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

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- 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
Keratoconus and keratoectasia
Decreased BSCVA

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

Conventional treatment (PRK/LASIK)

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

RGP TESTING

If no improvement in BVA: problem is not at cornea: NO CORNEAL SURGERY

If WP = MR, proceed with wavefront enh (LASIK/PRK)

If WP ≠ MR, Hold off wavefront tx If decentered, consider C-CAP

Improvement in BVA: problem is at Cornea (IA)
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 **reduced** best-corrected visual acuity that **improves only with gas permeable lenses**;
- A cylinder measurement on autorefraction and wavefront that **differs** from manifest refraction;
- A history of reduced vision **immediately** 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 decenteration 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 decenteration and WaveScan **can not** obtain any data, do C-CAP first to **“pull the center of ablation back to the center first”**, 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 astigmatism 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
3-D stereo corneal topography:
Images (3-AstraMax camera, checker board)
**Case 1:** Improved sensitivity using 3-D topo: Diplopia after LASIK, causes unclear, but topo measurement inconsistent 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.
Case 1 con’t: 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 topographer
- Vision 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 Ellipse 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
C-CAP Case JC

- 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”
C-CAP Case JC

- 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 Case JC
C-CAP Case JC

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Etcv. Diff.: -2.6 µ
From Vertex
X Offset: 0.0 mm
Y Offset: 0.0 mm
From Pupil
X Offset: 0.2 mm
Y Offset: -0.1 mm
Ref. Sph.: 43.33 D
Pupil Size: 3.02 mm

OD
09/13/2002
3:36:47 PM

VTX: 13.1 mm
K1: 43.50 D
K2: 42.62 D
K2 Axis: 116 Deg.

Add Up:
1
-3.00 +43 6.0 2.7 0.4 0.6 -1.8 7 M Cylinder

Treatment: CAP Method

C-CAP Case JC

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Elev. Diff.: -1.3 μ
From Vertex
X Offset: 0.8 mm
Y Offset: 0.8 mm
From Pupil
X Offset: 0.2 mm
Y Offset: -0.1 mm
Ref. Sph.: 43.33 D
Pupil Size: 3.62 mm

OD 09/19/2002
3:38:47 PM

VTX
T3.1
mm
K1: 43.50
D.
K2: 42.62
D.
K2 Axis: 116 Deg.

Add
Up
Def
Down

Sph Cyl Axis Dim.1 Dim.2 Trans XOff YOff Depth Surf.

1 -1.50 147 4.0 1.8 0.5 0.9 1.0 2 M Cylinder

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
20/30

1 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)
Treatment plan (C-CAP PG)
Treatment plan (C-CAP PG)
Treatment plan (C-CAP PG)
Treatment plan (C-CAP PG)
Treatment plan (C-CAP PG)
Treatment plan (C-CAP 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 (1\textsuperscript{st} and 2\textsuperscript{nd} 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 stabilize, with full medical therapy, 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 self-resolution of decentration

December 2002: -9.5 microns

February 2003: -5.4 microns
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)
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)
RC: CustomVue treatment for decentered ML os

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manifest refraction</td>
<td>-1.75 DS +0.00 DC @ 12.50 mm</td>
</tr>
<tr>
<td>Cylinder</td>
<td>0.00 DC</td>
</tr>
<tr>
<td>Astigmatic correction</td>
<td>45°</td>
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<tr>
<td>Corneal Thickness (µm)</td>
<td>444</td>
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<tr>
<td>Scotopic Pupil Size (mm)</td>
<td>6.00</td>
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<tr>
<td>Treatment Type</td>
<td>LASIK</td>
</tr>
<tr>
<td>Correction Type</td>
<td>Wavefront</td>
</tr>
</tbody>
</table>

**Treatment Parameters**

- Optical Zone (mm): 6.00 x 6.53
- Ablation Zone (mm): 8.00
- Max. Ablation Depth (µm): 27.3
- No. of tissue pulses: 146
- Treatment time (sec): 15

**Surgical Parameters**

- Flap Diameter (mm): 9.00
- Flap Thickness (µm): 130
- Residual Bed (µm): 287

**Additional Information**

The manifest and WaveScan refractions do not match.
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 decenttered 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)
DG CustomVue treatment plan for decentered ML os

Manifest: -1.25 DS +0.25 DC x 55° @ 12.50 mm
Cycloplegic:
Auto:
Auto+Cyclo:
K1 (D): 43.50  K2 (D): 43.50  K2 axis(*):
Corneal Thickness (µ): 518
Scotopic Pupil Size (mm): 6.00
Treatment Type: LASIK  Correction Type: Wavefront

Physician Adjustments - SPH (D): -0.50  CYL (D): +0.00  Axis(*):  VTX(mm): 0.00
Total Correction - SPH (D): -2.28  CYL (D): +1.36  Axis(*): 93  VTX(mm): 0.00

Optical Zone (mm): 6.00 x 6.67
Ablation Zone (mm): 8.00
Max. Ablation Depth (µ): 41.6
No. of Tissue Pulses: 229
Treatment Time (sec): 23
Surgical Parameters
Flap Diameter (mm): 9.00
Flap Thickness (µ): 130
Residual Bed (µ): 346

Additional Information
The Manifest and WaveScan refractive data do not match

Ablation Depth (microns)
DG s/p CustomVue treatment for decentered ML os

At 3 months:
VA:sc 20/30
MR +1.75 20/25+ with no diplopia
DG with decentered ML OS, pre-custom treatment and post-custom treatment.
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. **Strength:**
   Addresses the refractive error; more predictable (customized to the extent of decentration);

2. **Weakness:**
   For severely decentered treatment, wavefront often can’t map, or coma not dominant, or its refraction does not agree with MR;

3. **Cautions:**
   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