Refractive CXL!

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AJK is a consultant for Alcon, Wavelight and Avedro.

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Our Athens team's CXL innovations:

- Applying topo-guided PRK in CXLed ectatic corneas **2004**
- Combining CXL with topo-guided reshaping of irregular corneas Athens Protocol: **2005**
- Higher fluence: **2006**
- Intrastromal treatments through femto-pockets: **2007**
- LASIK Xtra: **2008** (ESCRS)
- LASIK Xtra for hyperopia: **2011** (ASCRS)
- PiXL CXL corneal differentials: **2013** (AAO)

Acknowledgments

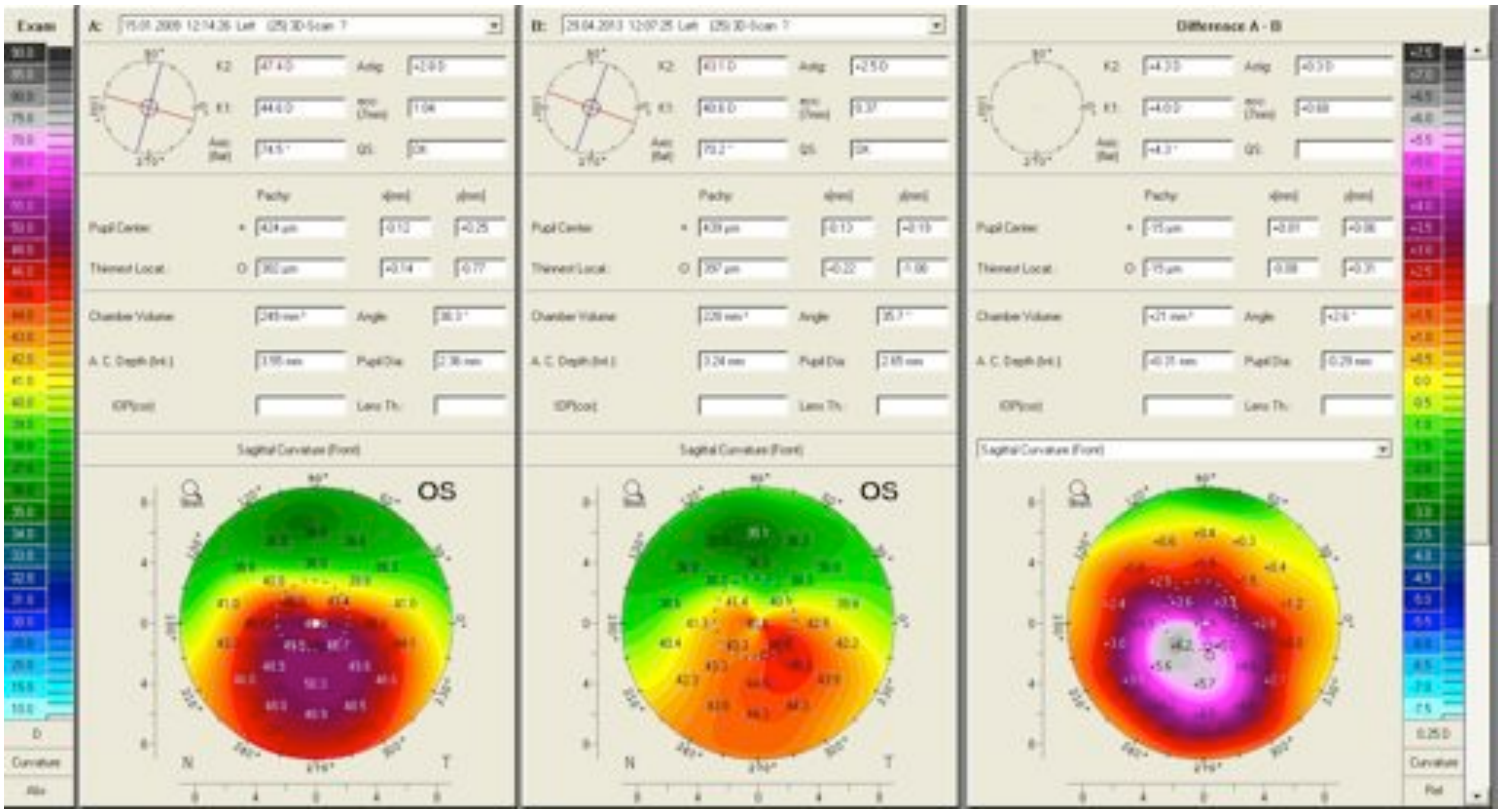
- Theo Seiler-founder of the CXL concept
- Satish Herakar-a mentor in our CXL.. journey
- B.J. Dupps-CCF design of treeatment patterns on computer models
- David Muller-Avedro: Design and implementation of a highly customised device
- The Athens Laservision.gr team


Is CXL is a powerful 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!!!



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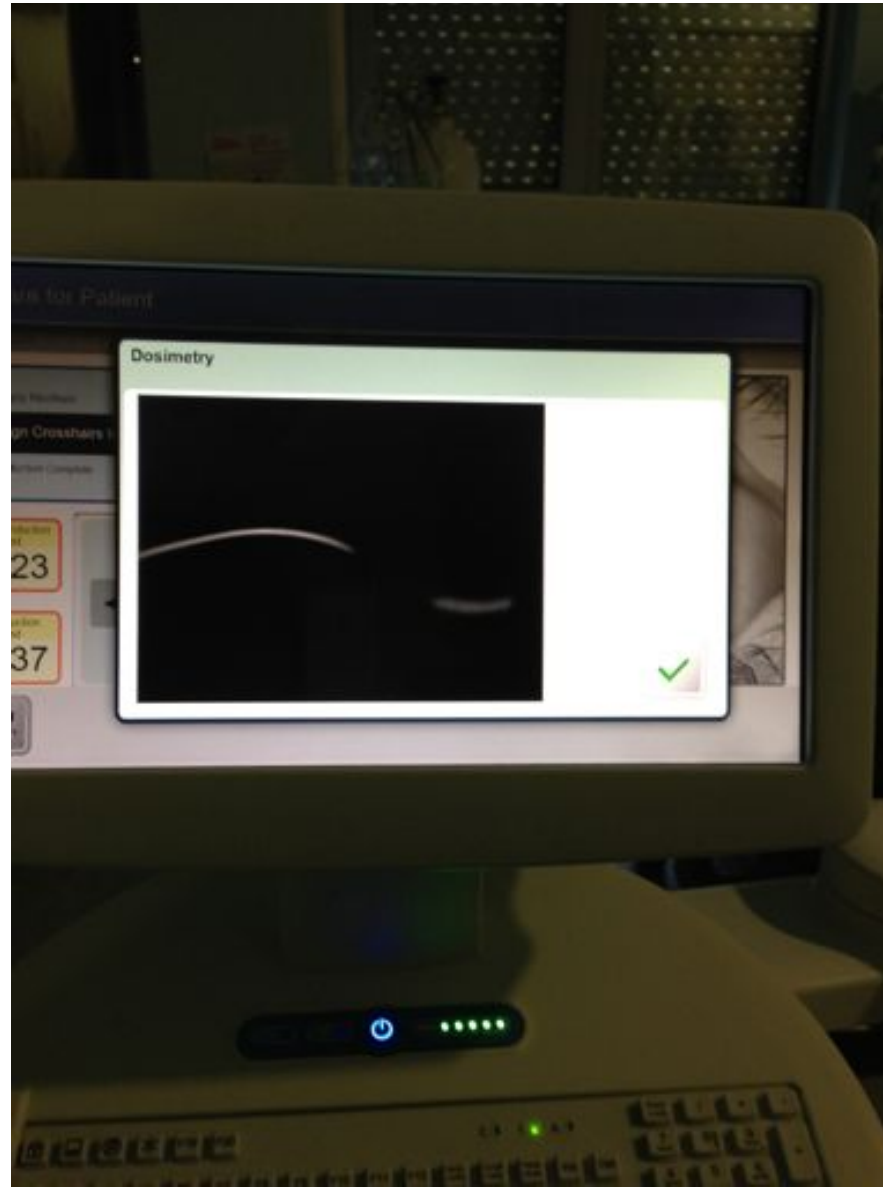
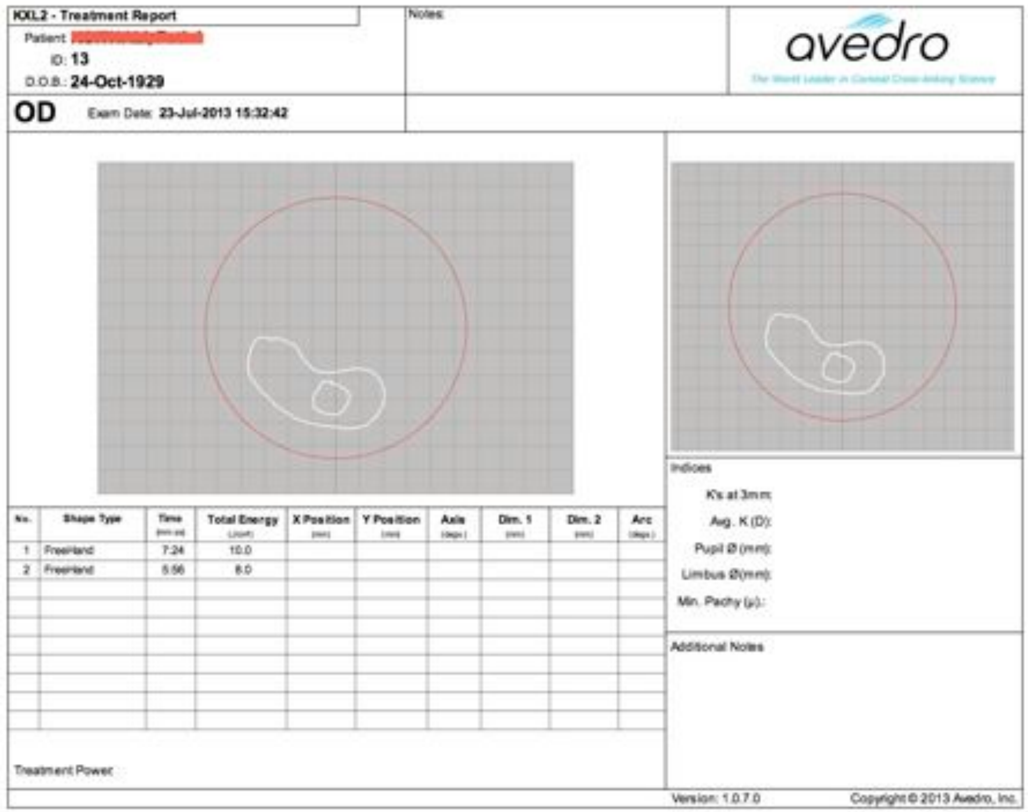
Novel Avedro KXL-II Device

Riboflavin penetration captured
by Build –in Scheimpflug image



Custom profile (topo-guided) transepi 4min Paracel+6min VibexXtra


KXL2 - Treatment Report

Patient: [redacted]

ID: 13

D.O.B.: 24-Oct-1929

Notes:

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OD Exam Date: 23-Jul-2013 15:32:42

No.	Shape Type	Time	Total Energy	X Position	Y Position	Axis	Dim. 1	Dim. 2	Arc
1	FreeHand	7:24	10.0						
2	FreeHand	5:56	8.0						

Indices

K's at 3mm:

Avg. K (D):

Pupil Ø (mm):

Limbus Ø(mm):

Min. Pachy (μ):

Additional Notes

Treatment Power:

Version: 1.0.7.0

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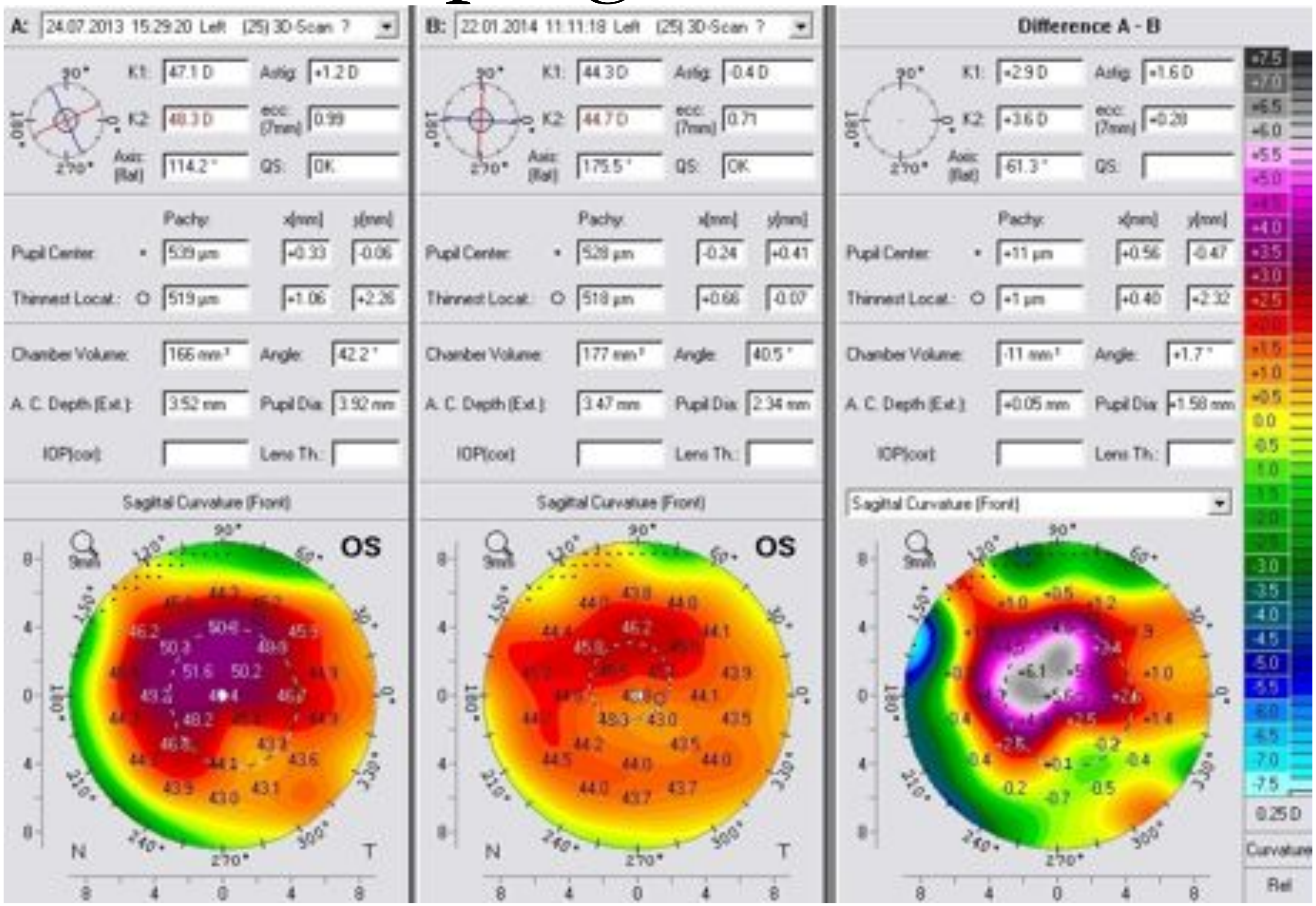
PiXL topo-guided 7 months



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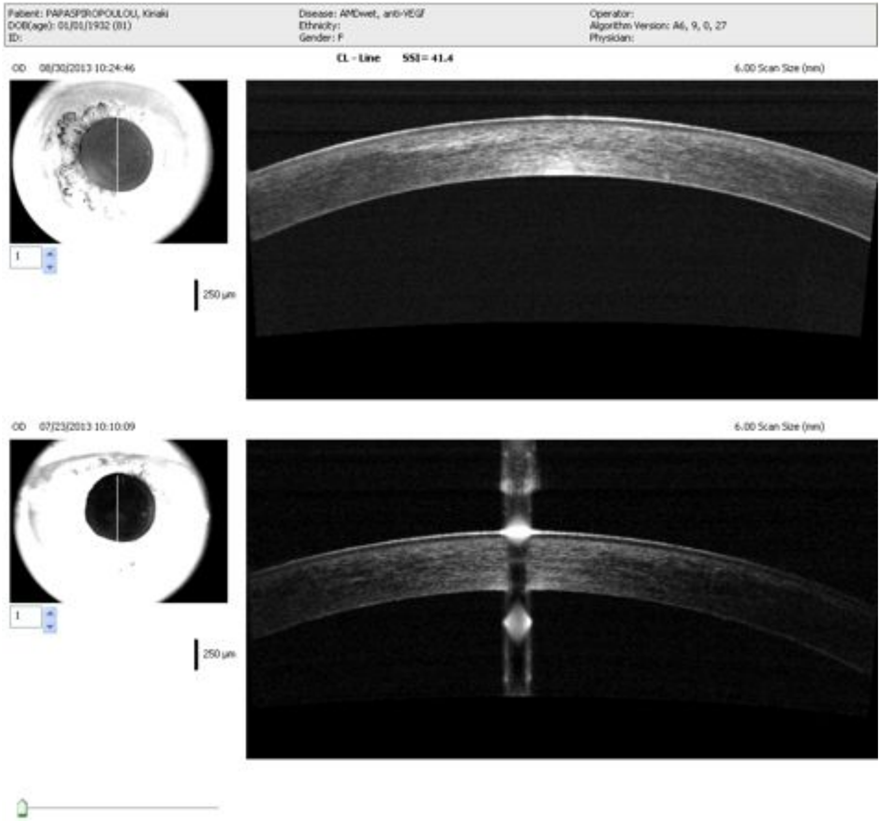
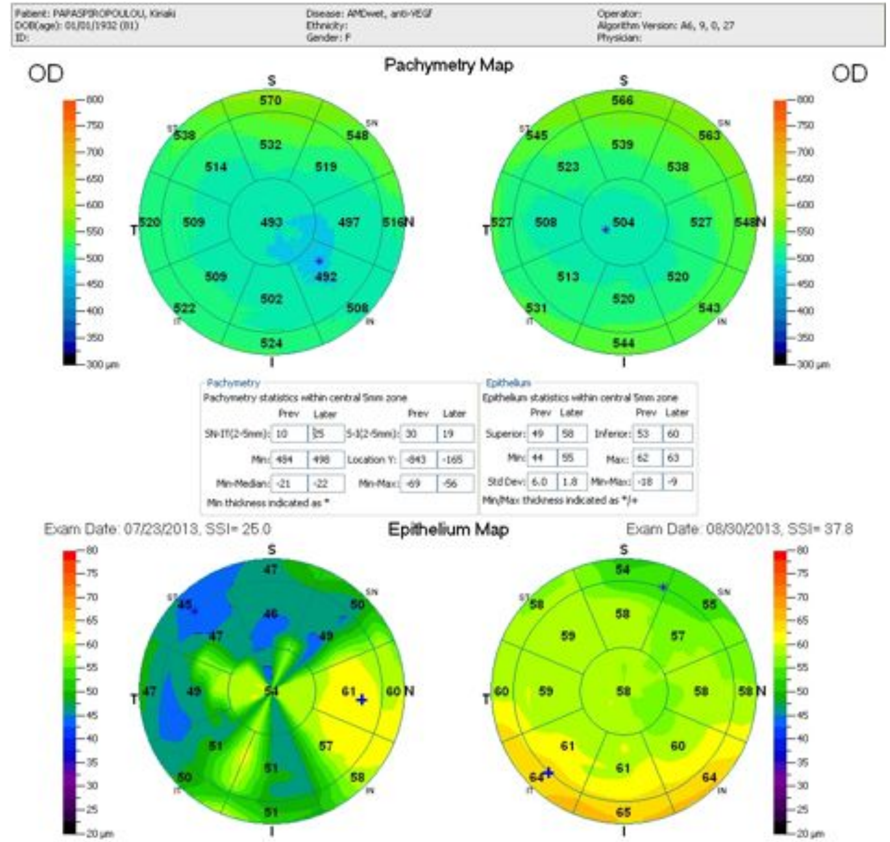
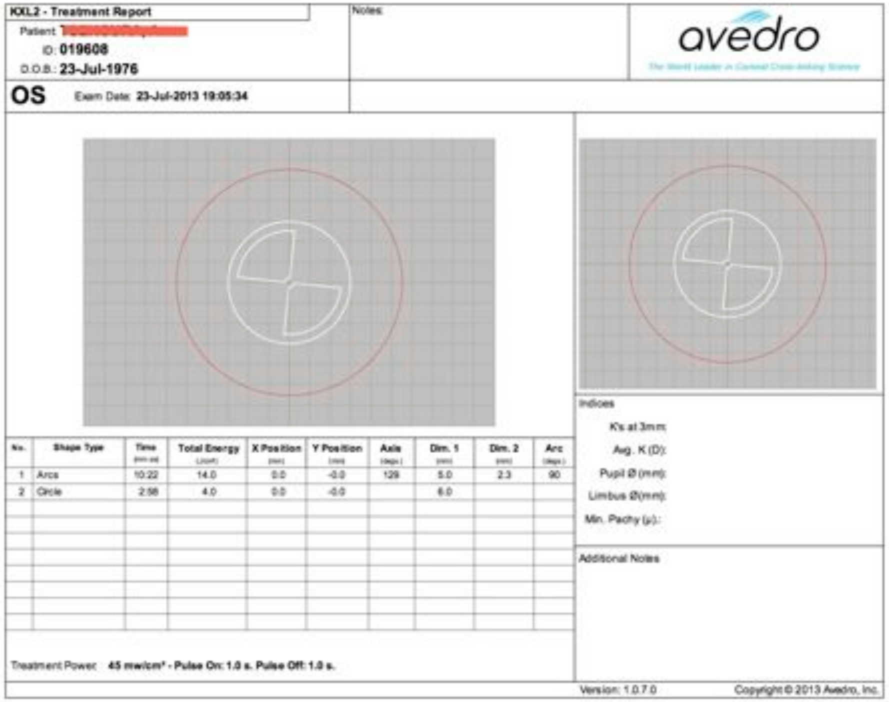
Irregular astigmatism treatments





Toric profile-transepi:
4min Paracel+6min VibexXtra



KXL2 - Treatment Report

Patient: [redacted]
ID: 019608
D.O.B.: 23-Jul-1976

Notes:

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OS Exam Date: 23-Jul-2013 19:05:34

No.	Shape Type	Time	Total Energy	X Position	Y Position	Axis	Dim. 1	Dim. 2	Arc
1	Arcs	10:22	14.0	0.0	-0.0	129	5.0	2.3	90
2	Circle	2:58	4.0	0.0	-0.0		6.0		

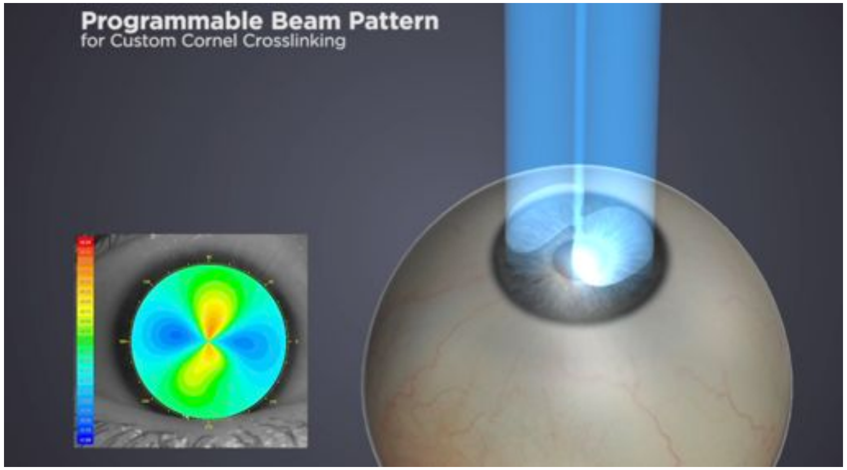
Treatment Power: 45 mw/cm² - Pulse On: 1.0 s. Pulse Off: 1.0 s.

Indices

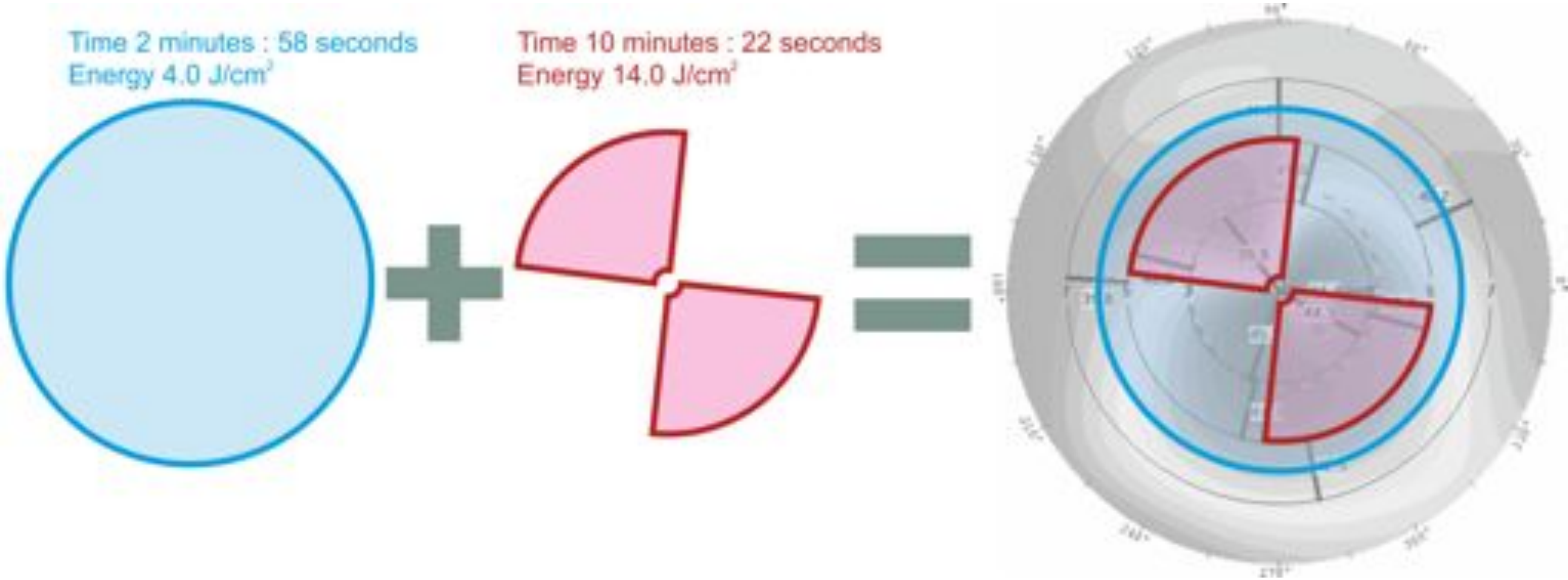
K's at 3mm:
Avg. K (D):
Pupil Ø (mm):
Limbus Ø(mm):
Min. Pachy (µ):

Additional Notes

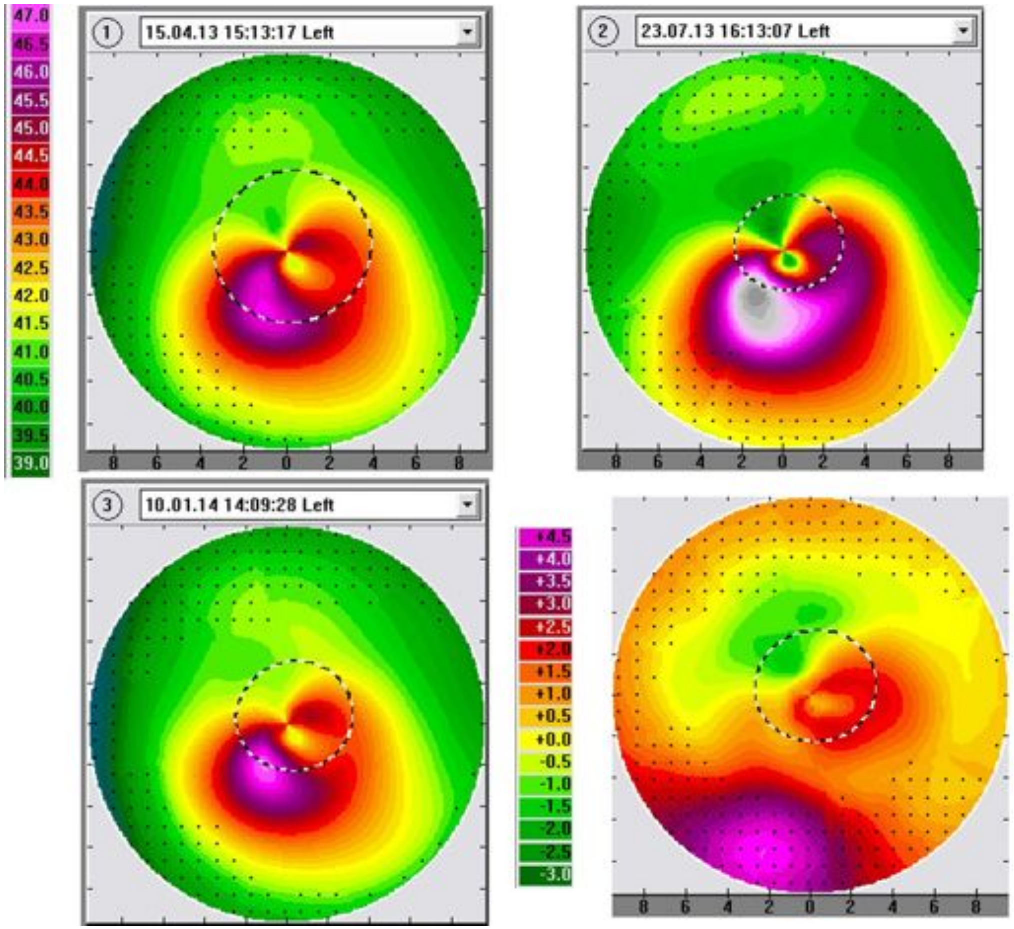
Version: 1.0.7.0

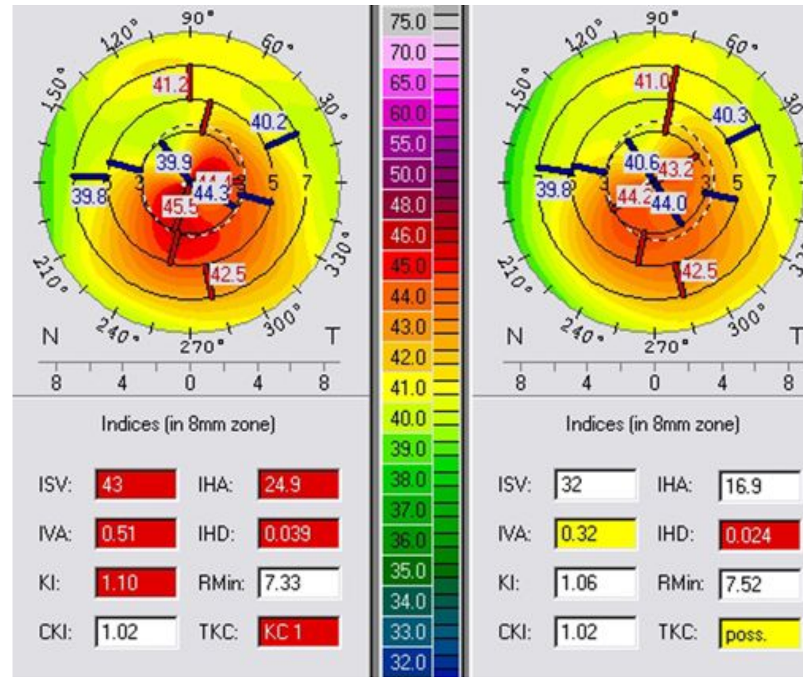


8 month topography-customised tran-epithelial CXL treatment



Customized astigmatism correction





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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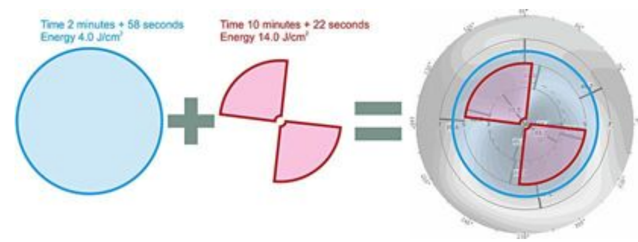

Fig. 1. Customized treatment profile employed in the treatment. Left panel: details of the applied customizable pattern and parameters for UVA exposure; right panel: overlay of the pattern on the sagittal curvature map.

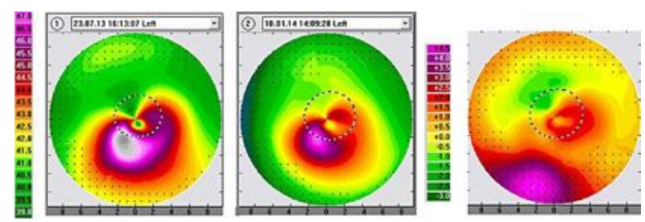

Fig. 2. Placido disk topography data showing sagittal curvature maps depicting significant refractive changes along the axis of the customized cross-linking pattern. Panel 1: 1 day preoperatively. Panel 2: 6 months postoperatively. Panel to the right: difference 2–1.

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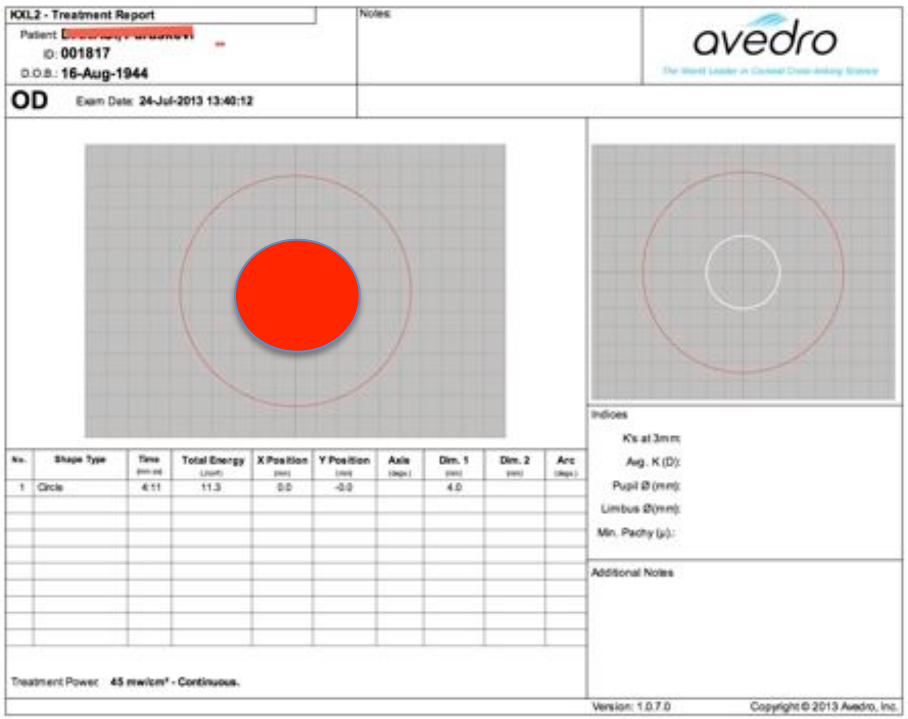
Myopic profile central 4mm OZ with 6mm PTK epithelium scrape



KXL2 - Treatment Report

Patient: [redacted]
ID: 001817
D.O.B.: 16-Aug-1944

Notes:

avedro

OD Exam Date: 24-Jul-2013 13:40:12

No.	Shape Type	Time	Total Energy	X Position	Y Position	Axis	Dim. 1	Dim. 2	Arc
1	Circle	4:11	11.3	0.0	-0.0		4.0		

Indices
K's at 3mm:
Avg. K (D):
Pupil Ø (mm):
Limbus Ø(mm):
Min. Pachy (µ):

Additional Notes

Treatment Power: 45 mw/cm² - Continuous.

Version: 1.0.7.0

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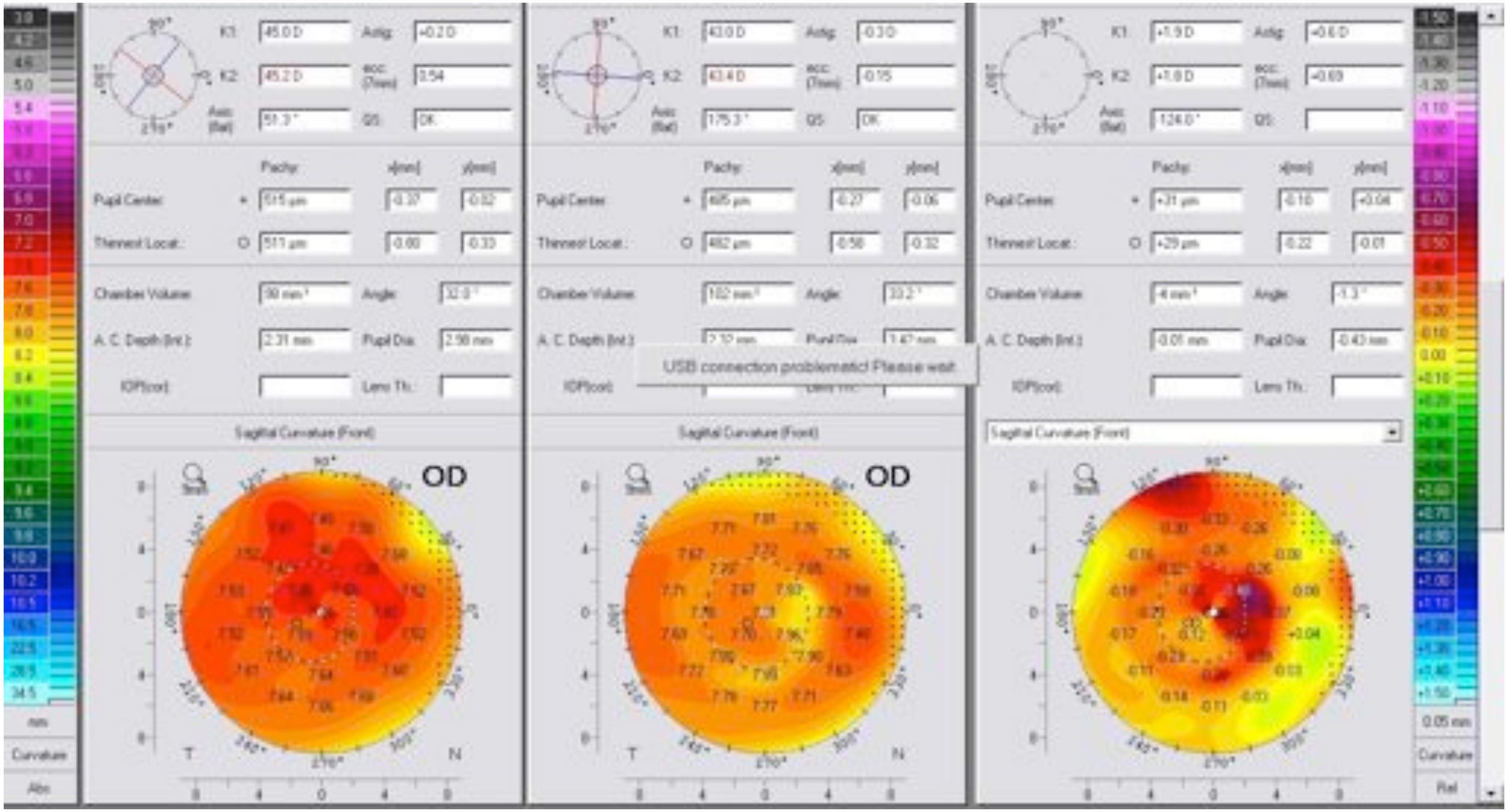
6 months myopic treatments **4D flattening** !



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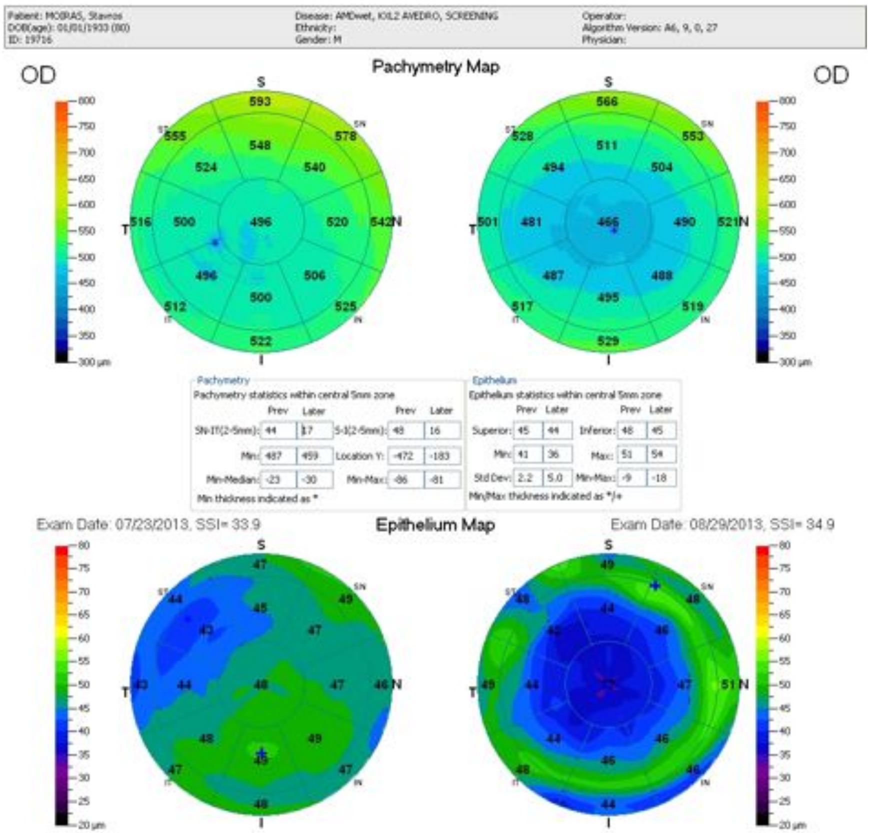
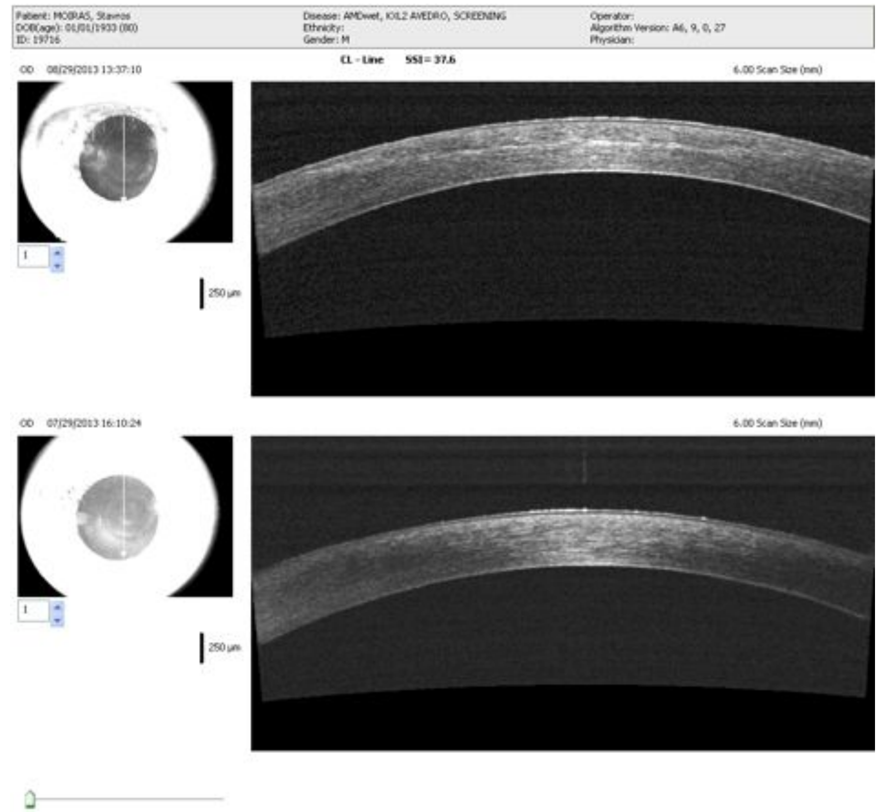
6 month PTK + myopic treatments





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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

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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/cm^2, 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/1eiR39A

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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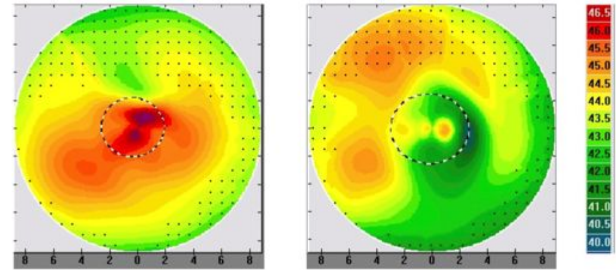

Figure 1 Placido disc topography for patient 3 preoperatively (left) and 6 months postoperatively (right) depicting the significant and regular central corneal flattening effect.

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/cm^2 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

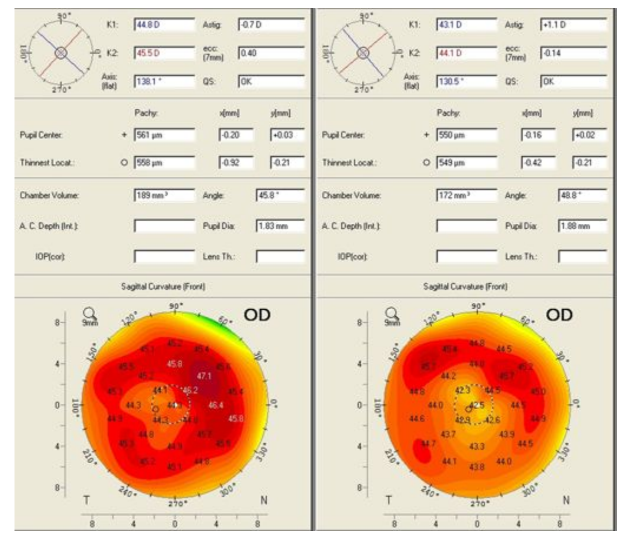

Figure 2 Scheimpflug imaging data for patient 3 preoperatively (left) and 6 months postoperatively (right) depicting the significant and regular central corneal flattening effect.
Abbreviations: D, diopters; OD, right eye.

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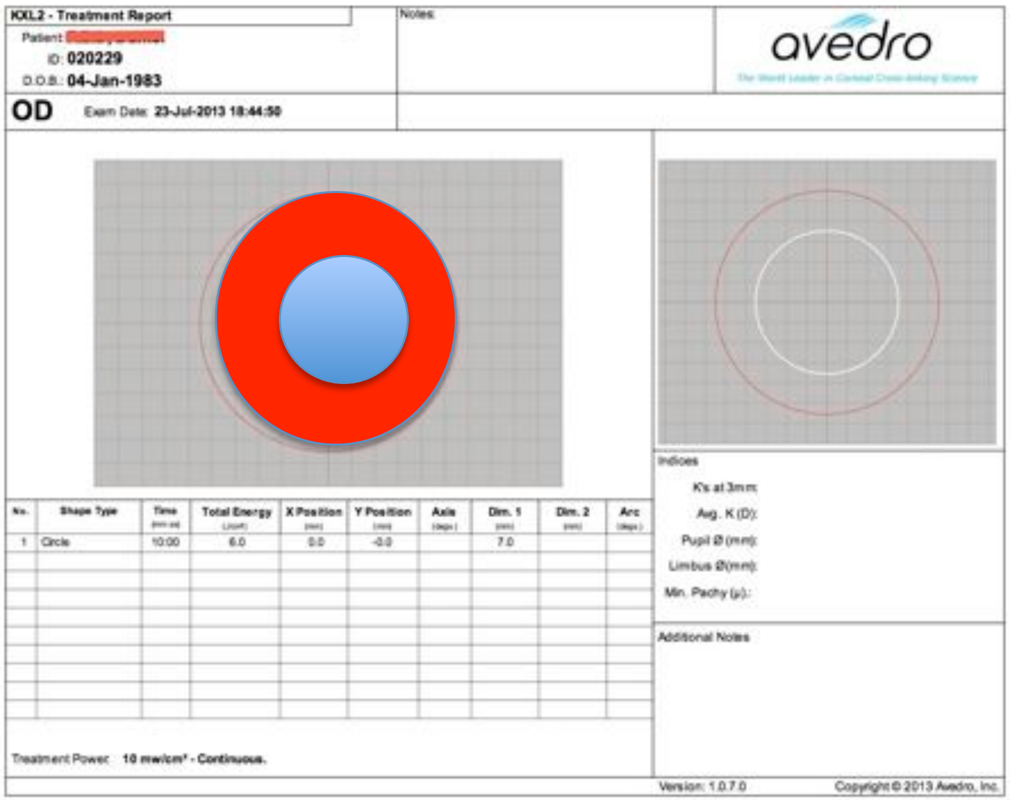
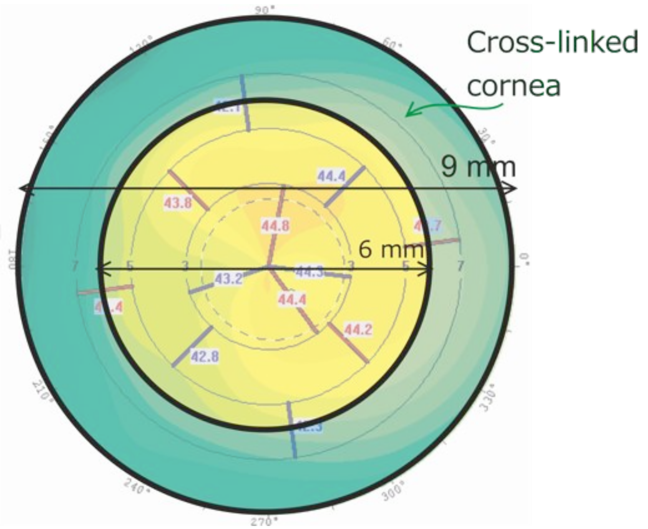
“ profile Hyperopic” oz 6-9mm
“hyperopic PTK” 6-9oz 30 microns





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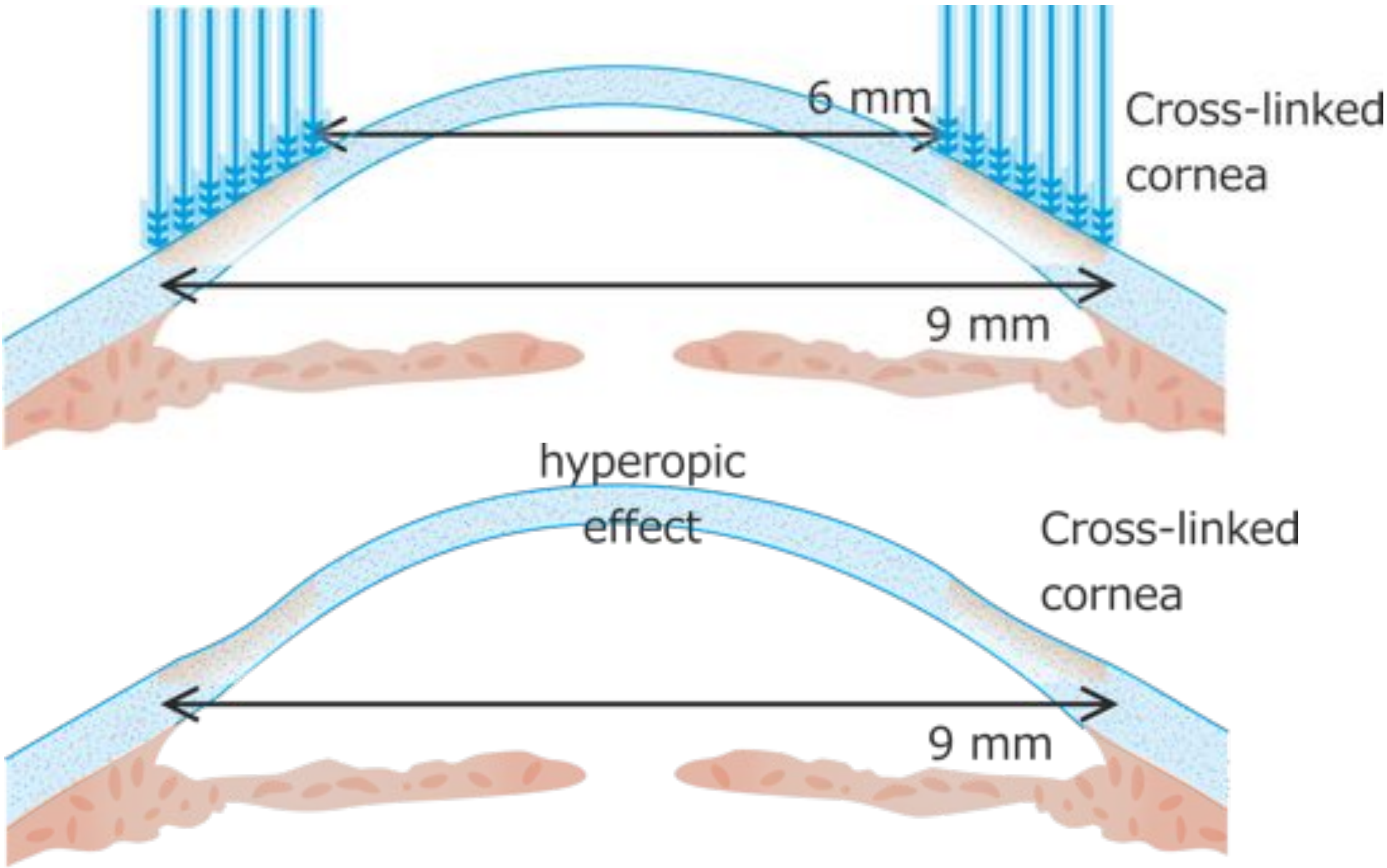
The myopic shift
(hyperopia-presby treatment)



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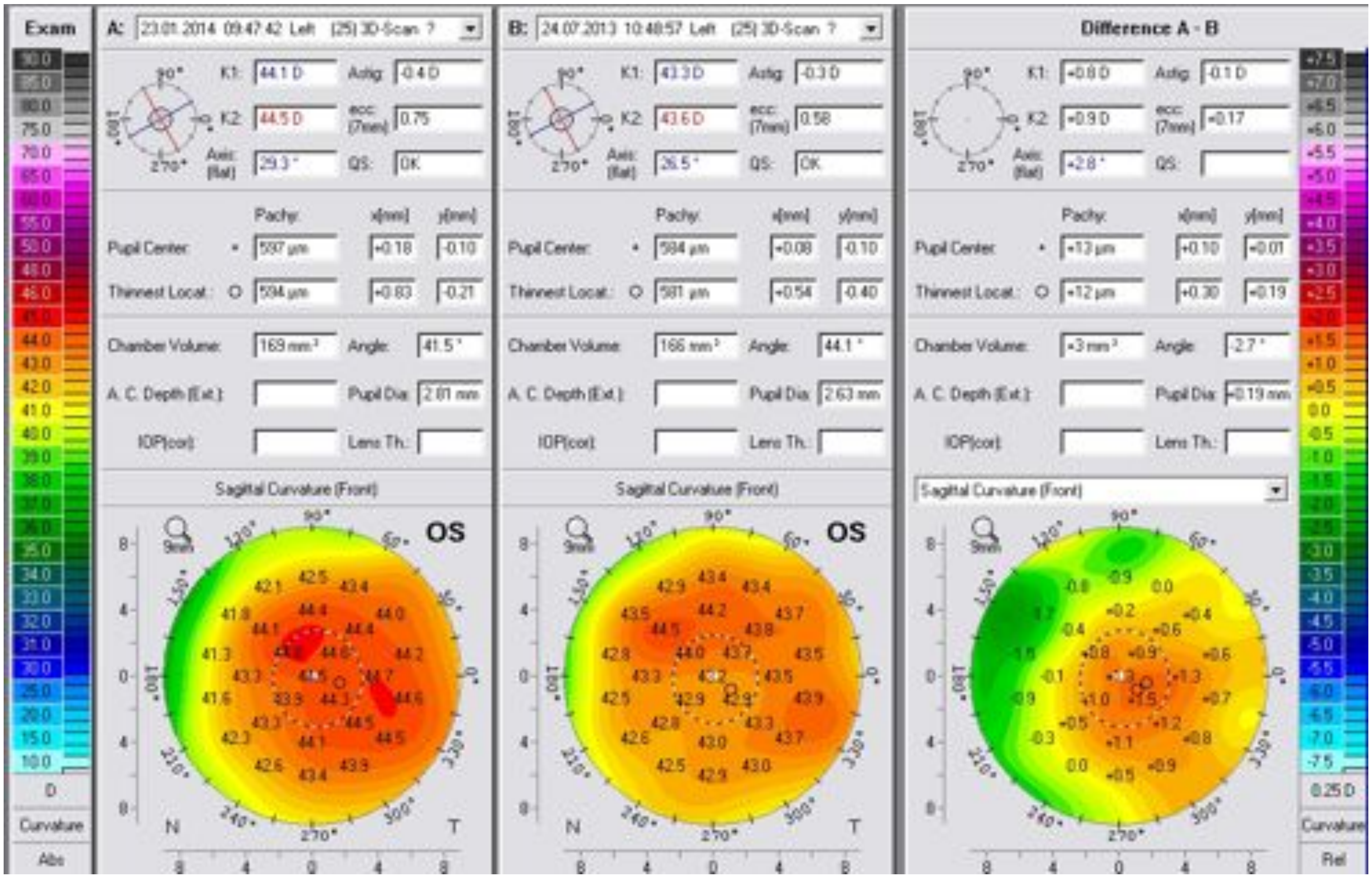
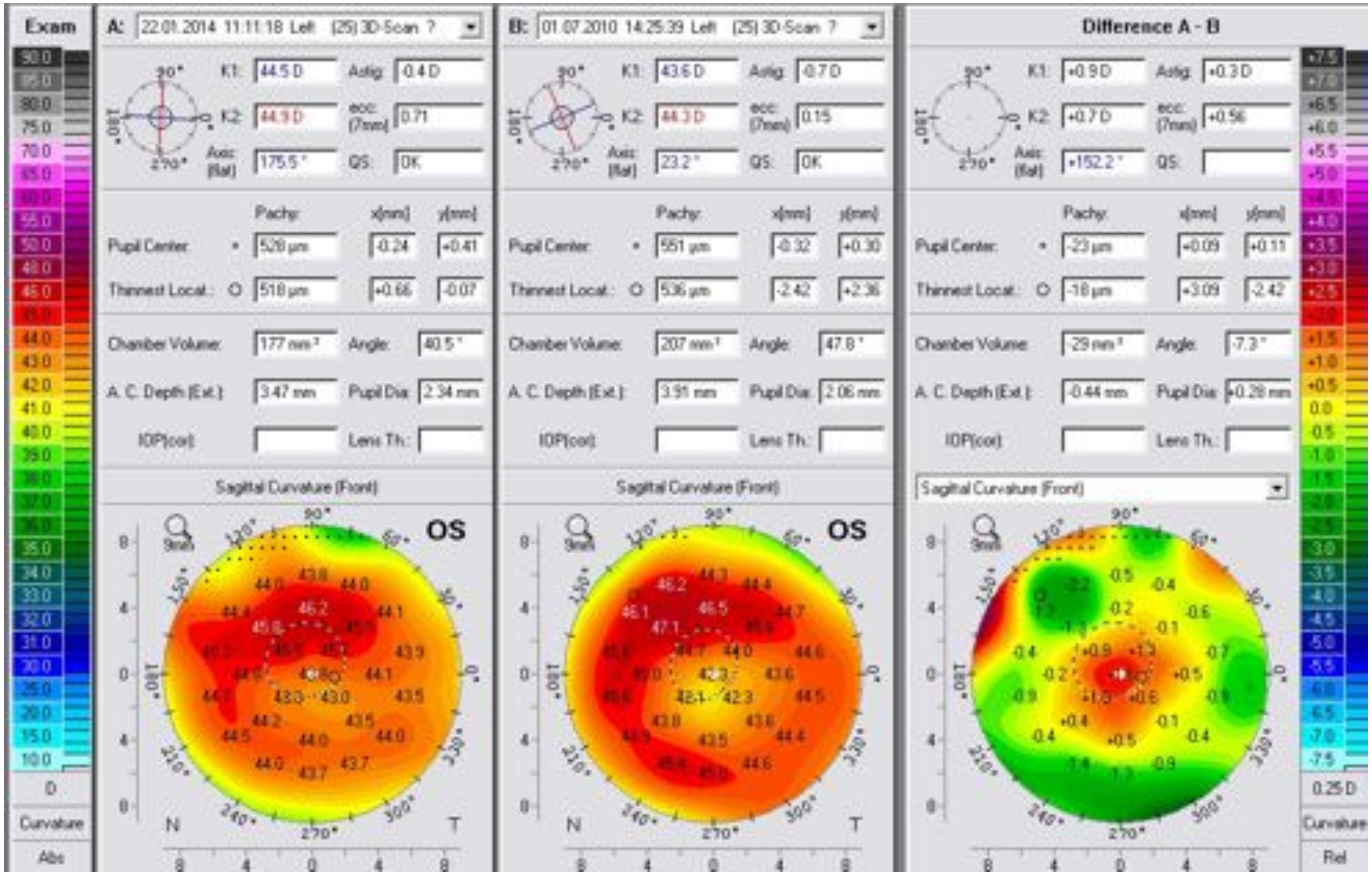
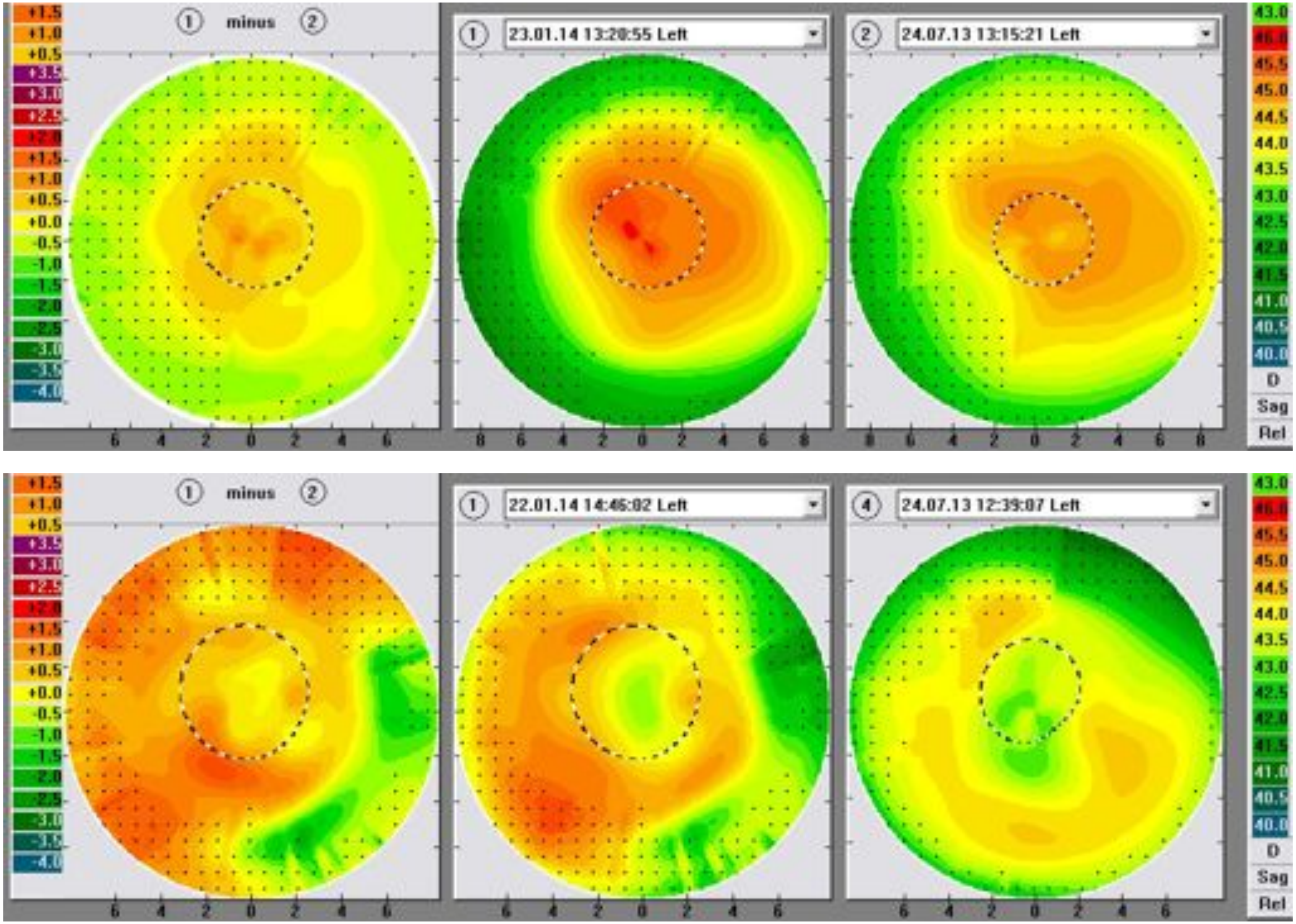
Presby treatment 180 days



Another similar case 180 days



Placido topo data compelling cornea multifocality



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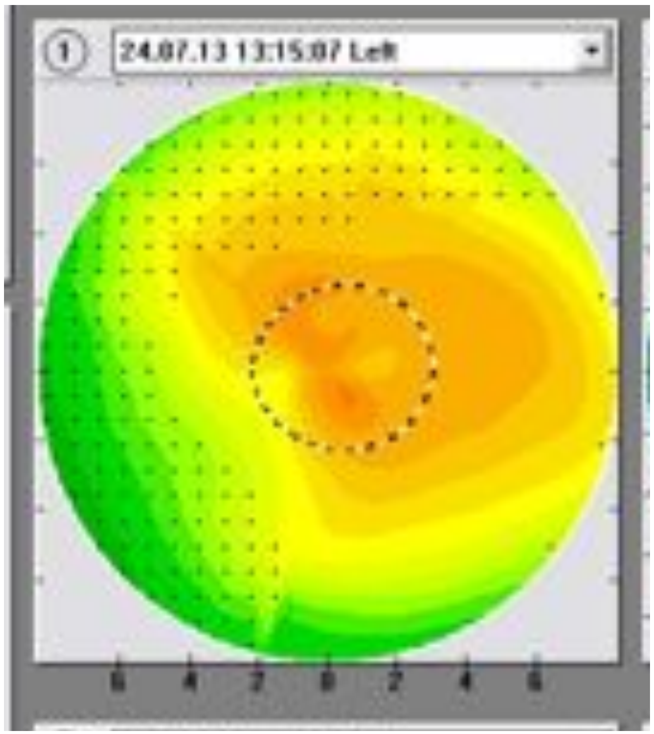
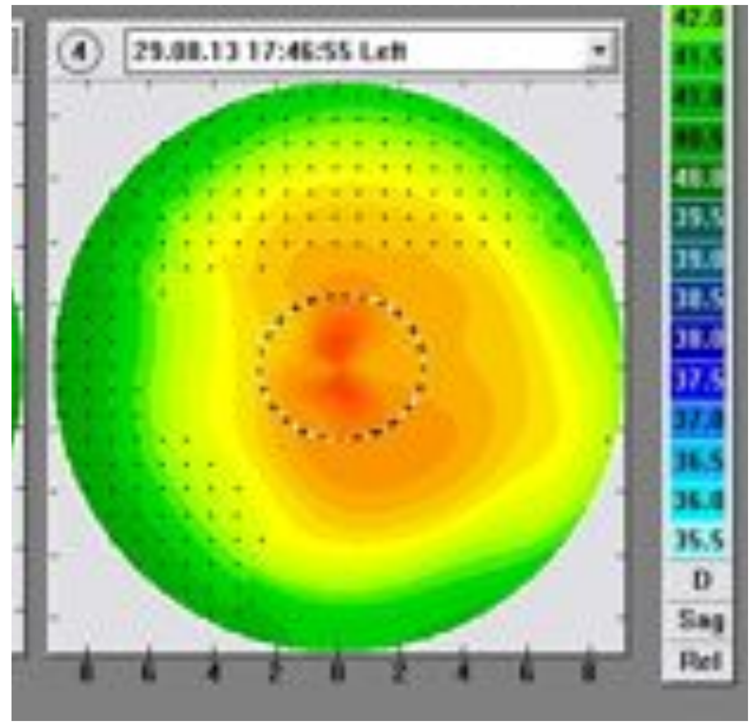
8 weeks hyperopic (presby)!
No epithelial changes



PiXL

→



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Conclusions

- CXL differentials can provide corneal refractive changes (as they always had with classic CXL in a “crude” way!)
- **Photorefractive** intrastromal CXL treatments with the **KXL II** have proven safe and effective
- The clinical experience of 12 months now proved effective and safe! (no scarring, haze)

Conclusions

- **PiXL can offer significant presbyopic treatments by dramatically increasing Q value and slight myopic shift**
- **Changes in reading ability from J7 to J1!**
- **Long term data are monitored for stability**
- **1 year data very stable afetr 1 month 30% regression**