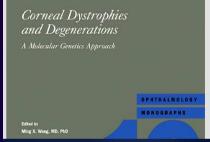
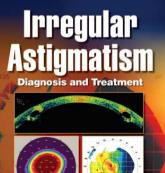
Patient Management with Customized Ablation of Irregular Astigmatism due to decentered LASIK treatment





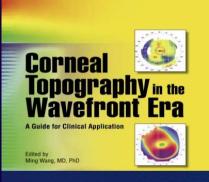
Edited by Ming Wang, MD, P

SLACK Incorporated

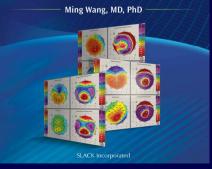
Ming Wang, MD, PhD

Clinical Associate Professor of Ophthalmology of University of Tennessee Director, Wang Vision Institute Nashville, TN, USA

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Collaborators

- Helen Boerman, O.D., FAAO
- Shawna Hill, O.D., FAAO
- Dora Sztipanovits, OD., MS
- Financial interest: none.

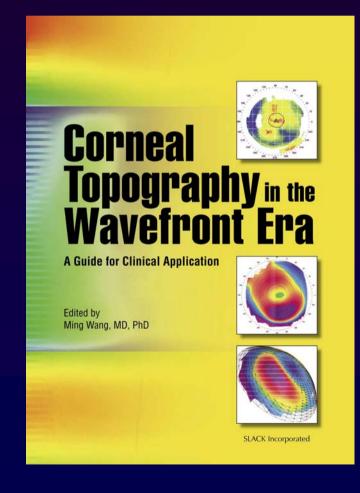
The importance of developing better technologies to treat irregular astigmatism due to LASIK complications

"Do no harm"

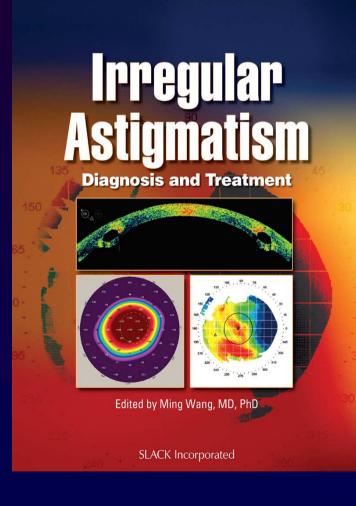
The two parts involved in treating corneas with irregular astigmatism

Imaging (corneal topography)Treatment (customized)

Imaging of the cornea with irregular astigmatism

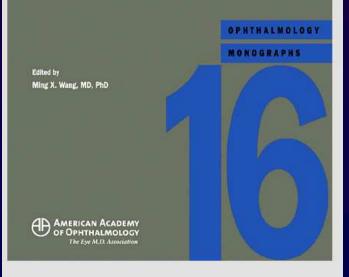


Treating irregular astigmatism in the cornea



Understanding keratoconus

Corneal Dystrophies and Degenerations A Molecular Genetics Approach

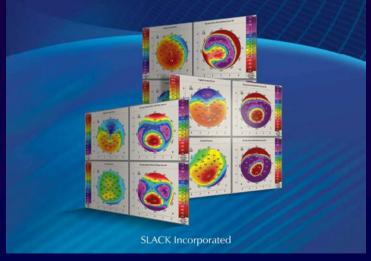


Keratoconus and keratoectasia



Prevention, Diagnosis, and Treatment

Ming Wang, MD, PhD



Decreased BSCVA

>50% reduction of symptoms with manifest refraction= REGULAR ASTIGMATISM <50% reduction of symptoms with manifest refraction= IRREGULAR ASTIGMATISM

RGP TESTING

Conventional treatment (PRK/LASIK) lf no improvement in BVA: problem is not at cornea: NO CORNEAL SURGERY Improvement in BVA: problem is at Cornea (IA)

If WP=MR, proceed with wavefront enh (LASIK/PRK) If WP≠MR, Hold off wavefront tx If decentered, consider C-CAP

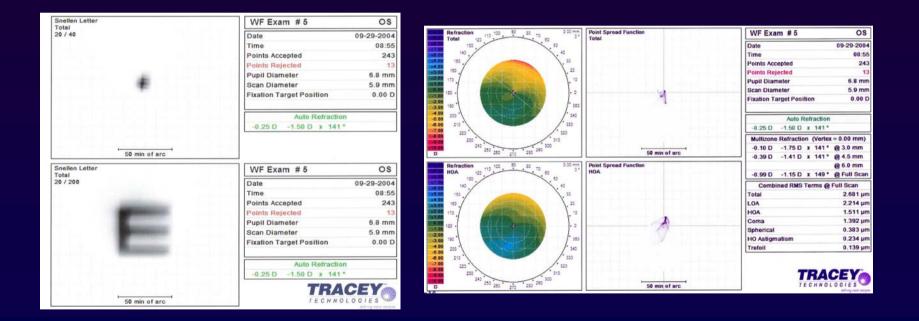
Irregular astigmatism caused by decentered ablation

- A decentered ablation on corneal topography;
- Increased higher order aberrations as measured using wavefront aberrometry, predominantly coma;
- The appearance of a tail on point spread functions;
- Manifest refraction with <u>reduced best-corrected visual</u> acuity that <u>improves</u> only with gas permeable lenses;
- A cylinder measurement on autorefraction and wavefront that differs from manifest refraction;
- A history of reduced vision <u>immediately</u> following surgery that fails to improve with time.

Topo criteria for decentered ablation (height difference in elevation map)

 At least 6 microns difference on the elevation topography, from the lowest point to the highest point, over a 6.5 mm diameter or over the patient's pupil diameter as measured by the Zeiss Humphrey topographer, which ever is larger.

Aberrometry of decentered ablation (coma)



A sequential and logical approach to treating irregular astigmatism (caused by decentered ablation) – VISX system

Contour Cornea Ablation Pattern (C-CAP)
CustomVue

A step-wise general strategy for treating decentered ablation

- If cornea is mild to moderately irregular and decentration is not too severe, WaveScan can map it, shows coma, AND WS refraction is consistent with MR, do CustomVue custom ablation;
- If the cornea is too irregular due to large decentration and WaveScan can not obtain any data, do C-CAP first to <u>"pull the center of ablation back</u> <u>to the center first</u>", then, do CustomVue ablation.

C-CAP

- Custom contoured ablation pattern
- The only FDA-approved (HDE) treatment for post-LASIK irregular astigmatism (decentration)

FDA C-CAP indications

Symptoms:

- Reduced BSCVA
- Debilitating glare
- Monocular diplopia
- Debilitating halos

Clinical evaluation for C-CAP

- Required Information from primary Treatment and all enhancements:
 - BCSVA pre treatment
 - Pachymetry
 - Ablation depth
 - Flap thickness

Clinical evaluation for C-CAP con't

- VA: UCVA, BCSVA
- Refraction
 - Manifest
 - Cycloplegic
 - Stability
- Keratometry
- Pupillary Exam

Clinical evaluation for C-CAP con't

- Evaluation of BSCVA loss
 - The etiology of the BSCVA loss or symptoms must be the result of decentered ablation
 - HCLVA: allows one to differentiate between reduced VA from irregular astimgatism vs. corneal opacification or lenticular changes

Clinical evaluation for C-CAP con't

- Slit lamp
- Tonometry
- Dilated Fundus examination
- Pachymetry by ultrasound
- Humphrey topography

The first step: accurate mapping, using devices with the highest sensitivity for elevation

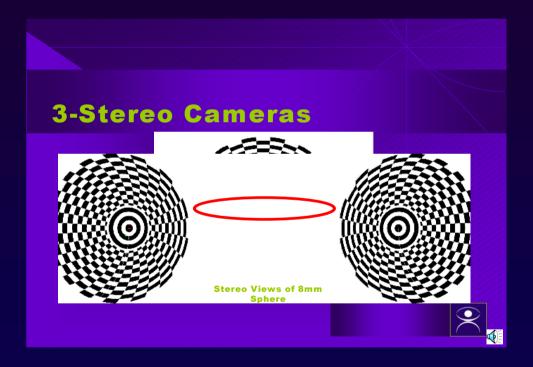
3-D stereo corneal topographer



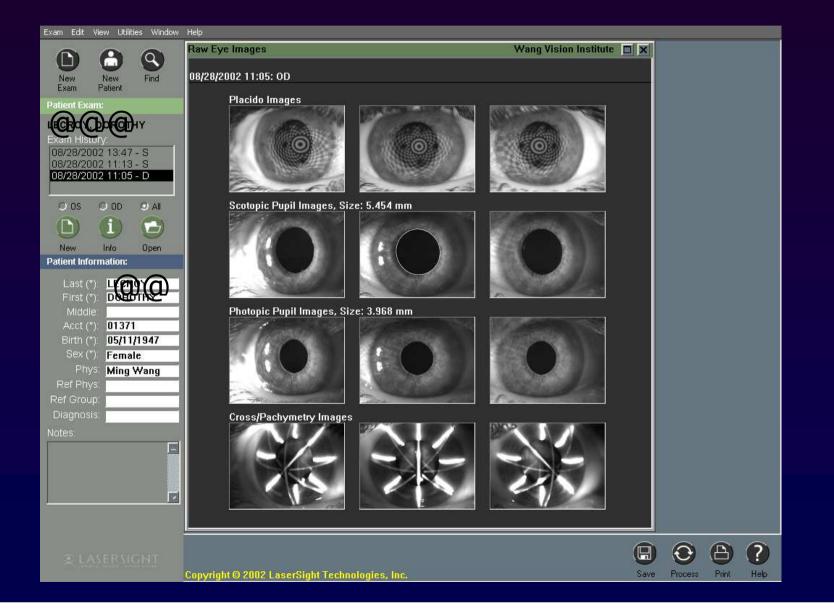
astramax

3-D STEREO TOPOGRAPHER

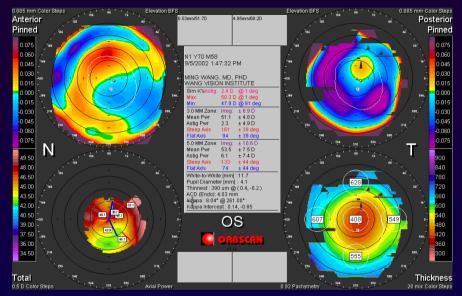
3-D stereo corneal topography:



Images (3-AstraMax camera, checker board)

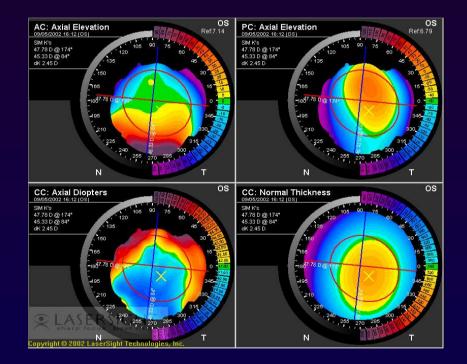


<u>Case 1:</u> Improved sensitivity using 3-D topo: Diplopia after LASIK, causes unclear, but topo measurement inconsisent and variable due to dry eyes.



Repeated scans were highly variable and showed artifactual "steepening", due to dry eyes. Topographic systems that require long eye exposure time are more prone to aberrant optical artifact arising from dry corneal surface.

<u>Case 1 con't:</u> AstraMax's 3-D successfully showed positive finding (of decentered treatment).

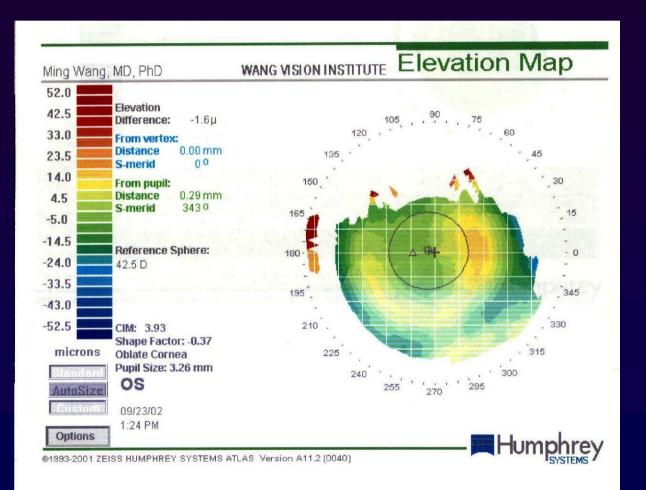


AstraMax, with its short eye exposure time (0.2 sec), and multi-camera incoming shots, is less likely to be affected by optical artifact due to dry corneal surface.

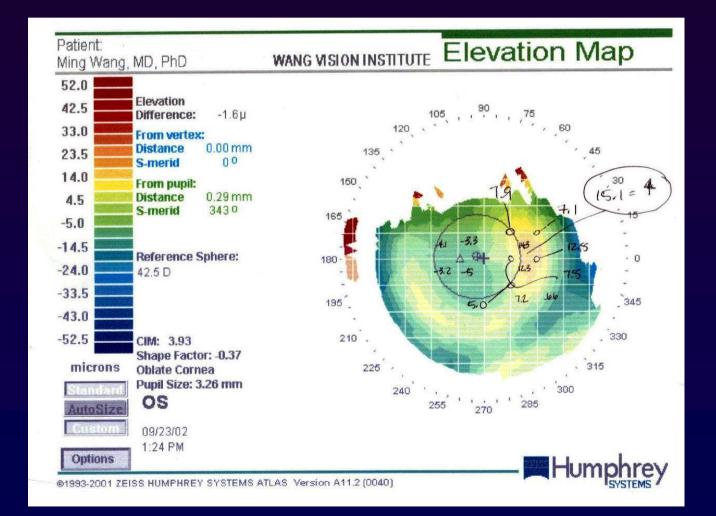
Step-wise approach to C-CAP to treat decentered treatment

- Humphrey Altas topographerVision Pro software
 - Customized ablation program
 - Demonstrate the ablations effect on topography

Step 1: Elevation Map



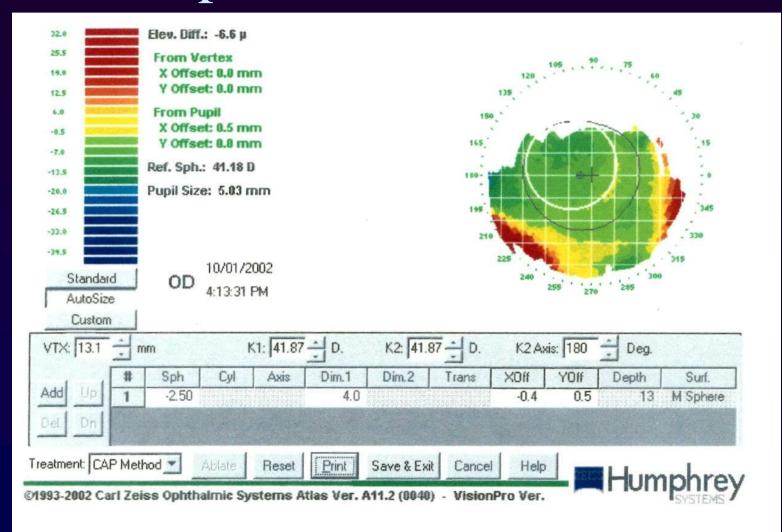
Step 2: Locate highest point



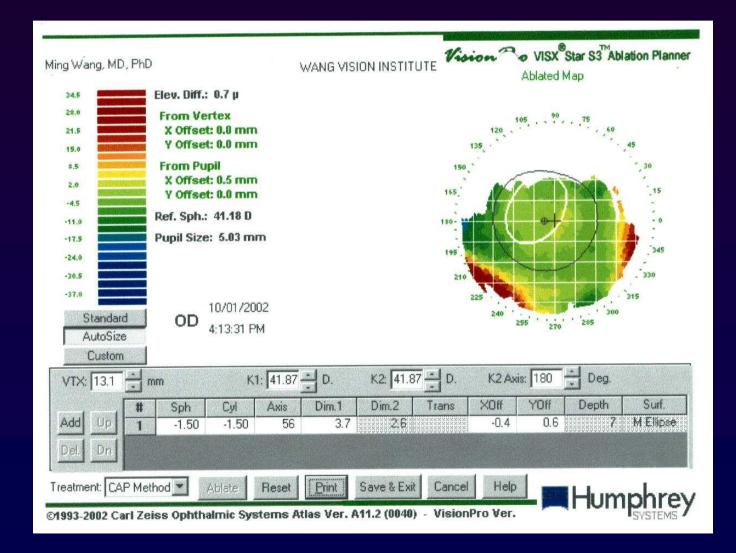
Step 3: C-CAP ablation patterns

- Myopic Sphere
- Myopic Astigmatism
- Myopic Ellipse

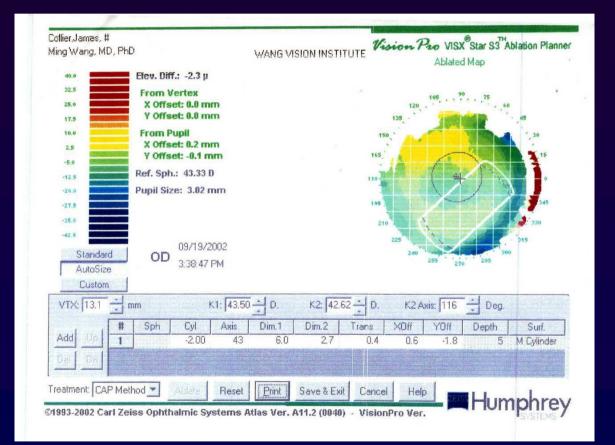
Spherical Treatment



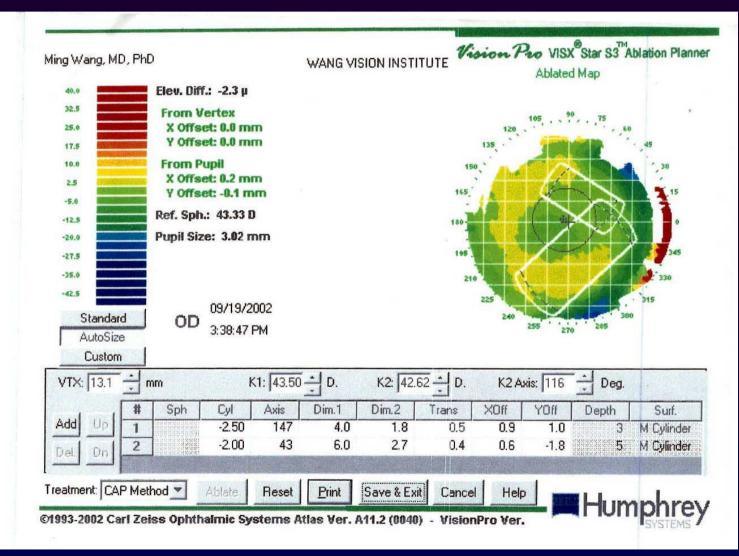
Myopic Elipse Treatment



Myopic Astigmatism Treatment



Combination Treatments



Step 4: Print final pattern

- Documentation for Chart:
 - Includes all parameters necessary to complete treatment
 - Use this data to program the laser

Step 5: Input patterns into laser

CAP card required

Software update is required

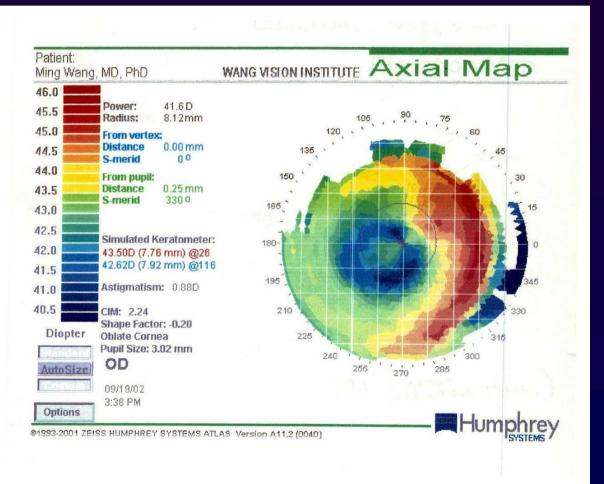
Step 6: Perform treatment

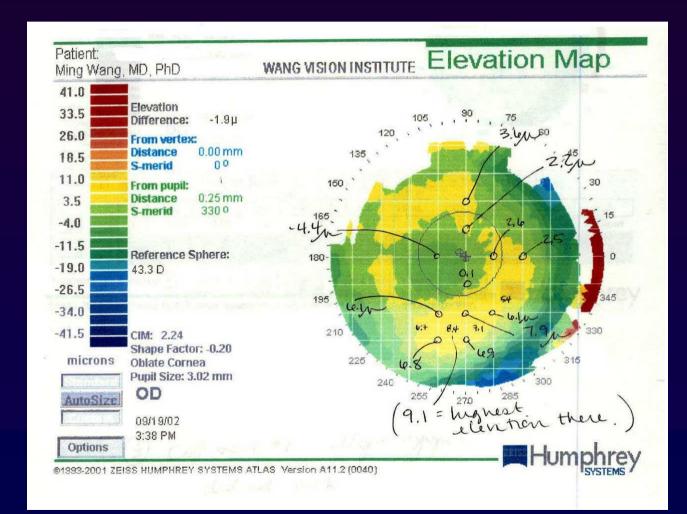
- Technique identical to performing typical enhancement
- Short treatment times

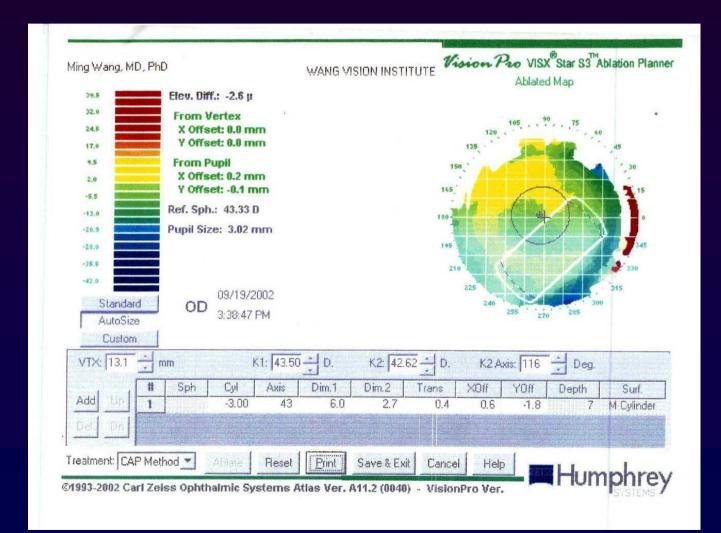
- 47 yo Male
- S/P LASIK OU January 2001 by area surgeon with grade 4 DLK requiring flap lift OU at one week
- CC: "Visual distortion with glasses. RGP's required for comfortable vision, but CL's are making my eyes dry"

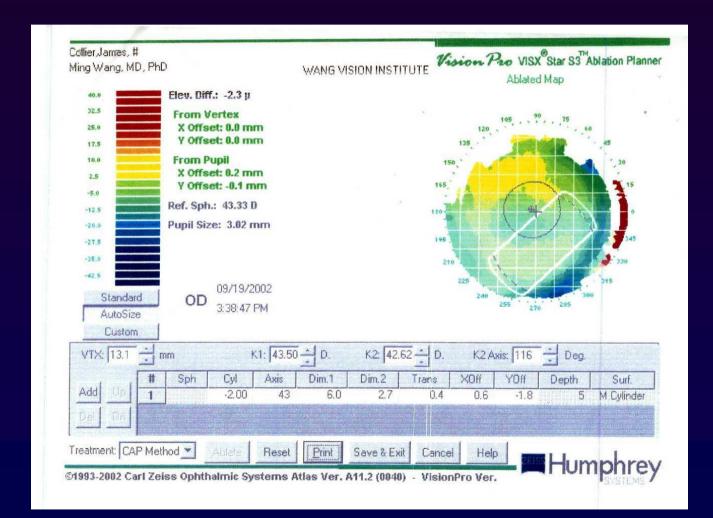
- Unaided VA: 20/80
- MR -1.25+1.75 x 45, 20/30
- Cyclo -1.00+1.75 x 45
- RGP VA 20/20
- Ultrasound Pach 578/588/574 microns
- IOP, anterior and posterior segment healthy

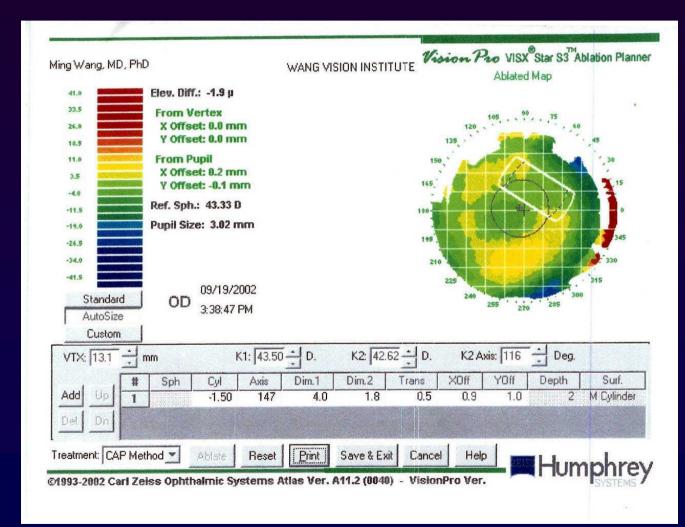
Case JC "Decentration not due to primary laser treatment, but due to secondary tissue digestion (DLK)"

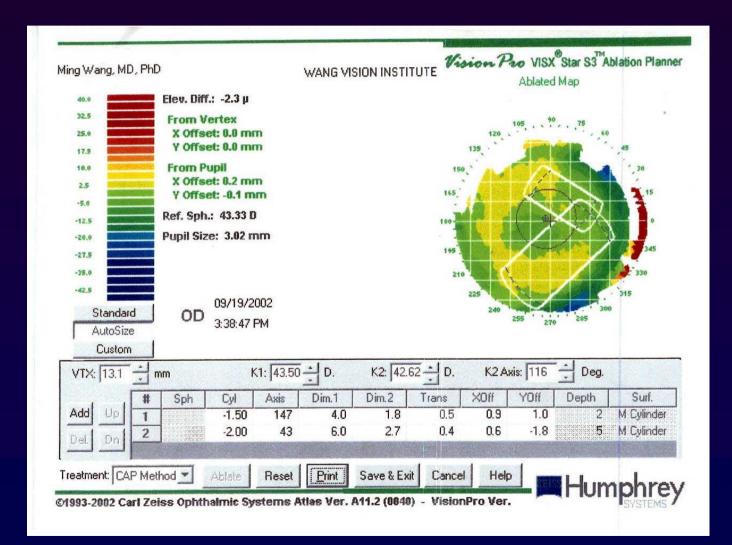


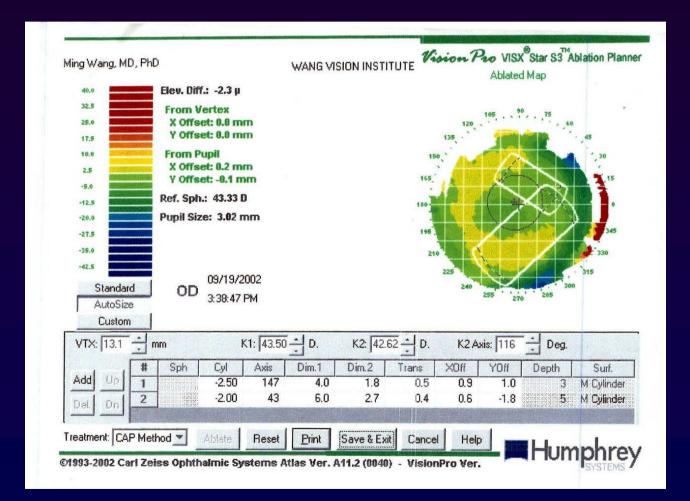




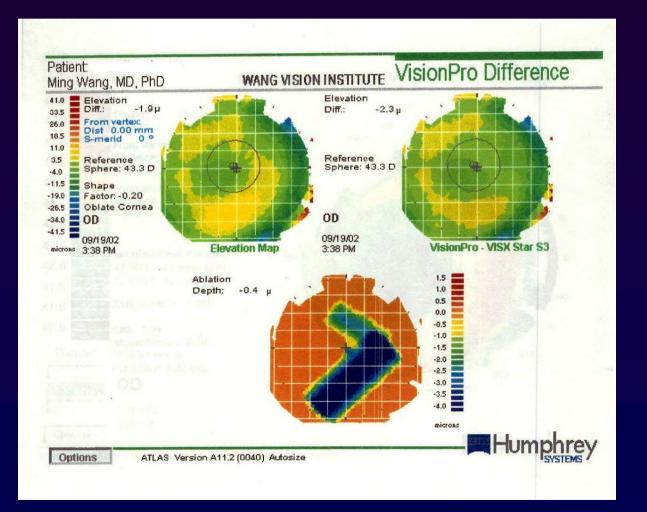








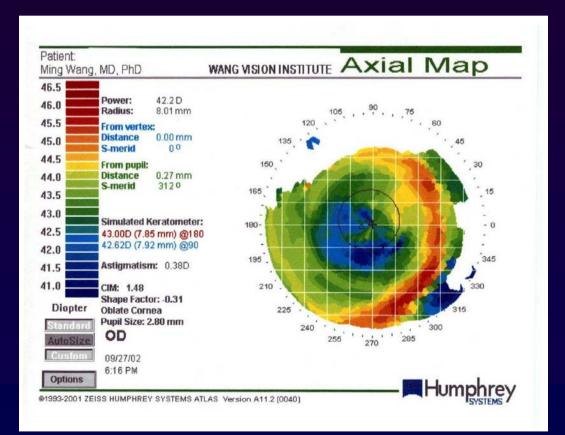
C-CAP pre, post and difference elevation map (Case JC)



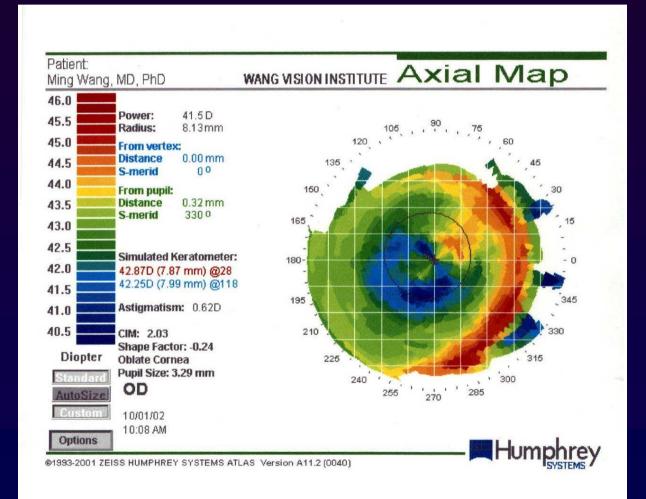
- Final treatment plan:
 - M Cylinder I: 3 microns x 147 (4.0x1.8 mm);
 Offsets: X +0.9 mm, Y +1.00
 - M Cylinder II: 5 microns x 043 (6.0x2.7 mm); Offsets: X +0.6 mm, Y -1.8mm

Case JC: 1 day s/p C-CAP

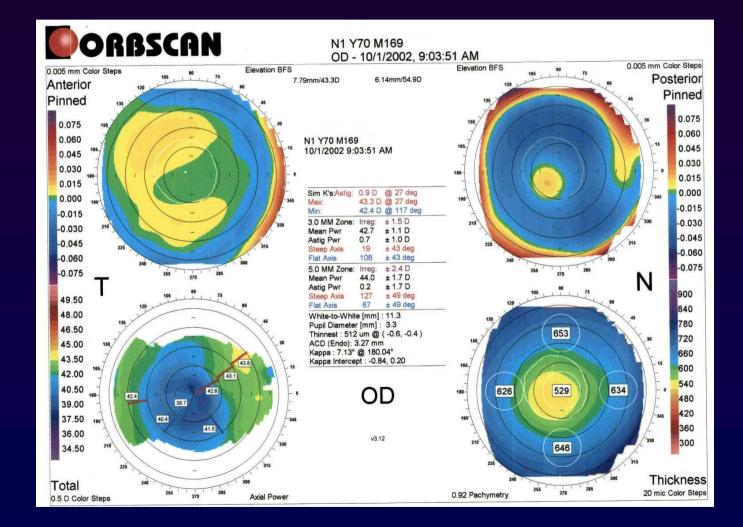
- POD #1 CC: smear is much better, equal to the other eye
- VA sc 20/60



Case JC: 1 week s/p C-CAP

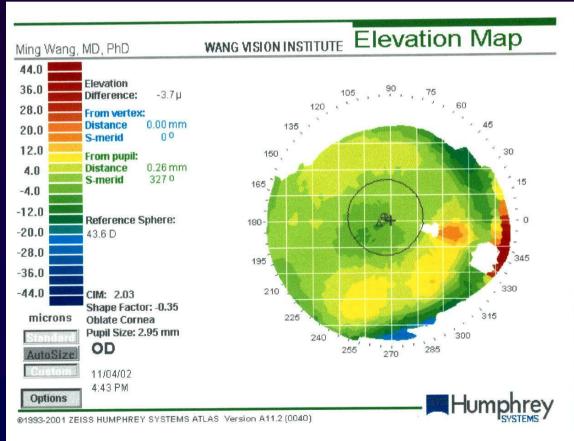


Case JC: 1 week s/p C-CAP



Case JC: 1 month s/p C-CAP

Pre-Op: Unaided VA: 20/80 MR -1.25+1.75 x 45 20/301 Mo PO: Unaided VA: 20/70 MR -0.75+1.00 x 31 20/20



Case JC: 3 months s/p C-CAP

- JC returned wearing soft toric Cl for refractive correction, reporting nearly 100% resolution of the visual distortion
- VA sc 20/30, with BCVA of 20/20
- Requested refractive enhancement, which was successfully performed at 4 months

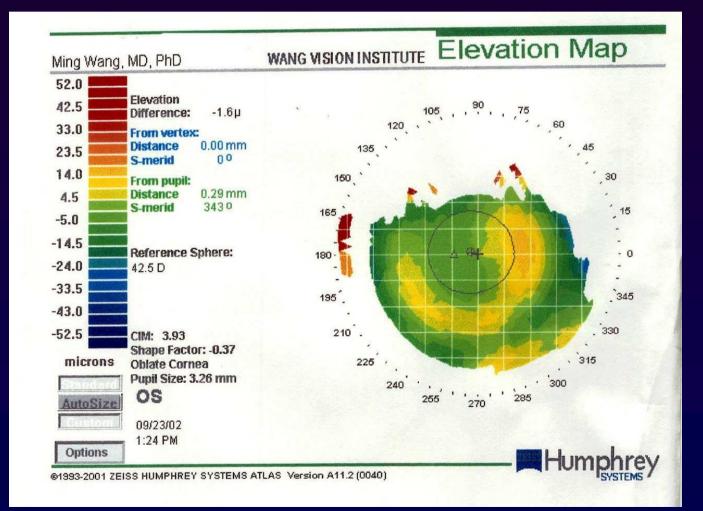
Second C-CAP Case: PG

49 yo Male
S/P LASIK OU 1997 with enhancements OU 1998 by area surgeon
CC: "Double Vision"

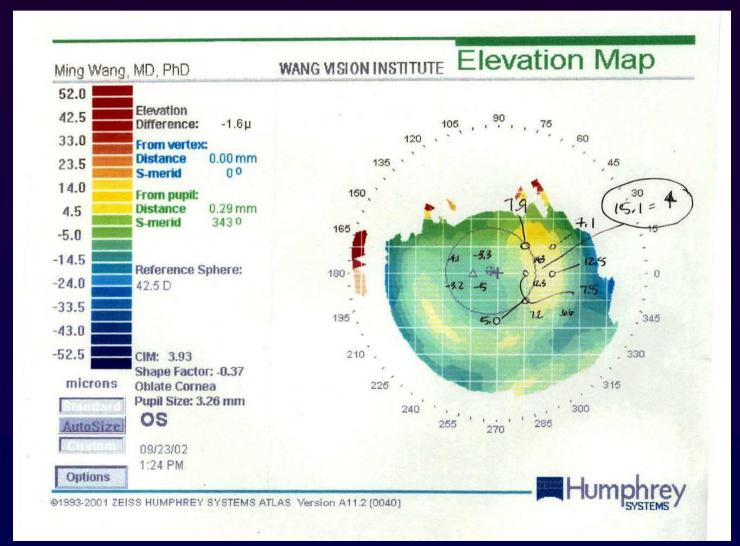
C-CAP Case PG

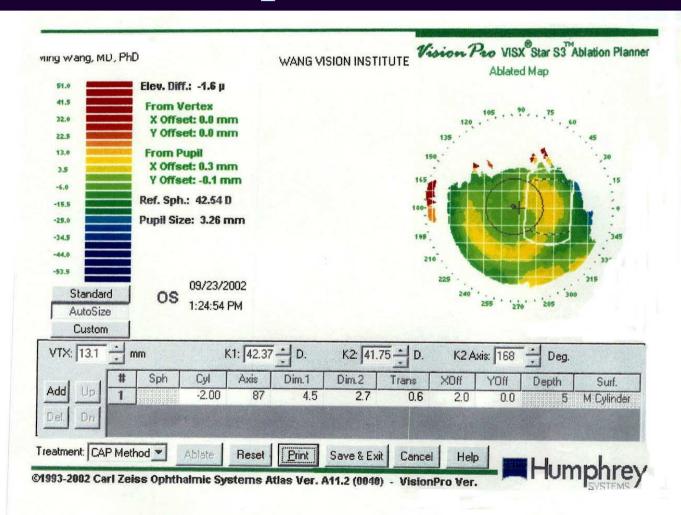
- Unaided VA: 20/60
- MR -2.75+1.75 x 135, 20/30
- Cyclo -2.75+1.00 x 135
- RGP VA 20/40 (poor fit) but subjective improvement in VA with CL noted
- Ultrasound Pach 475/480/477 microns
- IOP, anterior and posterior segment healthy

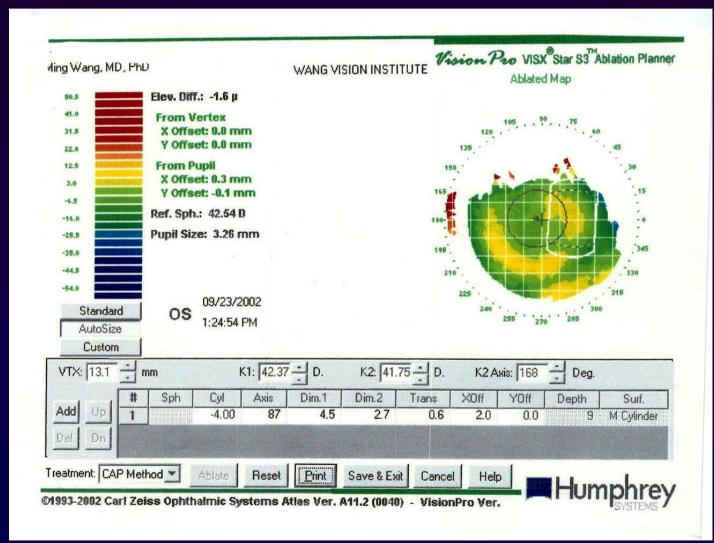
Elevation map (C-CAP Case PG)

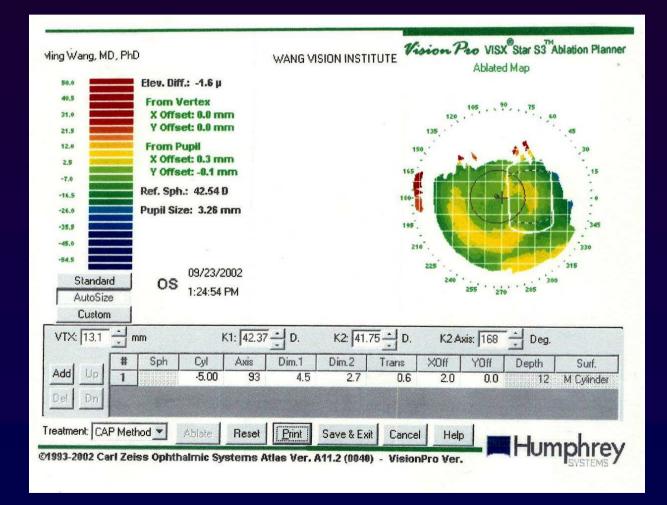


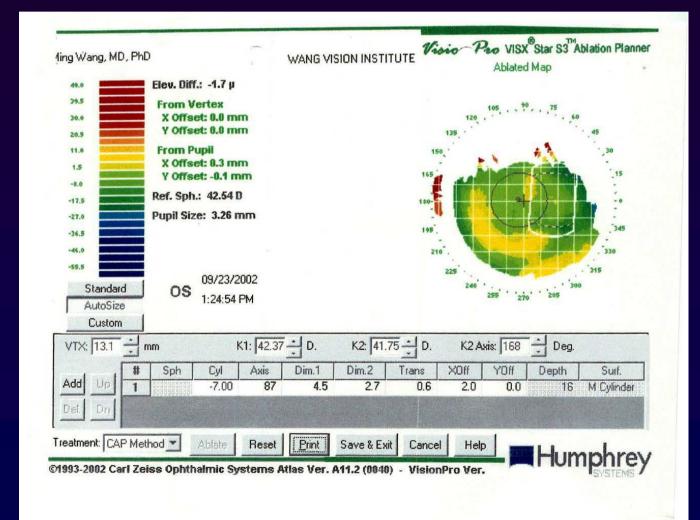
Elevation map with height values (PG)

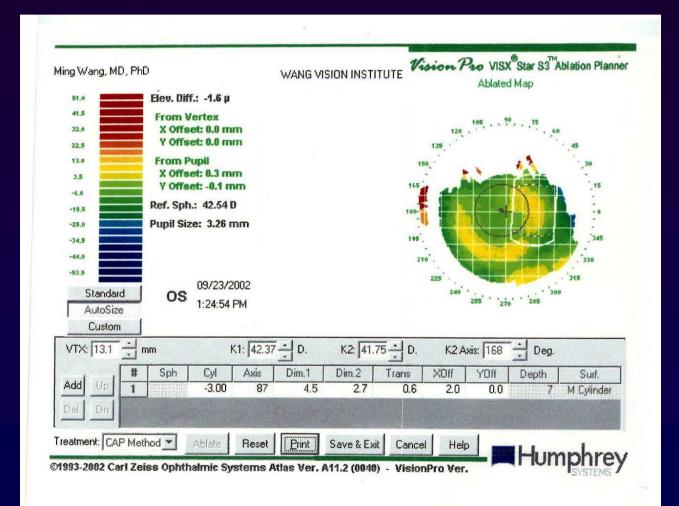


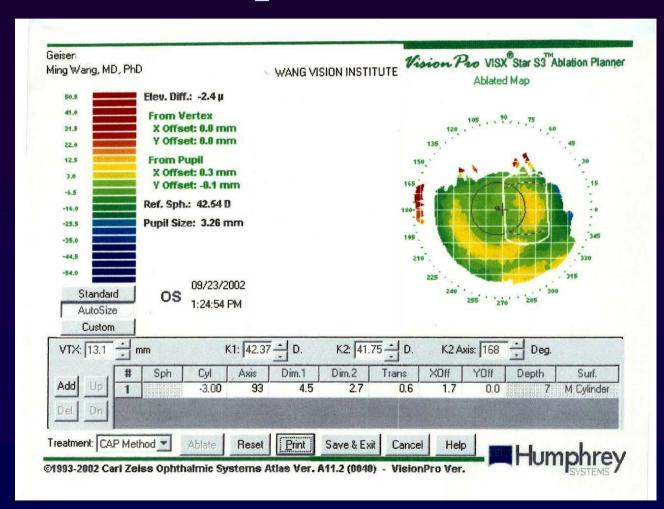




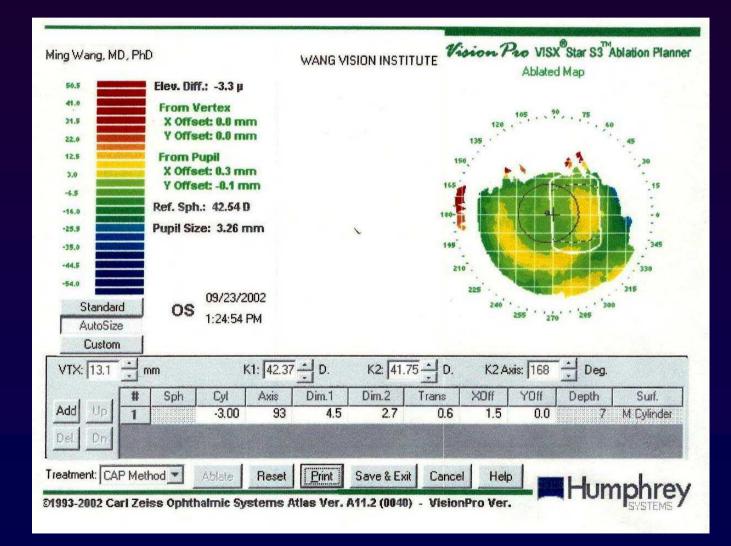








Final treatment plan (C-CAP PG)



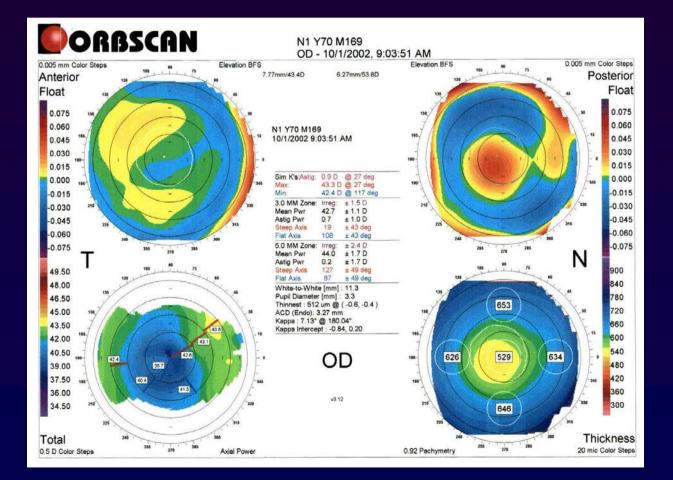
C-CAP Case PG

Final treatment plan:
M Cylinder I: 7 microns x 93 (4.5 x 2.7mm); Offsets: X +1.5 mm, Y +0.00

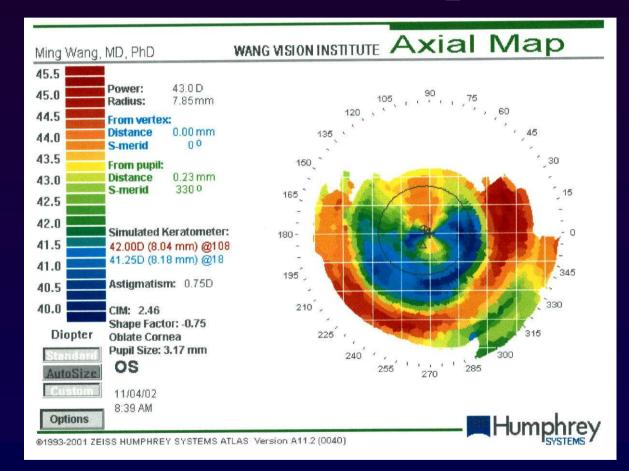
C-CAP Case PG

POD #1 s/p
 C-CAP: Felt
 less double
 vision

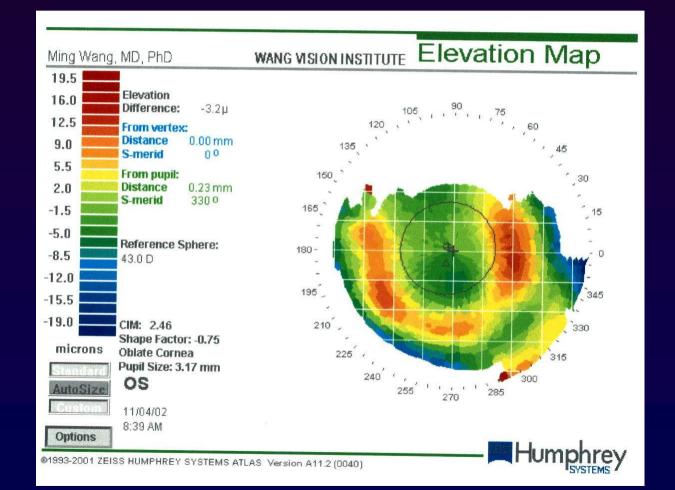
■ VA sc 20/200



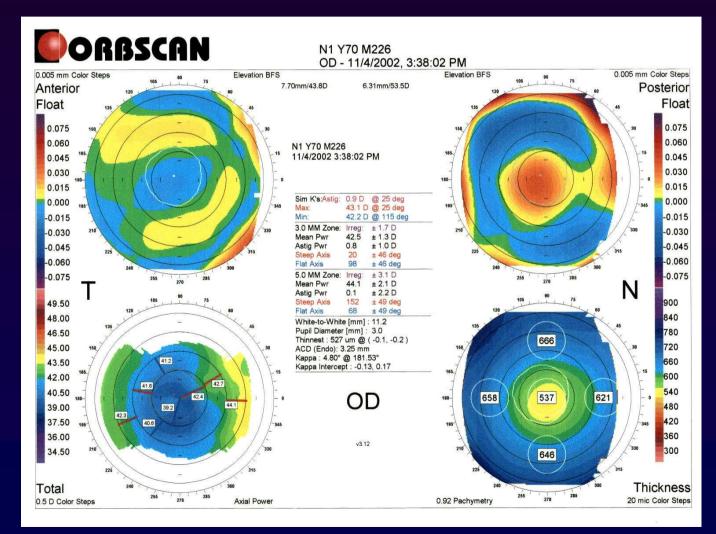
Case PG: 1 month s/p C-CAP



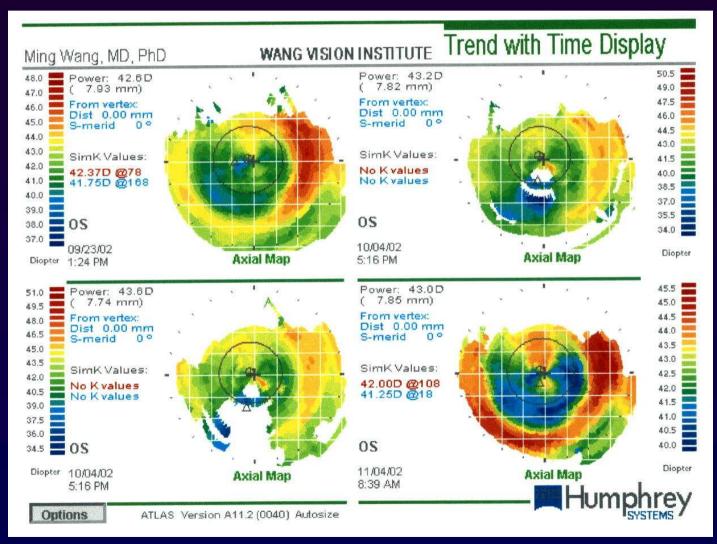
Case PG: 1 month s/p CAP



Case PG: 1 month s/p CAP



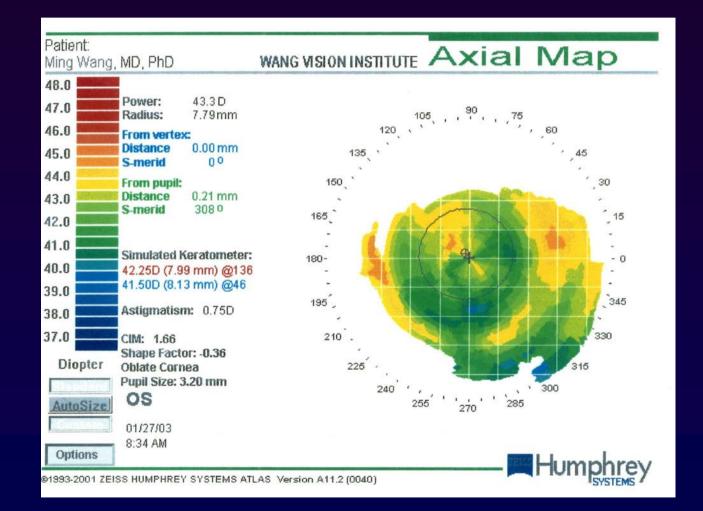
Case PG: 2 mo Time Trend



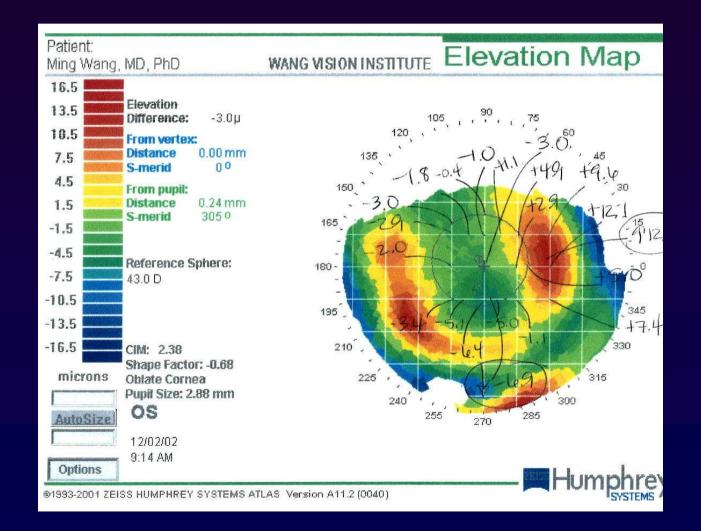
Case PG

Decentration regressed;
More aggressive C-CAP enhancement

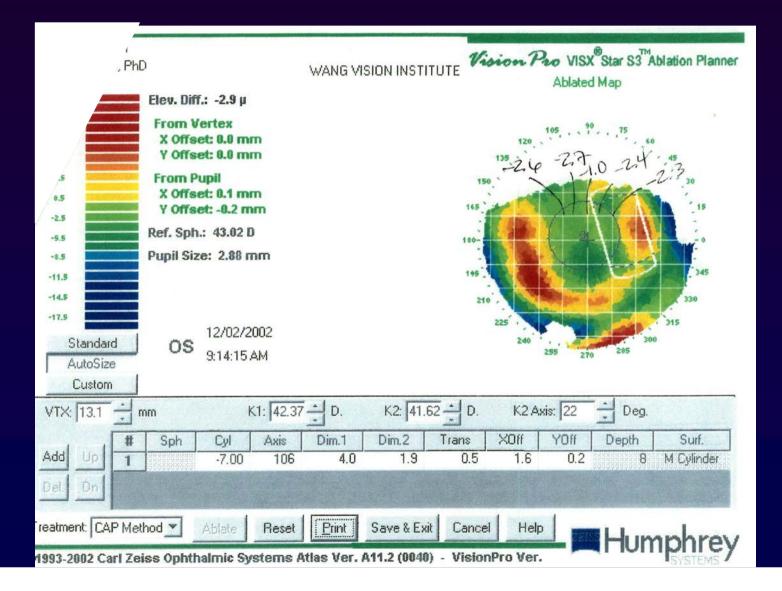
Case PG (C-CAP enh)



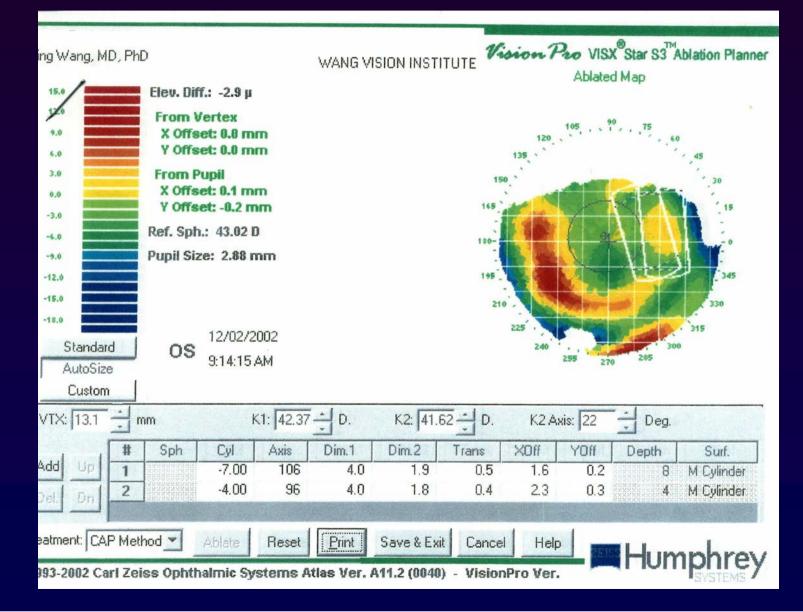
Case PG (C-CAP enh)



Case PG (C-CAP enh)



Case PG (C-CAP enh)



Case PG (1st and 2nd C-CAP)

- First Treatment:
 - M Cylinder I: 7 microns x 93 (4.5 x 2.7mm);
 Offsets: X +1.5 mm, Y +0.00
- Second Treatment:
 - M Cylinder I: 8 microns x 106 (4.0 x 1.9mm);
 Offsets: X +1.6 mm, Y +0.2
 - M Cylinder I: 4 microns x 96 (4.0 x 1.8mm);
 Offsets: X +2.3 mm, Y +0.3

Case PG (two C-CAPs)

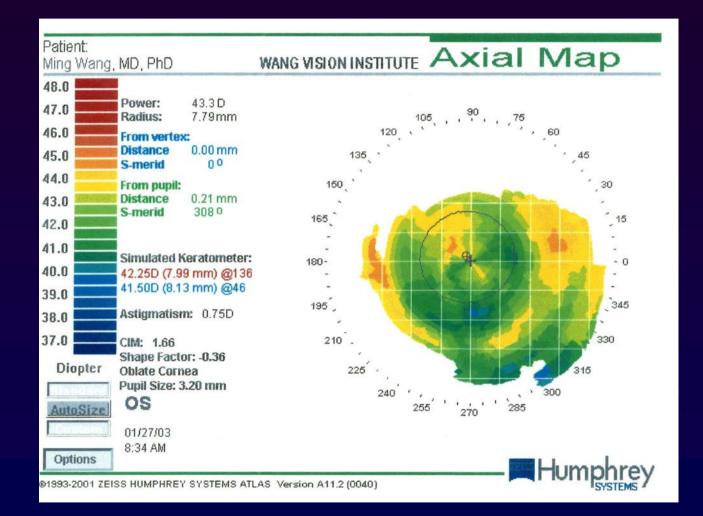
POD #1: "less double vision OS"

Pre-C-CAP: Vsc=20/60, MR –2.75+1.75 x 45, 20/30 (diplopic)

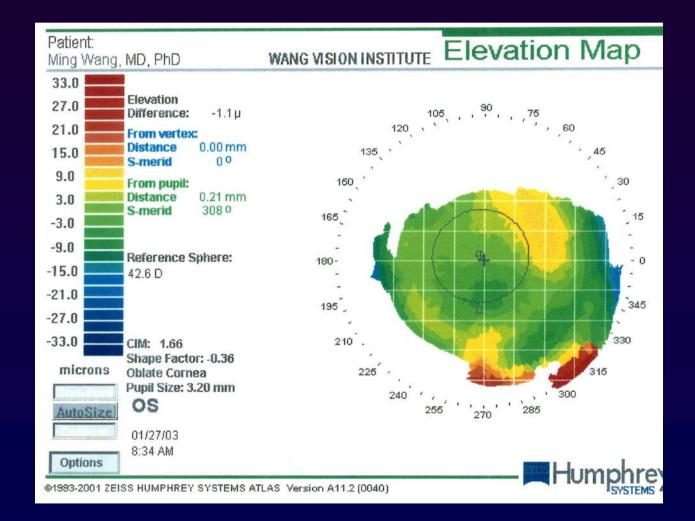
Post-two C-CAPs: Vsc = 20/70, MR= -4.25+0.50 x 110 20/25 ("much less" diplopic)

Refractive treatment

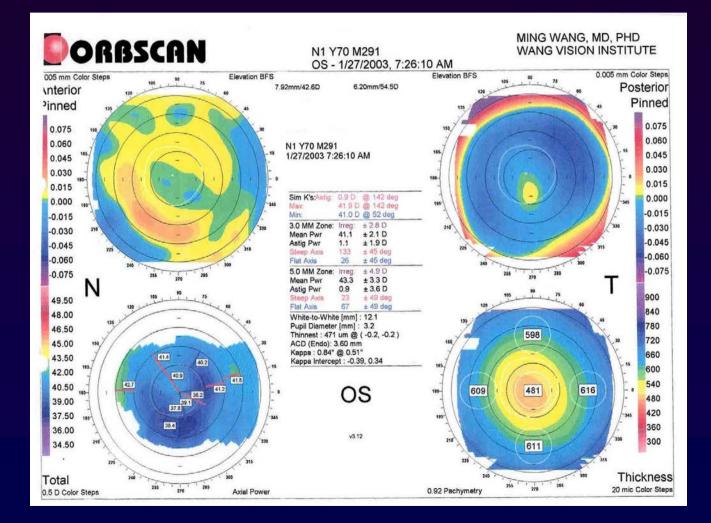
Case PG (after two C-CAP, axial)



Case PG (after two C-CAPs, elevation)



Case PG (after two C-CAPs)



C-CAP Case DC

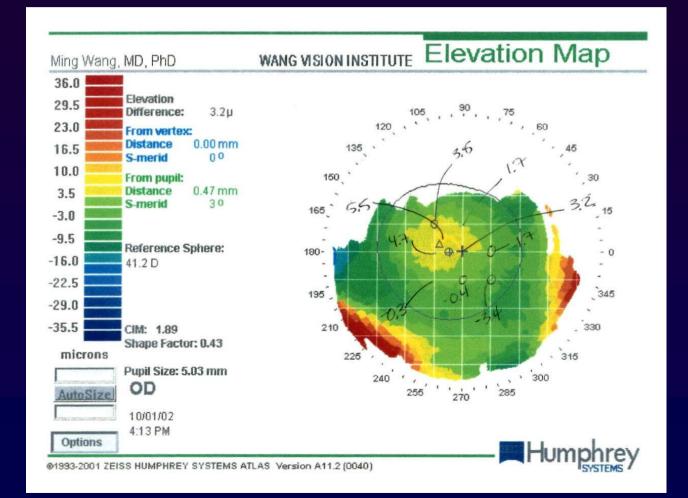
- 48 yo male
- S/P myopic LASIK March 2002 followed by hyperopic LASIK-E OD June 2002 by area surgeon
- Complains of blurred vision even with glasses
 OD ever since the enhancement

C-CAP Case DC

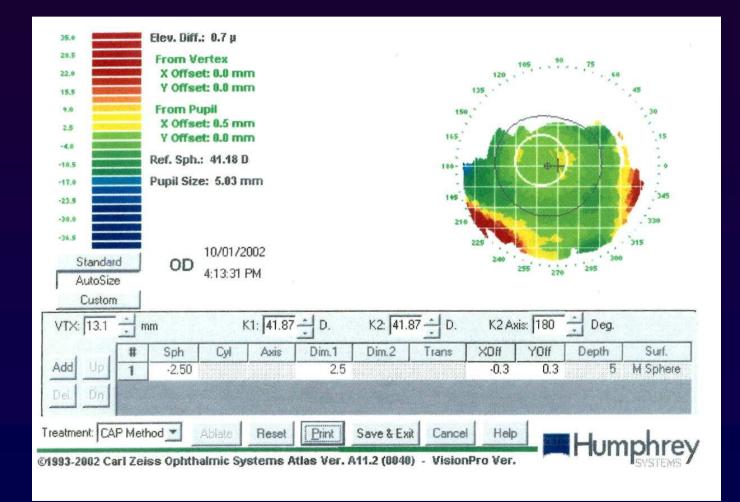
Unaided VA: 20/30-

- MR –0.50+2.00 x 11 (20/25-, blurred)
- Cyclo –0.25+2.00 x 11 (20/25-, blurred)
- RGP VA 20/20 (not blurred)
- Ultrasound Pachy 503 microns

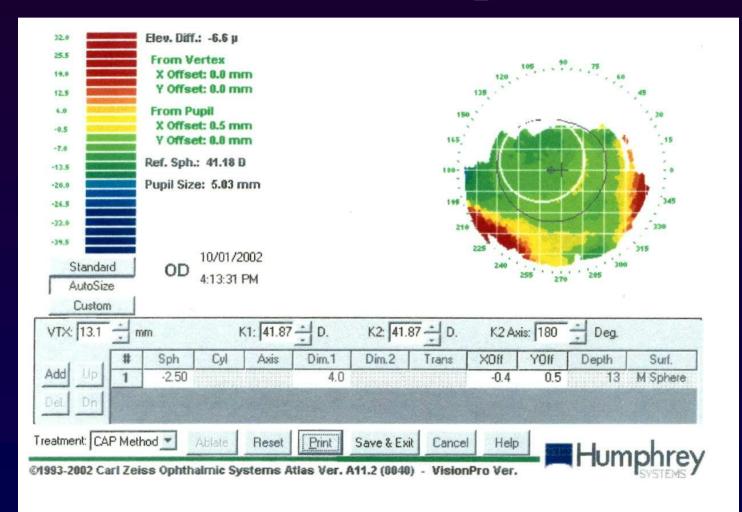
Elevation map with height values C-CAP Case DC (s/p HL)



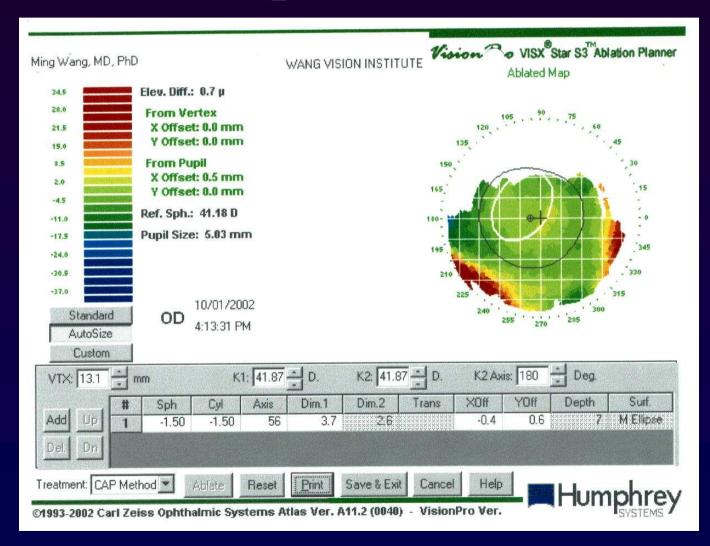
Treatment plan (C-CAP DC)



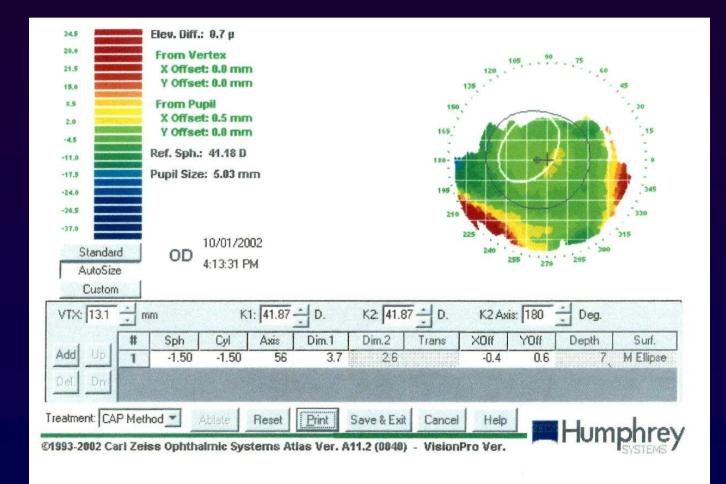
C-CAP Treatment plan (DC)



Treatment plan (C-CAP DC)



Final treatment plan (C-CAP DC)



Final treatment plan

Final C-CAP treatment plan:
M Cylinder I: 7 microns x 56 (3.7 x 3.6mm); Offsets: X -0.4 mm, Y 0.6mm

C-CAP Case DC (s/p HL)

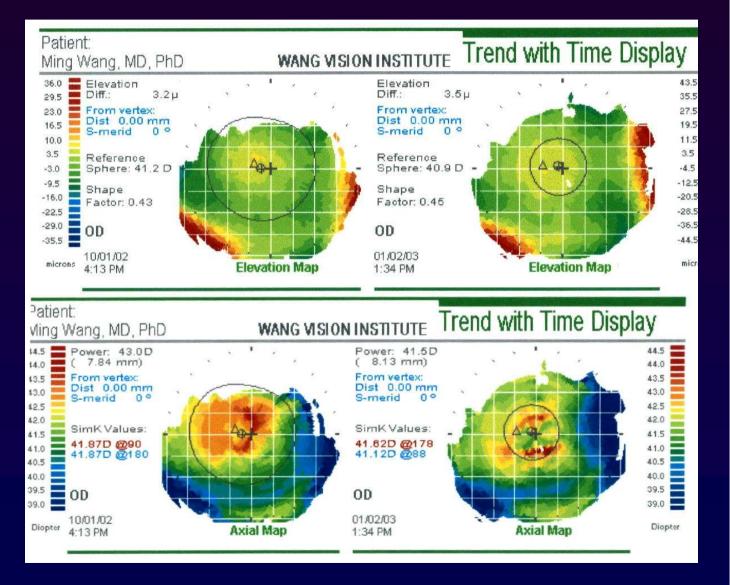
POD #1

- CC: "Doing well"
- VA sc 20/30
- 3 mo PO
 - Unaided VA: 20/70
 - Symptoms of distortion resolved
 - MR −1.00+1.00 x 40, 20/25+ (bluriness 90% gone)
 - Patient requests refractive enhancement

Case DC: 3 mo s/p C-CAP

 Patient requested refractive enhancement at three months after C-CAP

 Vsc = 20/25
 POD #1
 After
 refractive
 treatment



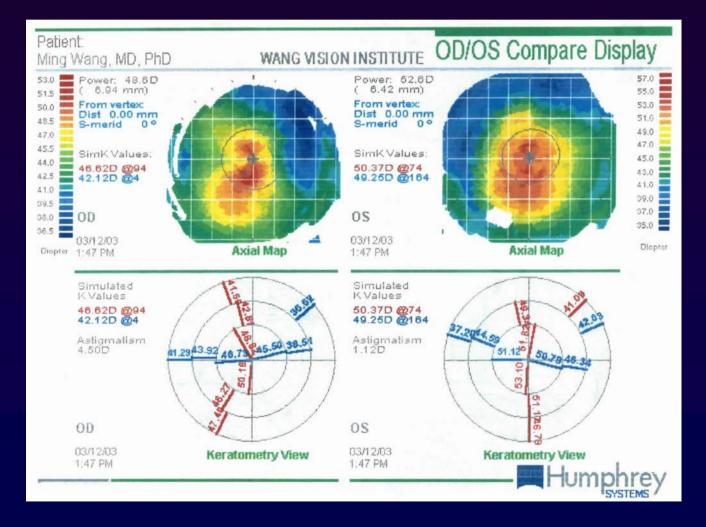
Cautionary note #1 on C-CAP: Always look at the elevation map at the end

- JJ presented with distance vision complaints OS after having LASIK by an area surgeon
- POHx:
 - H-LASIK OS 11/99
 - LASIK enh 4/01
 - CE with IOL 3/02
 - Myopic astigmatism LASIK 7/02

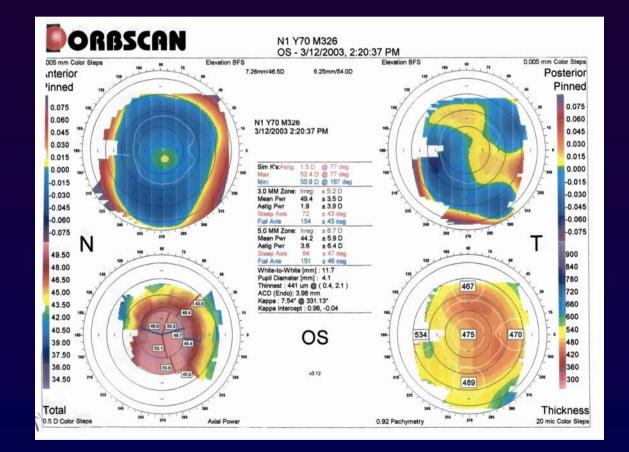
Case JJ: Always look at elevation map

MR OS -4.00+2.25 x 110, 20/100
PH 20/40
RGP OR VA 20/30***

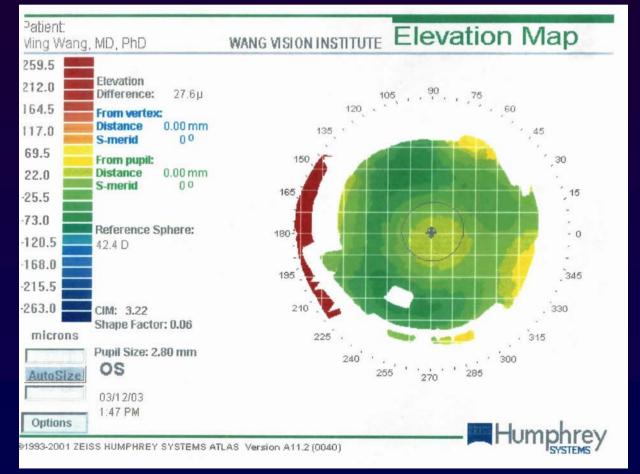
Case JJ: Axial maps (OS, appeared to be inferiorly decentered)



Case JJ: Axial maps (OS, inferior decentration)



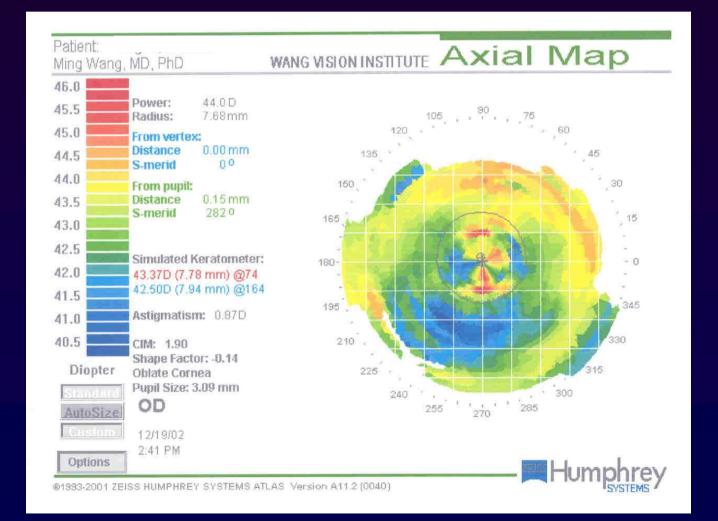
Case JJ: Elevation map (OS no significant decentration, so no C-CAP is needed)



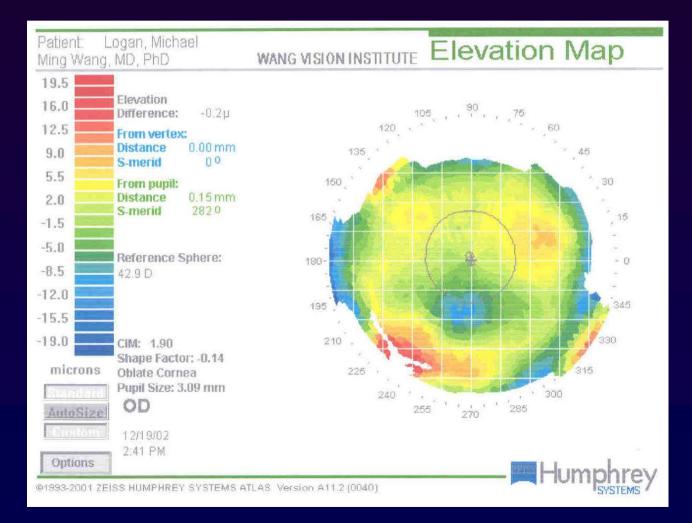
Cautionary note #2 on C-CAP: need to wait for decentration to stablize, with full medical theraphy, before doing any surgery such as C-CAP (ML)

- Patient presented with complaints of visual distortion and poor visual quality OD after LASIK in October 2002
- VA sc 20/60
- MR OD -2.00+1.00x102 20/40 (blurry)
- Cyclo –1.75+0.75 x 105 20/30 (blurry)

Case ML: Decentration

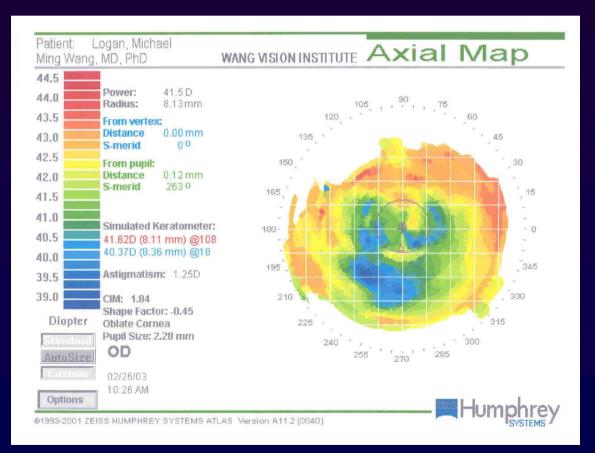


Case ML: Decentered myopic LASIK (elevation map)



Case ML: Self resolution of decentration

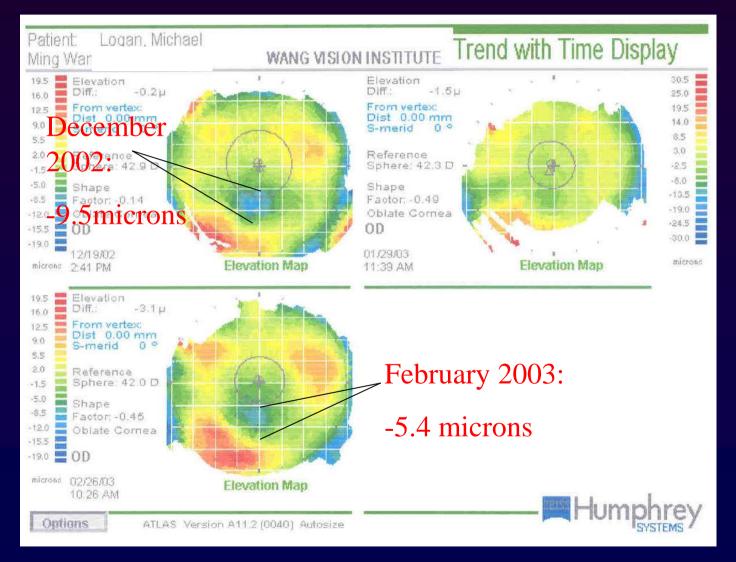
- DES: plugged RLL;
- FU 6 wks later
- MR -1.50 +0.50x125
 20/25+ (improved!)
 - Decentration is improving
 - Dry eye has improved OD;



Case ML: Self resolution of decentration

- 4 months PO
 - CC: "vision is clearing, plug helped"
 - VA sc 20/40+2
 - MR –1.50+0.75 x 100 20/20 No distortion! "Significant improvement in shadows with refraction".

Case ML: Time course of selfresolution of decentration



Case ML: Self resolution of decentration with dry eye treatment

- 20/20 BVA with spectacle correction with full resolution of ghosting by treating the ocular surface disease (dryness)
- No need for Custom-CAP!

CustomVue Ablation: Wavefront-guided

- Using wavefront to correct decentered ablations, when
- 1. The decentration is not too severe;
- 2. WaveScan can map;
- 3. WS indeed show high coma;
- 4. WS refraction is similar to MR

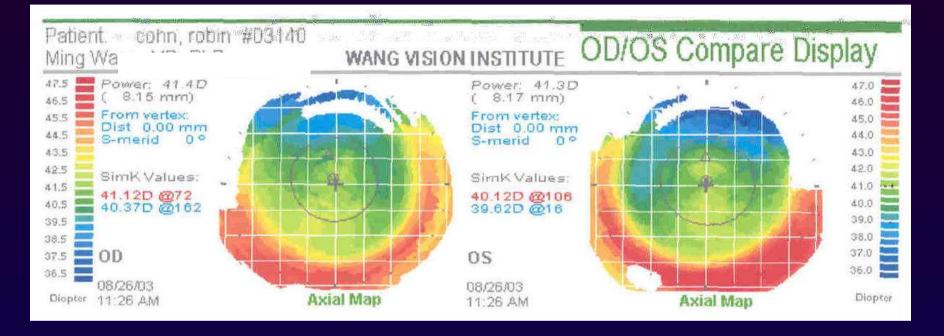
Case RC (Custom treatment of decentration)

42 yo Female "tired of wearing glasses"
MR: OD -7.75+1.00 x 010, 20/20 OS -10.20+1.00 x 175, 20/20
Pach's: OD 552 (ave), OS 560 (ave)
Good ocular health and TPG
Plan: LASIK for distance OU using Intralase (90% OD, 80% OS)

RC: 1 day s/p ML

VA's OD 20/30, OS 20/100
Flaps in place, no inflammation, striae or debris
Moderate edema OS.
Tx'd with Pred (4/3/2/1 x 1 wk)

RC decentration os s/p ML



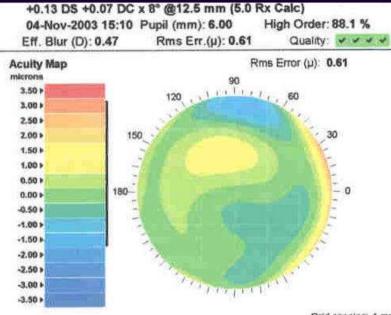
3 mos PO: slightly decentered ablations on Atlas OS VA OD 20/30, MR -0.50D 20/30+1 VA OS 20/100, MR -2.00 20/30 (blurry)

RC 3 mos s/p decentered ML: Orbscan OS



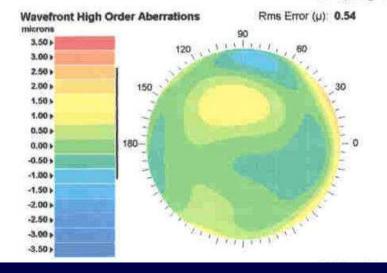
RC s/p decentered ML os (high coma)

OS



All Aberrations - Log 50% Eff. Blur(D): 0.47

Grid spacing: 1 mm.

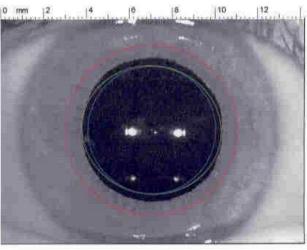


Normalized Polar Zernike Coefficients Table (µ)

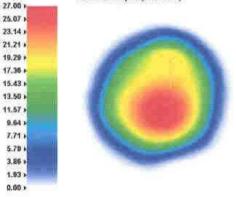
	Value	Name	0.0 0.38440	Axis
Z 20	-0.00771	Defocus		
Z 22	0.28799 @ 177*	Astigmatism		
Z 31	0.36440 @ 315"	Coma		
Z 13	0.17263 @ 18"	Trefoil	Name and Address of Concession, Name of Conces	100
Z	0.13576	Sph. Aberration	Concerning of the second se	
-	0.16594 @ 178*			
Z	0.11213 @ 39"			10
Z 11	0.17923 @ 53*			4
Z 53	0.02368 @ 32"	1	and .	
the second	0.06885 @ 34*	1	Noneman (()
Zei	0.16663			
Z (12	0.02901 @ 90*		100	1
ZM	0.01325 @ 69"	1		10
-	0.01889 @ 4"		BB	1.

RC: CustomVue treatment for decentered ML os

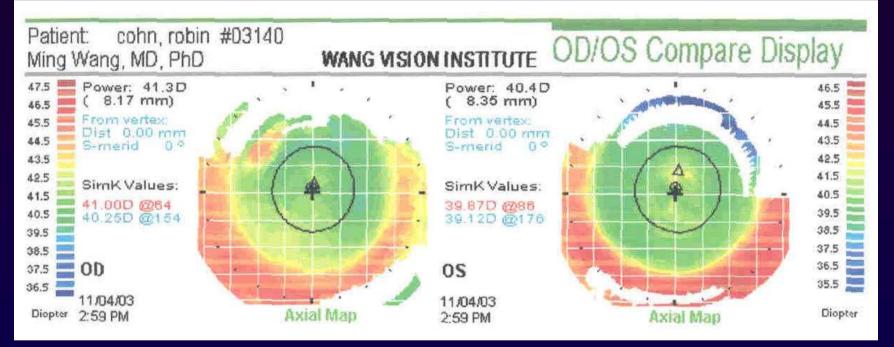
OS -0.84 DS +0.23 D 26-Aug-2003 12:* Eff. Blur (D): 1.02	13 Pupil (mm		ligh Ord			
Manifest: -1.75 DS +0.	00 DC @	12.50 mm				
Cycloplegic:						
Auto:						
Auto+Cyclo:						
K1 (D): 43.50 K2 (K2 axis(°):				
Corneal Thickness (µ):						
Scotopic Pupil Size (mm):			Marrie			
Treatment Type: LASIK	Corre	ection Type:	waven	ront		
Physician Adjustments - SPH (8	D): -0.50 CY	'L (D): +0.00	Axis("):		VTX(mm)	0.00
Total Correction - SPH (I	0): -1.33 CY	'L (D): +0.23	Axis(*)	170	VTX(mm)	0.00
Treatment Paran	eters			on of VS	S Pulse Dian	neters
Optical Zone (mm)	6.00 x 6.5	3 °	0			
Ablation Zone (mm)	8.00	Number of Fulses	-			
Max. Ablation Depth (µ)	27.3	D. B.				K.
No. of Tissue Pulses	: 146	nder.	2			
Treatment Time (sec)	: 15	Nun				
Surgical Param	ieters	2	0			
Flap Diameter (mm)	9.00			2-3 3- Tulse Diar	neter (mm)	96
Flap Thickness (µ)	130					
Residual Bed (µ)	287					
Additional Infor	mation					
The Manifest and WaveScan refra		ch				



Ablation Depth (microns)

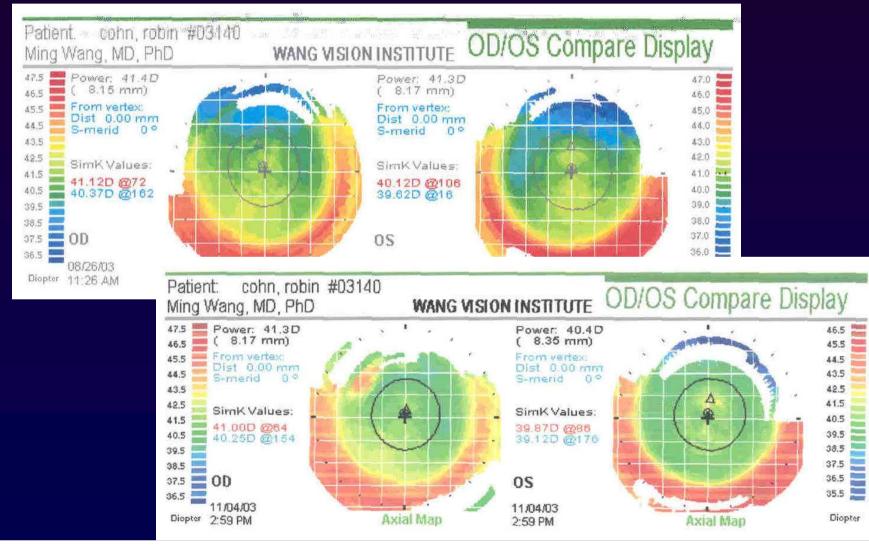


RC S/P CustomVue treatment for decentered ML os



6 weeks: OS 20/25 "Doing well" AR -0.50+0.25 x 100.

OS pre and post Custom treatment for treating decentered ML



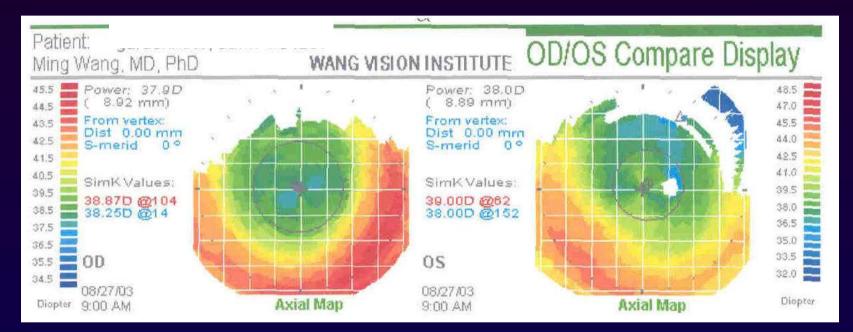
Custom treatment for decentered ML OS (DG)

45 yo Female complaining of: Monocular diplopia, OS "Difficulty with night glare" OU, OS > OD "Glasses for night driving don't help" Original RX before ML was: OD -7.50+1.25 x 005, 20/25 OS -9.75+2.00 x 20, 20/20 S/P Lasik May 2000 Enh OS December 2000.

DG with decentered ML OS

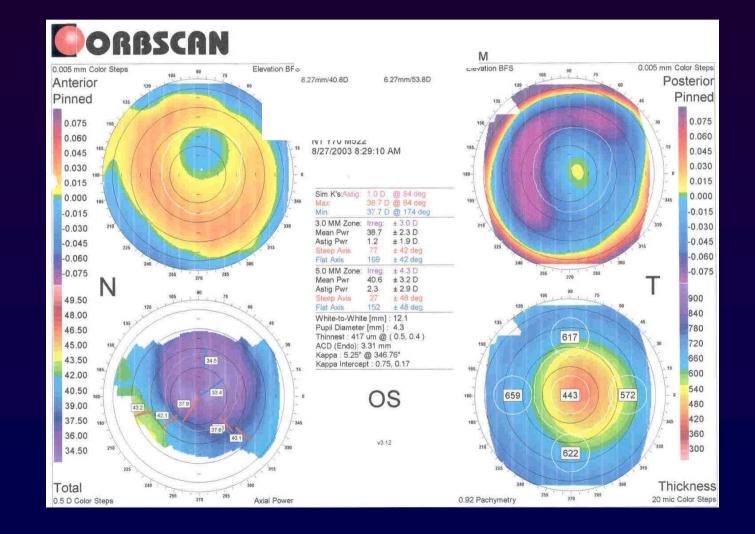
MR OD -0.50 DS, 20/25
MR OS -0.75+0.25 x 55, 20/30 (blurry) with only 10% improvement in vision subjectively with MR
Cyclo OS -1.50 DS, 20/40 (blurry)
Wavescan RX -1.45+0.44 x 64, WS CAN map AND agrees with MR.

DG with decentered ML os



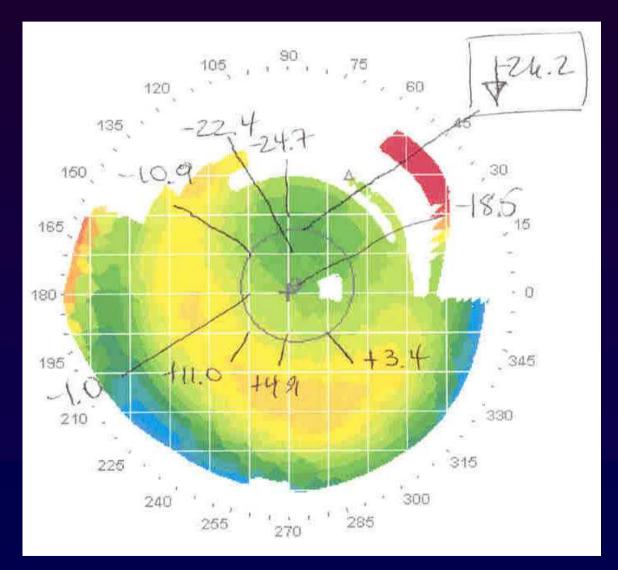
US pach's OD 479 (ave), OS 469 (ave)

DG superioly decentered ML OS (elevation)

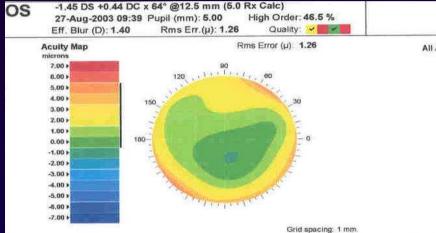


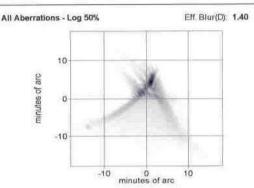
DG height values OS on elevation

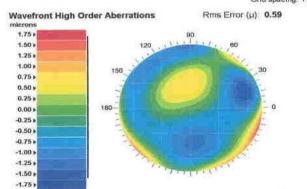
Values on elevation map show significant decentration



DG Wavescan map for the decentered ML OS (high coma)



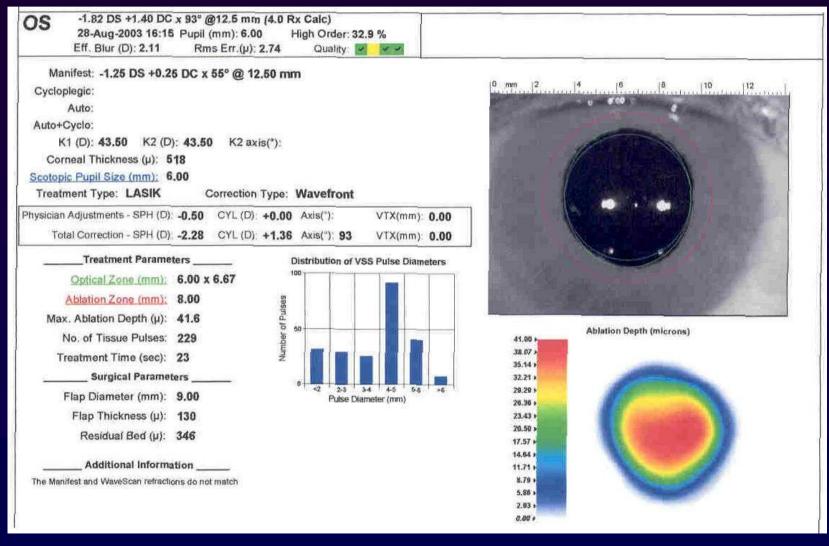




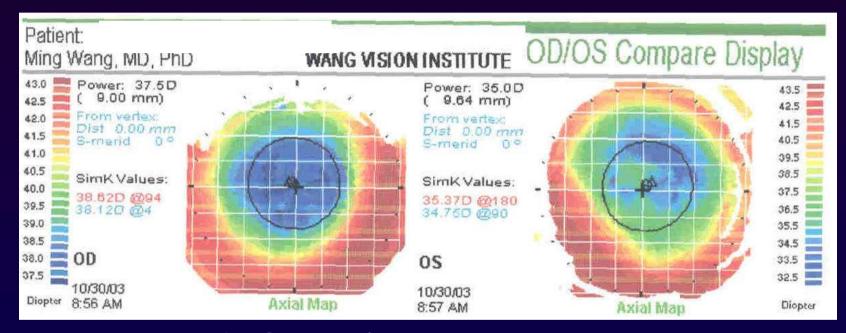
Normalized Polar Zernike Coefficients Table (µ)

	Value	Name	0.0 0.41505	Axis
Z 10	1.08563	Defocus		
Z 32	0.27276 @ 64*	Astigmatism		
Z 31	0.41506 @ 291*	Coma		•
Z 10	0.21007 @ 81"	Trefoil		1
Zau	0.23877	Sph. Aberration		
Z.42	0.11069 @ 16"			
Z.	0.14236 @ 56°			10
Z	0.10301 @ 104"			
Z ES	0.06634 @ 26*			()
Z 38	0.07709 @ 58*			
Z 110	0.07327			
Zin	0.03589 @ 179*	1	PARK .	-
Z 44	0.06397 @ 24*	1	Steam I	197
Z	0.08845 @ 51*		1	10

DG CustomVue treatment plan for decentered ML os

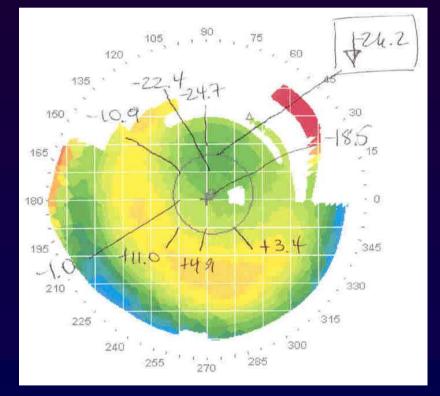


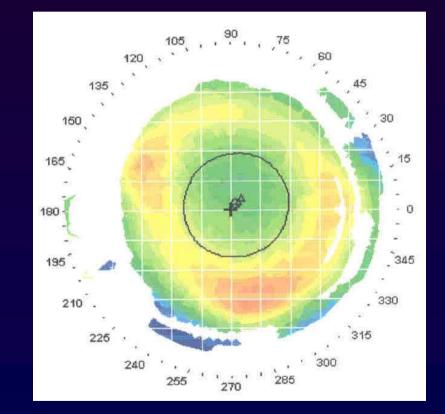
DG s/p CustomVue treatment for decentered ML os



At 3 months: VAsc 20/30 MR +1.75 20/25+ with no diplopia

DG with decentered ML OS, precustom treatment and post-custom





After-custom

Pre-custom

Strength and weakness of C-CAP for treating decentered ablation (sg)

1. Strength:

Large scale treatment, can "pull" the ablation back to center, in severely decenter-treated corneas in which WaveScan can't map;

2. Weakness:

Trial and error geometric shapes;

Has to have another refractive treatment;

3. Cautions:

Always look at the elevation map;

Keeping in mind that some decentration will self resolve (with DES treatment for example).

Custom Guided Treatment for decentered ablation (pg)

1. <u>Strength:</u>

Addresses the refractive error; more predictable (customized to the extent of decentration);

2. <u>Weakness:</u>

For severely decentered treatment, wavefront often can't map, or coma not dominant, or its refraction does not agree with MR;

3. <u>Cautions:</u>

Custom treatment secondarily address the topographical issues – less control; Wavescan refraction is often LESS accurate in post-keratorefractive surgery eyes.

Summary: treating irregular astigmatism (decentration) using C-CAP/CustomVue – VISX

- Be sure the decentered ablation is the reason the VA is reduced. RGP VA is important!
- C–CAP treatment work well in some severely decentered cases
- C-CAP induces refractive error changes, usually NOT in a positive way, and hence will need secondary refractive treatment;
- Wavefront CustomVue can treat, though imaging in severely decentered cases is hard. It is affected by lens HOA;
- Ideal treatment: topography-guided treatment

