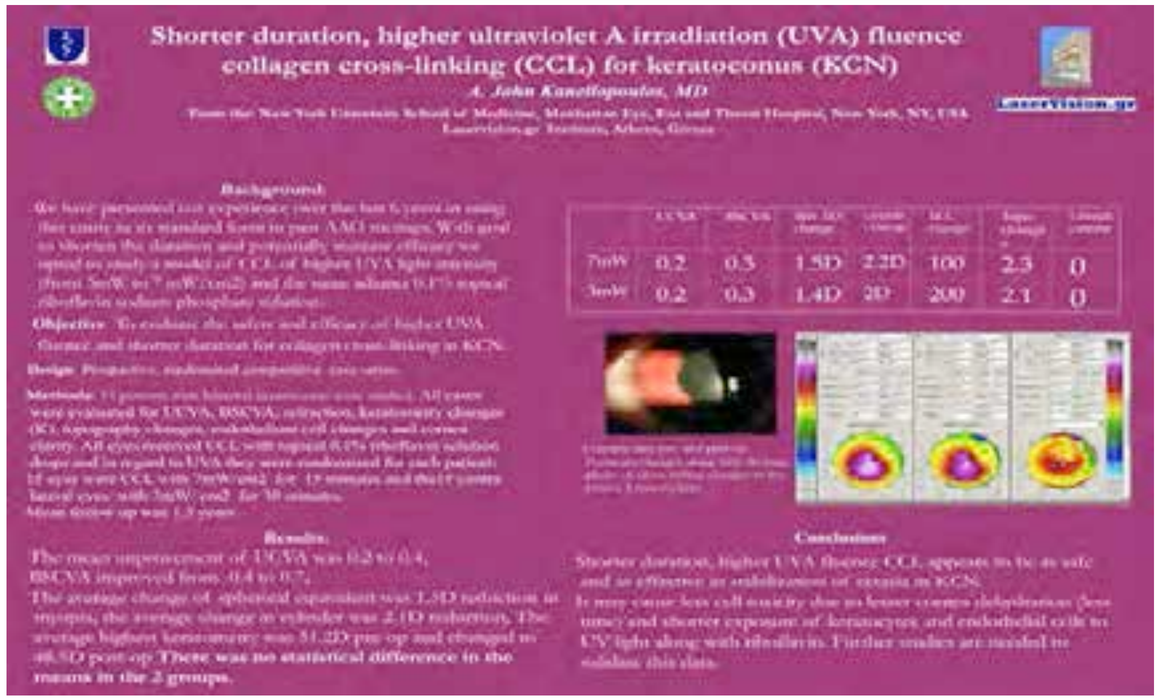
introduced: Higher fluence CXL: 6, 7, 9, 10 and 12mW/cm2

AAO 2008:

CXL for 15 minutes utilizing $7mW/cm^2$ fluence



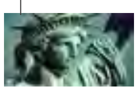
2007: Introduction of riboflavin in a femto-pocket

NEW TECHNIQUE

Collagen Cross-linking in Early Keratoconus With Riboflavin in a Femtosecond Laser-created Pocket: Initial Clinical Results

Anastasios John Kanellopoulos, MD

New York University School of Medicine



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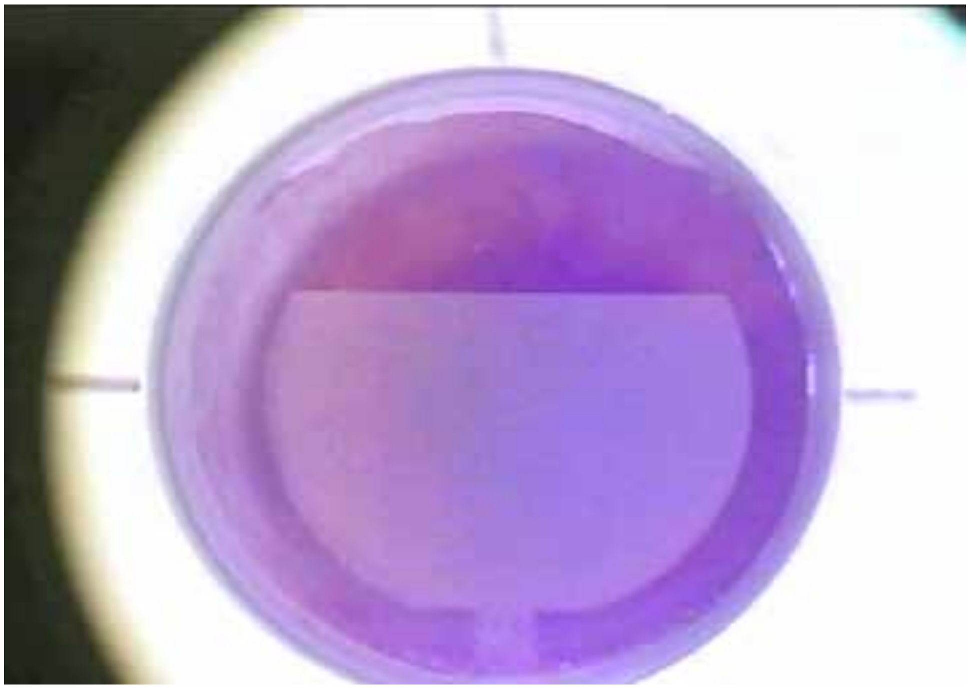
Introduced Prophylactic CXL in PRK and LASIK 2008



Clinical Ophthalmology

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ORIGINAL RESEARCH

Comparison of prophylactic higher fluence corneal cross-linking to control, in myopic LASIK, one year results

Anastasios John Kanellopoulos[1,2]
George Asimellis[1]
Costas Karabatsas[1]

[1]LaserVision.gr Clinical and Research Eye Institute, Athens, Greece; [2]New York University Medical School, New York, NY, USA

Purpose: To compare 1-year results: safety, efficacy, refractive and keratometric stability, of femtosecond myopic laser-assisted in situ keratomileusis (LASIK) with and without concurrent prophylactic high-fluence cross-linking (CXL) (LASIK-CXL).
Methods: We studied a total of 155 consecutive eyes planned for LASIK myopic correction. Group A represented 73 eyes that were treated additionally with concurrent prophylactic high-fluence CXL; group B included 82 eyes subjected to the stand-alone LASIK procedure. The following parameters were evaluated preoperatively and up to 1-year postoperatively: manifest refractive spherical equivalent (MRSE), refractive astigmatism, visual acuity, corneal keratom-

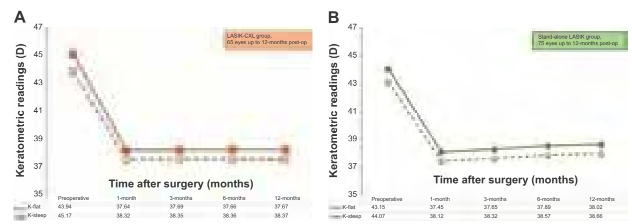

Figure 8 Stability of corneal keratometry for (**A**) the LASIK-CXL group and (**B**) the stand-alone LASIK group, expressed in diopters (D), up to 1-year postoperatively.
Abbreviations: CXL, cross-linking; LASIK, laser-assisted in situ keratomileusis.

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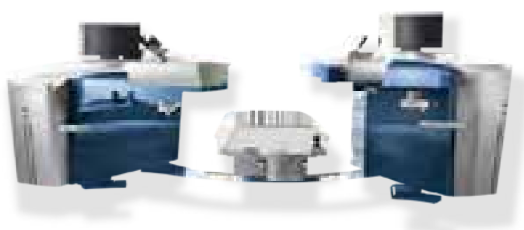
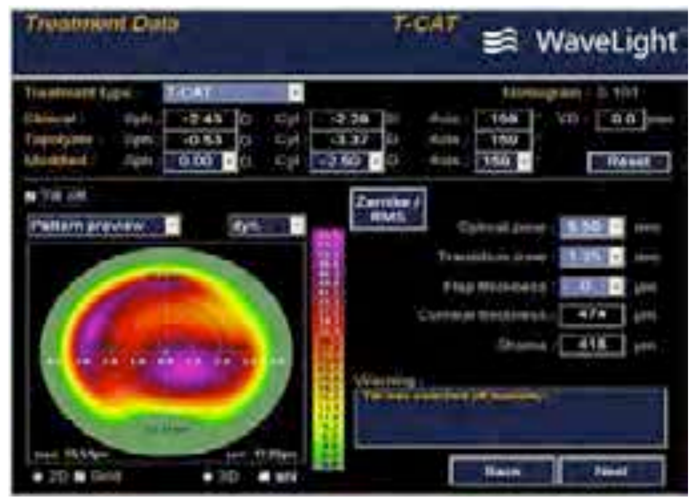
Athens Protocol:Topo-guided partial PRK + CXL

1-Topolyzer:Placido disc topography
2-Pentacam (Oculyzer)
3-Pentacam HD (oculyzer II)-Refractive suite
4-Vario (placido disc +pupil sensor+iris recognition+limbal landmarks recognition)



WaveLight® Refractive Suite
Similar technologies: Zeiss, Schwind, Ivis



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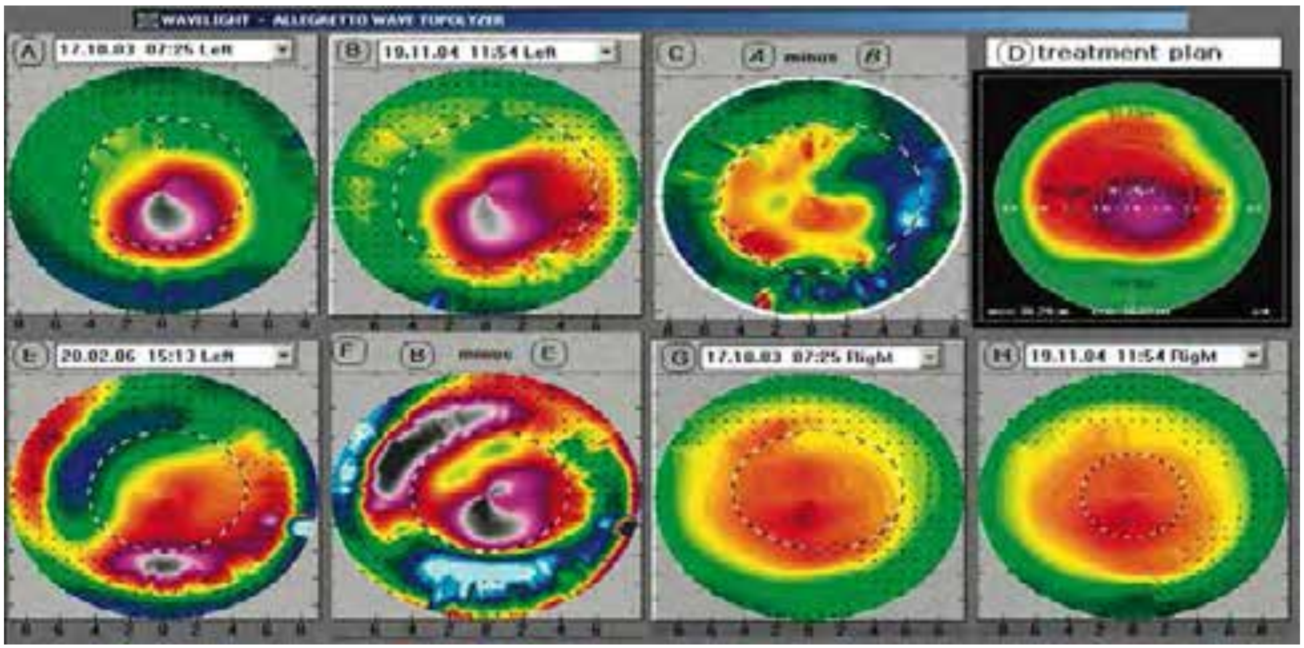
2004: Over the last 12 years we have introduced and treated over 3000 cases of KCN and ectasia with CXL combined with a topo-guided excimer normalization: the "Athens Protoco" now practiced globally!!!

J Cornea 2007




CASE REPORT

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§*

CASE REPORT

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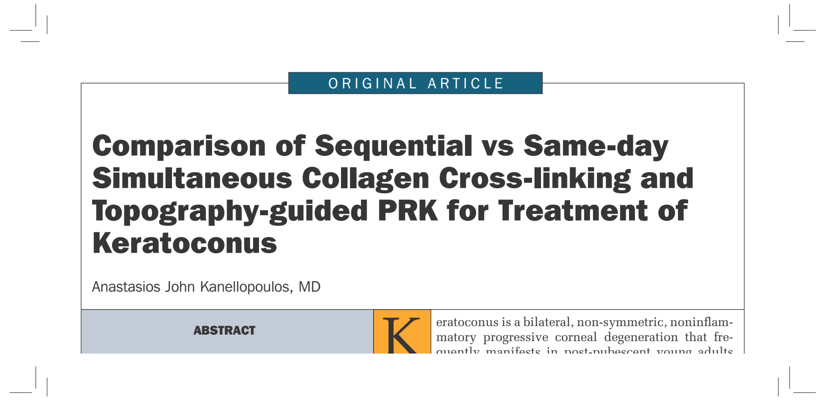
The Athens Protocol 4 steps:

same day PTK > topoPRK > MMC > CXL (6mW/cm2 x 15 min)



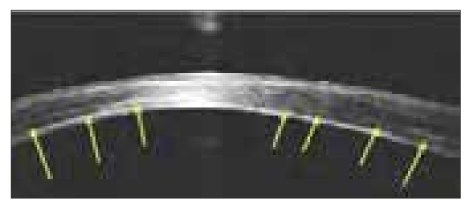
ORIGINAL ARTICLE

Comparison of Sequential vs Same-day Simultaneous Collagen Cross-linking and Topography-guided PRK for Treatment of Keratoconus

Anastasios John Kanellopoulos, MD

ABSTRACT

Keratoconus is a bilateral, non-symmetric, noninflammatory progressive corneal degeneration that frequently manifests in post-pubescent young adults



Sequential vs Simultaneous Topography-guided PRK and CXL/Kanellopoulos

Figure 2. Cornea optical coherence tomography demonstrates hyper-reflective intracorneal stromal "lines" at 2/3 depth (arrows) corresponding with the clinical presence of the corneal collagen cross-linking (CXL) demarcation line in a patient from the simultaneous group 3 years following the combined topography-guided photorefractive keratectomy and CXL procedure.

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Kanellopoulos AJ: ***JRS Sept 09***: 358 cases with over 2 year follow-up: 160 cases Sequential (left) Vs 198 cases same-day Combined (right)

	PreOp	PostOp
UCVA LogMar	0.9 ±0.3	0.49 ±0.25
BSCVA LogMar	0.41 ±0.25	0.16 ±0.22
Mean Decrease MRSE		2.50±1.2
Mean K Decrease		2.75±1.3
Mean Haze Score		1.2±0.5
Mean CCT	465±45	395±25

Sequential CXL and after TCAT

	Pre-op	Post-op
UCVA LogMar	0.96 ±0.2	0.3 ±0.2
BSCVA LogMar	0.39 ±0.3	0.11 ±0.16 (p<0.001)
Mean Decrease MRSE		3.2±1.4 (p<0.005)
Mean K Decrease		3.50±1.3 (p<0.005)
Mean Haze Score		0.5±0.3 (p<0.0052
Mean CCT	475±55	405±35

Combined TCAT + CXL: The Athens Protocol

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ORIGINAL ARTICLES

Management of Corneal Ectasia After LASIK With Combined, Same-day, Topography-guided Partial Transepithelial PRK and Collagen Cross-linking: The Athens Protocol

Anastasios John Kanellopoulos, MD; Perry S. Binder, MS, MD

Management of Corneal Ectasia After LASIK/Kanellopoulos & Binder

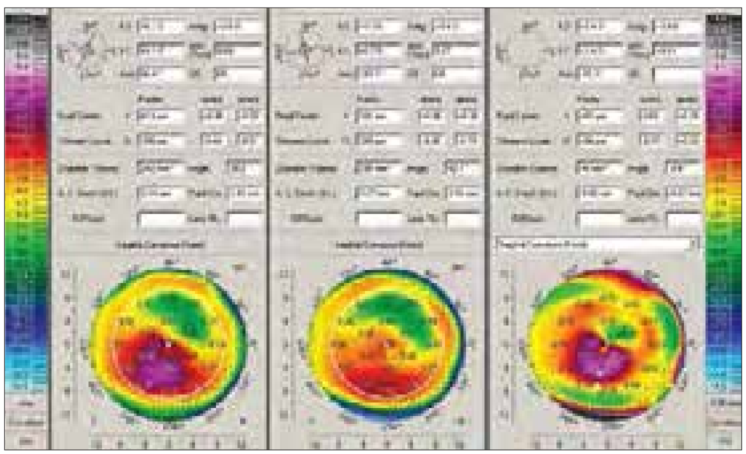

Figure 4. *Case 4.* Pentacam comparison of the right eye. The left column shows the data and topography before topography-guided PRK/CXL. The center column shows the postoperative data and topography. The right column shows the difference (pre- minus postoperative).

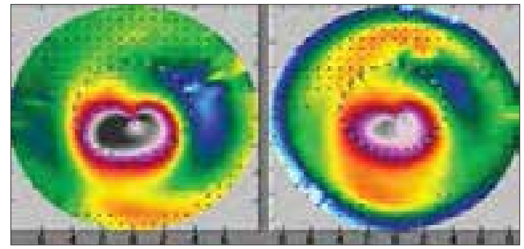

Figure 2. *Case 2.* Topography on the left shows marked inferior steepening before topography-guided PRK/CXL treatment. The topography on the right shows the same cornea 18 months after topography-guided PRK/CXL with marked flattening of the corneal ectasia and normalization of the cornea.

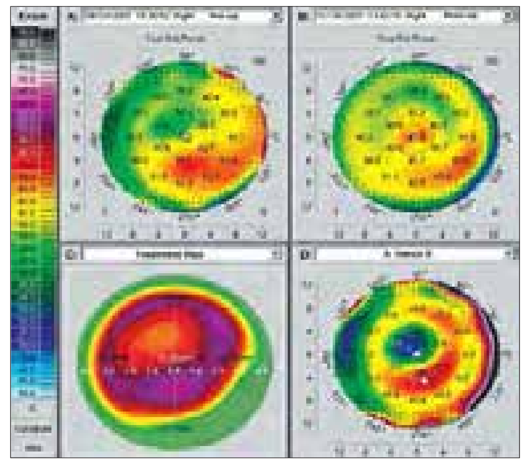

Figure 3. *Case 3.* Clinical course of the right eye. **A)** Topography 3 years after LASIK demonstrates irregular astigmatism and marked inferior corneal steepening. Uncorrected distance visual acuity was 20/40 and corrected distance visual acuity was 20/20 with refraction of +1.50 −2.00 × 65. **B)** Topography 3 months after topography-guided PRK/CXL procedure demonstrates a flatter and normalized cornea. Uncorrected distance visual acuity was 20/15. **C)** Topographic reproduction of the topography-guided PRK treatment plan with the WaveLight platform. This platform plans to remove tissue in an irregular fashion to normalize the corneal ectasia seen in Figure 3A. **D)** Comparison map, derived from subtracting image B from A, represents the topographic difference in this case 3 months after the combined treatment. The paracentral flattening is self-explanatory, as the PRK and CXL have flattened the cone apex. The superior nasal arcuate flattening represents the actual part-hyperopic correction, which the topography-guided treatment has achieved, to accomplish steepening in the area central to this arc. Thus, the topography-guided treatment has normalized the ectatic cornea by flattening the cone apex and at the same time by "steepening" the remainder of the central cornea.

ectasia and was offered Intacs (Addition Technology Inc, Des Plaines, Illinois) or a corneal transplant.

He presented to our institution in September 2007, 3 years after LASIK. Uncorrected distance visual acuity was 20/40 in the right eye and 20/15 in the left eye. Manifest refraction was +1.50 −2.00 × 65 (20/20) in the right eye and plano (20/15) in the left eye. Keratometry was 41.62@65/43.62@155 in the right eye and 41.75/42.12@10 in the left eye. Central ultrasound pachymetry was 476 µm in the right eye and 490 µm in the left eye.

On September 13, 2007, 39 months after LASIK,

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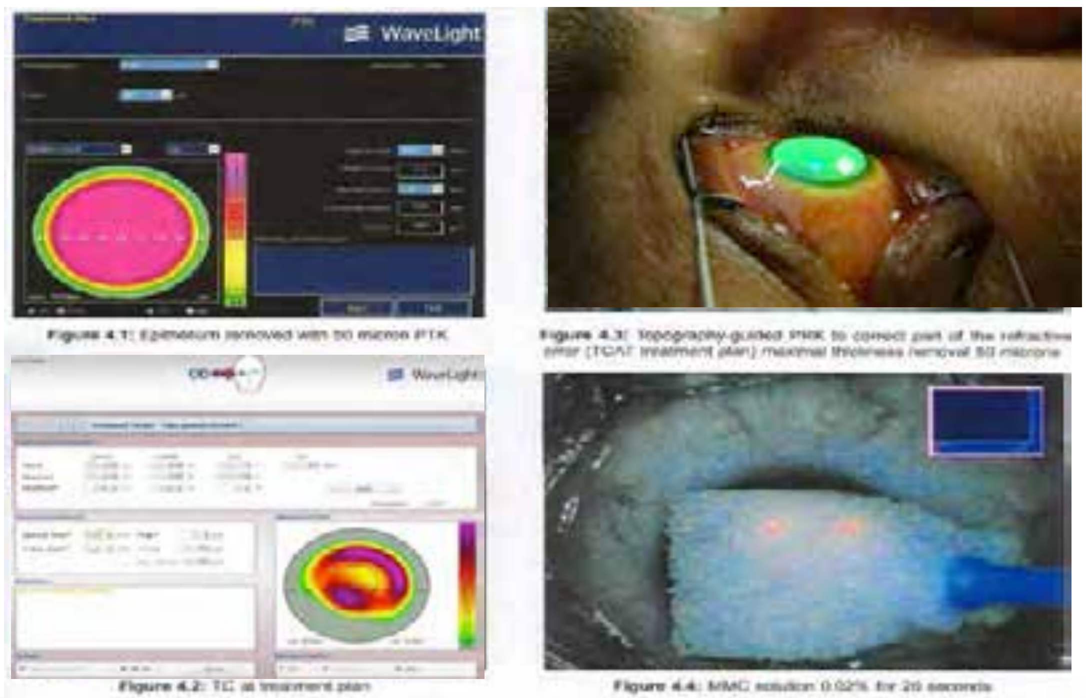
The Athens Protocol 4 steps:

same day partialPRK > PTK > MMC > CXL (6mW/cm2 x 15 min)

2-PTK

1- topo -guided PRK

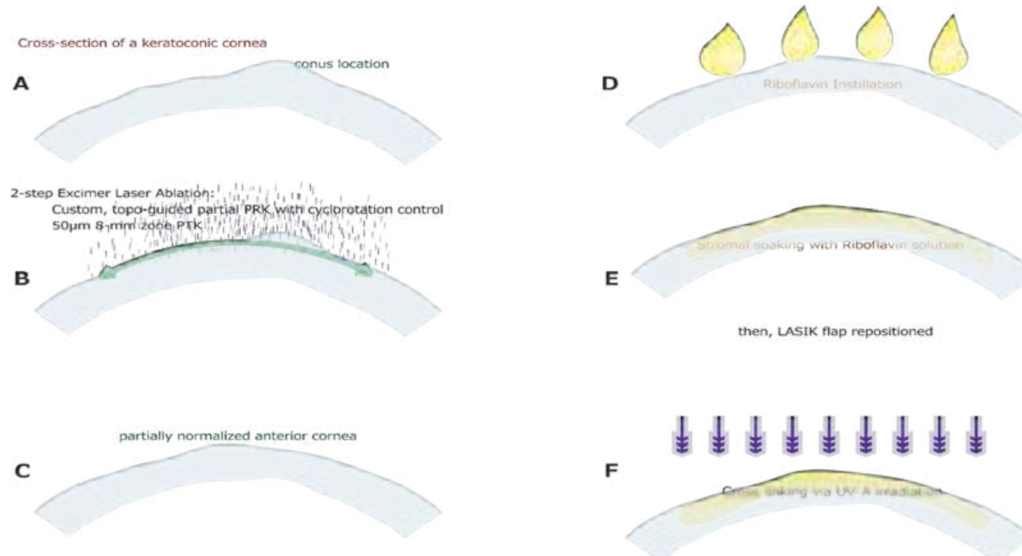


4-: CXL

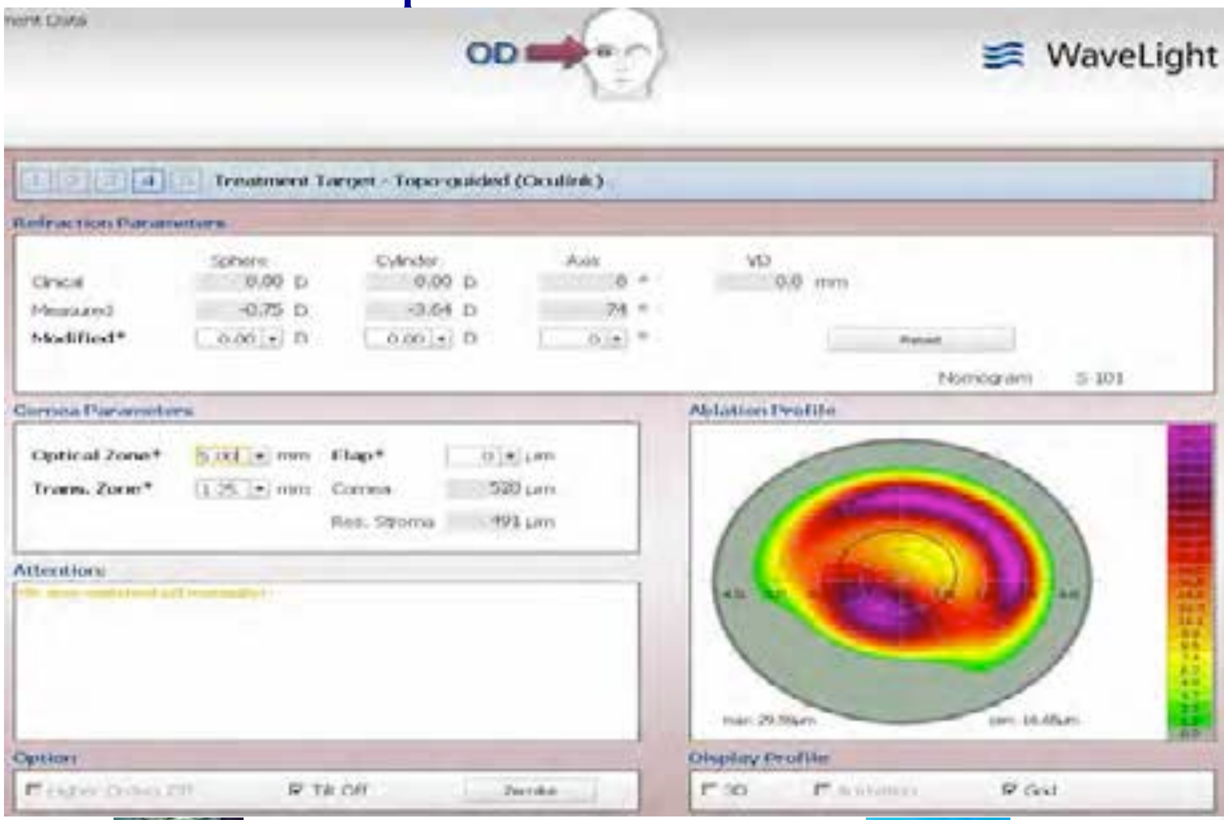
3- 30" MMC

Surgical Procedure

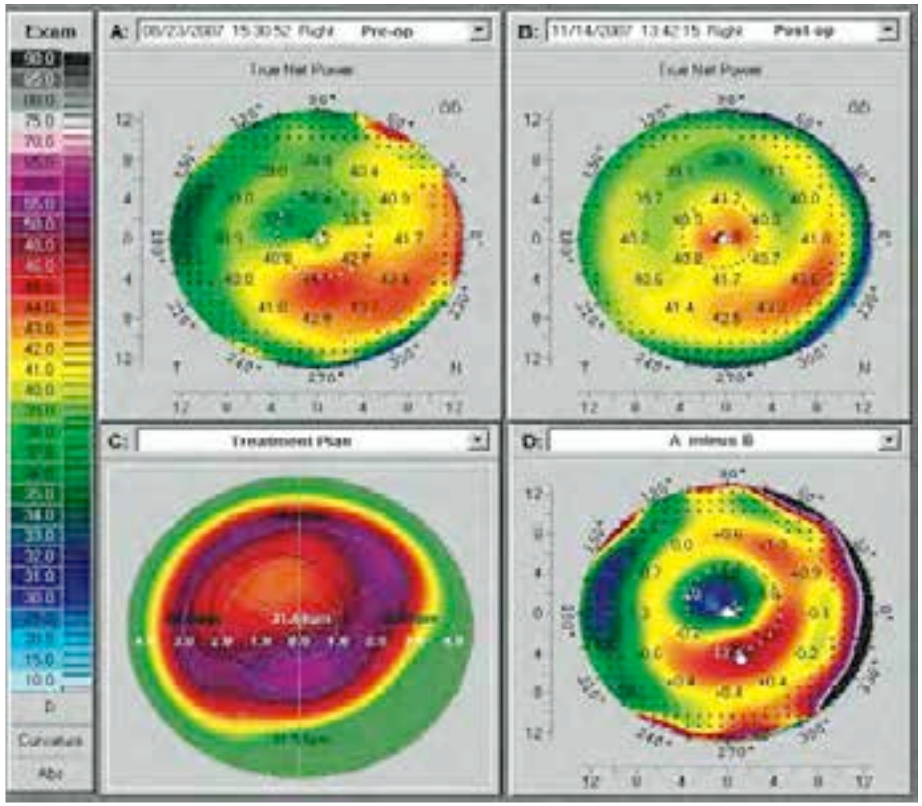
1. Partial topography-guided excimer-laser ablation, employing photorefractive keratectomy (PRK) in combination with the T-CAT procedure. Optical zone 5.00 to 5.50 mm.
2. Excimer-laser ablation (uniform 50 µm over a 7.00 mm zone), employing the PTK mode.
3. CXL with UV-A irradiance of 6 mW/cm², applied for 15' employing the KXL I or II system (Avedro Inc., Waltham, MA).

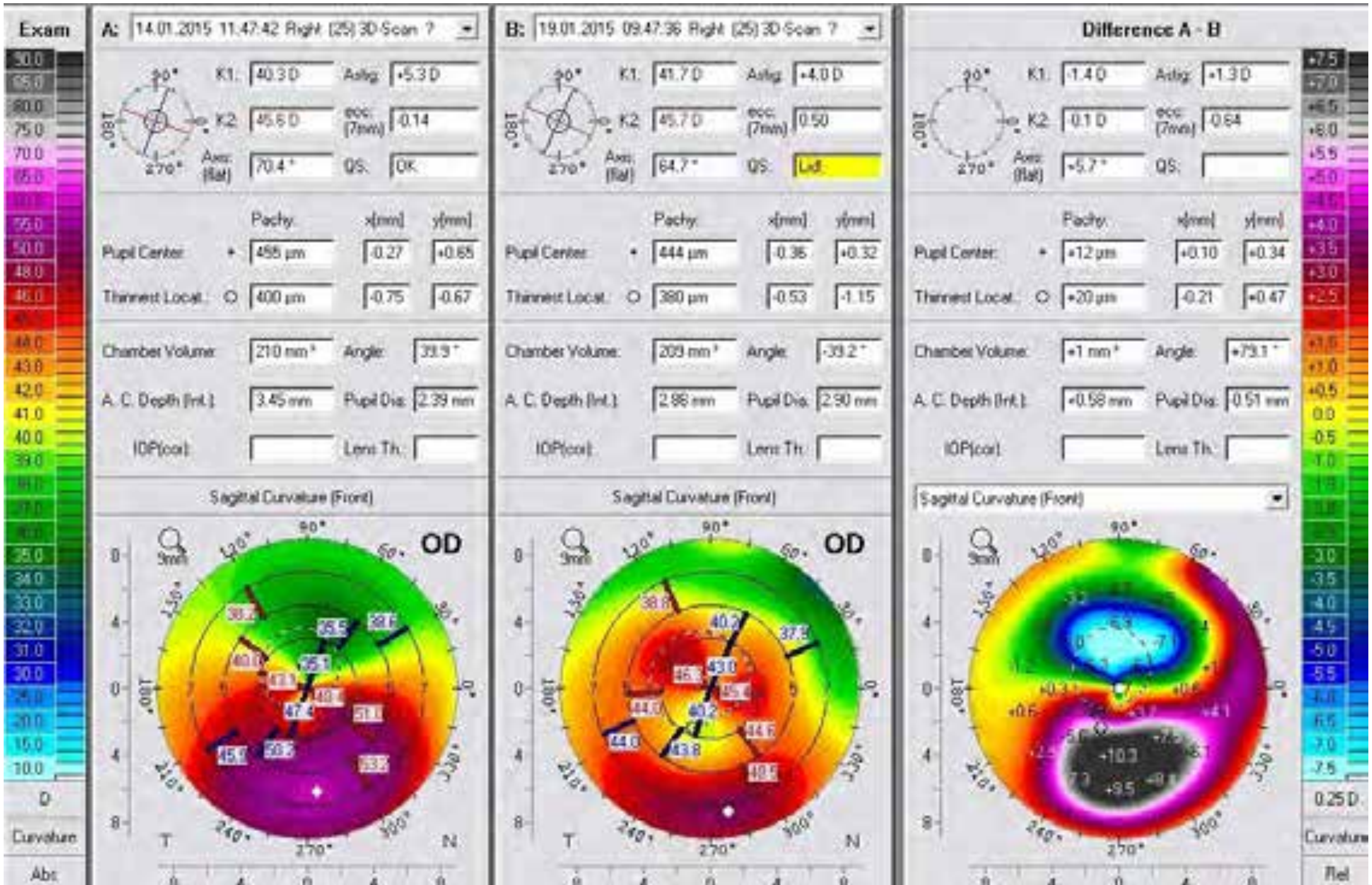


Step 4: attempted Rx to 0, OZ to 5 or 5.5mm, cyl axis to match topo axis not refractive axis



Post LASIK ectasia: 26y/o pilot, from UCVA 20/60 to 20/15





A. John Kanellopoulos, MD

ORIGINAL ARTICLE

Novel Placido-derived Topography-guided Excimer Corneal Normalization With Cyclorotation Adjustment: Enhanced Athens Protocol for Keratoconus

Anastasios John Kanellopoulos, MD; George Asimellis, PhD

ABSTRACT

PURPOSE: To comparatively investigate the efficacy of the enhanced Athens Protocol procedure guided by novel Placido-derived topography with cyclorotation compensation (the cyclorotation adjusted group) to similar cases guided by Scheimpflug-derived tomography without cyclorotation compensation (the non-cyclorotation adjusted group).

METHODS: Two groups were evaluated: the cyclorotation adjusted group (n = 110 eyes) and the non-cyclorotation adjusted group (n = 110 eyes). Analysis was based on digital processing of Scheimpflug imaging derived curvature difference maps preoperatively and 3 months postoperatively. The vector (r, ϑ) corresponding to the steepest corneal point (cone) on the preoperative surgical planning map (r_p, ϑ_p) and on the curvature difference map (r_d, ϑ_d) were computed. The differences between the peak topographic angular data ($\Delta\vartheta = |\vartheta_p - \vartheta_d|$) and weighted angular difference ($W\Delta\vartheta = \Delta\vartheta \times \Delta r$) were calculated.

RESULTS: For the cyclorotation adjusted group, Δϑ was 7.18° ± 7.53° (range: 0° to 34) and WΔϑ was 3.43 ± 4.76 mm (range: 0.00 to 21.41 mm). For the non-cyclorotation adjusted group, Δϑ was 14.50° ± 12.65° (range: 0° to 49°) and WΔϑ was 10.23 ± 15.15 mm (range: 0.00 to 80.56 mm). The cyclorotation adjusted group appeared superior to the non-cyclorotation adjusted group, in both the smaller average angular difference between attempted to achieved irregular curvature normalization and in weighted angular difference, by a statistically significant margin (Δϑ: *P* = .0058; WΔϑ: *P* = .015).

CONCLUSIONS: This study suggests that employment of the novel Placido-derived topographic data of highly irregular corneas, such as in keratoconus, treated with topography-guided profile with cyclorotation compensation leads to markedly improved cornea normalization.

[*J Refract Surg.* 2015;31(11):768-773.]

Corneal cross-linking (CXL) is considered a valid option for progressive keratoconus/corneal ectasia treatment.[1] By increasing corneal biomechanical strength, CXL results in keratectasia arrest.[2] In addition, CXL has also been shown to improve corneal irregularity and reduce central anterior corneal steepening.[3]

Combined with CXL, partial anterior surface normalization via topography-guided customized partial excimer laser ablation may offer, in addition to keratectasia arrest, improved topographic and refractive outcomes.[3,4] The Athens Protocol comprises phototherapeutic keratectomy (PTK) of 50 μm, a partial photorefractive keratectomy (PRK) for the topography-guided customized anterior surface normalization, and high-fluence CXL for corneal stabilization.[5] Long-term results[6] and anterior segment optical coherence tomography quantitative findings[7] have demonstrated the stability of the procedure in large cohorts of patients. Variations of this technique have been applied and reported globally.[8-14]

Because the topography-guided ablation step of the procedure bears a high degree of customization, the impact of effective alignment between treatment planning based on the topography-derived data and surgically applied ablation pattern is pivotal for a successful outcome. Critical parameters affecting alignment are horizontal and vertical eye movements, eye pupil centroid shift, and possible cyclorotation. The significance of these principles has been reported preoperatively and intraoperatively in refractive procedures.[15] High-speed active eye tracking along with cyclorotational topographic adjustment (CTA) has been introduced during the past 2 years in refractive lasers such as the EX500 excimer laser (Alcon Laboratories, Inc., Fort Worth, TX), which

From Laservision.gr Clinical and Research Eye Institute, Athens, Greece (AJK); and NYU Medical School, Department of Ophthalmology, New York, New York (GA).

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Dr. Kanellopoulos is a consultant for Alcon/WaveLight, Allegran, Avedro, and i-Optics. Dr. Asimellis has no financial or proprietary interest in the materials presented herein.

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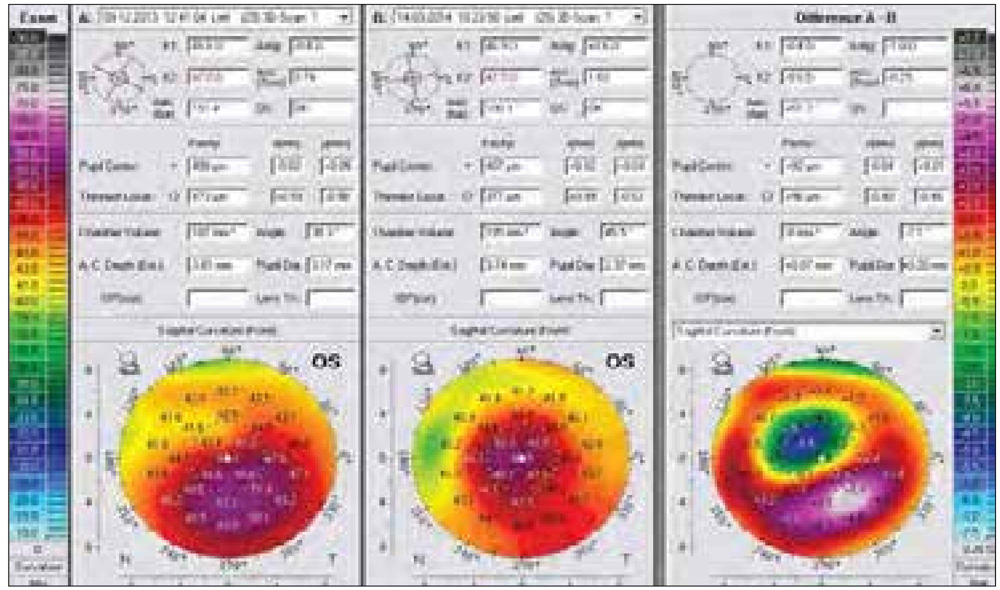

Figure B. The 'compare 2 exams' output from the Scheimpflug imaging device. (Left) The preoperative sagittal curvature map, (middle) the postoperative map, and (right) the difference of the two maps.

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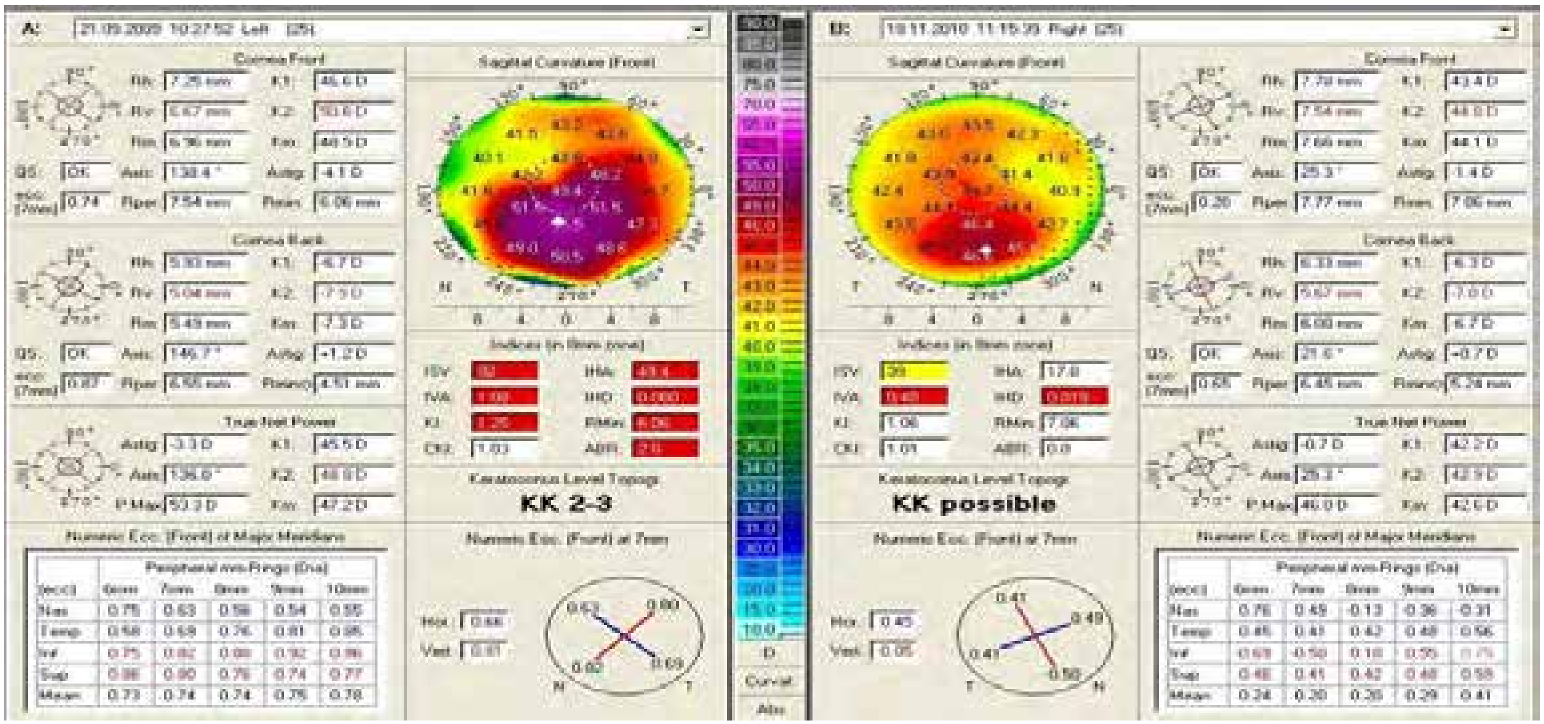
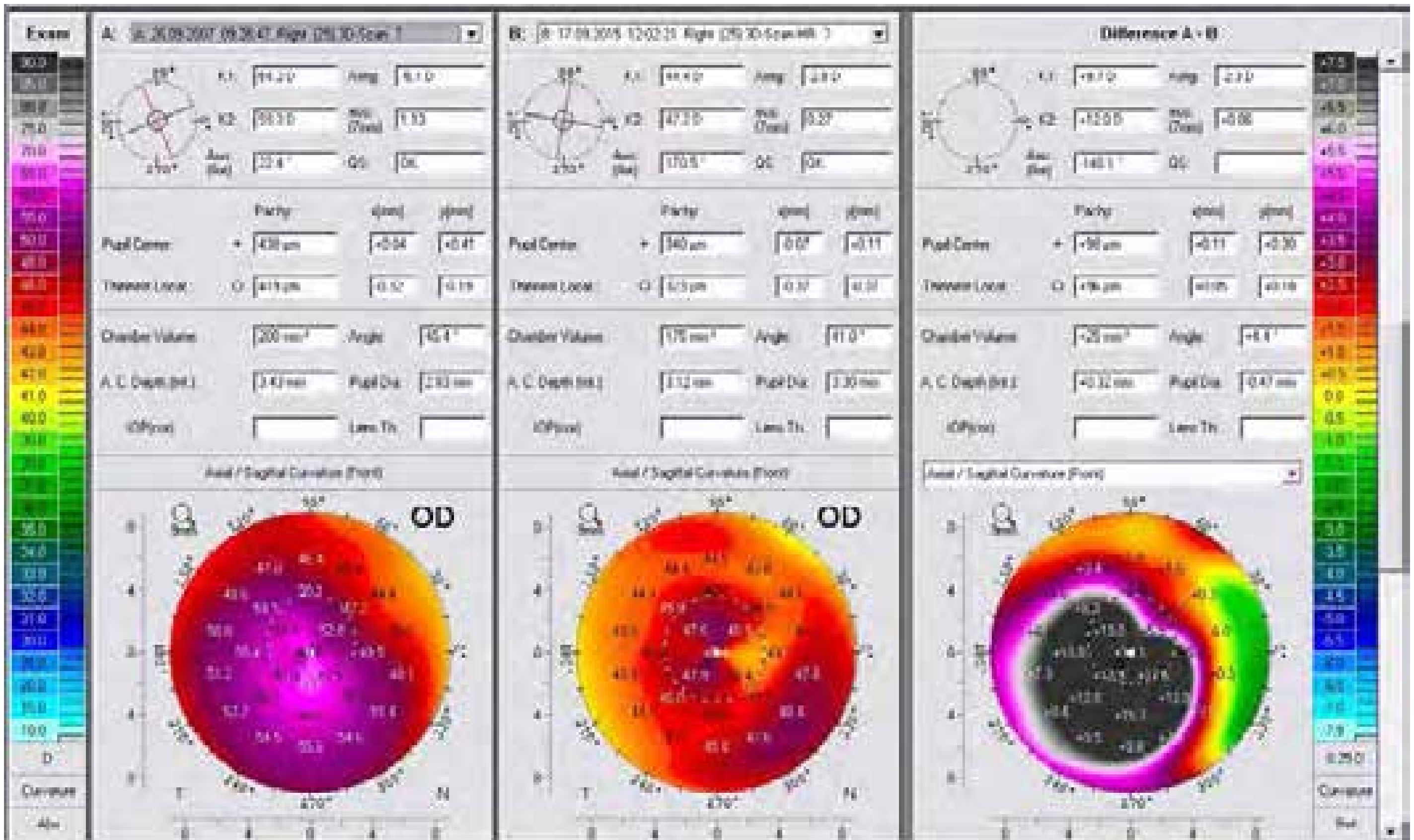
Average K from 48.5 to 44
Refraction -2.5-4.5@155 (20/70) to -1-1.5@10 (20/20)



Caution: marked refractive effect with the 3mW protocols



ORIGINAL ARTICLE

Corneal Refractive Power and Symmetry Changes Following Normalization of Ectasias Treated With Partial Topography-Guided PTK Combined With Higher-Fluence CXL (The Athens Protocol)

Anastasios John Kanellopoulos, MD; George Asimellis, PhD

ABSTRACT

[illegible]

[J Refract Surg. 2014;30(5):345-346.]

Keratoconus assessment employs indicators such as keratometric values, inferior-superior index, skew percentage, astigmatism, and the KISA% index.[1] Acceptable quantitative keratometric criteria include central corneal refractive power larger than 47.2 diopters (D), inferior-superior dioptric asymmetry larger than 1.2 D, and simulated astigmatism, expressed as the difference between steep and flat keratometric values greater than 1.5 D.[2] The steep and flat meridian keratometric values correspond to the smaller and larger anterior corneal curvature radius, respectively.

Corneal cross-linking (CXL) is an in vivo intrastromal photo-oxidative technique with riboflavin and ultraviolet-A light aiming to address the advancing corneal ectasia and, consequently, the keratoconus progression. With CXL, additional covalent bonding between stromal collagen can be achieved, which stabilizes the collagen framework structure.[3] The remodeling effects of CXL on the cornea can be described by the reduction of mean anterior surface keratometric values.[4] Few studies have been published on the quantitative link between anterior and posterior keratometric values in keratoconic eyes or particularly on the postoperative effects of CXL on either corneal surface.

This study aims to investigate the distribution of and relationship between anterior and posterior corneal keratometric values and simulated anterior and posterior astigmatism on a large group of clinically diagnosed, untreated keratoconic eyes, and the 1-year postoperative effects on both anterior and posterior keratometric values and astigmatism induced by a combined procedure known as the Athens Protocol,[5,6] which intends to arrest the keratoconus progression and normalize the anterior corneal surface.

From Laservision.gr Eye Institute, Athens, Greece (AJK, GA); and New York University School of Medicine, New York, New York (AJK).

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

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ORIGINAL ARTICLE

Keratoconus Management: Long-Term Stability of Topography-Guided Normalization Combined With High-Fluence CXL Stabilization (The Athens Protocol)

Anastasios John Kanellopoulos, MD; George Asimellis, PhD

ABSTRACT

PURPOSE: To investigate refractive, topometric, pachymetric, and visual rehabilitation changes induced by anterior surface normalization for keratoconus by partial topography-guided excimer laser ablation in conjunction with accelerated, high-fluence cross-linking.

METHODS: Two hundred thirty-one keratoconic cases subjected to the Athens Protocol procedure were studied for visual acuity, keratometry, pachymetry, and anterior surface irregularity indices up to 3 years postoperatively by Scheimpflug imaging (Oculus Optikgeräte GmbH, Wetzlar, Germany).

RESULTS: Mean visual acuity changes at 3 years postoperatively were +0.38 ± 0.31 (range: -0.34 to +1.10) for uncorrected distance visual acuity and +0.20 ± 0.21 (range: -0.32 to +0.90) for corrected distance visual acuity. Mean K1 (flat meridian) keratometric values were 46.56 ± 3.83 diopters (D) (range: 39.75 to 58.30 D) preoperatively, 44.44 ± 3.97 D (range: 36.10 to 55.30 D) 1 month postoperatively, and 43.22 ± 3.80 D (range: 36.90 to 53.70 D) up to 3 years postoperatively. The average Index of Surface Variance was 98.48 ± 43.47 (range: 17 to 208) preoperatively and 76.80 ± 38.41 (range: 7 to 190) up to 3 years postoperatively. The average Index of Height Decentration was 0.091 ± 0.053 µm (range: 0.006 to 0.275 µm) preoperatively and 0.067 ± 0.040 µm (range: 0.001 to 0.208 µm) up to 3 years postoperatively. Mean thinnest corneal thickness was 451.91 ± 40.02 µm (range: 297 to 547 µm) preoperatively, 353.95 ± 53.90 µm (range: 196 to 480 µm) 1 month postoperatively, and 370.52 ± 58.21 µm (range: 218 to 500 µm) up to 3 years postoperatively.

CONCLUSIONS: The Athens Protocol to arrest keratoconus progression and improve corneal regularity demonstrates safe and effective results as a keratoconus management option. Progressive potential for long-term flattening validates using caution in the surface normalization to avoid overcorrection.

[J Refract Surg. 2014;30(2):88-92.]

Keratoconus is a degenerative bilateral, noninflammatory disorder characterized by ectasia, thinning, and irregular corneal topography.[1] The disorder usually has onset at puberty and often progresses until the third decade of life, may manifest asymmetrically in the two eyes of the same patient, and can present with unpredictable visual acuity, particularly in relation to corneal irregularities.[2] One of the acceptable options[3] for progressive keratoconus management is corneal collagen cross-linking (CXL) with riboflavin and ultraviolet-A.[4]

To further improve the topographic and refractive outcomes, CXL can be combined with customized anterior surface normalization.[5-7] Our team has developed a procedure[8,9] we have termed the Athens Protocol,[10] involving sequentially excimer laser epithelial debridement (50 µm), partial topography-guided excimer laser stromal ablation, and high-fluence ultraviolet-A irradiation (10 mW/cm²), accelerated (10', or minutes) CXL. Early results[11] and anterior segment optical coherence tomography quantitative findings[12] are indicative of the long-term stability of the procedure.

Detailed studies on postoperative visual rehabilitation and anterior surface topographic changes by such combined CXL procedures are rare,[13-16] particularly those reporting results longer than 1 year. This study aims to investigate safety and efficacy of the Athens Protocol procedure by analysis of long-term (3-year) refractive, topographic, pachymetric, and visual rehabilitation changes on clinical keratoconus management with the Athens Protocol in a large number of cases.

PATIENTS AND METHODS

This clinical study received approval by the Ethics Committee of our Institution and adhered to the tenets of the Declaration

From Laservision.gr Eye Institute, Athens, Greece (AJK, GA); and New York University School of Medicine, New York, New York (AJK).

Submitted: April 6, 2013; Accepted: August 21, 2013; Posted online: January 31, 2014

Dr. Kanellopoulos is a consultant for Alcon/WaveLight. The remaining author has no financial or proprietary interest in the materials presented herein.

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doi:10.3928/1081597X-20140120-03

Conclusions

- The Athens Protocol (partial topo-guided PTK combined with CXL) appears to be safe and effective in ectasia stabilization, and visual rehab over 12 years later.
- Alternative treatments are CXL alone
- Contact lenses: RGPs and/or Scleral lenses
- ICRS
- Lamellar keratoplasty
- Penetrating keratoplasty

ORIGINAL ARTICLE

Corneal Refractive Power and Symmetry Changes Following Normalization of Ectasias Treated With Partial Topography-Guided PTK Combined With Higher-Fluence CXL (The Athens Protocol)

Anastasios John Kanellopoulos, MD; George Asimellis, PhD

TABLE 1
Anterior and Posterior Corneal Surface Keratometry and Astigmatism as Measured in the 8-mm Diameter Zone Before and After Treatment

	Before Treatment				After Treatment			
Parameter	Average (D)	SD (D)	Max (D)	Min (D)	Average (D)	SD (D)	Max (D)	Min (D)
Anterior cornea								
Flat	47.06	±6.02	78.50	33.70	43.97	±5.81	73.2	30.1
Steep	51.24	±6.75	80.70	39.50	47.04	±6.86	81.3	33.9
Mean	49.03	±6.21	78.80	38.80	46.37	±6.73	80.9	31.9
Astigmatism	-1.97	±6.21	11.30	-12.40	-1.56	±3.80	12.4	-11.5
Posterior cornea								
Flat	-6.70	±0.99	-4.60	-9.90	-6.58	±1.05	-3.3	-10.4
Steep	-7.67	±1.15	-5.60	-11.00	-7.69	±1.22	-5.2	-13.2
Mean	-7.08	±1.40	8.50	-10.20	-7.08	±1.06	-4.2	-11.5
Astigmatism	+0.53	±1.02	+4.00	-2.60	+0.45	±1.29	+4.3	-5.3

SD = standard deviation; D = diopters; Max = maximum; Min = minimum

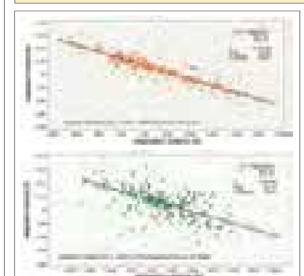

Figure 1. Scatter and fitted line plots of posterior astigmatism expressed in diopters (D) versus anterior astigmatism (also expressed in D) with 95% confidence intervals (CI) and 95% prediction intervals (PI). (Top) Before and (bottom) after treatment.

treatment, r^2 was 0.407 and P value less than .001 (**Table 2**).

Data analysis indicates that the mean of the paired differences regarding the flat anterior keratometric values was reduced (flattened) postoperatively by -3.09 ± 2.69 D, or -6.56%, and was statistically significant ($P < .05$) (**Table 2**). The uncertainty associated with estimating the difference from sample data indicated, with a 95% confidence interval, that the true difference was between -2.76 and -3.41 D. The steep anterior keratometric values showed a postoperative flattening by -4.19 ± 2.96 D, or -8.19%, again statistically significant ($P < .05$). The true 95% difference was between -3.84 and -4.55 D.

The mean of the paired differences regarding the flat posterior keratometric values showed an increase of +0.12 ± 0.61 D, or -1.76% (considering the negative sign of the posterior keratometric values). The 95% true difference was between -0.191 and -0.0449 D. The analysis for the steep posterior keratometric values showed a postoperative change of -0.02 ± 0.55 D or +0.04% (95% true difference between -0.0485 and +0.0829 D). These differences were not statistically significant (flat $P = .135$, steep $P = .606$).

DISCUSSION

In this study, a rotating Scheimpflug camera was employed to measure both the anterior and posterior corneal curvature in a large number (267) of keratoconic cases, before and after (1 year postoperatively) a combined CXL and anterior surface excimer laser normalization. In the case of keratoconus, highly irregular keratometric values were present. For example, the simultaneous investigation of anterior and posterior corneal keratometric values has indicated statistically significant differences between normal and keratoconus-suspect eyes.[16] In a study evaluating keratometric values in keratoconic compared to normal eyes, the

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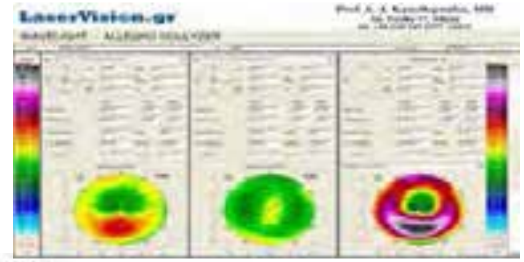
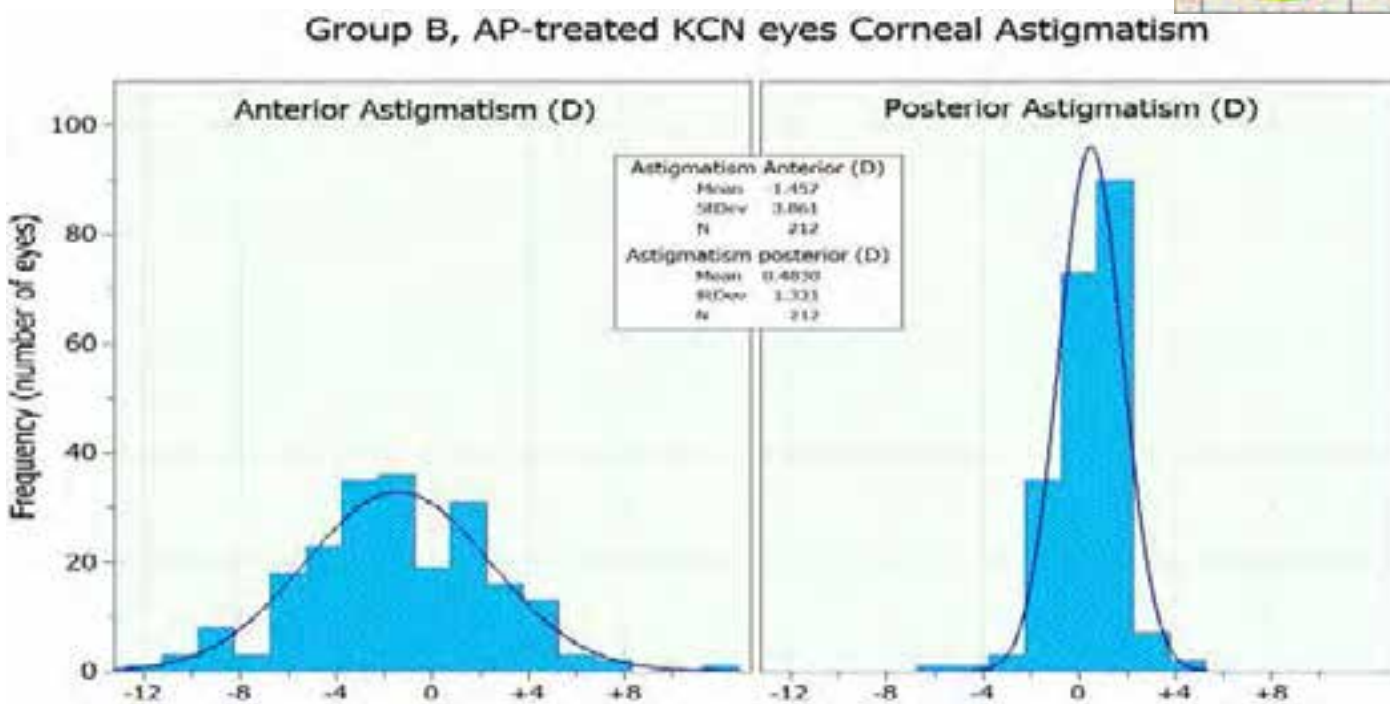
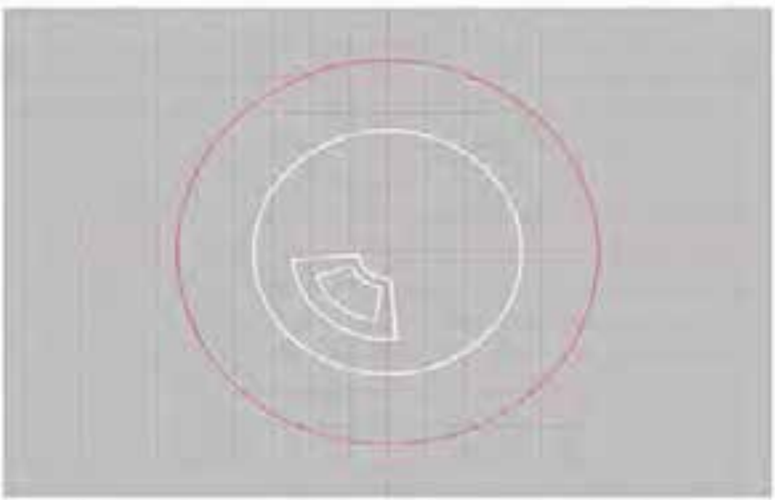
Athens Protocol: improved anterior corneal profile, but what about the posterior?





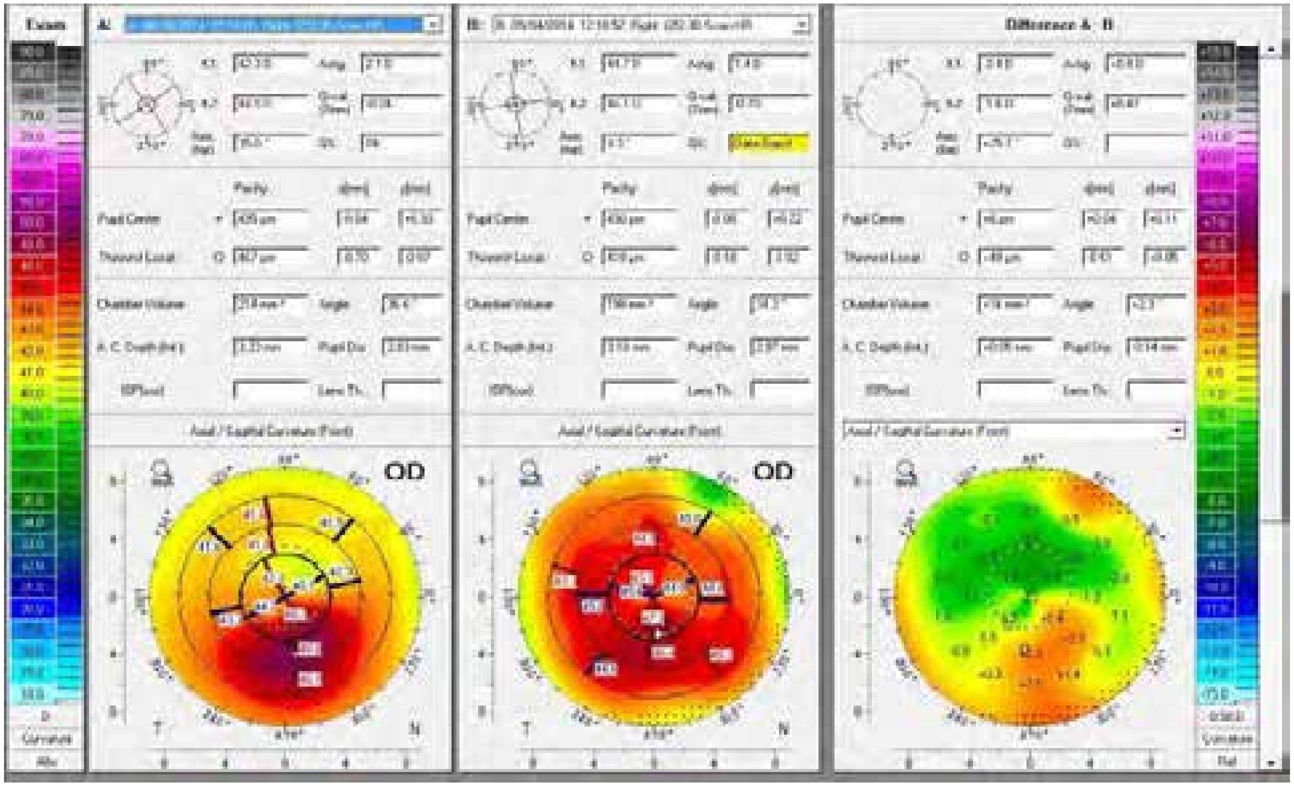
Variable Fluence, topo-customized pattern CXL

KXL II device (Avedro, Waltham, MA, USA) CE marked 2013



No.	Shape Type	Time	Total Energy	X Position (mm)	Y Position (mm)	Axis (degs.)	Dim. 1 (mm)	Dim. 2 (mm)	Arc (degs.)
1	Arc_Single	5:33	15.0	0.0	-0.0	231	4.0	1.0	60
2	Arc_Single	3:42	10.0	0.0	-0.0	230	5.0	1.7	90
3	Circle_7mm	1:29	4.0	0.0	-0.0		7.0		

The Athens Protocol evolution
topo-guided PTK+variable fluence topo-customized CXL



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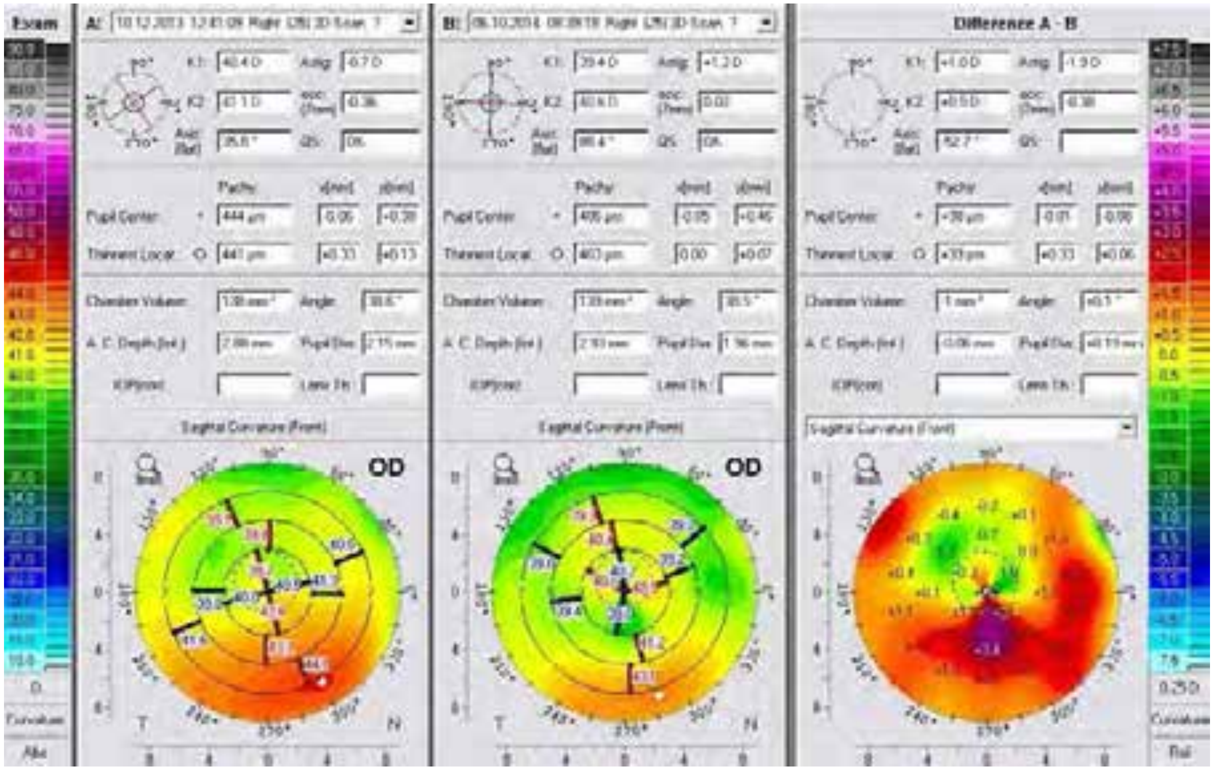
The Athens Protocol evolution
topo-guided PTK+variable fluence topo-customized CXL



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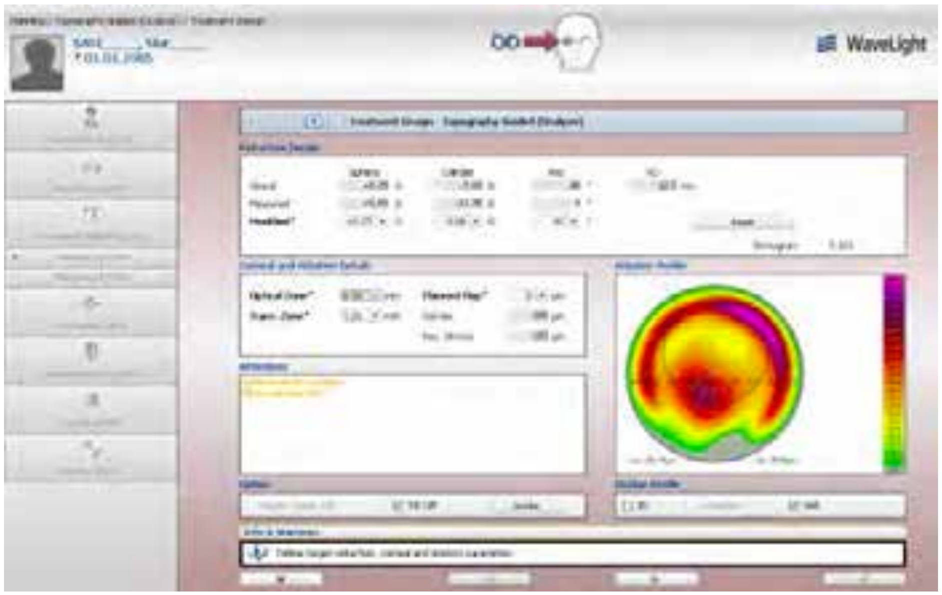
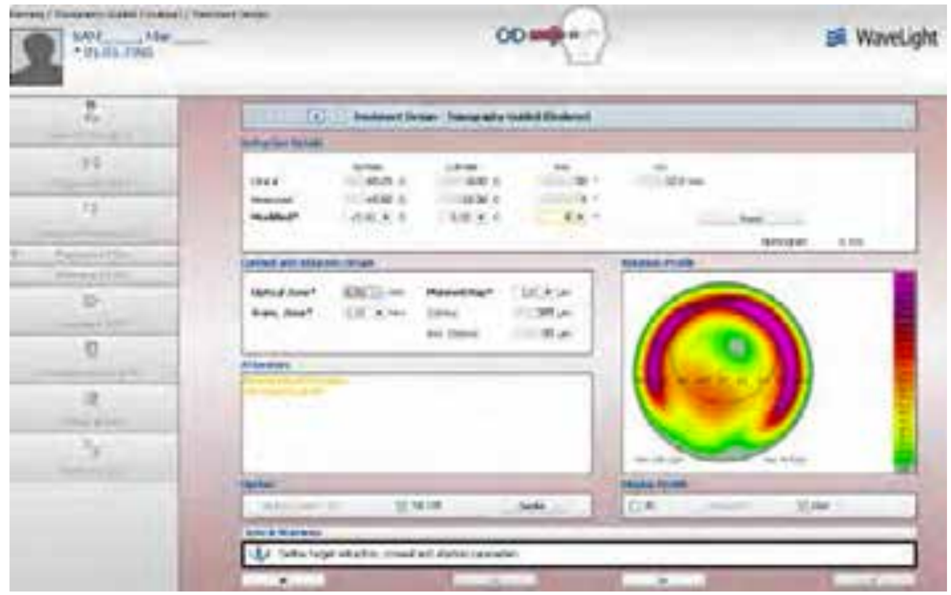
The Athens Protocol evolution
Minimal cone ablation





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Recent FDA topography-guided LASIK data-2013

4.8. Efficacy Outcomes

Changes In Manifest Refraction, Refractive Stability, Vector Analyses, Changes In UCVA, Patient-Reported Outcomes

A summary of key efficacy variables at each of the postoperative visits is provided below in Table 16 for the myopia cohort treated with Topo-guided (T-CAT) LASIK.

		Month 1	Month 3	Month 6	Month 9	Month 12
EFFICACY VARIABLES						
MRSE ± 0.50 D	n/N	220/248	227/247	227/244	221/237	218/230
	(%)	(88.71%)	(91.90%)	(93.03%)	(93.25%)	(94.78%)
	(CI)	(84.1, 92.4)	(87.8, 95.0)	89.1, 95.9)	(89.3, 96.1)	(91.1, 97.3)
MRSE ± 1.00 D	n/N	244/248	244/247	241/244	235/237	229/230
	(%)	(98.39%)	(98.79%)	(98.77%)	(99.16%)	(99.57%)
	(CI)	(95.9, 99.6)	(96.5, 99.7)	(96.4, 99.7)	(97.0, 99.9)	(97.6,100.0)
MRSE ± 2.00 D	n/N	248/248	247/247	243/244	237/237	230/230
	(%)	(100.0%)	(100.0%)	(99.59%)	(100.0%)	(100.0%)
	(CI)	(98.5,100.0)	(98.5,100.0)	(97.7,100.0)	(98.5,100.0)	(98.4,100.0)
UCVA 20/20 or better	n/N	217/248	229/247	217/244	212/237	213/230
	(%)	(87.50%)	(92.71%)	(88.93%)	(89.45%)	(92.61%)
	(CI)	(82.7, 91.3)	(88.7, 95.6)	(84.3, 92.6)	(84.8, 93.1)	(88.4, 95.6)
UCVA 20/40 or better if BCVA 20/20 or better preop	n/N	239/242	239/241	235/238	231/232	224/225
	(%)	(98.76%)	(99.17%)	(98.74%)	(99.57%)	(99.56%)
	(CI)	(96.4, 99.7)	(97.0, 99.9)	(96.4, 99.7)	(97.6,100.0)	(97.5,100.0)

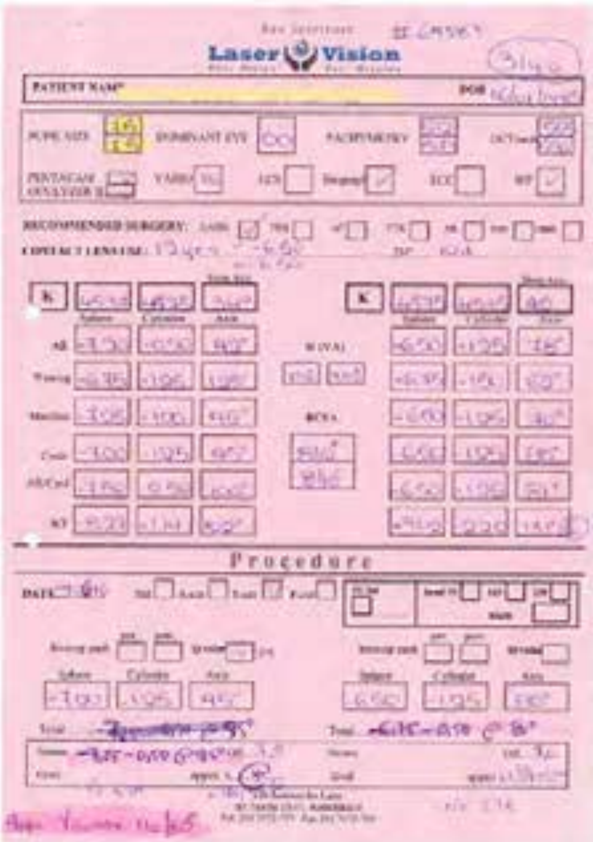
Table 16: Summary Of Key Efficacy Parameters After Topo-guided (T-CAT) LASIK

http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020050S012b.pdf

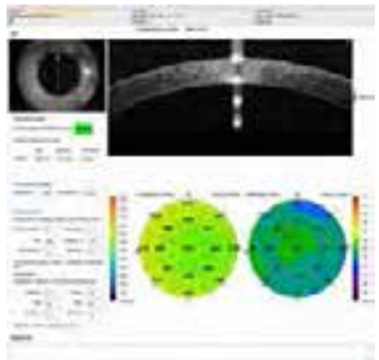
UCVA 20/20 or better	n/N	217/248	229/247	217/244	212/237	213/230
	(%)	(87.50%)	(92.71%)	(88.93%)	(89.45%)	(92.61%)
	(CI)	(82.7, 91.3)	(88.7, 95.6)	(84.3, 92.6)	(84.8, 93.1)	(88.4, 95.6)
UCVA 20/40 or better if BCVA 20/20 or better preop	n/N	239/242	239/241	235/238	231/232	224/225
	(%)	(98.76%)	(99.17%)	(98.74%)	(99.57%)	(99.56%)
	(CI)	(96.4, 99.7)	(97.0, 99.9)	(96.4, 99.7)	(97.6,100.0)	(97.5,100.0)

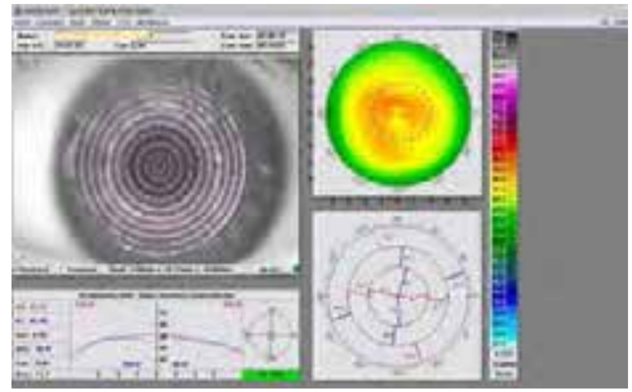
Table 16: Summary Of Key Efficacy Parameters After Topo-guided (T-CAT) LASIK

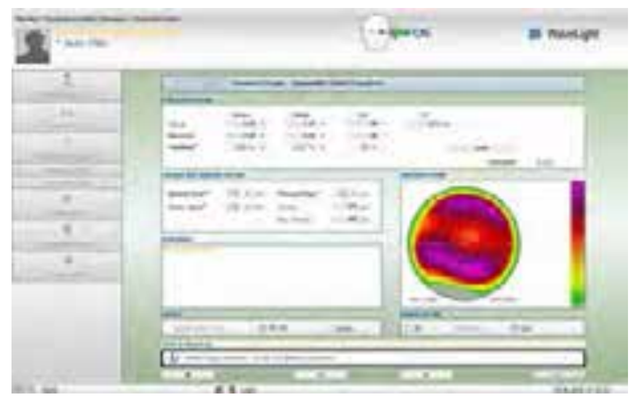
TMR: Topography-modified refraction
Astigmatism adjustment



decreased cyl







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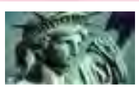

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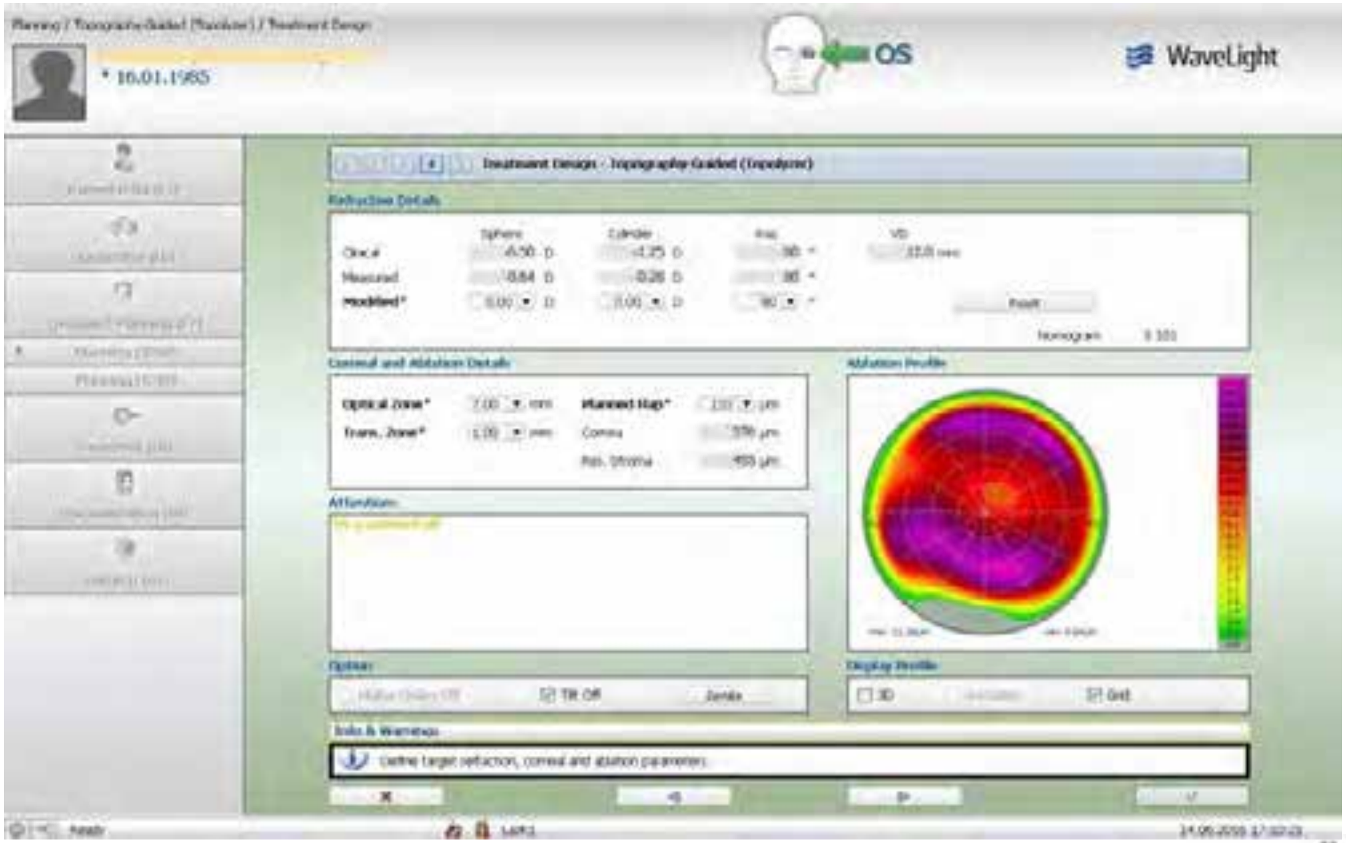
TMR: Topography-modified refraction
Astigmatism adjustment: decreased cyl



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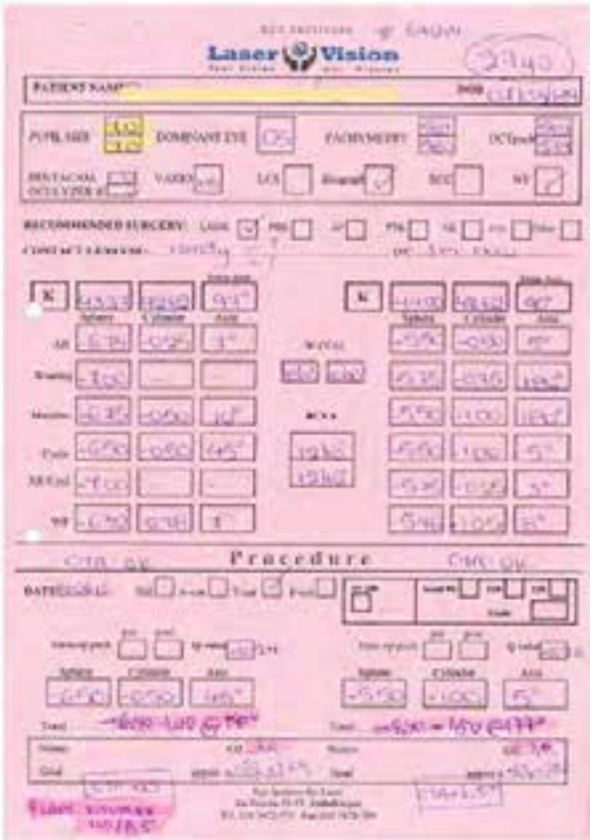
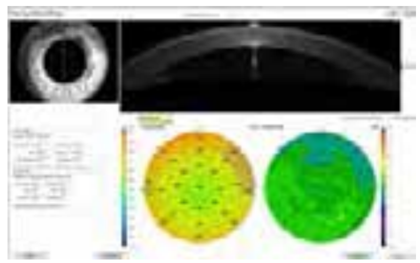
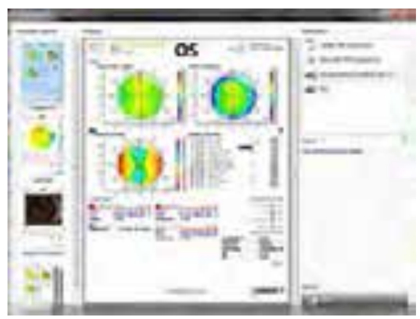
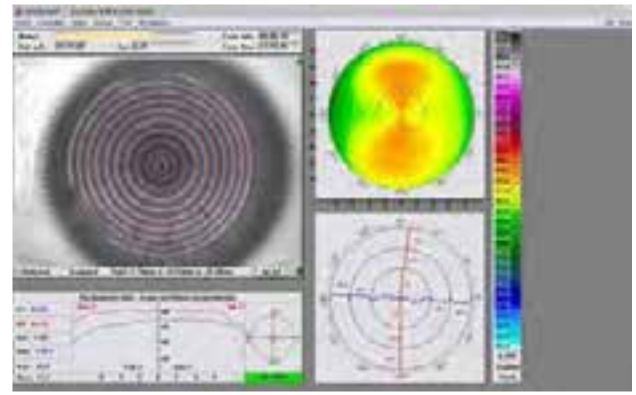
TMR : Topography-Modified refraction
Astigmatism adjustment

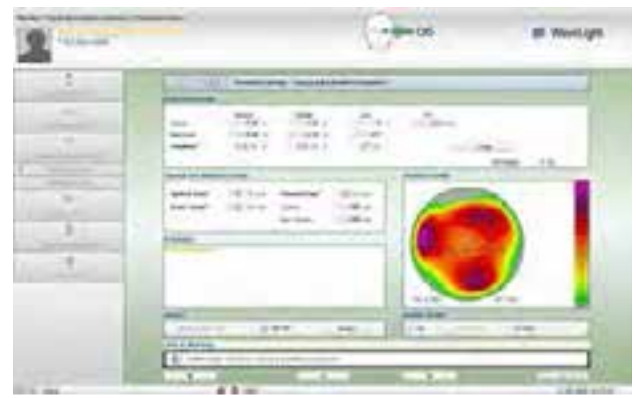


increased cyl









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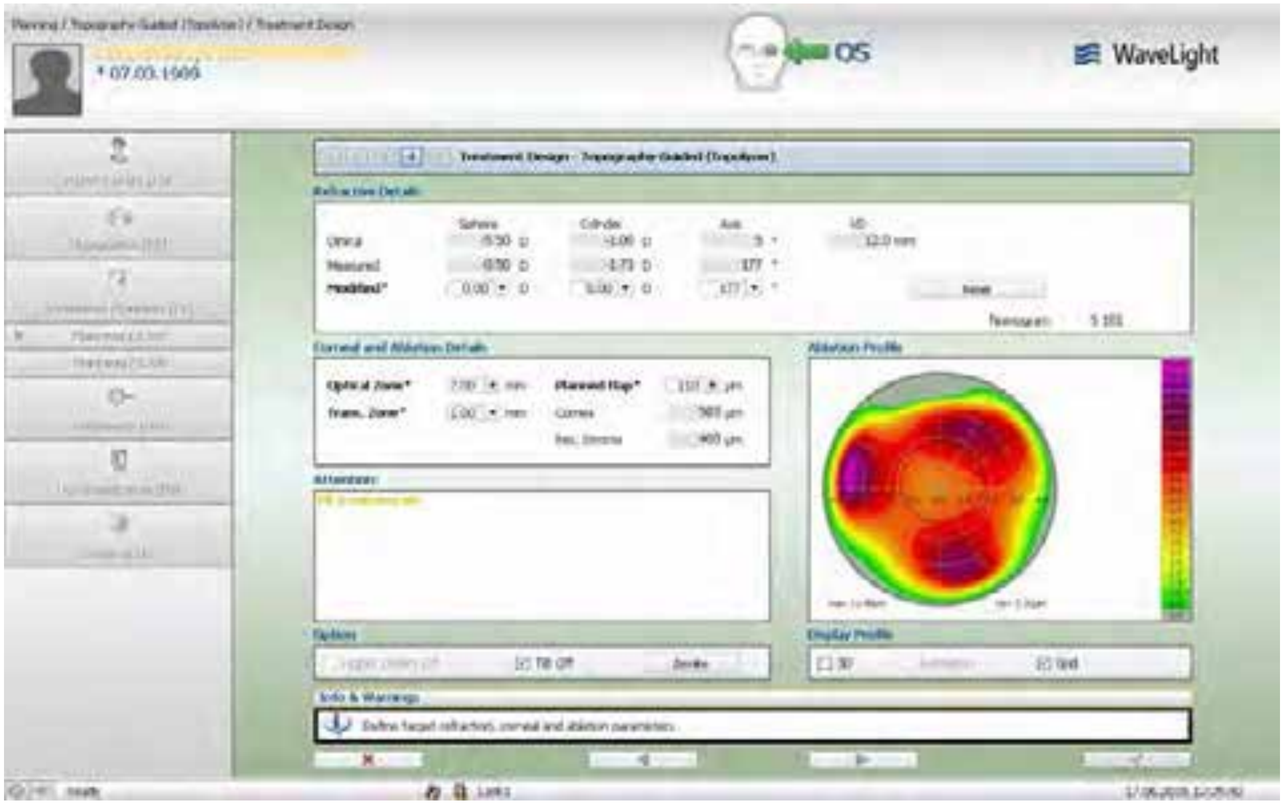
TMR : Topography-Modified refraction
Astigmatism adjustment: increased cyl



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TMR : Topography-Modified refraction
Astigmatism adjustment

Clinical Ophthalmology
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Open Access Full Text Article
ORIGINAL RESEARCH

Topography-modified refraction (TMR): adjustment of treated cylinder amount and axis to the topography versus standard clinical refraction in myopic topography-guided LASIK

Anastasios John Kanellopoulos[1,2]
[1]LaserVision Clinical and Research Institute, Athens, Greece;
[2]Department of Ophthalmology, NYU Medical School, New York, NY, USA

Purpose: To evaluate the safety, efficacy, and contralateral eye comparison of topography-guided myopic LASIK with two different refraction treatment strategies.
Setting: Private clinical ophthalmology practice.
Patients and methods: A total of 100 eyes (50 patients) in consecutive cases of myopic topography-guided LASIK procedures with the same refractive platform (FS200 femtosecond and EX500 excimer lasers) were randomized for treatment as follows: one eye with the standard clinical refraction (group A) and the contralateral eye with the topographic astigmatic power and axis (topography-modified treatment refraction; group B). All cases were evaluated pre- and post-operatively for the following parameters: refractive error, best corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), topography (Placido-disk based) and tomography (Scheimpflug-image based), wavefront analysis, pupillometry, and contrast sensitivity. Follow-up visits were conducted for at least 12 months.
Results: Mean refractive error was –5.5 D of myopia and –1.75 D of astigmatism. In group A versus group B, respectively, the average UDVA improved from 20/200 to 20/20 versus 20/16; postoperative CDVA was 20/20 and 20/13.5; 1 line of vision gained was 27.8% and 55.6%; and 2 lines of vision gained was 5.6% and 11.1%. In group A, 27.8% of eyes had over –0.50 diopters of residual refractive astigmatism, in comparison to 11.7% in group B ($P<0.01$). The residual percentages in both groups were measured with refractive astigmatism of more than –0.5 diopters.
Conclusion: Topography-modified refraction (TMR): topographic adjustment of the amount and axis of astigmatism treated, when different from the clinical refraction, may offer superior outcomes in topography-guided myopic LASIK. These findings may change the current clinical paradigm of the optimal subjective refraction utilized in laser vision correction.
Keywords: TMR, topography-modified refraction, myopic LASIK, femtosecond laser, FS200, EX500 excimer laser, long-term stability, regression, astigmatism correction, post-LASIK refraction

Introduction

Laser vision correction has been established over the last 2 decades as a safe and effective intervention, with Laser-assisted in situ keratomileusis (LASIK) being one of the main techniques practiced globally.[1,2]

Femtosecond laser-assisted LASIK has become a popularized modification over the last decade and over the standard LASIK technique utilizing mechanical microkeratomes.[3,4]

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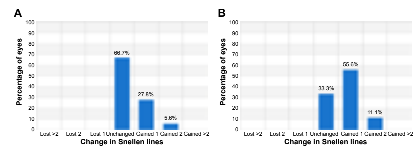

Figure 4 Safety distance visual acuity graph (percentage of eyes with gain/loss in Snellen lines), at 3-month visit: (**A**) group A and (**B**) group B.
Notes: Group A: one eye with the standard clinical refraction; Group B: the contralateral eye with the topographic astigmatic power and axis (topography-modified treatment refraction).

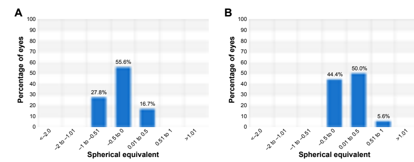

Figure 5 Defocus equivalent results at 3-month visit: (**A**) group A and (**B**) group B.
Notes: Group A: one eye with the standard clinical refraction; Group B: the contralateral eye with the topographic astigmatic power and axis (topography-modified treatment refraction).

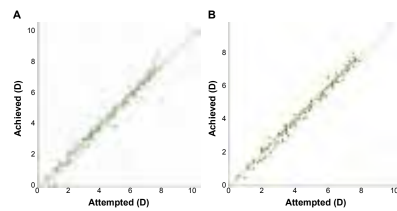

Figure 6 Predictability of spherical equivalent (SE) correction, showing achieved SE versus attempted SE: (**A**) group A and (**B**) group B.
Notes: Group A: one eye with the standard clinical refraction; Group B: the contralateral eye with the topographic astigmatic power and axis (topography-modified treatment refraction). Green marks show outcomes within 0.25 diopters of attempted vs achieved; blue marks show attempted vs achieved of under 0.25 diopters (under-corrections); red marks show attempted vs achieved of over 0.25 diopters (over-corrections).

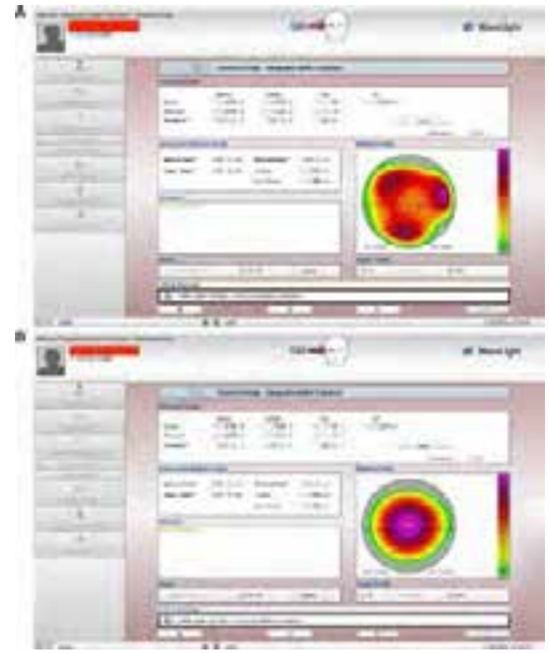

Figure 1 Image **A** shows the topography-guided treatment when refractive error is adjusted by the user to zero sphere and zero cylinder. This image allows the user to visualize the corrections made by the software and added to the excimer correction in order to normalize the anterior cornea curvature to the cornea vertex. Image **B** illustrates the topography treatment pattern after the refraction has been adjusted by the user to the desired sphere and cylinder and includes the changes noted in image **A**.
Notes: "Clinical" is the clinical refraction dialed by the user into the system; the "measured" refraction is the cylindrical amount and axis calculated by the topography software, to be corrected so the anterior cornea can me maximally normalized in regard to the cornea vertex; "modified" represents the surgeon/user adjusted data.
Abbreviations: 3D, three-dimensional; max, maximum, cen, center; trans, transition zone; res, residual; VD, vertex distance.

the right of the top image in Figure 1. The trefoil-like image is also presented here in correlation with the pupillary aperture, also captured by the Vario topographer, and in this top window it shows clearly decentration to the trefoil-like normalization ablation, revealing angle-kappa compensation by the topography software. This ablation pattern will induce some myopia and it was calculated that in order to keep it neutral there is a need to add –0.25 D of myopia to the clinical

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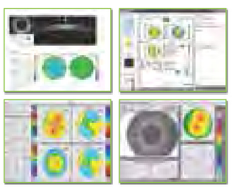
Topography - Guided University Courses 2016:

Become proficient interpreting in cornea diagnostics and designing expert topography guided laser treatments!

Topography - Guided University Courses 2016:

Become proficient interpreting in cornea diagnostics and designing expert topography guided laser treatments!

Didactic course and hands-on treatment designing of multiple case scenarios (virgin eyes, complicated therapeutic treatments: older decentered or irregular ablations, cornea scars, ectasia and keratoconus).
How to adjust optical zone, transition zone, and account for topography spherical neutralization.
Each participant will bring his or her clinical cases and design a treatment, and/or will be given all of the case scenarios noted above to design a treatment.
Anticipate spherical change surprises
Modulation of biomechanics with various CXL protocols.



- Outline and 2016 locations
- Pre-ESCRS
- Pre-AAO

Course Director: **A. John Kanellopoulos, MD**

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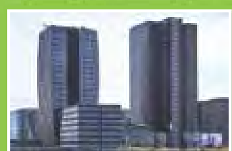
Copenhagen'16 course logistics



Friday September 9th, 2016
(pre-ESCRS)

8:00 AM to 15:30 PM

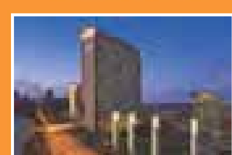
At the Crowne Plaza
Copenhagen Towers
Ørestads Boulevard 114 - 118
2300 København S, Denmark
info@cpcopenhagentowers.com
Tel: +45 8877 6655
Fax: +45 8877 6611

Chicago '16 course logistics

Thursday October 13th, 2016
(pre-AAO)

8:00 AM to 15:30 PM

At the Hyatt Regency McCormick Place
2233 S Martin Luther King Dr,
Chicago, 60616, IL, USA
Tel: +1 312 567 1234



2016 Course's Mutual Outline (Copenhagen and Chicago)

8:00
Breakfast - Registration

8:30-11:30
- Introduction to current cornea diagnostics and their relative differences: Placido Topography, Scheimpflug tomography, Anterior segment OCT, LED color reflection topography.
- Corneal epithelial mapping and its clinical relevance in diagnosis and treatment
- Basic principles in employing topography data (Scheimpflug based and/or Placido-based) in the customization of an excimer corneal ablation. Technology overview and case presentations, with the Wavelight, Schwind and Ivis platforms.
- Topography astigmatism, centroid and angle kappa considerations for possible revision of the clinical refraction used in each ablation

11:30-12:30
Discussion lunch

12:30-15:30
- Topography customized methodology for virgin myopic and hyperopic eyes
- Topography customized methodology for irregular corneas (previously treated: RK, decentered and/or irregular ablations, as well as irregular and ectasia cases)
- Anticipating asphericity and sphere compensatory nomograms for better spherical correction and emmetropia.
- Participants will gain access to an online database with over 100 cases examples (pre-op data, treatment design, treatment video, postop data and overview of what went well and what potentially went off-target)
- Complications assessment and management.

- **Each participant will have the chance to design several treatments on site!**

The course will be limited to 30 participants.
Advanced registration and information:
http://www.topo-guided.com/

Topography - Guided University Courses 2016:

- Correlation of multiple corneal imaging devices may enhance accuracy of assessment by including possible epithelial remodeling data, and limiting specific limitations of Placido-based, Scheimflug-based and color LED refraction topography.
- When using topography maps in laser corneal ablation, all these parameters are considered under a much more meticulous and critical perspective. Although originally designed to treat irregular eyes, it has recently become apparent, hat topo-guided treatments may be superior for routine myopic and/or hyperopic laser vision correction.
- This vigorous didactic course and wet lab on topography-customized corneal ablations will focus on familiarizing the small number of participants on multiple imaging assessment and interpretation, data acquisition and treatment modifications with hands-on the design platforms and data present on-site.
- Additionally, the participants will be offered access to a very large databank with most topo-guided scenario treatments and outcomes.

Course Director:
A. John Kanellopoulos, MD

Disclaimer:
Please be advised that if you are traveling from outside the US for a US course or within the EU for a European course, you would be responsible for obtaining the appropriate visas on your own.
The AJKMD course services will provide a letter of invitation upon confirmation of your registration.
2-Our courses do not provide CME credits.
3-Our courses are purely instructional. Any medical procedure liability lays with the operating surgeon and the bylaws observed in the country and state of his/ her practice.

www.topo-guided.com

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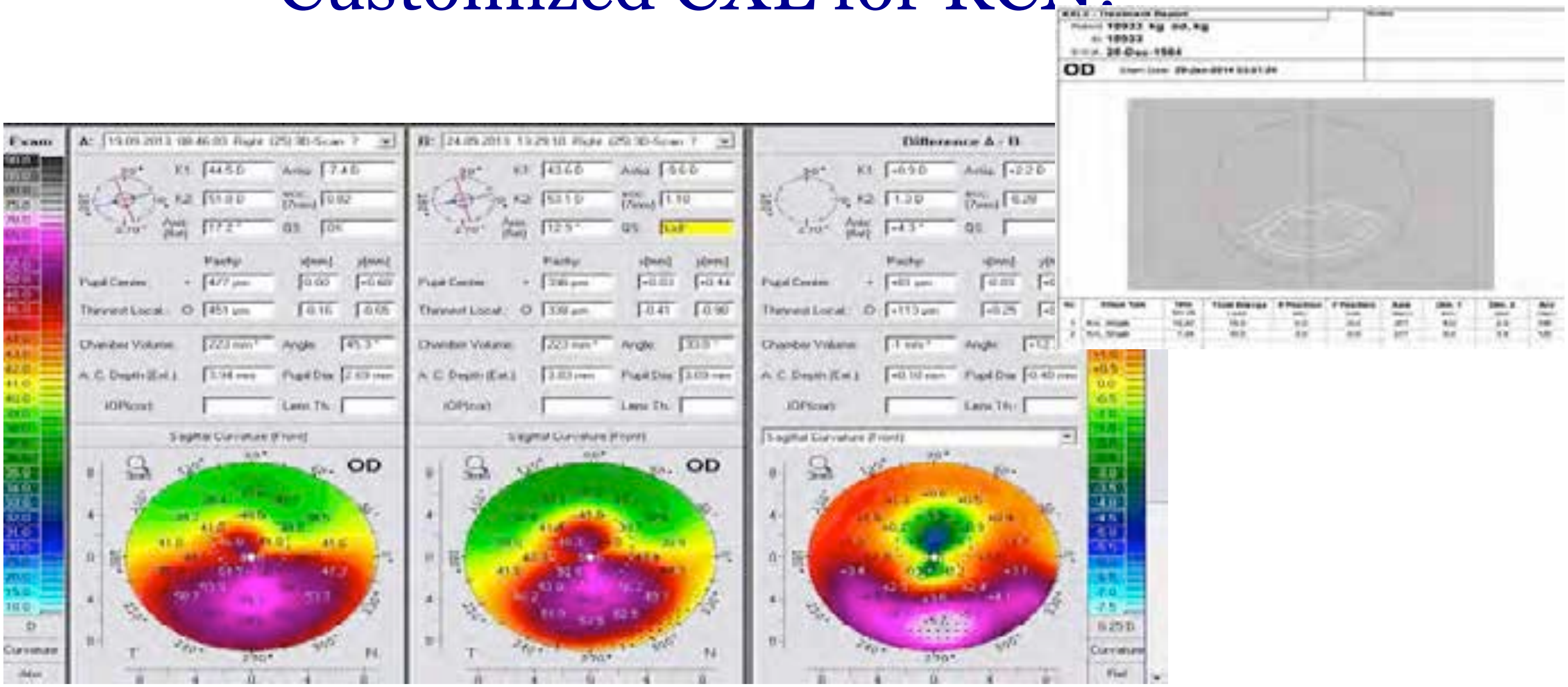
Customized CXL for KCN!



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Epithelial remodeling after partial topography-guided normalization and high-fluence short-duration crosslinking (Athens protocol): Results up to 1 year

Anastasios John Kanellopoulos, MD, George Asimellis, PhD

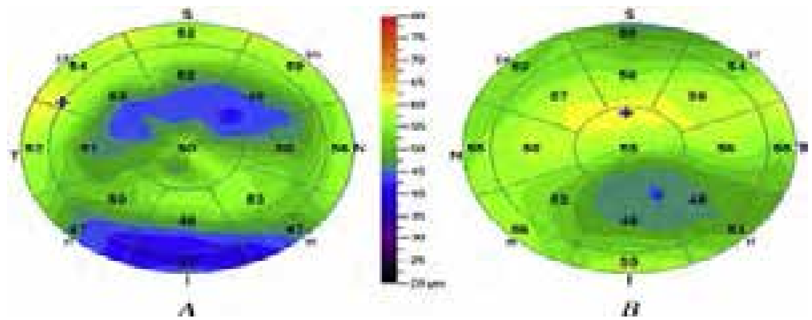

Figure 2. Comparative AS-OCT epithelial thickness (μm) 3-D maps shows an *image* from Group A taken 1 year postoperatively and an image from Group B (I = inferior; IN = inferior–nasal; IT = inferior–temporal; N = nasal; S = superior; SN = superior–nasal; ST = superior–temporal; T = temporal).

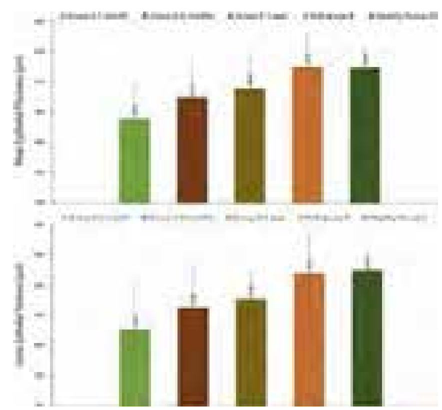

Figure 3. Mean and center epithelial thicknesses in the 3 groups. Error bars correspond to the SD (KCN = keratoconus, no treatment).

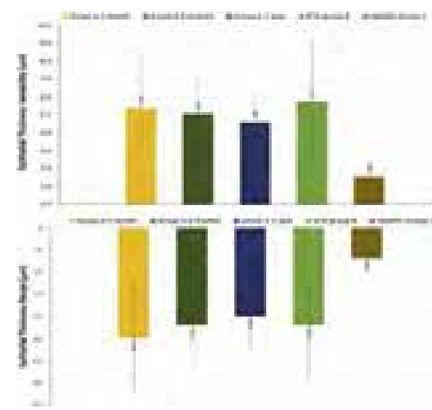

Figure 4. Epithelial thickness variability and range in the 3 groups. Error bars correspond to the SD (KCN = keratoconus, no treatment).

The findings in the current study agree with those in our previous study[1]; that is, although an overall thicker epithelium with large variations can be observed clinically and topographically in eyes with keratoconus, in eyes treated with CXL the variability in epithelium thickness and topographic thickness decreased by a statistically significant margin and was more uniform. We have theorized that epithelial hyperplasia in biomechanically unstable corneas (ie, increased epithelial regrowth activity) might be associated with a more elastic cornea.[1] The laboratory and clinical findings of increased corneal rigidity after CXL are widely accepted,[23–25] including in studies of accelerated high-fluence CXL.[26]

In conclusion, we present the results in a comprehensive study of the postoperative development of corneal epithelial thickness distribution after keratoconus management using combined anterior corneal normalization by topography-guided excimer ablation and accelerated CXL. The epithelial healing processes can be monitored by AS-OCT with ease in a clinical setting, expanding the clinical application of this technology. Our findings suggest less topographic variability and overall reduced epithelial thickness distribution in keratoconus eyes treated with CXL using the Athens protocol.

WHAT WAS KNOWN

- Postoperative epithelial remodeling after partial anterior surface normalization with an excimer laser and high-fluence CXL, assessed with high-frequency scanning UBM, results in reduced overall epithelial thickness and topographic variability.

WHAT THIS PAPER ADDS

- Detailed follow-up of Athens protocol–treated eyes up to 1 year confirmed previous ultrasound findings of the overall thinner and smoother epithelial thickness profiles compared with the profiles of untreated keratoconic eyes.

REFERENCES

1. Kanellopoulos AJ, Aslanides IM, Asimellis G. Correlation between epithelial thickness in normal corneas, untreated ectatic corneas, and ectatic corneas previously treated with CXL; is overall epithelial thickness a very early ectasia prognostic factor? Clin Ophthalmol 2012; 6:789–800. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3373227/pdf/opth-6-789.pdf. Accessed June 11, 2014
2. Kanellopoulos AJ. Long term results of a prospective randomized bilateral eye comparison trial of higher fluence, shorter duration ultraviolet A radiation, and riboflavin collagen cross

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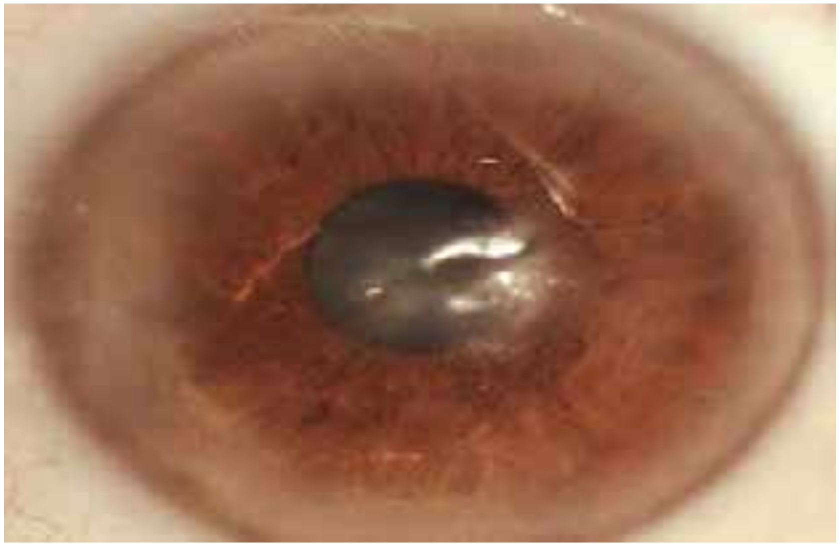
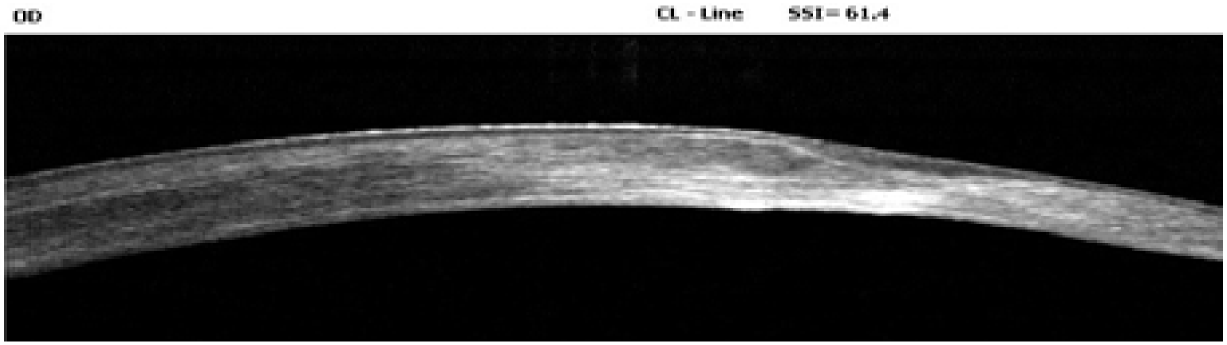
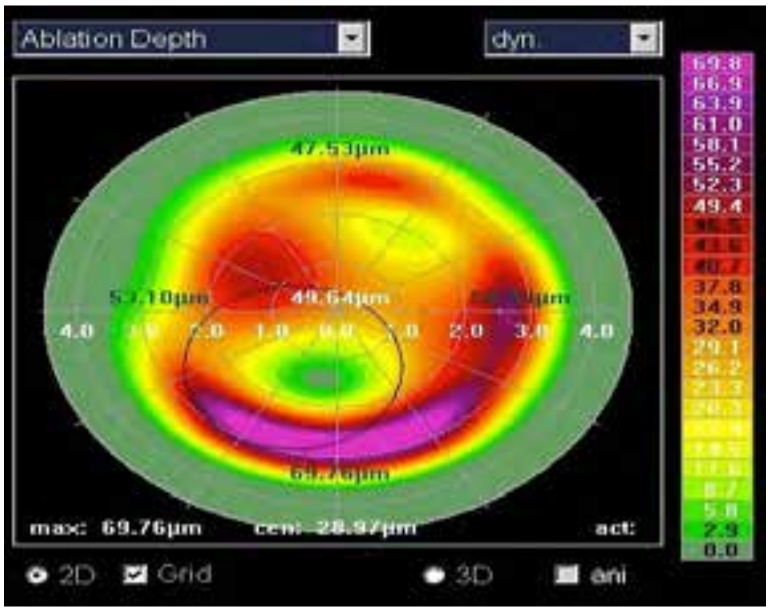
Eye Institute Laser Vision Your Vision Our Mission

Severe scar of the cornea
BCVA 20/200,
Lamellar or PK?







Ablation Depth
dyn.
69.8
66.9
63.9
61.0
58.1
55.2
52.3
49.4
37.8
34.9
32.0
29.1
26.2
5.8
2.9
0.0
47.53µm
57.10µm
49.64µm
4.0
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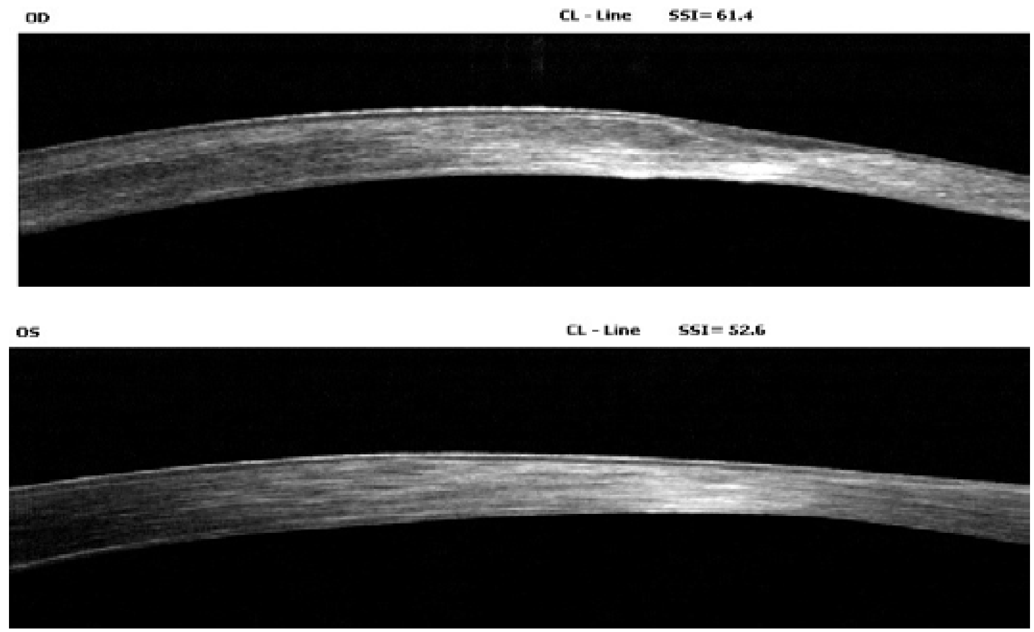
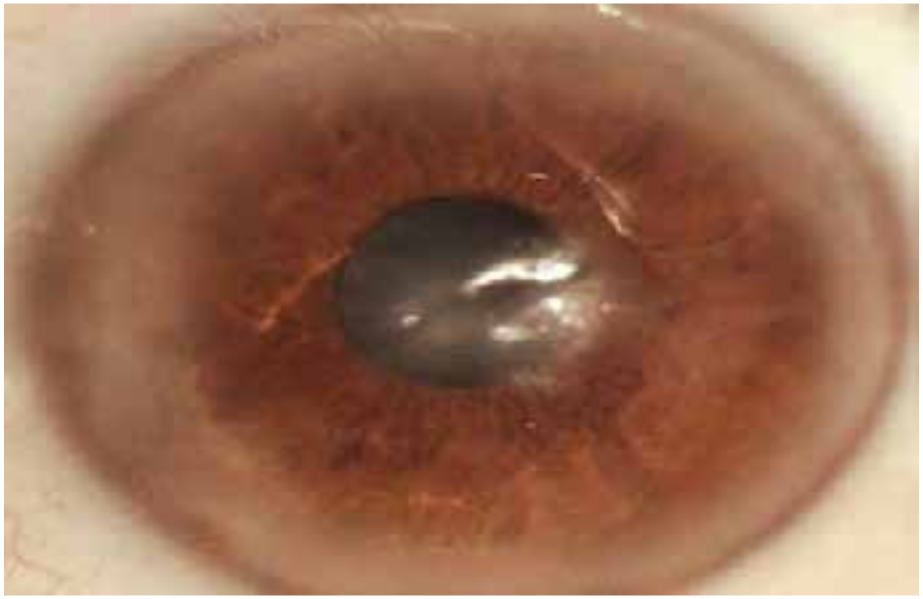
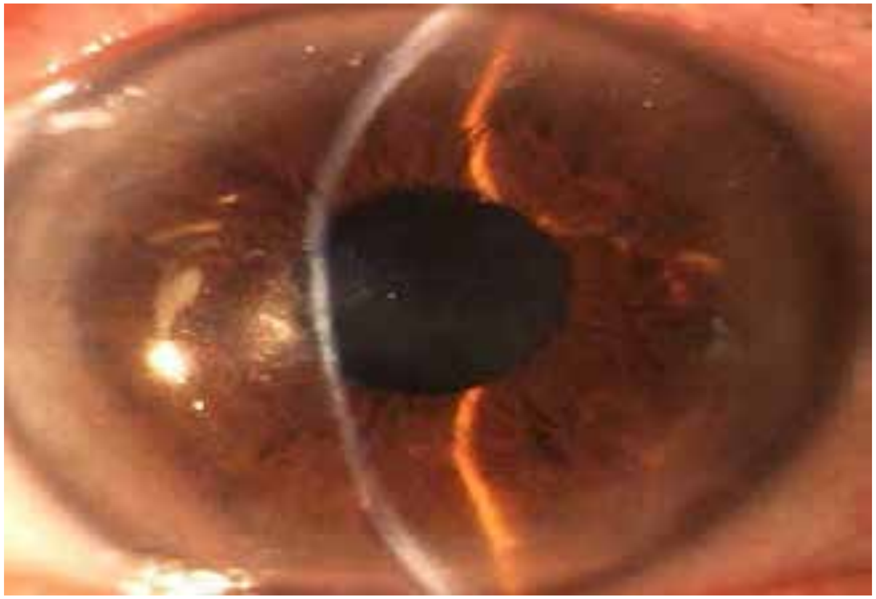


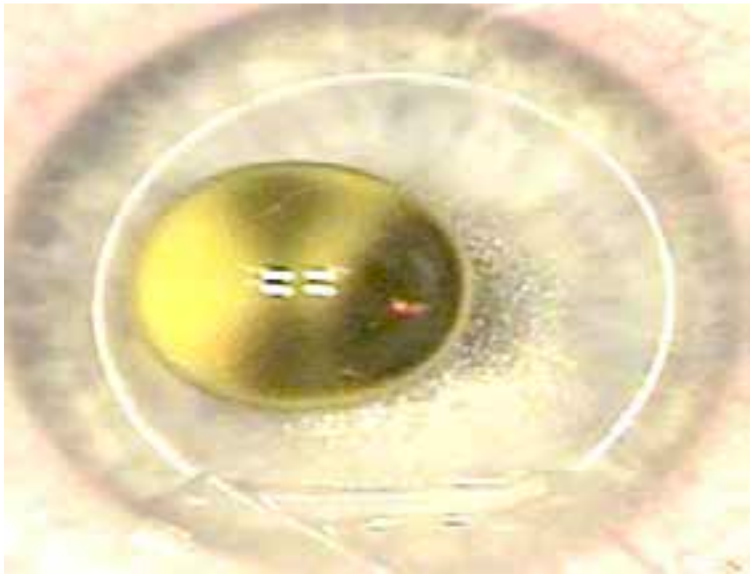
OD
CL - Line
SSI= 61.4
OS
CL - Line
SSI= 52.6

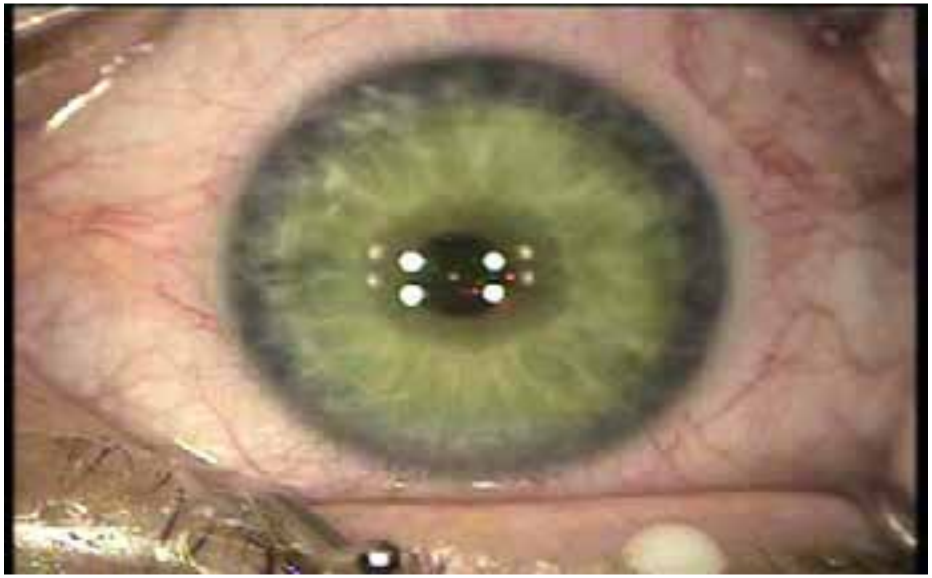
From 20/200 to 20/40!





Hyperopic LASIK
a drop of 0.1% riboflavin sodium phosphate solution,
spread over the exposed stromal bed for 60”





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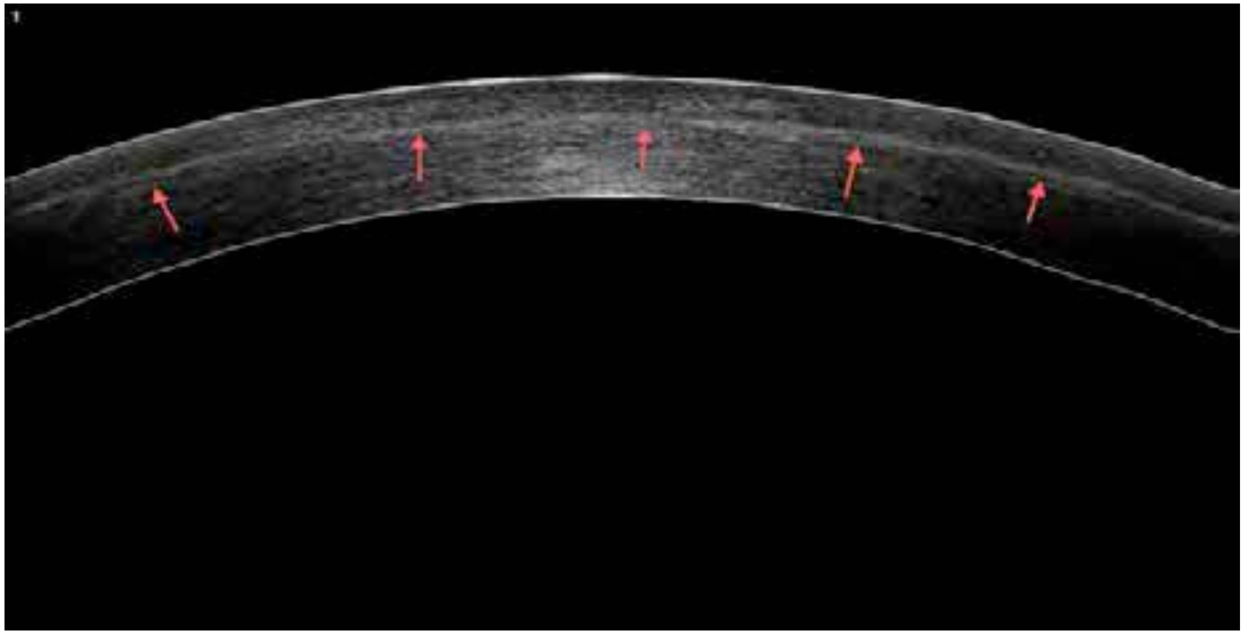
Compelling stability evidence in the contralateral eye hyperopic LASIK + CXL group



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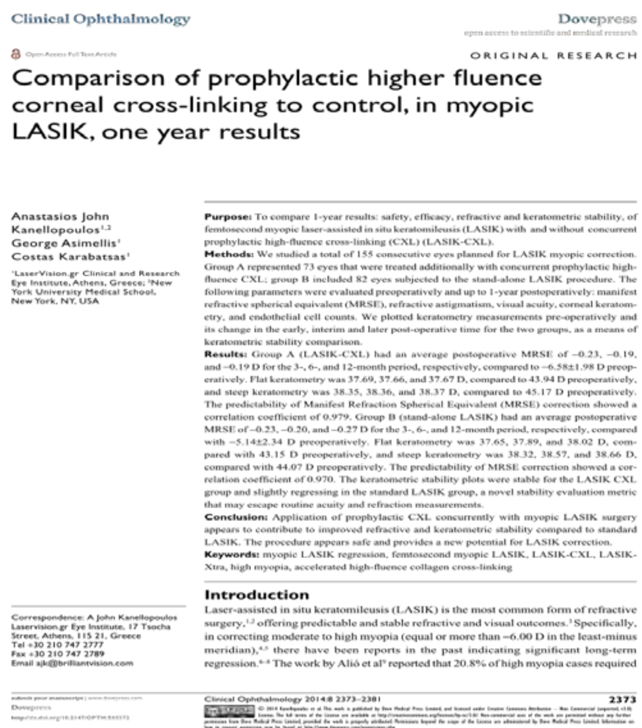
COMPARISON OF REFRACTIVE AND KERATOMETRIC STABILITY
MYOPIC LASIK VS LASIK+ CXL



Clinical Ophthalmology
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ORIGINAL RESEARCH

Comparison of prophylactic higher fluence corneal cross-linking to control, in myopic LASIK, one year results

Anastasios John Kanellopoulos[1,2]
George Asimellis[1]
Costas Karabatsas[1]
[1]LaserVision.gr Clinical and Research Eye Institute, Athens, Greece; [2]New York University Medical School, New York, NY, USA

Purpose: To compare 1-year results: safety, efficacy, refractive and keratometric stability, of femtosecond myopic laser-assisted in situ keratomileusis (LASIK) with and without concurrent prophylactic high-fluence cross-linking (CXL) (LASIK-CXL).
Methods: We studied a total of 155 consecutive eyes planned for LASIK myopic correction. Group A represented 73 eyes that were treated additionally with concurrent prophylactic high-fluence CXL; group B included 82 eyes subjected to the stand-alone LASIK procedure. The following parameters were evaluated preoperatively and up to 1-year postoperatively: manifest refractive spherical equivalent (MRSE), refractive astigmatism, visual acuity, corneal keratometry, and endothelial cell counts. We plotted keratometry measurements pre-operatively and its change in the early, interim and later post-operative time for the two groups, as a means of keratometric stability comparison.
Results: Group A (LASIK-CXL) had an average postoperative MRSE of −0.23, −0.19, and −0.19 D for the 3-, 6-, and 12-month period, respectively, compared to −6.58±1.98 D preoperatively. Flat keratometry was 37.69, 37.66, and 37.67 D, compared to 43.94 D preoperatively, and steep keratometry was 38.35, 38.36, and 38.37 D, compared to 45.17 D preoperatively. The predictability of Manifest Refraction Spherical Equivalent (MRSE) correction showed a correlation coefficient of 0.979. Group B (stand-alone LASIK) had an average postoperative MRSE of −0.23, −0.20, and −0.27 D for the 3-, 6-, and 12-month period, respectively, compared with −5.14±2.34 D preoperatively. Flat keratometry was 37.65, 37.89, and 38.02 D, compared with 43.15 D preoperatively, and steep keratometry was 38.32, 38.57, and 38.66 D, compared with 44.07 D preoperatively. The predictability of MRSE correction showed a correlation coefficient of 0.970. The keratometric stability plots were stable for the LASIK CXL group and slightly regressing in the standard LASIK group, a novel stability evaluation metric that may escape routine acuity and refraction measurements.
Conclusion: Application of prophylactic CXL concurrently with myopic LASIK surgery appears to contribute to improved refractive and keratometric stability compared to standard LASIK. The procedure appears safe and provides a new potential for LASIK correction.
Keywords: myopic LASIK regression, femtosecond myopic LASIK, LASIK-CXL, LASIK-Xtra, high myopia, accelerated high-fluence collagen cross-linking

Introduction

Laser-assisted in situ keratomileusis (LASIK) is the most common form of refractive surgery,[1,2] offering predictable and stable refractive and visual outcomes.[3] Specifically, in correcting moderate to high myopia (equal or more than −6.00 D in the least-minus meridian),[4,5] there have been reports in the past indicating significant long-term regression.[6–9] The work by Alió et al[9] reported that 20.8% of high myopia cases required

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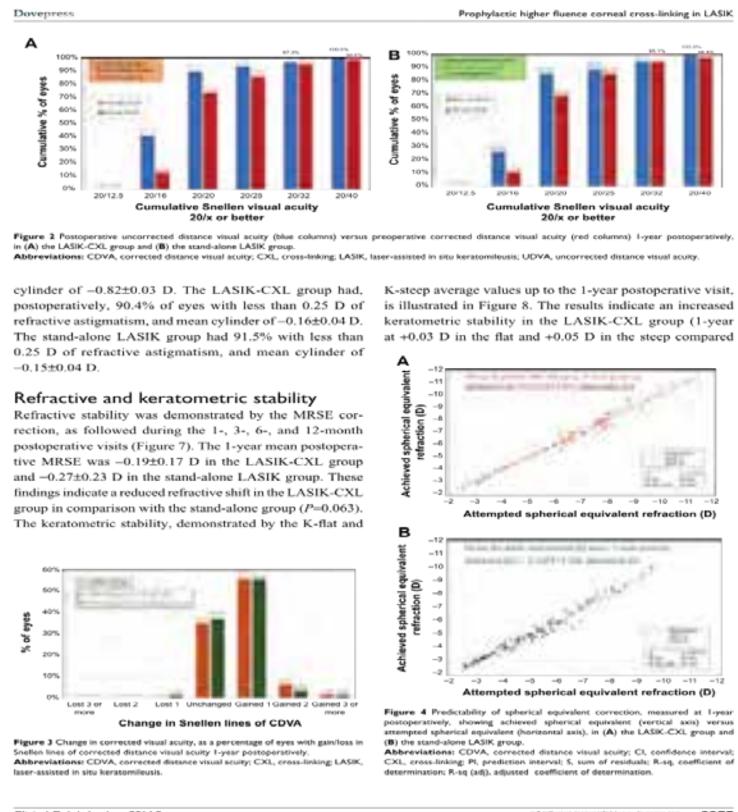

Figure 2 Postoperative uncorrected distance visual acuity (blue columns) versus preoperative corrected distance visual acuity (red columns) 1-year postoperatively, in (**A**) the LASIK-CXL group and (**B**) the stand-alone LASIK group.
Abbreviations: CDVA, corrected distance visual acuity; CXL, cross-linking; LASIK, laser-assisted in situ keratomileusis; UDVA, uncorrected distance visual acuity.

cylinder of −0.82±0.03 D. The LASIK-CXL group had, postoperatively, 90.4% of eyes with less than 0.25 D of refractive astigmatism, and mean cylinder of −0.16±0.04 D. The stand-alone LASIK group had 91.5% with less than 0.25 D of refractive astigmatism, and mean cylinder of −0.15±0.04 D.

Refractive and keratometric stability

Refractive stability was demonstrated by the MRSE correction, as followed during the 1-, 3-, 6-, and 12-month postoperative visits (Figure 7). The 1-year mean postoperative MRSE was −0.19±0.17 D in the LASIK-CXL group and −0.27±0.23 D in the stand-alone LASIK group. These findings indicate a reduced refractive shift in the LASIK-CXL group in comparison with the stand-alone group (P=0.063). The keratometric stability, demonstrated by the K-flat and K-steep average values up to the 1-year postoperative visit, is illustrated in Figure 8. The results indicate an increased keratometric stability in the LASIK-CXL group (1-year at +0.03 D in the flat and +0.05 D in the steep compared

Figure 3 Change in corrected visual acuity, as a percentage of eyes with gain/loss in Snellen lines of corrected distance visual acuity 1-year postoperatively.
Abbreviations: CDVA, corrected distance visual acuity; CXL, cross-linking; LASIK, laser-assisted in situ keratomileusis.

Figure 4 Predictability of spherical equivalent correction, measured at 1-year postoperatively, showing achieved spherical equivalent (vertical axis) versus attempted spherical equivalent (horizontal axis), in (**A**) the LASIK-CXL group and (**B**) the stand-alone LASIK group.
Abbreviations: CDVA, corrected distance visual acuity; CI, confidence interval; CXL, cross-linking; PI, prediction interval; S, sum of residuals; R-sq, coefficient of determination; R-sq (adj), adjusted coefficient of determination.

Kanellopoulos AJ, Asimellis G: Clin. Ophthalmol 2014

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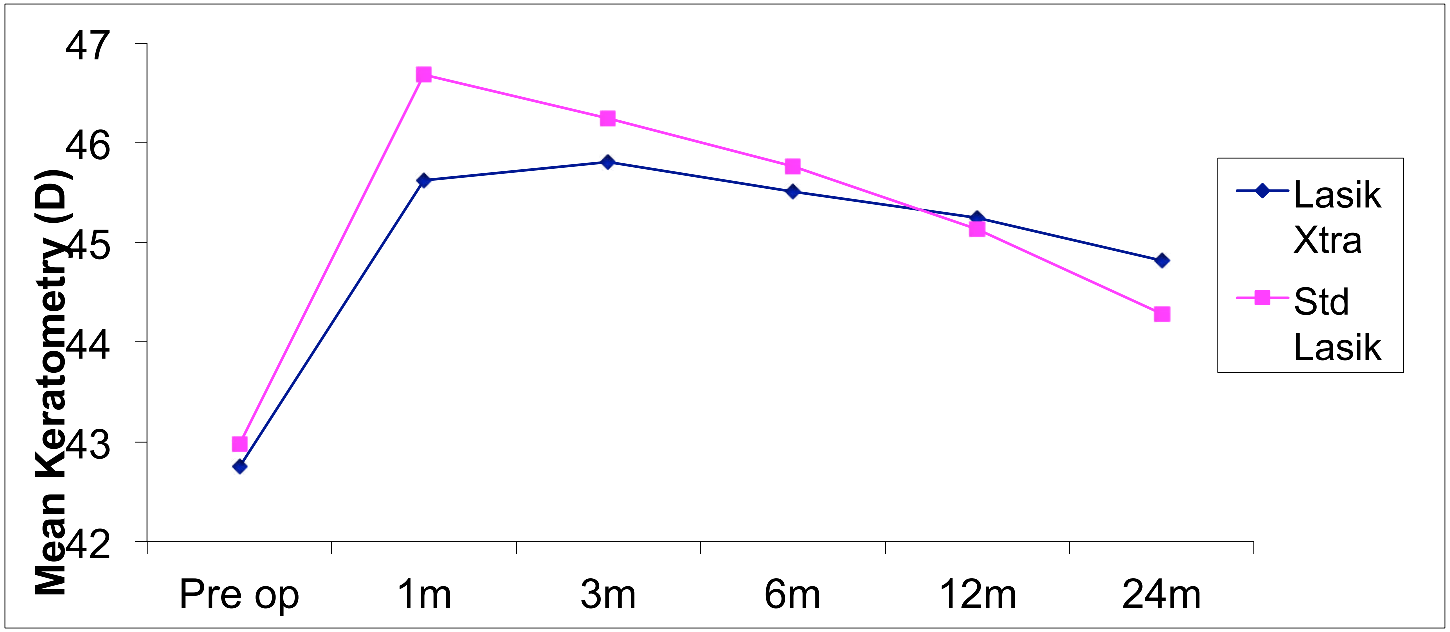
Comparison of keratometric stability compelling clinical evidence that LASIK+CXL works!



Kanellopoulos AJ, Kahn J: JRS November 2012

New York University School of Medicine

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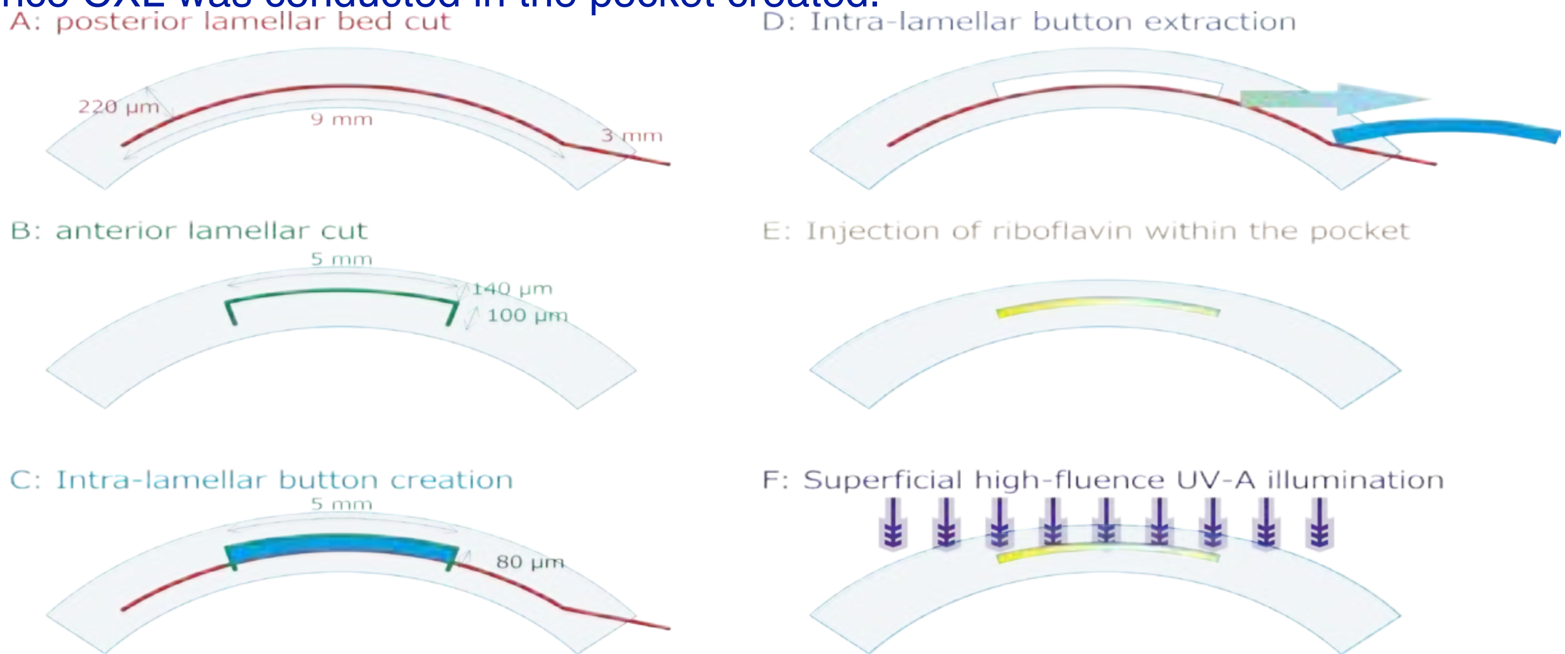
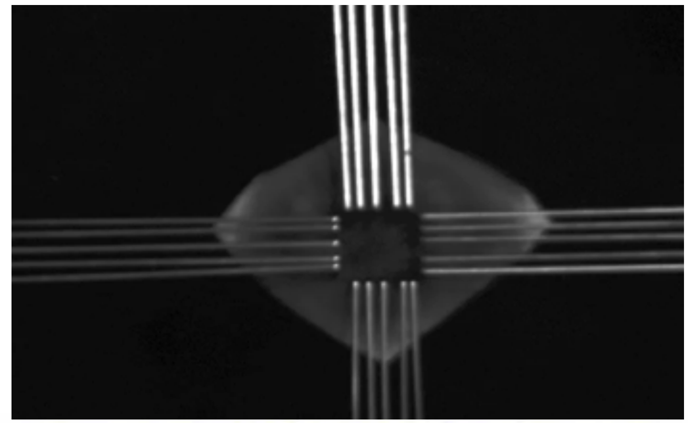
Does in situ CXL work? Ex-vivo evidence

Two-surface intra-lamellar bed corneal dissections were performed within a 5.5 mm optical zone. The lenticule was extracted through a 3.5 mm wide superior canal. High-fluence CXL was conducted in the pocket created.



2-dimentional biomechanical testing

	Stress	*units: kPa*			*Young's Shear Modulus*	*units: MPa*		
	@ 10% strain		@ 20% strain		@ 10% strain		@ 20% strain	
group-A (CXL study)	305.04	±23.30	1,284.79	±34.20	6.98	±1.12	11.46	±0.75
group-B (control)	147.39	±10.72	874.38	±29.40	4.04	±0.85	8.80	±0.72
Δ	107%		47%		73%		30%	
p	< 0.05		< 0.05		< 0.05		< 0.05	



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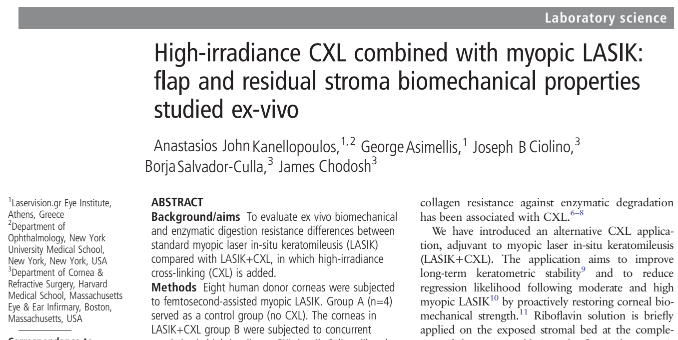
Results

Substantial (up to +100%) increase in biomechanical strength has been noted when using biaxial stress measurements.



Laboratory science

High-irradiance CXL combined with myopic LASIK: flap and residual stroma biomechanical properties studied ex-vivo

Anastasios John Kanellopoulos,[1,2] George Asimellis,[1] Joseph B Ciolino,[3] Borja Salvador-Culla,[3] James Chodosh[3]

[1]Laservision.gr Eye Institute, Athens, Greece
[2]Department of Ophthalmology, New York University Medical School, New York, New York, USA
[3]Department of Cornea & Refractive Surgery, Harvard Medical School, Massachusetts Eye & Ear Infirmary, Boston, Massachusetts, USA

ABSTRACT

Background/aims To evaluate ex vivo biomechanical and enzymatic digestion resistance differences between standard myopic laser in-situ keratomileusis (LASIK) compared with LASIK+CXL, in which high-irradiance cross-linking (CXL) is added.

Methods Eight human donor corneas were subjected to femtosecond-assisted myopic LASIK. Group A (n=4) served as a control group (no CXL). The corneas in LASIK+CXL group B were subjected to concurrent

collagen resistance against enzymatic degradation has been associated with CXL.[6–8]

We have introduced an alternative CXL application, adjuvant to myopic laser in-situ keratomileusis (LASIK+CXL). The application aims to improve long-term keratometric stability[9] and to reduce regression likelihood following moderate and high myopic LASIK[10] by proactively restoring corneal biomechanical strength.[11] Riboflavin solution is briefly applied on the exposed stromal bed at the comple-

ORIGINAL ARTICLE

Longitudinal Postoperative LASIK Epithelial Thickness Profile Changes in Correlation With Degree of Myopia Correction

Anastasios John Kanellopoulos, MD; George Asimellis, PhD

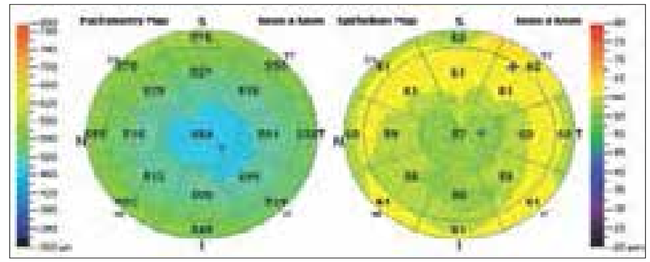


Figure 1. Detail from the analysis and report software main report, showing corneal and epithelial three-dimensional pachymetry maps over the 6-mm corneal diameter in a postoperative LASIK examination. The patient (left eye) received treatment for -4.75 diopters of sphere and -0.75 diopters of astigmatism, and was imaged 1 month postoperatively. * = thickness minimum (both corneal and epithelial maps); + = thickness maximum (epithelial map only).

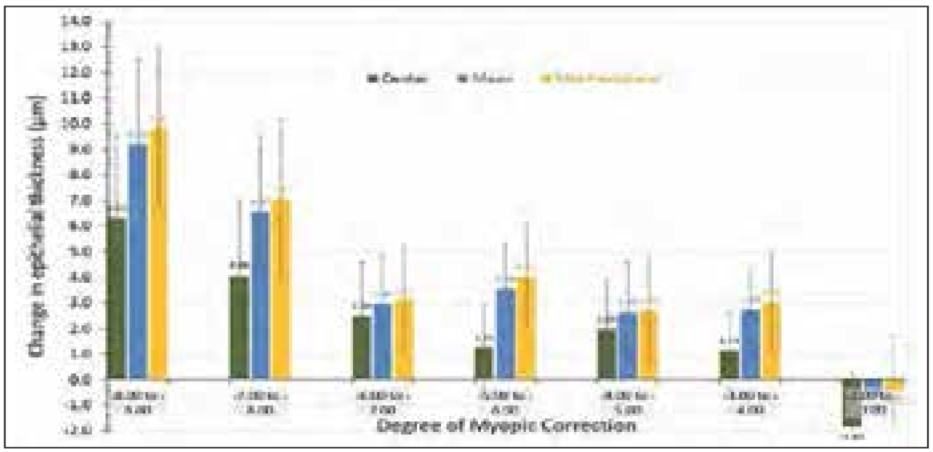


Figure 2. The correlation of increase in epithelial thickness at the center (green dots), on the mean over the 6-mm diameter (blue), and on the 5-mm mid-peripheral zone (yellow) 1 month following myopic LASIK correction. There were 4 cases between -8 and -9 diopters (D), 7 cases between -7 and -8 D, 10 cases between -6 and -7 D, 8 cases between -5 and -6 D, 15 cases between -4 and -5 D, 13 cases between -3 and -4 D, and 6 cases between -2 and -3 D. Error bars indicate standard deviation.

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MS NO: CORNEA-D-13-00497

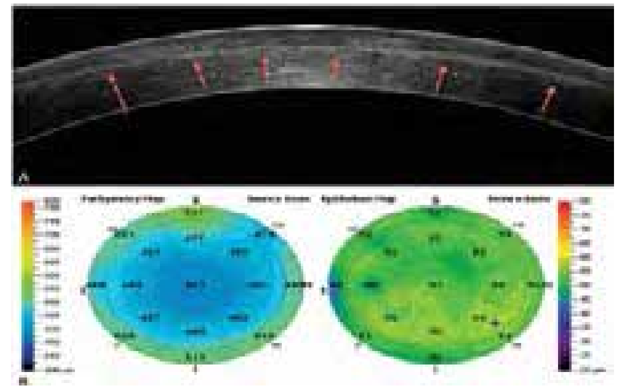
CLINICAL SCIENCE

Epithelial Remodeling After Femtosecond Laser–Assisted High Myopic LASIK: Comparison of Stand-alone With LASIK Combined With Prophylactic High-fluence Cross-linking

AU2

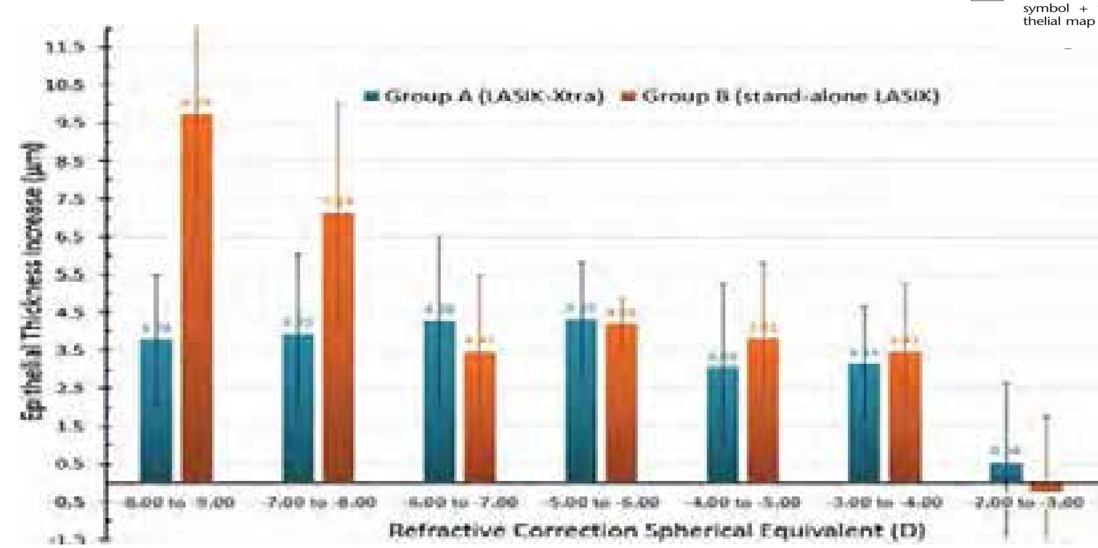
Anastasios J. Kanellopoulos, MD† and George Asimellis, PhD**

FIGURE 1. A, AS-OCT high-resolution cross-sectional meridional image of a right eye treated with LASIK-Xtra for −8.00 D of sphere and −0.25 D of astigmatism, and was it imaged 6 months postoperatively. There is a clear depiction of the central corneal epithelial layer, Bowman membrane, anterior stroma, Descemet membrane, and anterior chamber. Deep stromal hyperreflective lines may correlate with the depth of the CXL-effect achieved with the LASIK-Xtra procedure according to our previous reported findings. B, Detail from of the analysis and report software main report, showing corneal and epithelial 3-dimensional pachymetry maps over the 6-mm corneal diameter. The symbol * indicates thickness minimum (both corneal and epithelial maps), and the symbol + thickness maximum (epithelial map only).



nth 2014 Topographic Epithelial Profile Thickness Changes

AU14



ARTICLE

Combined laser in situ keratomileusis and prophylactic high-fluence corneal collagen crosslinking for high myopia: Two-year safety and efficacy

Anastasios John Kanellopoulos, MD, George Asimellis, PhD

PURPOSE: To evaluate the safety, efficacy, and refractive and keratometric stability of myopic femtosecond laser in situ keratomileusis (LASIK) with concurrent prophylactic high-fluence corneal collagen crosslinking (CXL) compared with the outcomes of standard femtosecond LASIK.

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Clinical Science

Long-Term Safety and Efficacy of High-Fluence Collagen Crosslinking of the Vehicle Cornea in Boston Keratoprosthesis Type 1

Anastasios J. Kanellopoulos, MD, and George Asimellis, PhD

914 | www.corneajrnl.com

Cornea • Volume 33, Number 9, September 2014

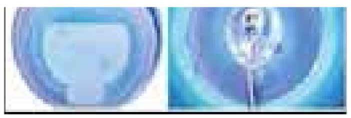

FIGURE 1.

www.corneajrnl.com | 915

FIGURE 4.

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FIGURE 2. CXL of the cornea, the anterior part of the donor cornea after epithelial debridement, and installation of riboflavin solution with very high-fluence CXL. A, The first crosslinking session of the donor cornea through intact epithelium and riboflavin solution injected in the lamellar pocket with 30 mW/cm² for 4 minutes. B, Scraping the donor corneal epithelium with a crescent blade before soaking the stromal surface, in preparation for the second crosslinking session. C, Soaking the deepithelialized donor cornea with riboflavin solution as a preparation for the second crosslinking session.

RESULTS

The mean age of the patients was 67 ± 14 years. Six patients were female and 5 were male. The visual acuity assessed from preoperative light perception and/or hand motion showed a 6-month postoperative improvement. The average UDVA was 20/80 (range: 20/100–20/40), and the CDVA was 20/70 (range: 20/80–20/32).

These patients are still being followed up. After the first postoperative year, each patient is evaluated at least annually. During the long follow-up time that these patients have been continuously monitored (minimum 1 year, maximum 9 years), 2 of the patients required subsequent injection of intracameral and triamcinolone and bevacizumab injection (Avastin; Genentech/Roche, San Francisco, CA) because of cystoid macular edema. Additionally, 1 patient needed yttrium aluminum garnet laser intervention for a retroprosthesis inflammatory membrane that was quite dense and had resulted in a CDVA reduction from 20/60 to 20/400. After this procedure, the patient's vision returned to 20/50.

FIGURE 3. Donor Cornea after 2.8-mm central trephination and just before the peripheral 9.5-mm trephination.

CXL of "vehicle" cornea in Boston Keratoprosthesis type I: J. Cornea 2014

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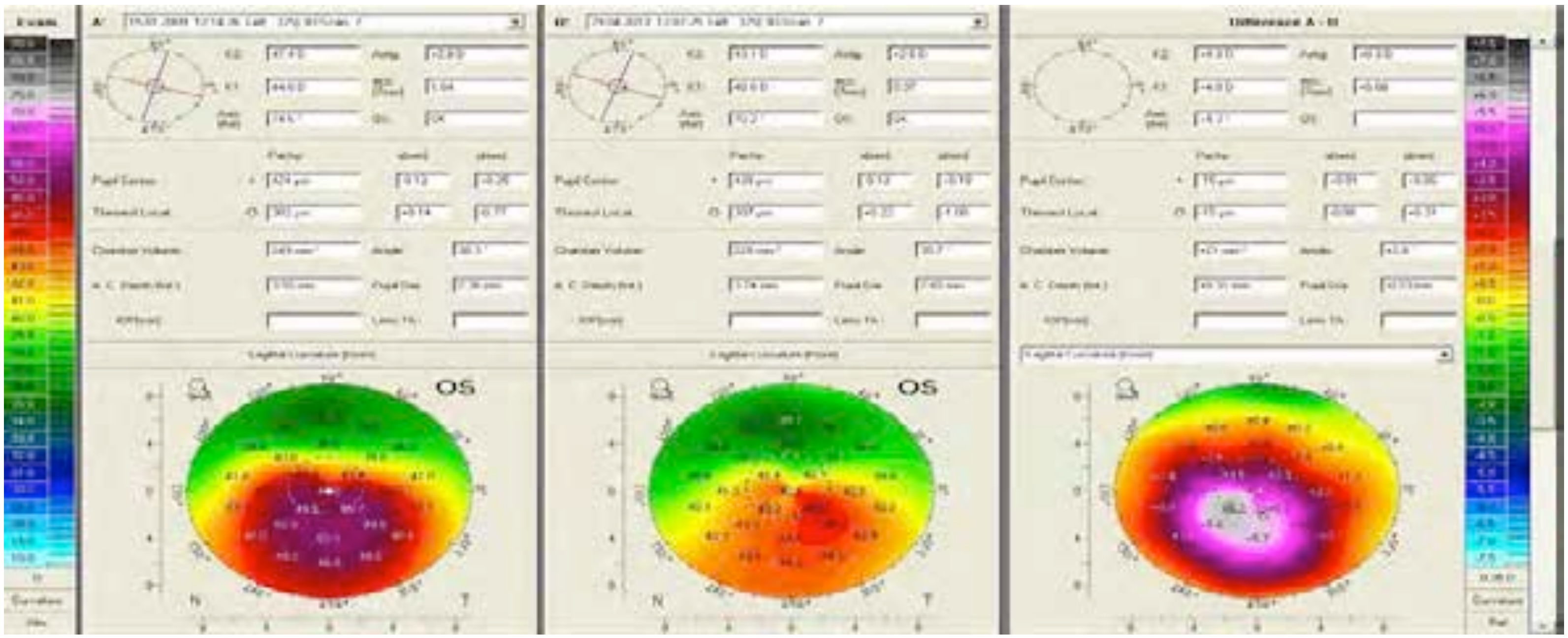
Is CXL a refractive procedure?

Most investigators speak of “disease reversal” when flattening occurs after CXL in ectasia

This is a simple 3mW CXL-alone case from **2005**

No scar developed, Now 2013 has Flattened 12D!!!



Clinical Ophthalmology

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ORIGINAL RESEARCH

Novel myopic refractive correction with transepithelial very high-fluence collagen cross-linking applied in a customized pattern: early clinical results of a feasibility study

Anastasios John Kanellopoulos

LaserVision.gr Institute, Athens, Greece, and New York Medical School, New York, NY, USA

Background: The purpose of this study is to report the safety and efficacy of a new application of collagen cross-linking using a novel device to achieve predictable refractive myopic changes in virgin corneas.

Methods: Four cases were treated with a novel device employing very high-fluence collagen cross-linking applied in a myopic pattern. Prior to treatment, riboflavin solution was applied to the intact epithelium. The collagen cross-linking device was then engaged for a total of 12 J/cm², to be applied transepithelially in a predetermined pattern. Cornea clarity, corneal keratometry, and corneal topography were evaluated by both Placido disc and Scheimpflug imaging, along with cornea anterior segment optical coherence tomography and endothelial cell counts.

Results: An average of 2.3 diopters was achieved in the first week in all four cases treated with the very high-fluence myopic collagen cross-linking intervention. There was a slight regression to 1.44 diopters at 1 month, which remained stable at 6-month follow-up. The mean keratometry change was from 44.90 diopters to 43.46 diopters. There was no significant change in endothelial cell counts or corneal clarity. There was some mild change in epithelial thickness distribution, with the treated area showing a slight but homogeneous reduction in mean thickness from 52 µm to 44 µm.

Conclusion: This report describes the novel application of very high-fluence collagen cross-linking with a predictable well defined myopic refractive (flattening) corneal effect. This technique has the advantages of essentially no postoperative morbidity, immediate visual rehabilitation, and the potential for tapering until the desired result is achieved.

Keywords: myopia, refractive correction, high-fluence collagen cross-linking, clinical results

Video abstract

Point your SmartPhone at the code above. If you have a QR code reader the video abstract will appear. Or use: http://dvpr.es/1oR39A

Introduction

Collagen cross-linking has been used for many years as a means of stabilizing cornea ectasia.[1–5] Although a multitude of treatments and techniques are available, it has been well documented that the procedure almost invariably results in some central anterior corneal flattening,[1–5] which has often been interpreted as "disease regression." As our understanding and the technology available for collagen cross-linking has progressed, it has been theorized that differential application of collagen cross-linking in specific areas of the cornea may produce predictable refractive changes. Several aspects of this theory need further investigation. Is it possible to achieve predictable refractive changes? Can this be achieved through an intact epithelium? Can the human cornea tolerate higher fluence of ultraviolet light? This paper describes the use of a novel

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Clinical Ophthalmology 2014:8 697–702

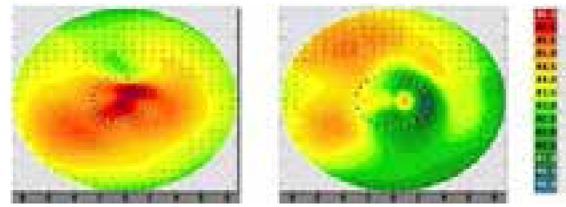

Figure 1 Placido disc topography for patient 3 preoperatively (left) and 6 months postoperatively (right) depicting the significant and regular central corneal flattening effect.

epithelial thickness over the treated area (Figure 3). The average epithelial thickness was 49 µm preoperatively, which decreased to 44 µm at 1 month postoperatively, and then increased to 48 µm at 5 months postoperatively.

Discussion

A multitude of reports have established the significant refractive changes that accompany classic collagen cross-linking[1–8] utilizing the classic Dresden protocol (3 mW/cm² for 30 minutes), as well as collagen cross-linking utilizing higher fluence,[9] and even cross-linking delivered in eyes that have had riboflavin placed within a femtosecond laser-created pocket or intrastromal corneal ring segment channels.[10,11] Over the years, most clinicians have referred to this process as "flattening," which has often been interpreted as "disease regression." We have long

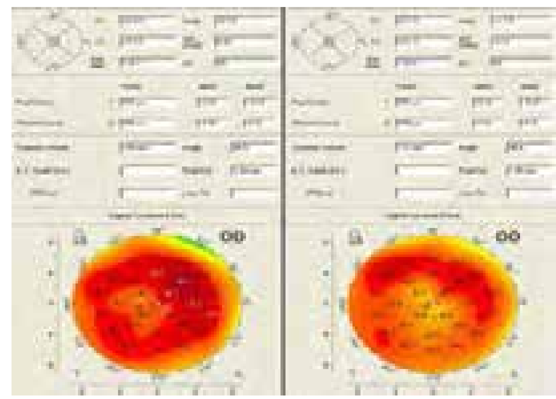

Figure 2 Scheimpflug imaging data for patient 3 preoperatively (left) and 6 months postoperatively (right) depicting the significant and regular central corneal flattening effect.
Abbreviations: D, diopters; OD, right eye.

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Case Reports in Ophthalmology

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Toric Topographically Customized Transepithelial, Pulsed, Very High-Fluence, Higher Energy and Higher Riboflavin Concentration Collagen Cross-Linking in Keratoconus

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Key Words
Topography customizable cross-linking · High-fluence cross-linking · Transepithelial cross-linking · Toric cross-linking · Keratoconus · Photorefractive intrastromal cross-linking · KXL II

Abstract
Purpose: To report a novel application of toric topographically customized transepithelial collagen cross-linking (CXL) aiming to achieve refractive astigmatic changes in a keratoconic cornea. ***Methods:*** Specially formulated riboflavin transepithelial administration and delivery of high-fluence UVA in a topographically customized pattern was applied in an eye with progressive keratoconus. Visual acuity, cornea clarity, keratometry, topography, and pachymetry with a multitude of modalities, as well as endothelial cell counts were evaluated for >6 months. ***Results:*** Uncorrected distance visual acuity changed from preoperative 20/40 to 20/25 at 6 months. A mean astigmatic reduction of 0.8 D, and significant cornea surface normalization was achieved 6 months postoperatively. There was some mild change in the epithelial distribution, with the treated area having a slight normalization in the average epithelial thickness. ***Conclusions:*** We introduce herein the novel application of a topograph-

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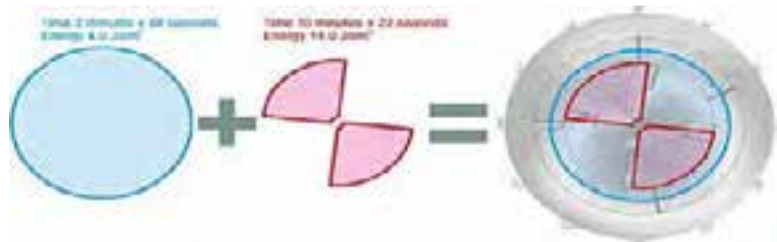

Fig. 1. Customized treatment profile employed in the treatment. Left panel: details of the applied customizable pattern and parameters for UVA exposure; right panel: overlay of the pattern on the sagittal curvature map.

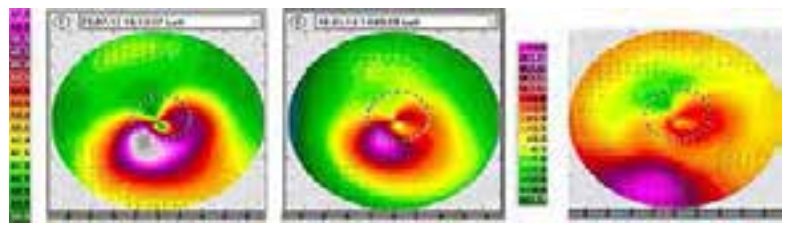

Fig. 2. Placido disk topography data showing sagittal curvature maps depicting significant refractive changes along the axis of the customized cross-linking pattern. Panel 1: 1 day preoperatively. Panel 2: 6 months postoperatively. Panel to the right: difference 2–1.

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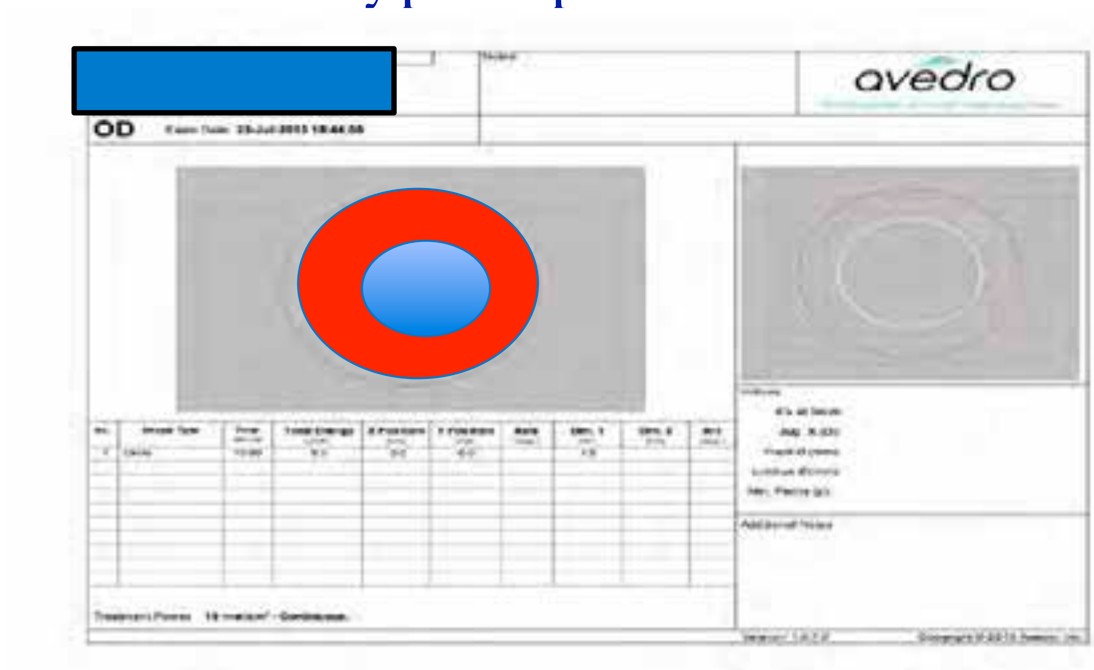
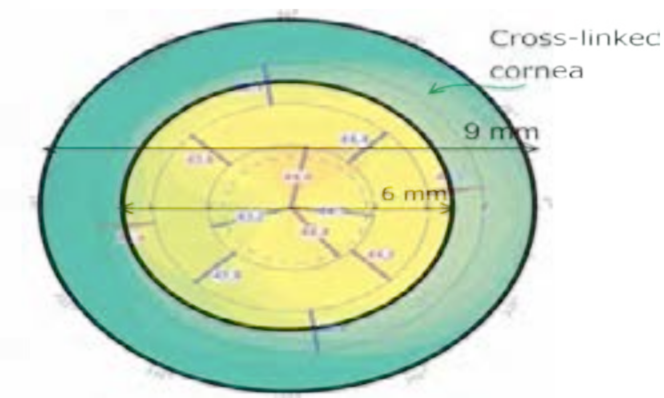
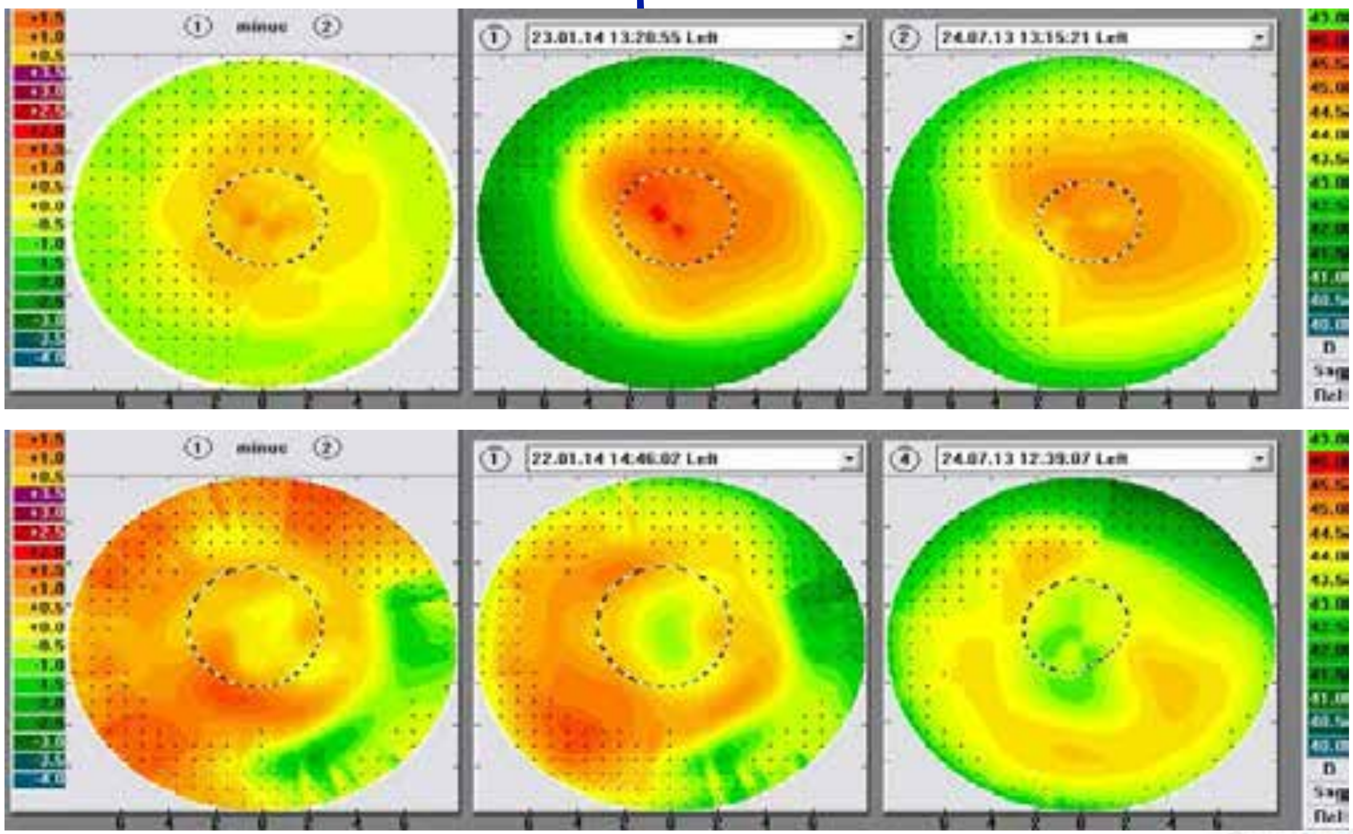
“ profile Hyperopic” oz 6-9mm
“hyperopic PTK” 6-9oz 30 microns

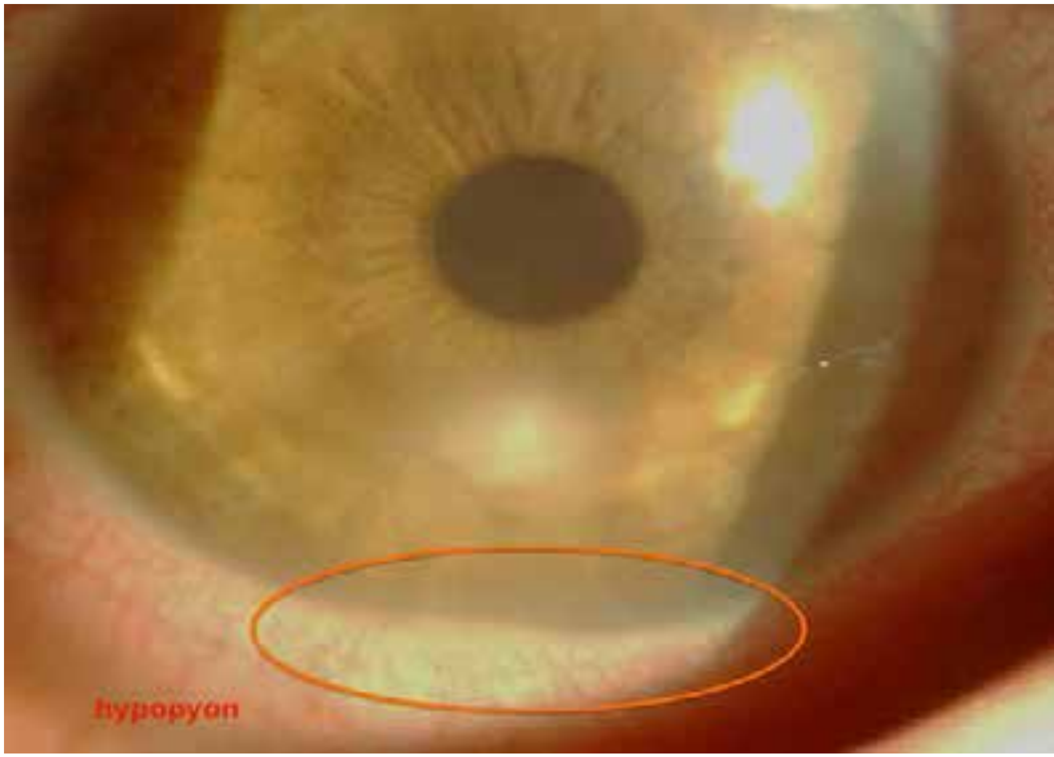


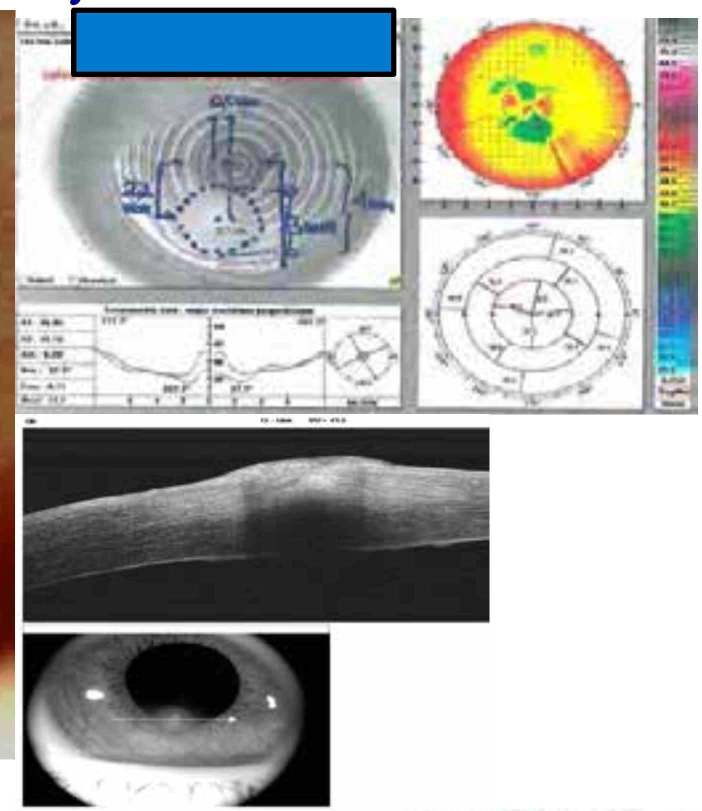


Placido topo data



Infectious Keratitis in a 38y/o F MD





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Customized infectious keratitis treatment

20mW/cm^{2}, 20 Joules
continuous for 10’

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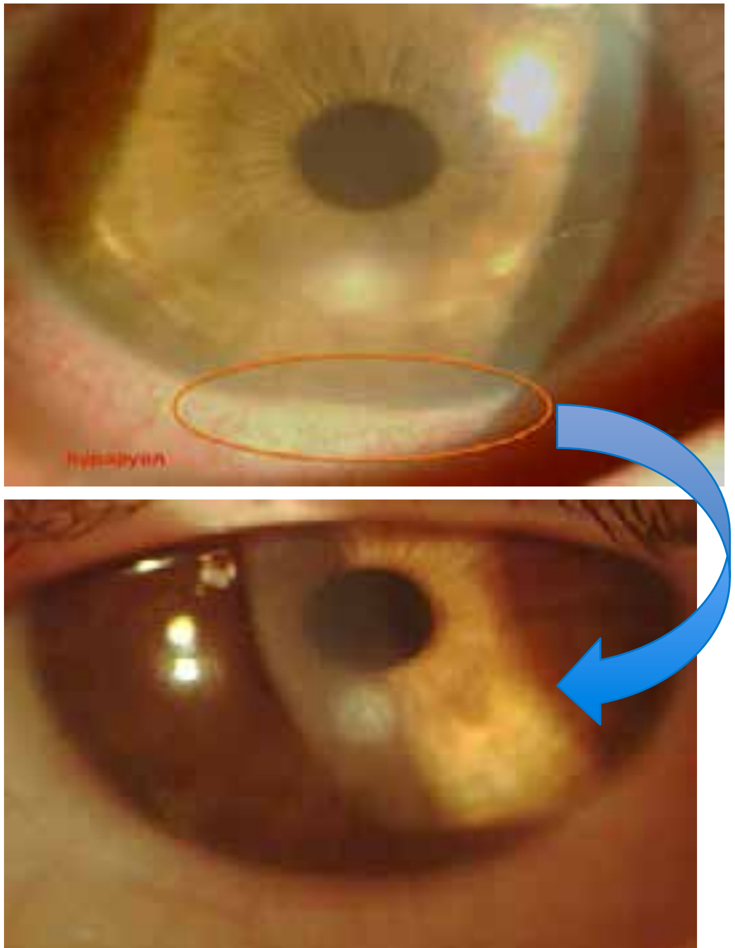

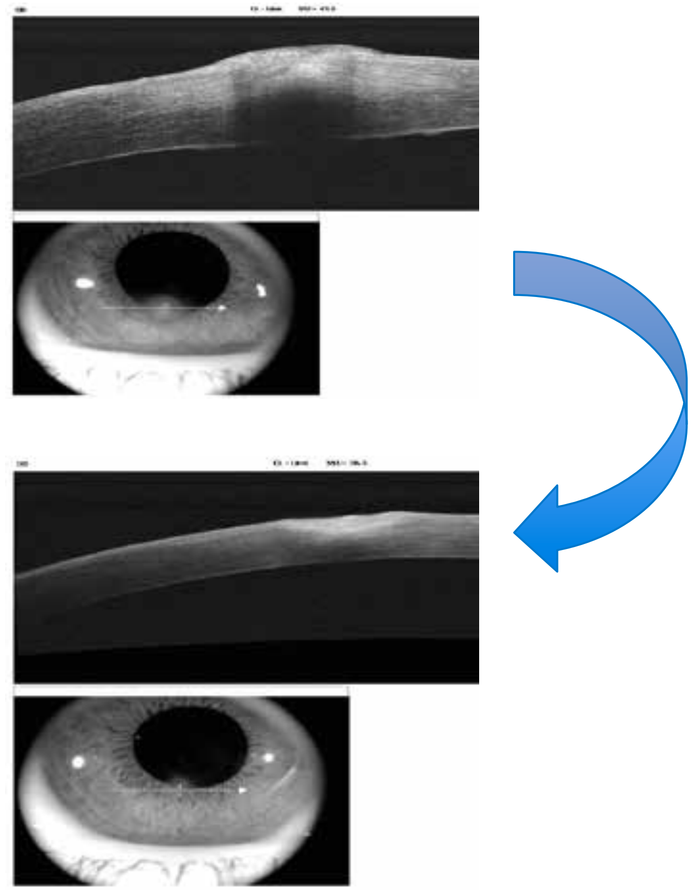

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Clinical Science

Long-Term Safety and Efficacy of High-Fluence Collagen Crosslinking of the Vehicle Cornea in Boston Keratoprosthesis Type 1

Anastasios J. Kanellopoulos, MD, and George Asimellis, PhD

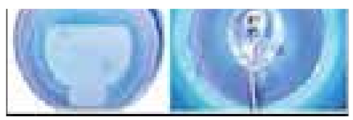

FIGURE 2. CXL of the cornea, the anterior part of the donor cornea after epithelial debridement, and installation of riboflavin solution with very high-fluence CXL. A, The first crosslinking session of the donor cornea through intact epithelium and riboflavin solution injected in the lamellar pocket with 30 mW/cm² for 4 minutes. B, Scraping the donor corneal epithelium with a crescent blade before soaking the stromal surface, in preparation for the second crosslinking session. C, Soaking the deepithelialized donor cornea with riboflavin solution as a preparation for the second crosslinking session.

RESULTS

The mean age of the patients was 67 ± 14 years. Six patients were female and 5 were male. The visual acuity assessed from preoperative light perception and/or hand motion showed a 6-month postoperative improvement. The average UDVA was 20/80 (range: 20/100–20/40), and the CDVA was 20/70 (range: 20/80–20/32).

These patients are still being followed up. After the first postoperative year, each patient is evaluated at least annually. During the long follow-up time that these patients have been continuously monitored (minimum 1 year, maximum 9 years), 2 of the patients required subsequent injection of intracameral and triamcinolone and bevacizumab injection (Avastin; Genentech/Roche, San Francisco, CA) because of cystoid macular edema. Additionally, 1 patient needed yttrium aluminum garnet laser intervention for a retroprosthesis inflammatory membrane that was quite dense and had resulted in a CDVA reduction from 20/60 to 20/400. After this procedure, the patient's vision returned to 20/50.

FIGURE 3. Donor Cornea after 2.8-mm central trephination and just before the peripheral 9.5-mm trephination.

CXL of "vehicle" cornea in Boston Keratoprosthesis type I: J. Cornea 2014

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Conclusions / Our current CXL protocols

1-Athens Protocol: topo partial PRK +15'x 6mw/cm^2

or combined with PiXL (4-20 Joules)

2-LASIK Xtra: 1' soaking and 60" 30mW/cm^2 (1.8 Joules) for all hyperopes, 80" for myopes (2.4 Joules)

2-PRK Xtra: 1' soaking 80" X 30mW/cm^2 (2.4 Joules)

5-Transepi CXL: 0.25% ribo + 30mW X 3'

6-Infection: 0.25% riboflavin + 20mW/cm^2 /20 Joules

7-PiXL 0.25% ribo + 30mW/cm^2 7.2-20 Joules

Prospective randomized trials have yet to establish the comparative efficacy of the multitude of CXL technique available today

Topography - Guided University Courses 2016:

Become proficient interpreting in cornea diagnostics and designing expert topography guided laser treatments!

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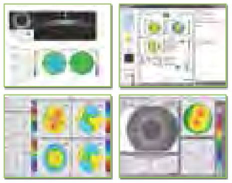
Become proficient interpreting in cornea diagnostics and designing expert topography guided laser treatments!

Didactic course and hands-on treatment designing of multiple case scenarios (virgin eyes, complicated therapeutic treatments: older decentered or irregular ablations, cornea scars, ectasia and keratoconus).
How to adjust optical zone, transition zone, and account for topography spherical neutralization.
Each participant will bring his or her clinical cases and design a treatment, and/or will be given all of the case scenarios noted above to design a treatment.
Anticipate spherical change surprises
Modulation of biomechanics with various CXL protocols.



- Outline and 2016 locations
- Pre-ESCRS
- Pre-AAO

Course Director: A. John Kanellopoulos, MD

www.topo-guided.com

Copenhagen'16 course logistics

Friday September 9th, 2016
(pre-ESCRS)

8:00 AM to 15:30 PM

At the Crowne Plaza
Copenhagen Towers
Ørestads Boulevard 114 - 118
2300 København S, Denmark
info@cpcopenhagentowers.com
Tel: +45 8877 6655
Fax: +45 8877 6611

Chicago '16 course logistics

Thursday October 13th, 2016
(pre-AAO)

8:00 AM to 15:30 PM

At the Hyatt Regency McCormick Place
2233 S Martin Luther King Dr,
Chicago, 60616, IL, USA
Tel: +1 312 567 1234

2016 Course's Mutual Outline (Copenhagen and Chicago)

8:00
Breakfast - Registration

8:30-11:30
- Introduction to current cornea diagnostics and their relative differences: Placido Topography, Scheimpflug tomography, Anterior segment OCT, LED color reflection topography.
- Corneal epithelial mapping and its clinical relevance in diagnosis and treatment
- Basic principles in employing topography data (Scheimpflug based and/or Placido-based) in the customization of an excimer corneal ablation. Technology overview and case presentations, with the Wavelight, Schwind and Ivis platforms.
- Topography astigmatism, centroid and angle kappa considerations for possible revision of the clinical refraction used in each ablation

11:30-12:30
Discussion lunch

12:30-15:30
- Topography customized methodology for virgin myopic and hyperopic eyes
- Topography customized methodology for irregular corneas (previously treated: RK, decentered and/or irregular ablations, as well as irregular and ectasia cases)
- Anticipating asphericity and sphere compensatory nomograms for better spherical correction and emmetropia.
- Participants will gain access to an online database with over 100 cases examples (pre-op data, treatment design, treatment video, postop data and overview of what went well and what potentially went off-target)
- Complications assessment and management.

- **Each participant will have the chance to design several treatments on site!**

The course will be limited to 30 participants.
Advanced registration and information:
http://www.topo-guided.com/

Topography - Guided University Courses 2016:

- Correlation of multiple corneal imaging devices may enhance accuracy of assessment by including possible epithelial remodeling data, and limiting specific limitations of Placido-based, Scheimflug-based and color LED refraction topography.
- When using topography maps in laser corneal ablation, all these parameters are considered under a much more meticulous and critical perspective. Although originally designed to treat irregular eyes, it has recently become apparent, hat topo-guided treatments may be superior for routine myopic and/or hyperopic laser vision correction.
- This vigorous didactic course and wet lab on topography-customized corneal ablations will focus on familiarizing the small number of participants on multiple imaging assessment and interpretation, data acquisition and treatment modifications with hands-on the design platforms and data present on-site.
- Additionally, the participants will be offered access to a very large databank with most topo-guided scenario treatments and outcomes.

Course Director:
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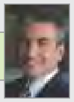

Disclaimer:
Please be advised that if you are traveling from outside the US for a US course or within the EU for a European course, you would be responsible for obtaining the appropriate visas on your own.
The AJKMD course services will provide a letter of invitation upon confirmation of your registration.
2-Our courses do not provide CME credits.
3-Our courses are purely instructional. Any medical procedure liability lays with the operating surgeon and the bylaws observed in the country and state of his/ her practice.

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Thank You!