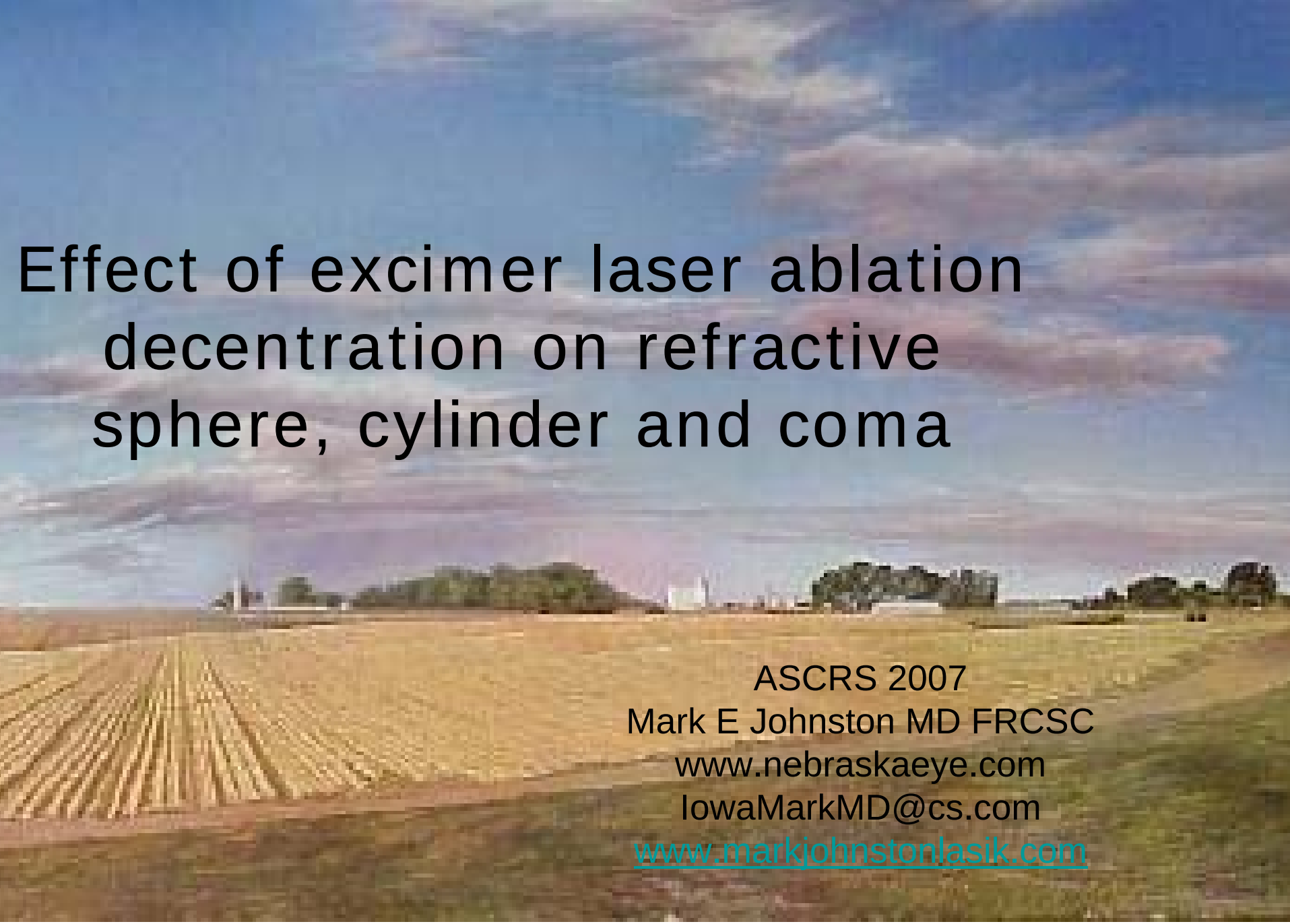

Effect of excimer laser ablation decentration on refractive sphere, cylinder and coma

ASCRS 2007
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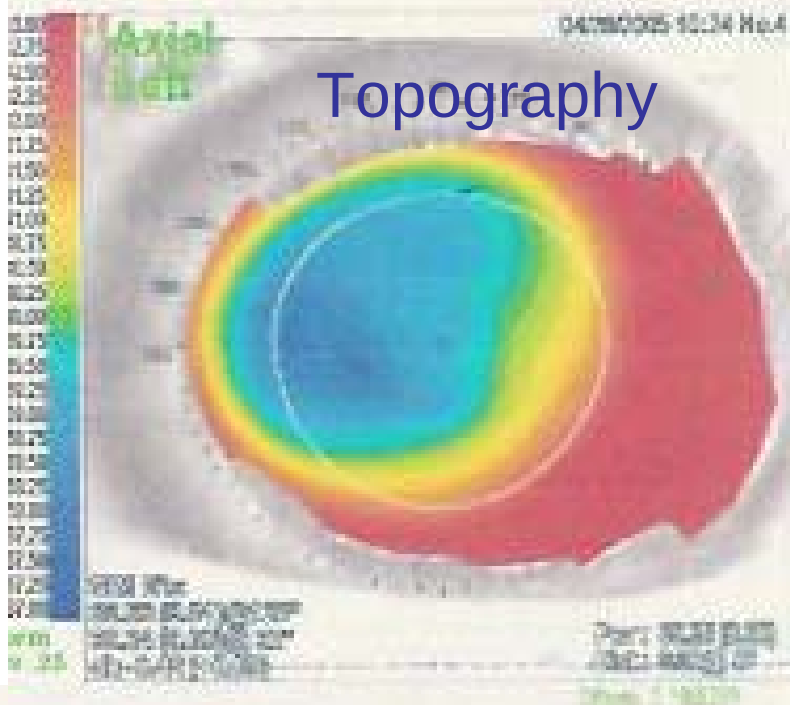
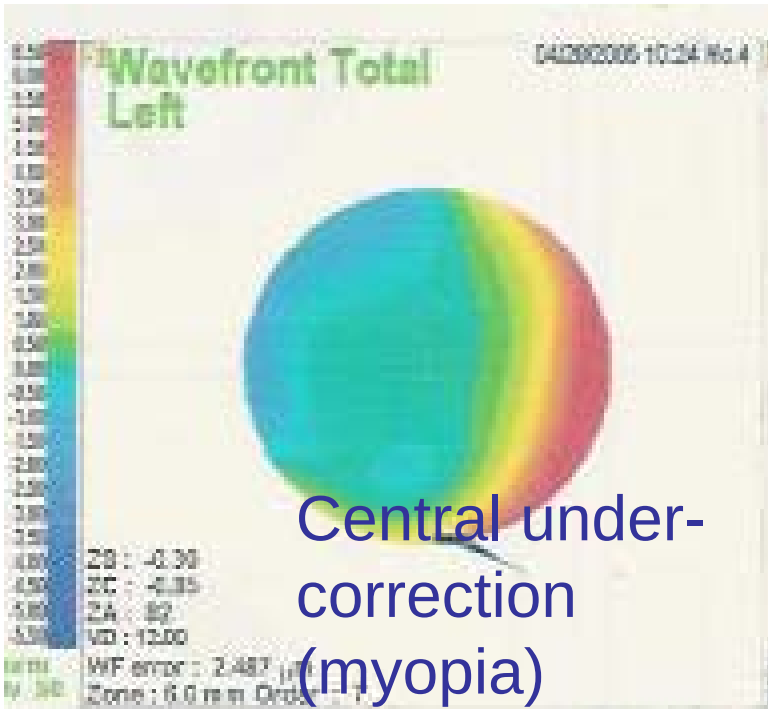
Purpose

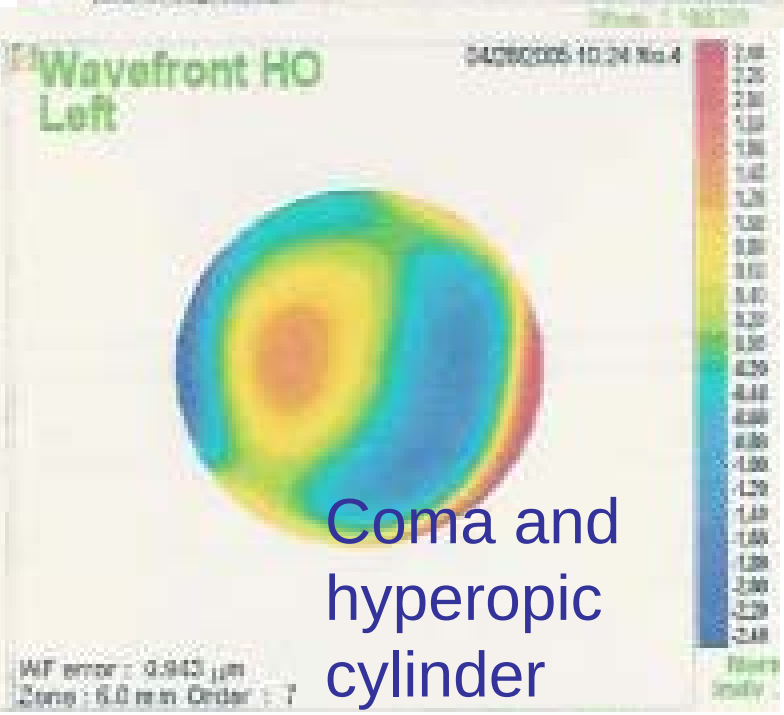
- To study the effect of decentration of excimer laser ablation on post-operative sphere, cylinder and coma

- To understand the relative importance of decentration to
  - the degree of under or over correction of sphere
  - induction of cylinder and coma.

- Sphere Decentration
  - Central myopic under-correction
  - **Coma and plus cylinder on decentration axis**





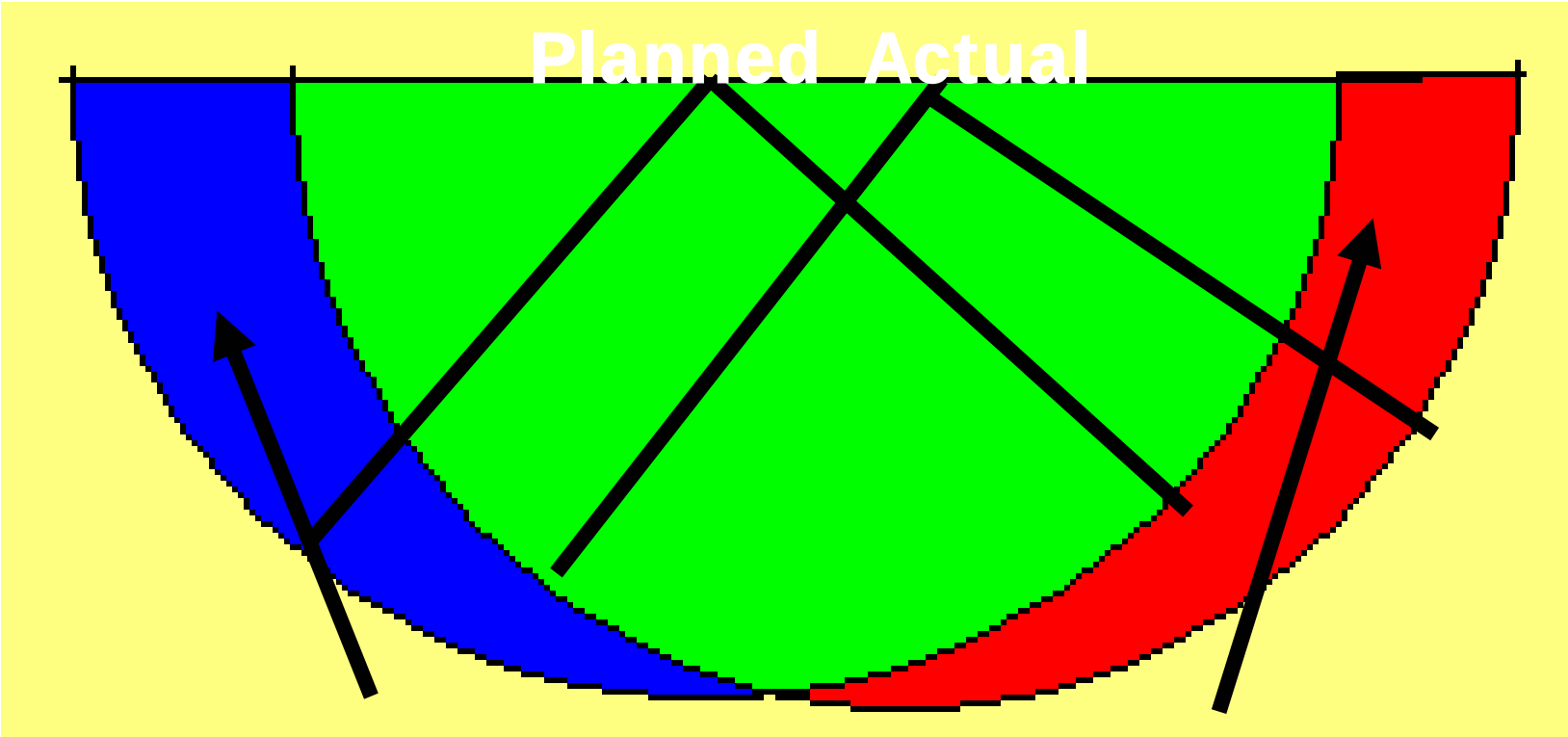


Purpose

- Decentration of the ablation is expected to cause
  - under-correction of sphere
  - residual plus cylinder
  - induced coma.

De-centered treatment is expected to create:

- Less depth of ablation over the visual axis
  - Residual myopia (under-correction)
    - More myopic effect on the minus cylinder axis which has a narrower optical zone
- A steeper than intended effective treatment cylinder (Green) over the visual axis
  - Residual hyperopic astigmatism (overcorrection)
    - More prominent on the minus cylinder axis which has a wider optical zone
- coma (Blue and Red)

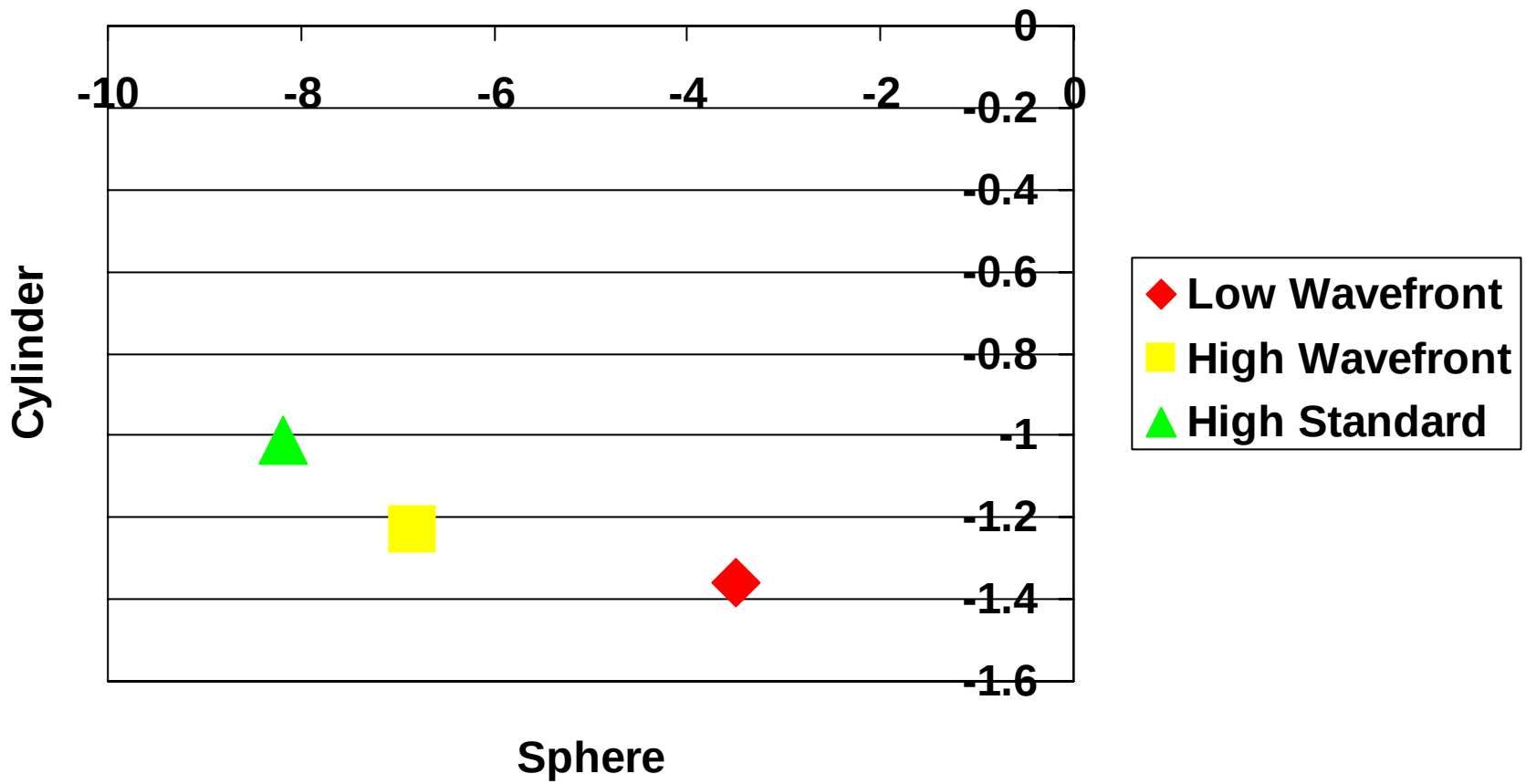


Under-treated Over-treated

Methods

- Sequential patients presenting for enhancement were reviewed. Laser profiles were:
  - Visx CustomVue™, one to six diopters (Low-Wavefront)
  - Visx CustomVue™, six to eleven diopters (High-Wavefront)
  - Visx Star™ for high myopia (High-Standard).
- Increase in coma after surgery was used as a measure of ablation decentration.
- Within each profile, linear regression between pre- and post-operative sphere, cylinder and coma was examined.

Pre-operative Sphere and Cylinder



Methods

- Average pre-enhancement manifest refraction was compared to the average predicted results using the Refractive Surgery Consultant™ (RSC), a commercial outcome software program which provides a best fit regression equation for both sphere and cylinder.

Refractive Surgical consultant ®

Best Fit Nomogram

Treatment Profile Statistics	
Date Created	10/18/2004
Created By	Jones Eye Clinic Omaha Administrator
Primary or Reoperations	Primary
Procedures to Date	4,043
Procedure Dates	2/8/2002 thru 3/8/2007
Spheres / Spherocylinders	0 / 4,043
Eyes with Postop > 20 Days	2,938

Major Treatment Profile Attributes	
Laser:	Visx Fourier
Laser Software:	Fourier
Hinge Location:	All Locations
Treatment Range:	Myopia
Minor Treatment Profile Attributes	
Hertz Rate:	/ Sec
Optical Zone Diam:	All Diameters
Keratome / Serial:	All Keratomes
Keratome Plate:	All Plates
User Defined:	NA

Sphere Nomogram Statistics	
Nomogram Type	Optimized HK-2
Date Processed	3/12/2007
# Profiles Sharing Nomogram	2
Number of Eyes Evaluated	775
Number of Eyes Eliminated	22
Number of Eyes Used to Create	753
Surgical Dates	3/15/2006 thru 1/19/2007
Mean / SD Follow Up (Days)	106.0 +/- 65.0
Follow Up Range (Days)	30 to 337
Nomogram R Squared Statistic	0.960
Standard Error of Regression	0.38

Cylinder Nomogram Statistics	
Nomogram Type	Optimized HK-2
Date Processed	3/12/2007
# Profiles Sharing Nomogram	2
Number of Eyes Evaluated	775
Number of Eyes Eliminated	26
Number of Eyes Used to Create	749
Surgical Dates	3/15/2006 thru 1/19/2007
Mean / SD Follow Up (Days)	106.0 +/- 64.8
Follow Up Range (Days)	30 to 330
Nomogram R Squared Statistic	0.970
Standard Error of the Regression	0.23

Variable	Coeff	Mean	Std Dev	Min	Max	p
Steep K - Flat K	0.06	1.07	0.75	0.00	6.15	<0.005
Sph Tmt Amount (D)	1.07	-2.78	1.47	-6.92	0.42	<0.005
Sph Tmt Amt Squared	0.02	9.89	9.12	0.00	47.82	<0.005
Cyl Tmt Amount (D)	0.28	-0.81	0.62	-3.21	-0.01	<0.005
Cyl Tmt Amt Squared	0.12	1.04	1.55	0.00	10.32	<0.005
Sph Tmt X Cyl Tmt	0.05	2.23	2.31	-0.34	16.19	<0.005
Recip of Age Squared	-80.20	0.00	0.00	0.00	0.00	<0.005

Variable	Coeff	Mean	Std Dev	Min	Max	p
Sph Tmt Amount (D)	0.02	-2.77	1.48	-8.05	0.42	0.002
Cyl Tmt Amount (D)	0.92	-0.80	0.62	-3.21	-0.01	<0.005
Cyl Tmt Amt Squared	-0.05	1.03	1.58	0.00	10.32	0.001
Sph Tmt X Cyl Tmt	0.02	2.19	2.32	-0.30	18.31	0.001

Sphere Nomogram Equation

Sphere Programmed Amount = + 1.07 X Sphere Correction + 0.02 X Sphere Correction Squared + 0.28 X Cylinder Correction + 0.12 X Cylinder Correction Squared + 0.05 X Sphere X Cylinder Correction + 0.06 X (Steep K - Flat K) + -80.20 X

Cylinder Nomogram Equation

Cylinder Programmed Amount = +0.02 X Sphere Correction + 0.92 X Cylinder Correction + -0.05 X Cylinder Correction Squared + 0.02 X Sphere X Cylinder Correction

Treatment Refractions

Planned Treatment Date:

	Sphere	Cylinder	Axis	Vertex
Preop Refraction:	-0.80	-2.01	98	12.5
Target Refraction:	0.00	Sphere		12.5

- Target is NOT age adjusted

Treatment Profile: Fourier Omaha

Preoperative Exam Information

Preoperative Exam Date: 1/26/2007

	Sphere	Cylinder	Axis	Vertex
Manifest:	Refraction Not Entered			
Cycloplegic:	Refraction Not Entered			

	Flat K	Steep K	Steep Mer	Mean K
Keratometry:	44.53	45.79	103	45.16

Major Treatment Profile Attributes

Laser:	Visx Fourier
Laser Software:	Fourier
Treatment Range:	Simple or Compound Myopic Astigmatism
Hinge Location:	All Locations

Minor Treatment Profile Attributes

Keratome:	0
Plate Thickness (u):	All Plates
Laser Hertz Rate:	All Hertz Rates
Outer Tmt Zone Diam:	All Diameters
User Defined:	None

Nomogram Results

	Sphere	Cylinder	Axis	Vertex
Desired Corr:	-0.80	-2.01	98	12.5
Sugg Prog Amt:	-0.88	-2.02	98	12.5

Depth Calculation

	Microns	Percent
Preoperative Pachymetry:	512	100.0%
Plate Thickness:	Not Specified	
Estimated Ablation Depth:	Missing Pachymetry and / or Zone Data	
Estimated Residual Stroma:	Cannot Calculate: Missing Essential Data	

Sphere Nomogram Accuracy

Local Standard Deviation of Prior Results for 10 Nearest Eyes:	+/- 0.38 D
2/3 Outcomes Expected to Fall Between:	-0.38 D and 0.38 D
95% Outcomes Expected to Fall Between:	-0.75 D and 0.75 D

Cylinder Nomogram Accuracy

Local Standard Deviation of Prior Results for 10 Nearest Eyes:	+/- 0.13 D
2/3 Outcomes Expected to Fall Between:	-0.13 D and 0.13 D
95% Outcomes Expected to Fall Between:	-0.27 D and 0.27 D

Suggested Programmed Amount Vertex 12.5

	Sphere	Cylinder	Axis	Vertex
Vertex 13.0:	-0.88	-2.02	98	12.5

Suggested Programmed Amount Vertex 0

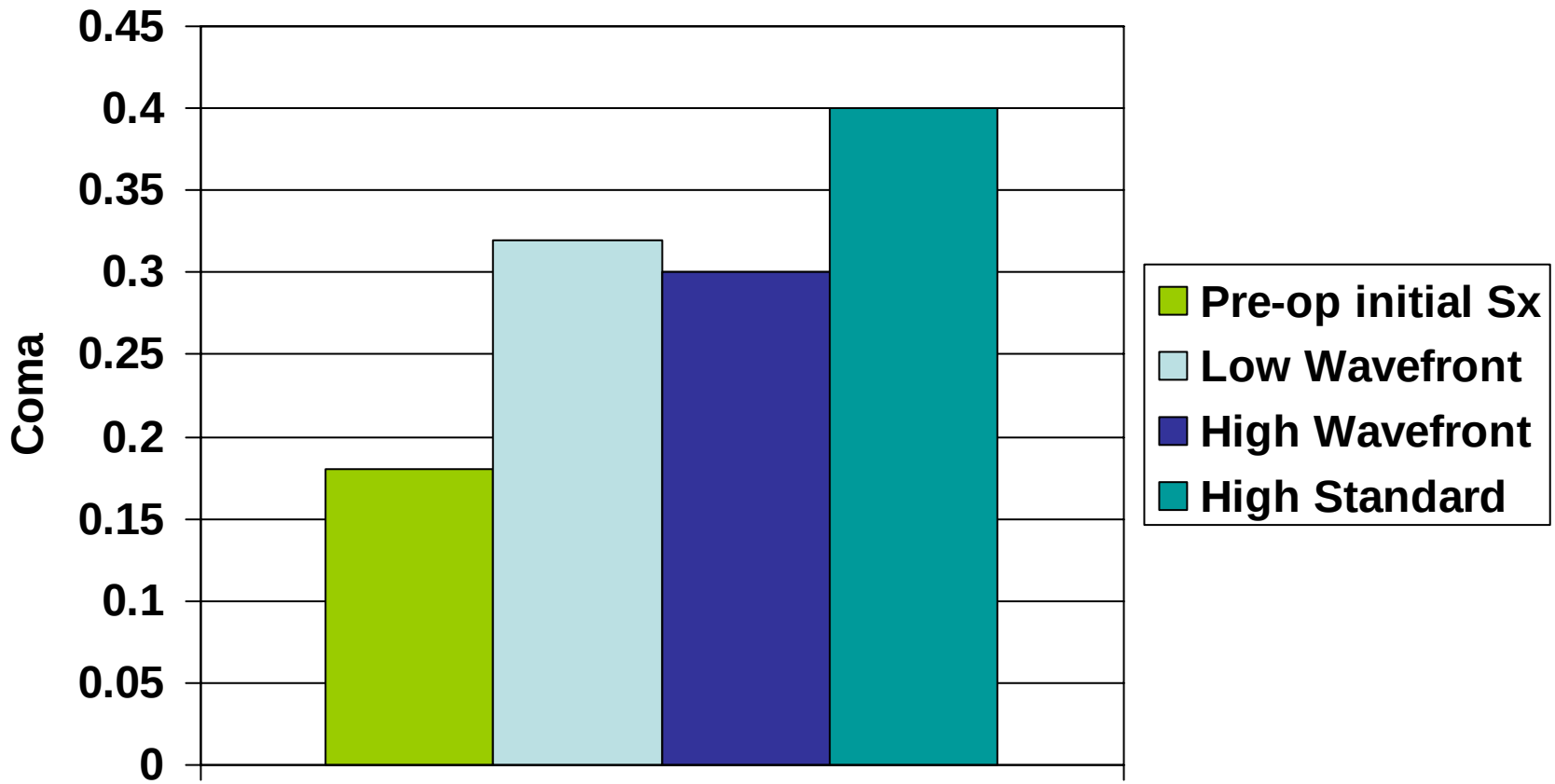
	Sphere	Cylinder	Axis	Vertex
Vertex 0:	-0.87	-1.93	98	0

Notes

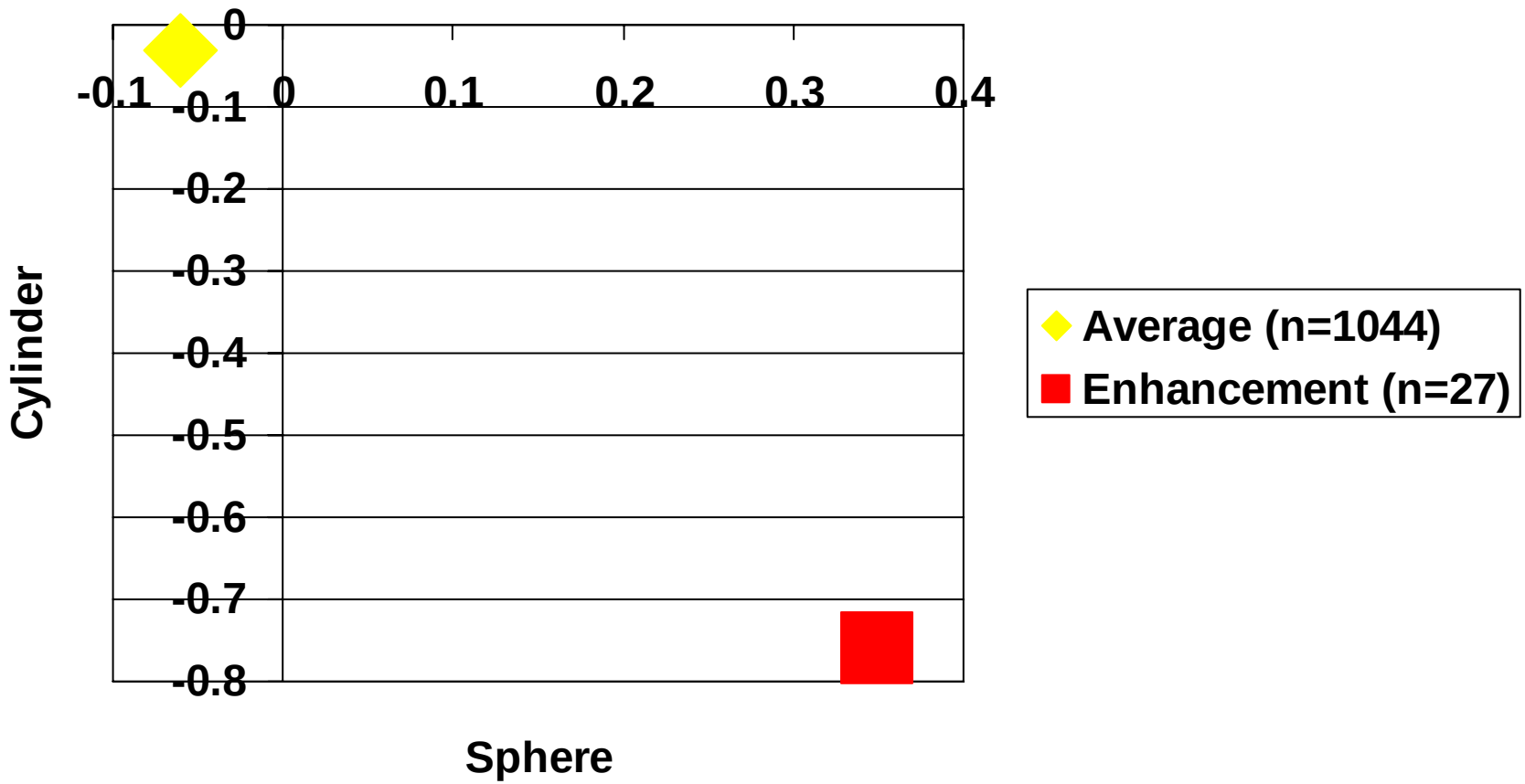
Results

- Low-Wavefront (27 eyes),
  - average primary sphere/cylinder(s/c) -3.49/-1.36)
  - average pre-enhancement
    - coma of 0.32um
    - manifest s/c +0.35/-0.76
      - compared to a predicted RSC result of s/c -0.06/-0.03.
- High-Wavefront (13 eyes),
  - s/c -6.85/-1.23)
  - Pre-enhancement
    - coma of 0.30 um
    - s/c of +0.04/-1.00
      - compared to predicted s/c -0.10/-0.09.
- High Standard (18 eyes),
  - s/c -8.18/-1.01)
  - Pre-enhancement
    - coma 0.40 um
    - s/c of -0.37/-0.64
    - compared to predicted s/c+0.20/-0.44.

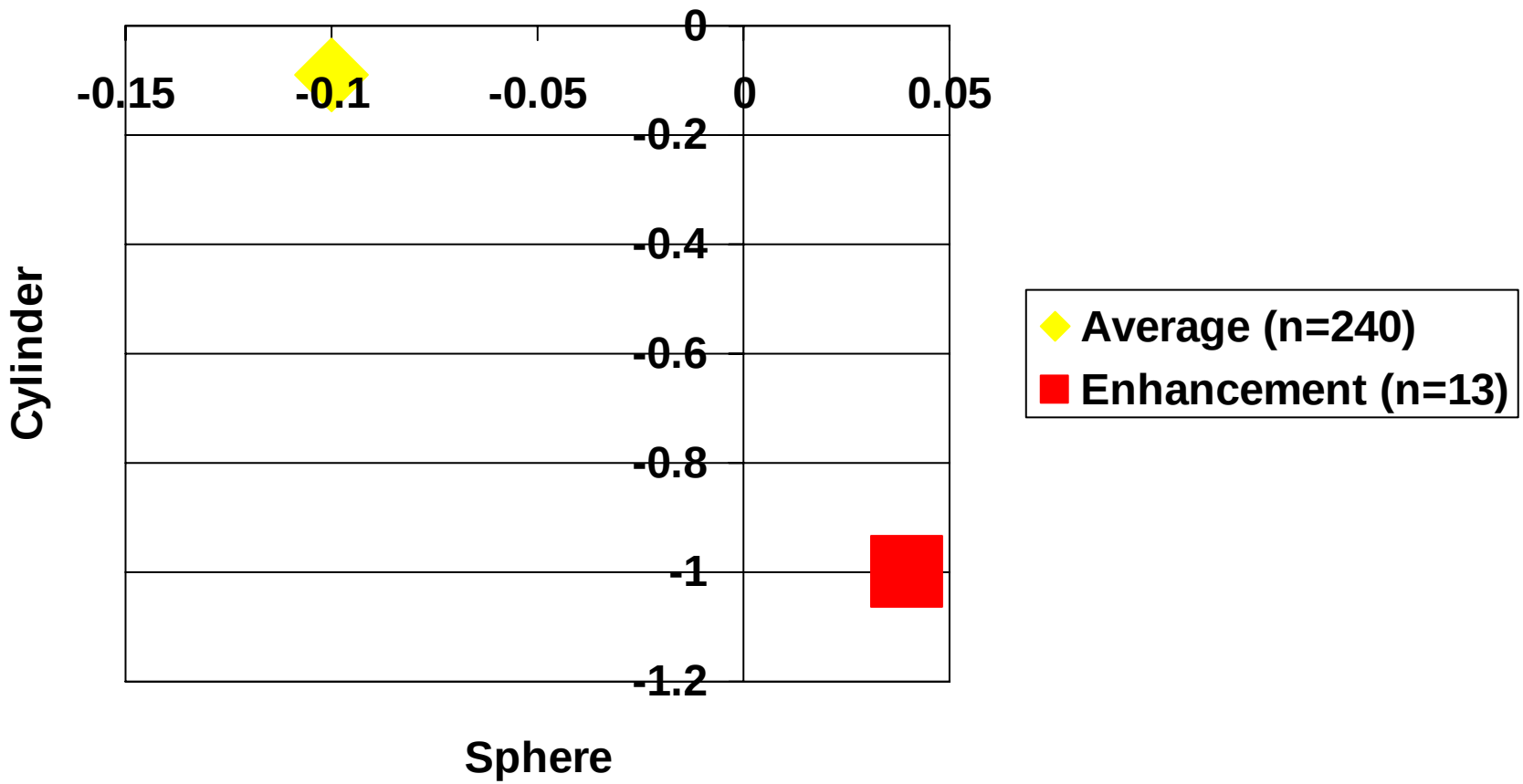
Pre-Enhancement Coma



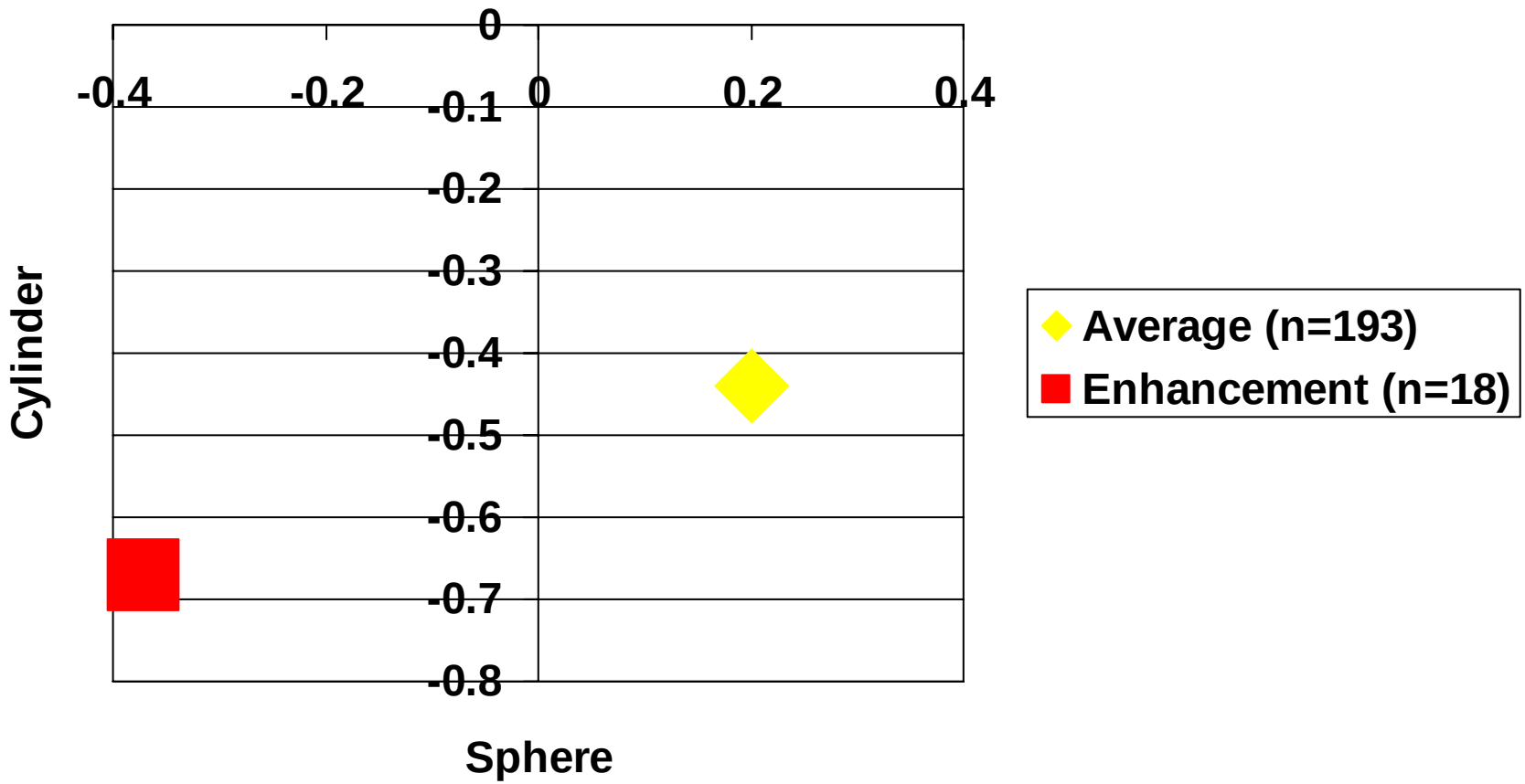
Outcomes with Low Myopia VISX Wavefront



Outcome with High Myopia VISX Wavefront



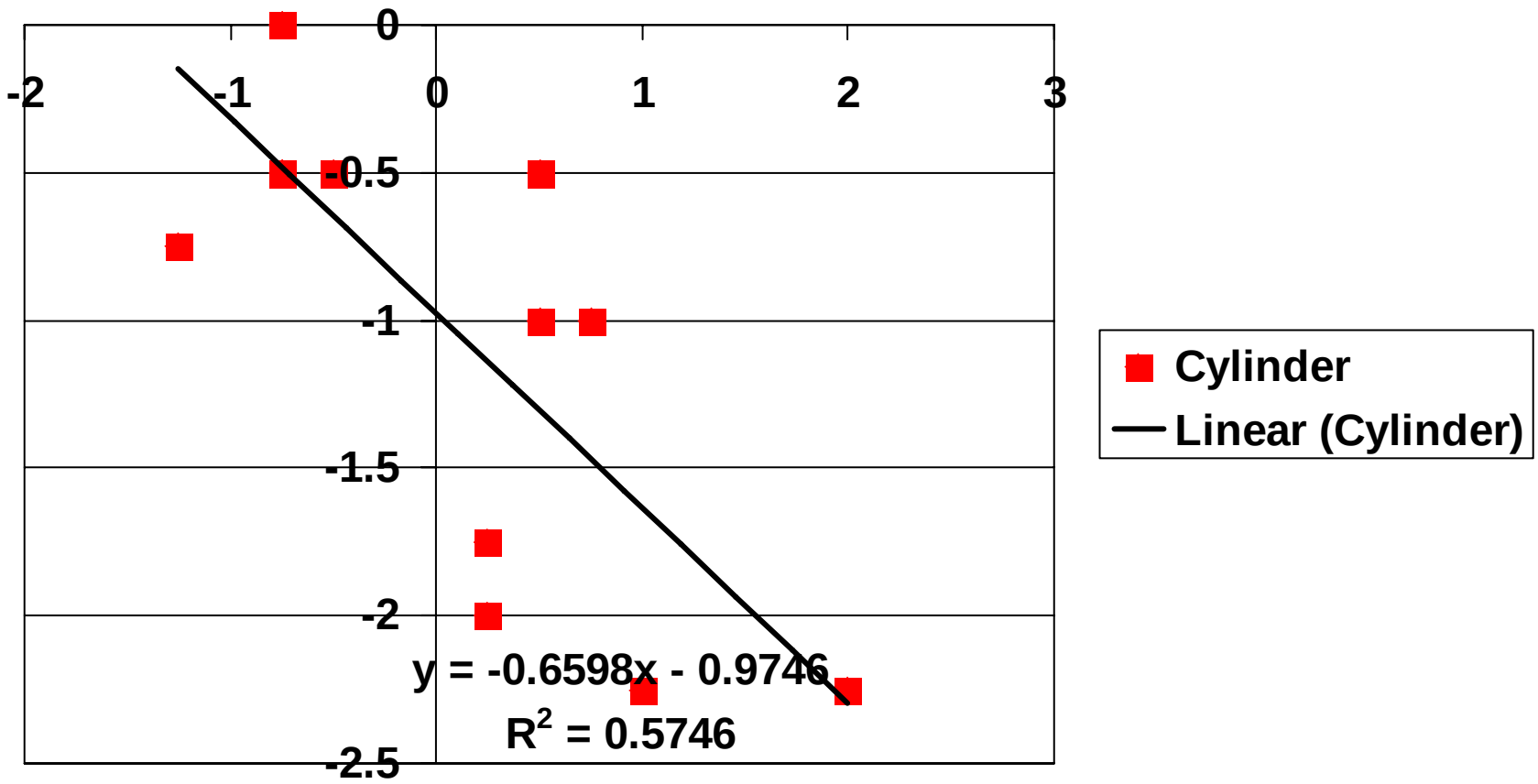
Outcome with High Myopia VISX Standard



Results

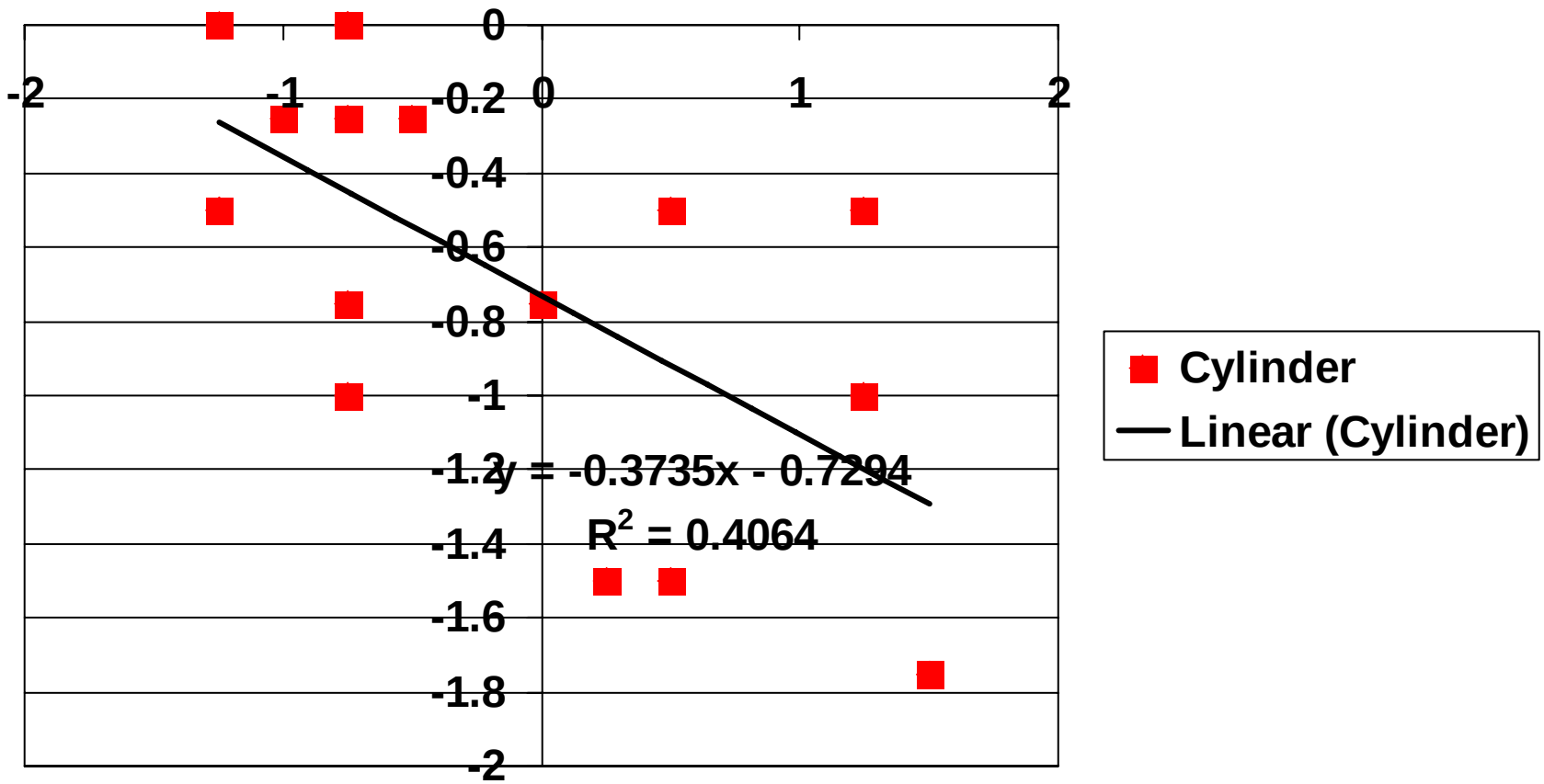
- Regression analysis within each laser profile show a moderate correlation between increasing residual cylinder and relative hyperopic shift in spherical equivalent
  - Low-Wavefront (r^2 0.45)
  - High-Wavefront (r^2 0.57)
  - High-Standard (r^2 0.41).

High myopia wavefront: refraction pre-enhancement



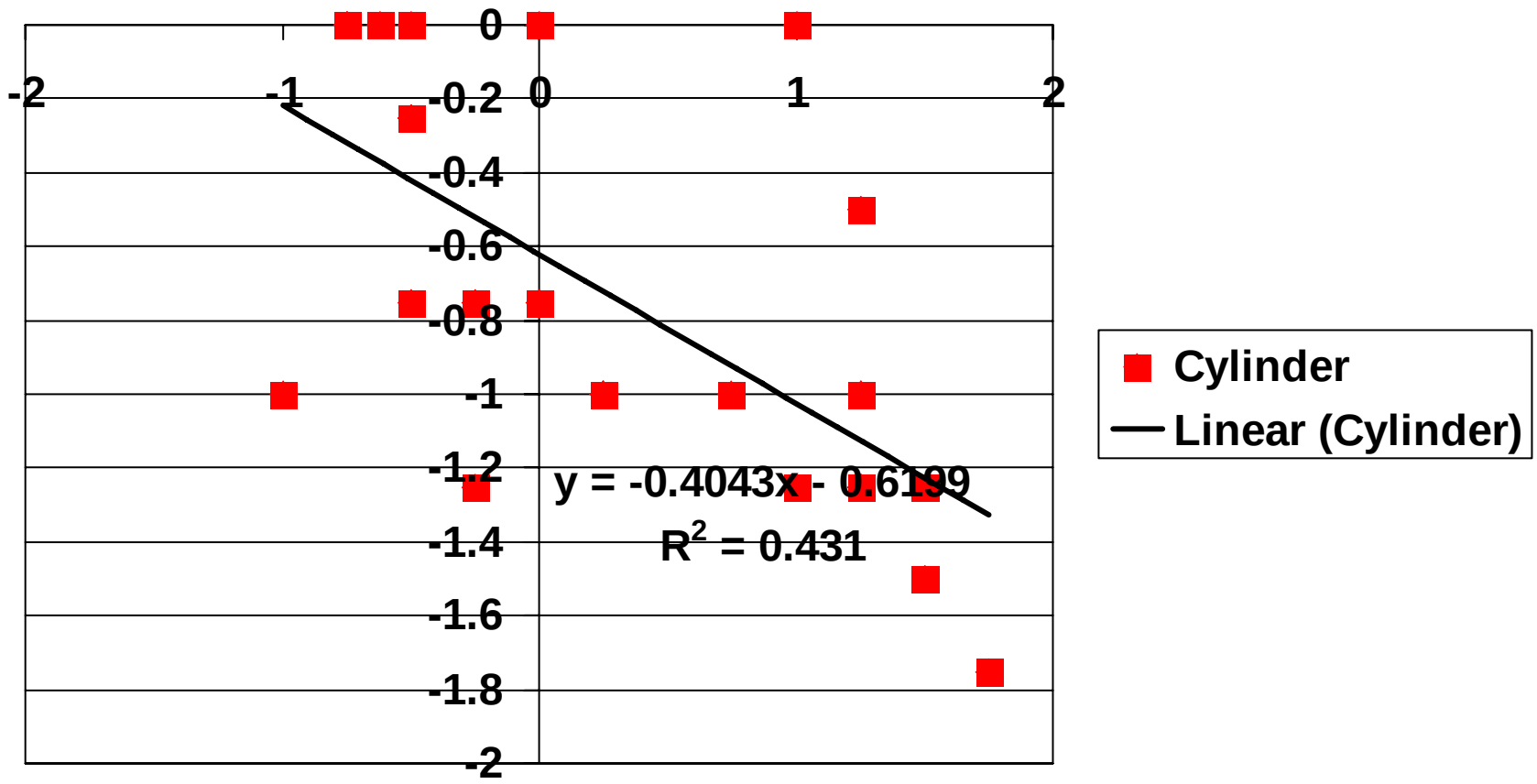
N=13

High myopia standard: refraction pre-enhancement



N=18

Low myopia wavefront: refraction pre-enhancement



N=27

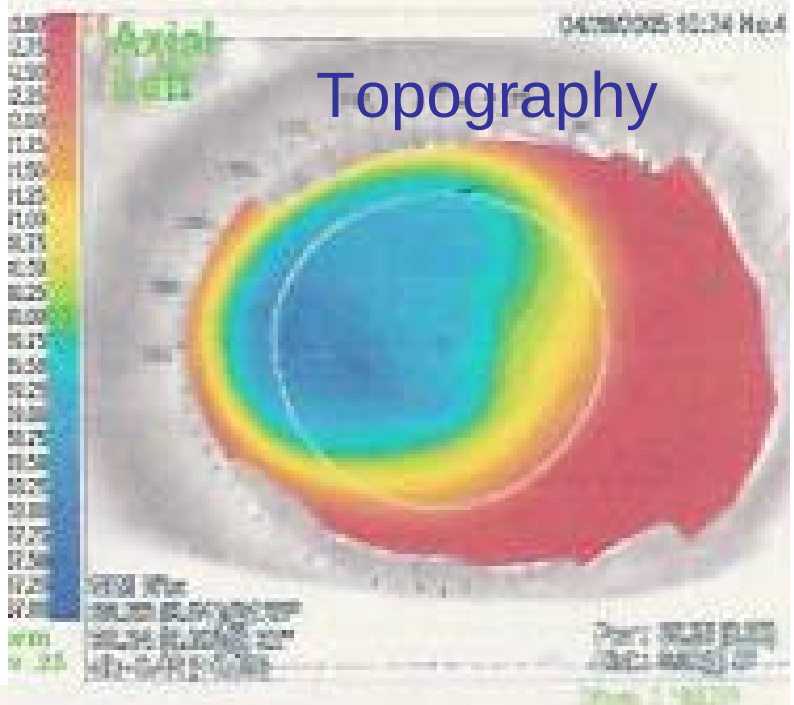
Conclusion

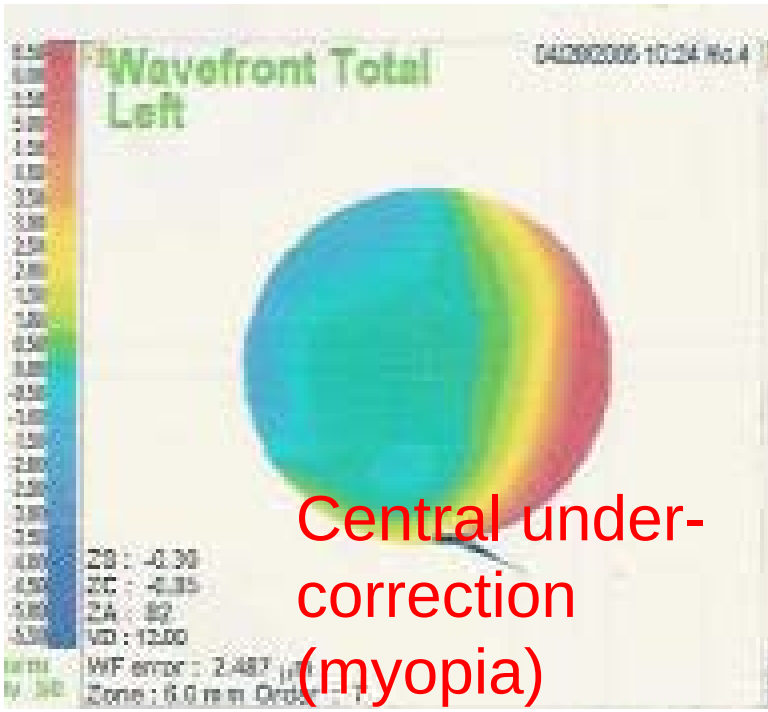
- Increased coma is consistent with decentration as an important cause of residual sphere and cylinder after excimer laser ablation.
- As expected, decentration with high myopia results in greater relative under-correction of sphere.
- Increased residual astigmatism is associated with a relative hyperopic shift in spherical equivalent consistent with decreased effective optical zone.

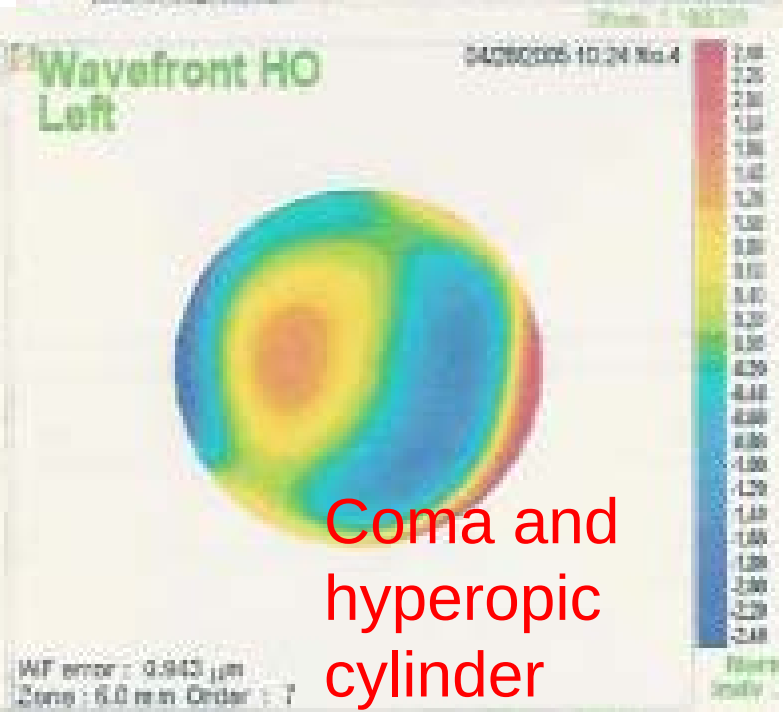
Conclusion

- Maximizing centration should improve the predictability of the refractive outcome

Decentration of the Ablation





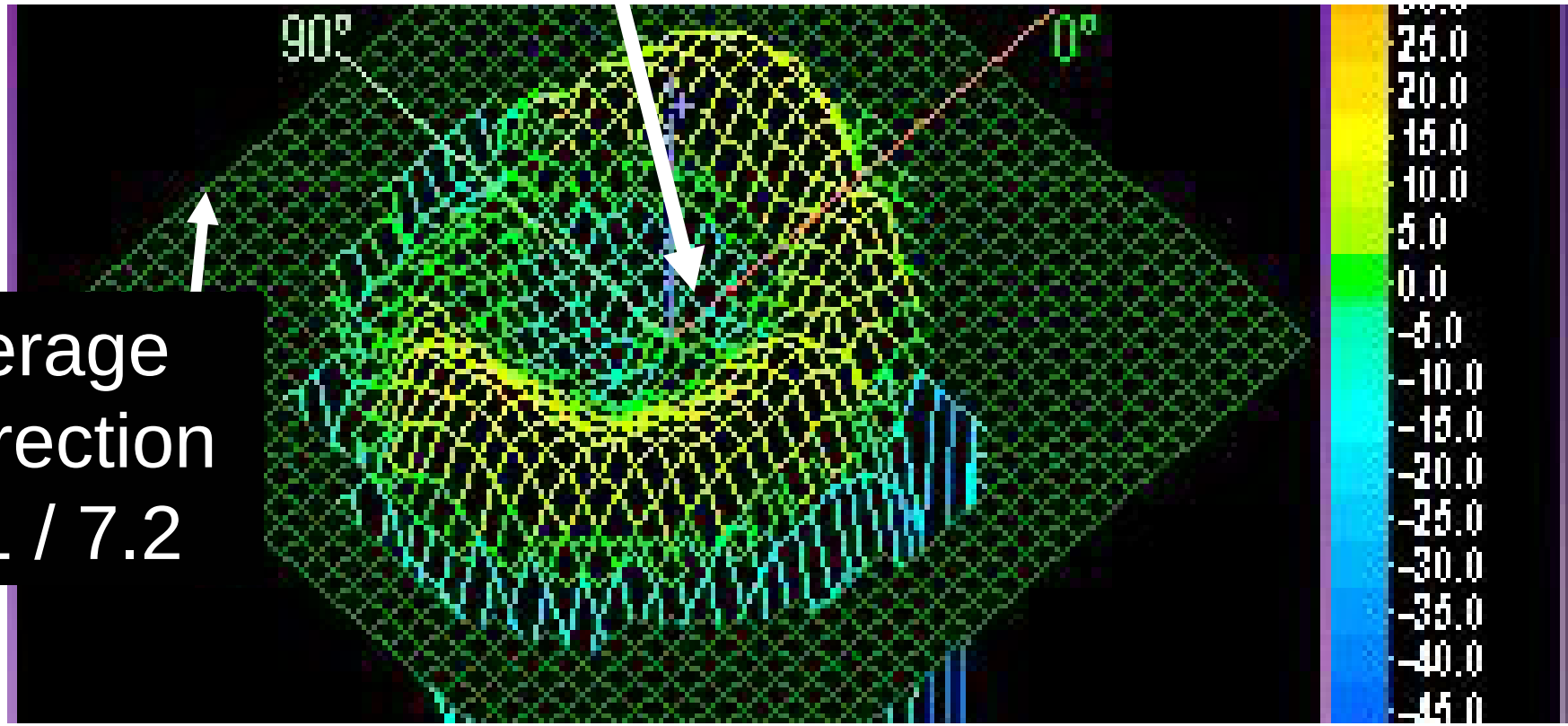


Best fit regression modeling of excimer lasers profiles

Mark Johnston ASCRS 2007

- **Purpose:** To compare excimer laser ablation patterns with a best fit regression formula of postoperative refractive outcomes. To compare our results with previous studies which show that, with increasing depth of spherical (and toric) ablation, there is a decreased effective optical zone, overcorrection and increased induced spherical (and toric) aberration.
  Methods: Refractive outcomes were analyzed using a commercial outcome software program, the Refractive Surgery ConsultantTM (RSC), which provides a best fit regression nomogram equation for both sphere(S) and cylinder(C). Standard graphing software (StudyworksTM) was used to plot the results within normal treatment profiles. Laser profiles studied were Visx StarTM with a peripheral blend (Standard); Visx CustomVueTM, one to six diopters (Low-Wavefront); Visx CustomVueTM, six to eleven diopters (High-Wavefront). Nomographs used to interpret the results were in minus cylinder for Standard and High-Wavefront ablations, and plus cylinder for Low-Wavefront. Surface ablation patterns were determined by reviewing surgical video and corneal topography.
  Results: Results for Standard ablation (202 eyes) are S=1.21s +0.04s2 +0.04sc (r2 0.97) and C=0.06s +0.011 s2 +1.18c +0.03c2 +0.05sc (r2 0.97). Results for Low-Wavefront ablation (1044 eyes) are S=1.07s +0.01s2 +0.17c +0.08c2 +0.05sc (r2 0.97) and C=1.02c +0.01sc (r2 0.85). Results for High-Wavefront ablation (179 eyes) are S=1.22s +0.04s2 (r2 0.98) and C=1.32c +0.06sc (r2 0.97). Standard and High-Wavefront ablations show non-linear increasing overcorrection with increasing sphere, cylinder and sphere times cylinder (coupling). Low-Wavefront ablation shows increasing sphere overcorrection with high cylinder and minimal over or under-correction of cylinder. Patients presenting for enhancement have less induced spherical aberration with Low-Wavefront (0.11u) and High-Wavefront (0.26u), than with Standard (0.52u).
  Conclusion: The calculated nomograms are consistent with the previously reported association between overcorrection and imbalance between central and peripheral ablation. Newer wavefront ablation profiles require less nomogram adjustment and induce less higher-order aberrations than previous standard ablation profiles.

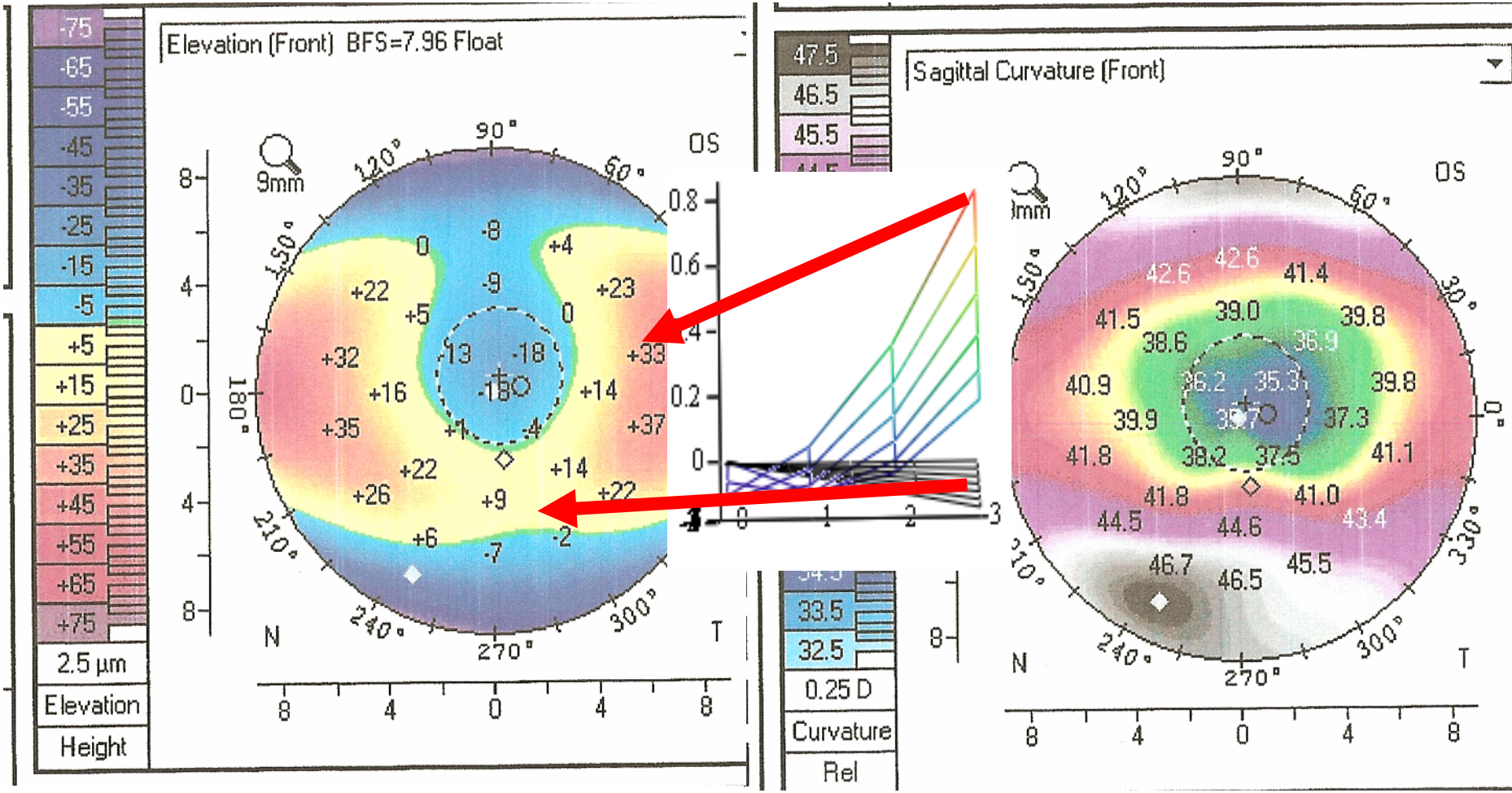
- Effective Optical Zone (EOZ) is the area within one diopter of central power
  - Significant role of Stiles-Crawford effect (Inverse Square)
- Both decreased ablation width and increasing spherical aberration
  - decreases the effective optical zone
  - increases the overcorrection



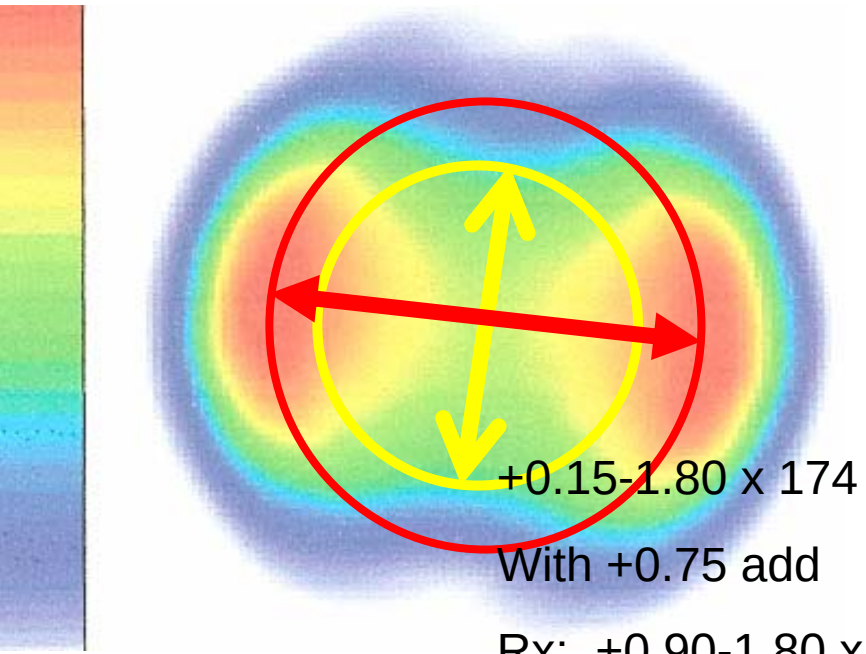
Average Correction 8.21 / 7.2

Ablation of high sphere/cylinder has significant spherical aberration, an associated hyperopic shift and a reduced “effective optical zone”

Data from Mark Johnston MD, Best Fit Regression Modeling of Excimer laser Ablation, ASCRS 2007, see attached abstract



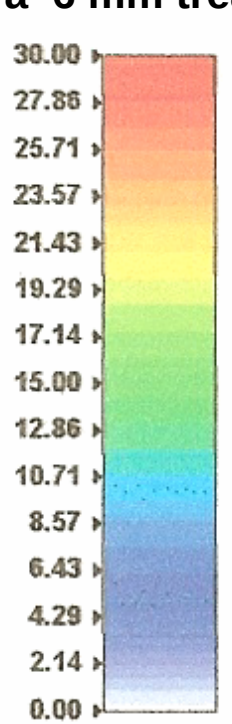
- Left: Wavefront minus cylinder ablation treatment can be divided unto
  - a mixed cylinder with an “effective treatment zone” of about 4.5 mm (yellow circle)
  - The negative spherical ablation should match the “effective treatment (cylinder) zone” rather than the larger hyperopic cylinder zone (Red circle)
- **Right: Routine Hyperopic astigmatism with a 6 mm treatment zone (green circle)**

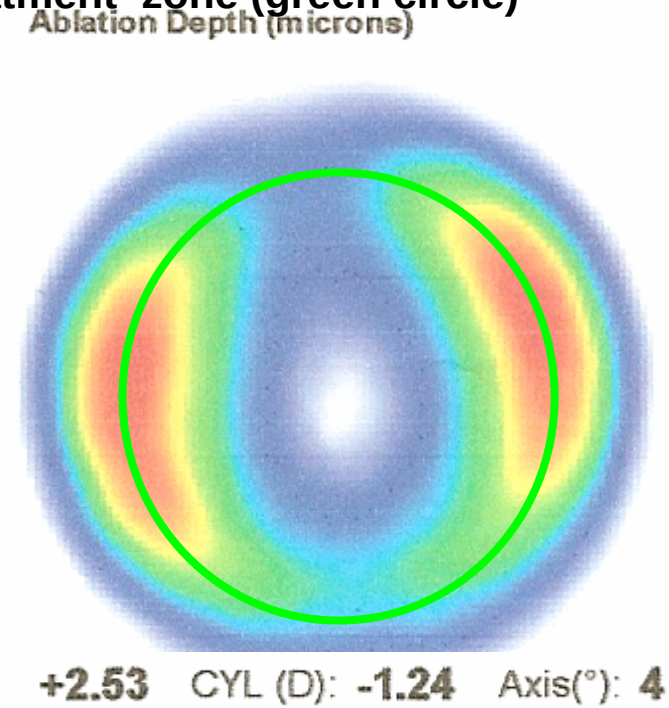


+0.15-1.80 x 174

With +0.75 add

Rx: +0.90-1.80 x 174





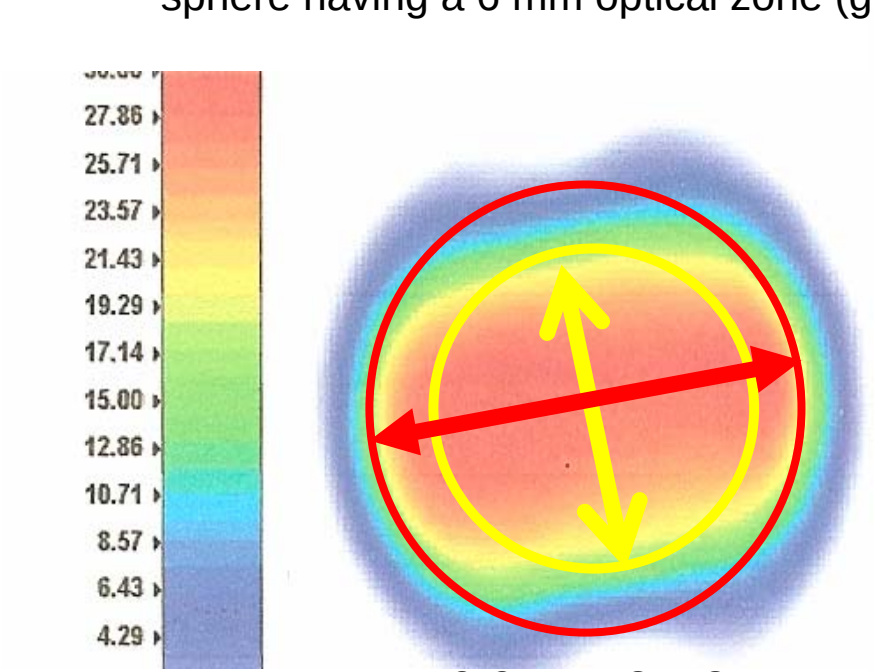
Treatment Parameters

Optical Zone (mm):	6.00
Ablation Zone (mm):	9.00
Max. Ablation Depth (µ):	28.4
No. of Tissue Pulses:	311
Treatment Time (sec):	16

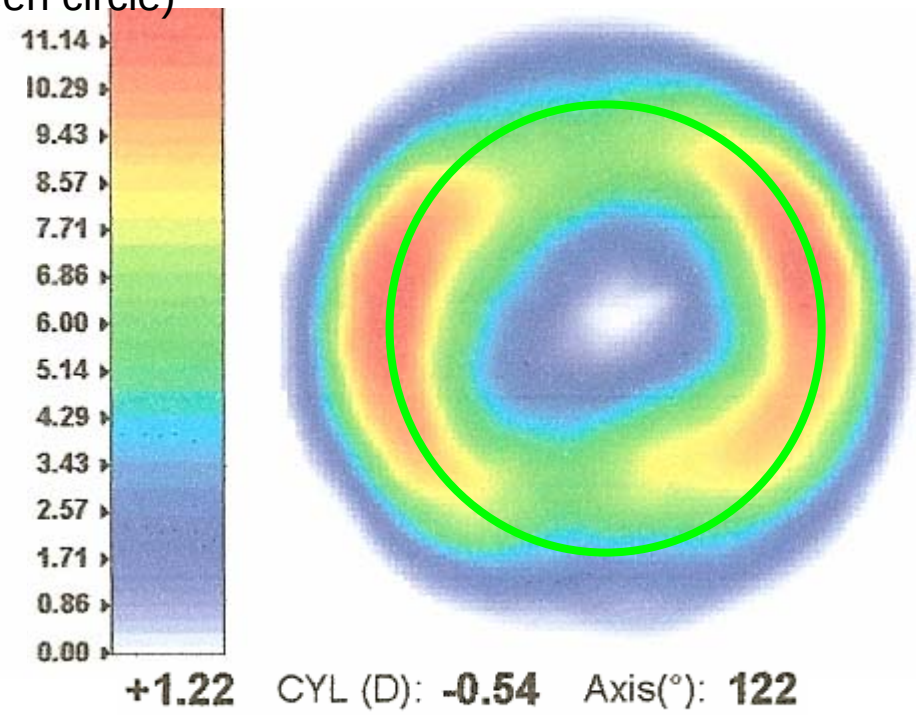
Treatment Parameters

Optical Zone (mm):	6.00
Ablation Zone (mm):	9.00
Max. Ablation Depth (µ):	29.1
No. of Tissue Pulses:	543
Treatment Time (sec):	27

- Ablation (Left): Minus cylinder (Wavefront) treatment can be divided into
  - a minus cylinder with an effective treatment zone of about 4.5 mm (yellow circle)
    - True wavefront should blend slowly (atoric blend) to 6.0 mm
  - A "neutral" axis set to 6.0 mm (red circle)
- Outcome (Right) Significant spherical overcorrection
  - consistent with the original calculation being based on both the plus cyl and negative sphere having a 6 mm optical zone (green circle)



+0.05-1.53 x 8



+1.22 CYL (D): -0.54 Axis(°): 122

Treatment Parameters

Optical Zone (mm):	6.00
Ablation Zone (mm):	9.00
Max. Ablation Depth (μ):	28.4
No. of Tissue Pulses:	311
Treatment Time (sec):	16

Treatment Parameters

Optical Zone (mm):	6.00
Ablation Zone (mm):	9.00
Max. Ablation Depth (μ):	29.1
No. of Tissue Pulses:	543
Treatment Time (sec):	27

Maximizing the blend zone to 9.0 will increase optical zone to 6.00/7.00

OD -0.80 DS -2.01 DC x 98° @12.5 mm (4.0 Rx Calc)
26-Jan-2007 10:31:56 W.F. Diam (mm): 6.00 High Order: 8.3 %
Eff. Blur (D): 2.15 Rms Err.(µ): 2.79 Quality: ✓ ✓ ✓ ✓

Manifest: -1.17 DS -1.39 DC x 91° @ 12.50 mm
Cycloplegic:
Auto:
Auto+Cyclo:
K1 (D): 44.53 K2 (D): 45.79 K2 Axis(°): 103
Corneal Thickness (µ): 512
Scotopic Pupil Size (mm): 6.00

Limbus Diam: 12.8 mm Pupil: 6.6 x 6.5 mm @85° (avg 6.5)

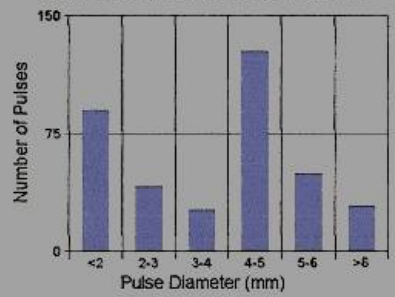
Treatment Type: LASIK Correction Type: CustomVue Nomogram Change: +10%
Physician Adjustments - SPH (D): +0.00 CYL (D): +0.00 Axis(°): VTX(mm): 0.00
Total Correction - SPH (D): -0.80 CYL (D): -1.92 Axis(°): 98 VTX(mm): 0.00

Treatment Parameters
Optical Zone (mm): 6.00 x 7.00
Ablation Zone (mm): 9.00
Max. Ablation Depth (µ): 41.3
No. of Tissue Pulses: 366
Treatment Time (sec): 19

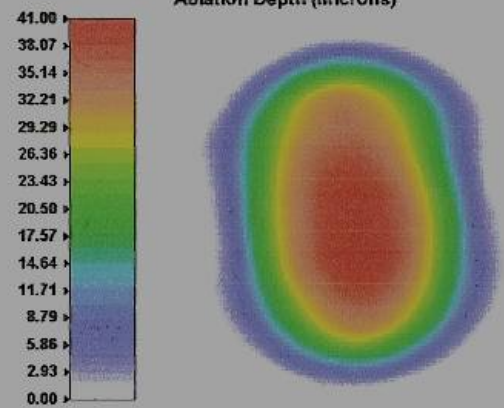
Surgical Parameters
Flap Diameter (mm): 9.50
Flap Thickness (µ): 140
Residual Bed Depth (µ): 331

Additional Information
The Manifest and WaveScan refractions do not match

Distribution of VSS Pulse Diameters



Ablation Depth (microns)

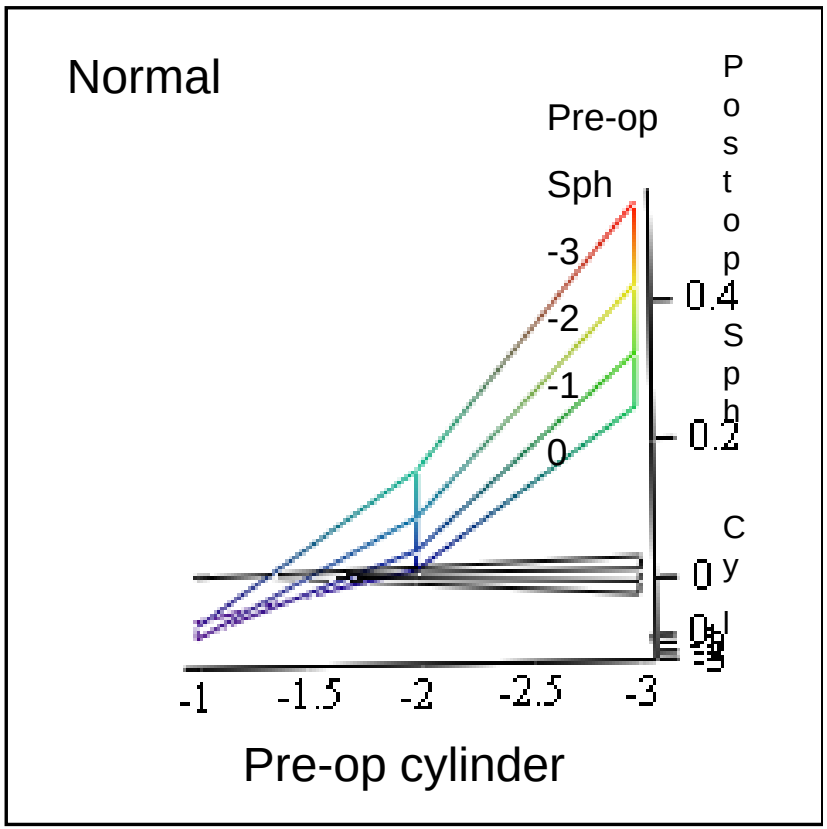


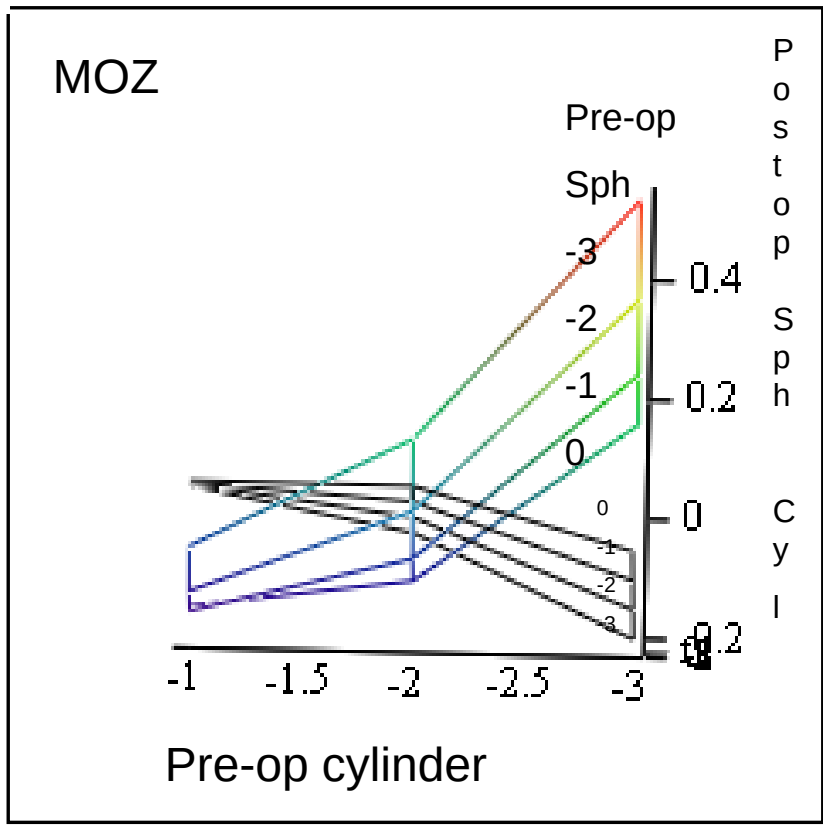
Normal vs maximized optical zone (MOZ)

Best fit curves calculated using the RSC best fit nomogram show:

Less induced plus sphere with maximized optical zone(6x7mm)

Less plus spherical equivalent with wide blend zone(6x7mm)



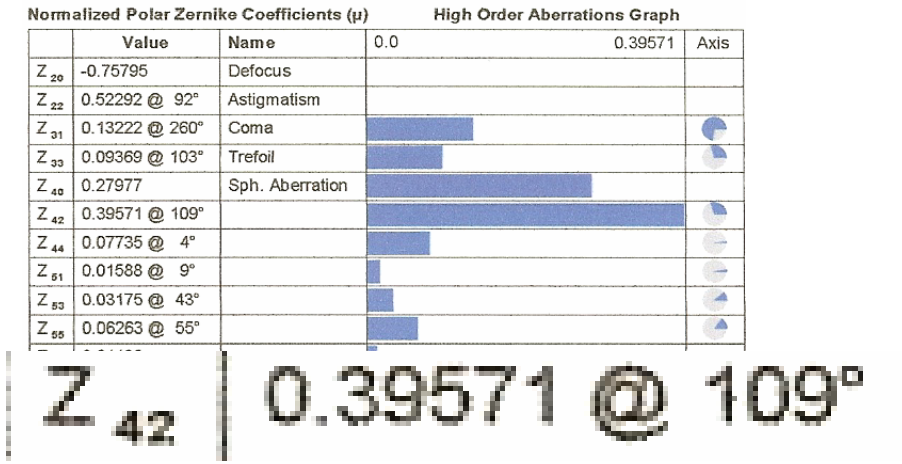


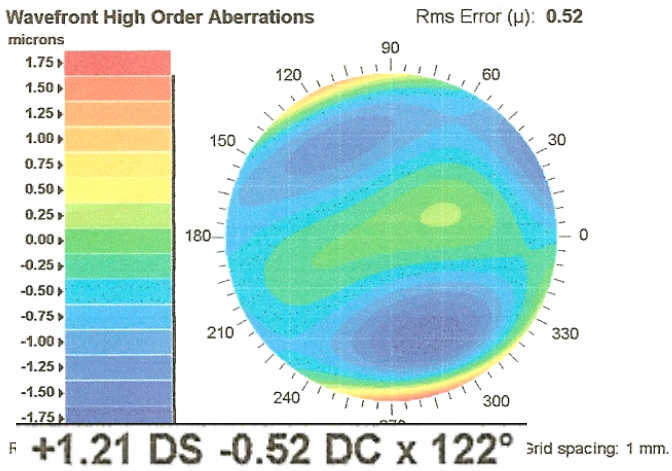
July 2006 n=1044

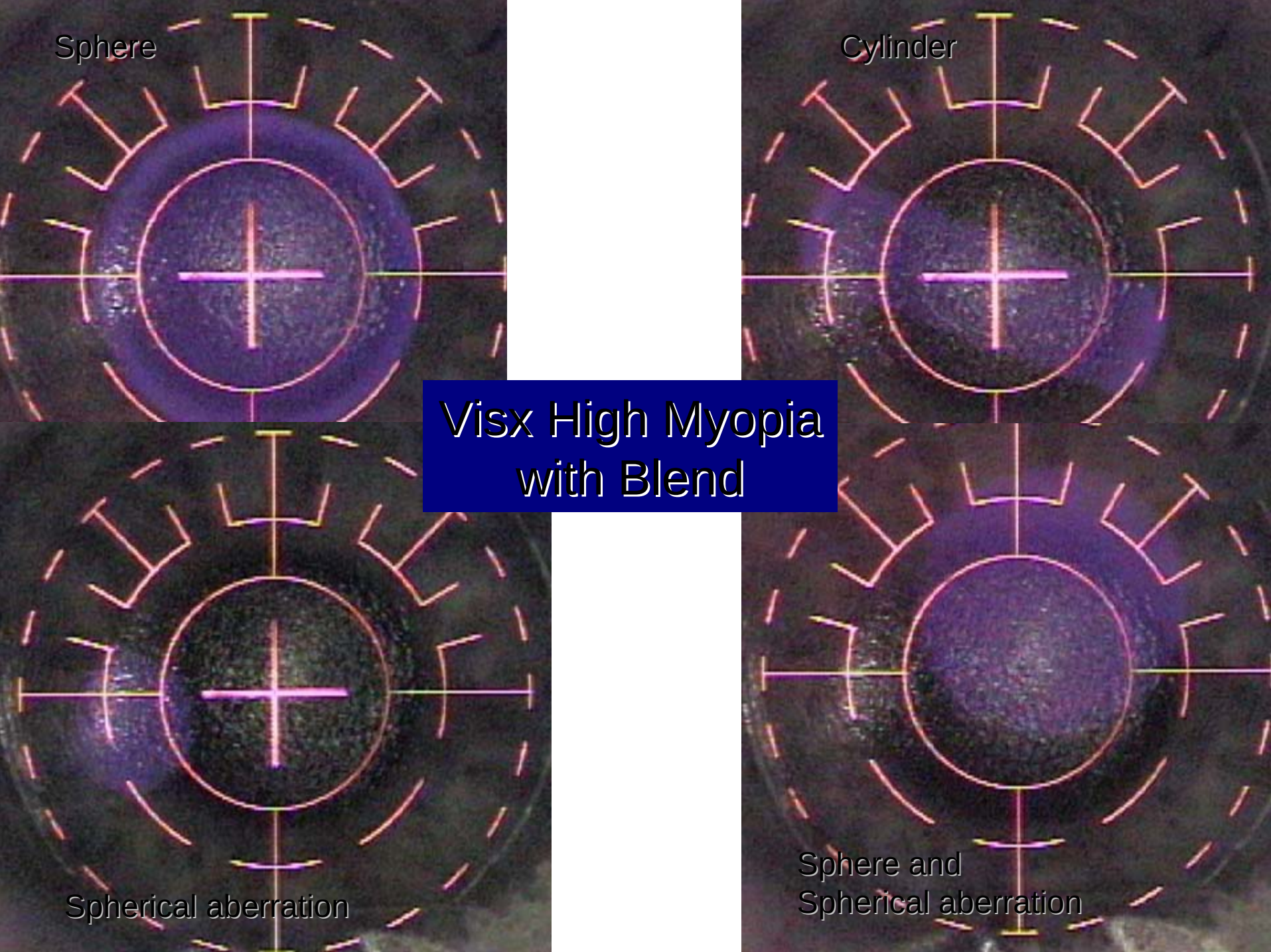
March 2007 n=753

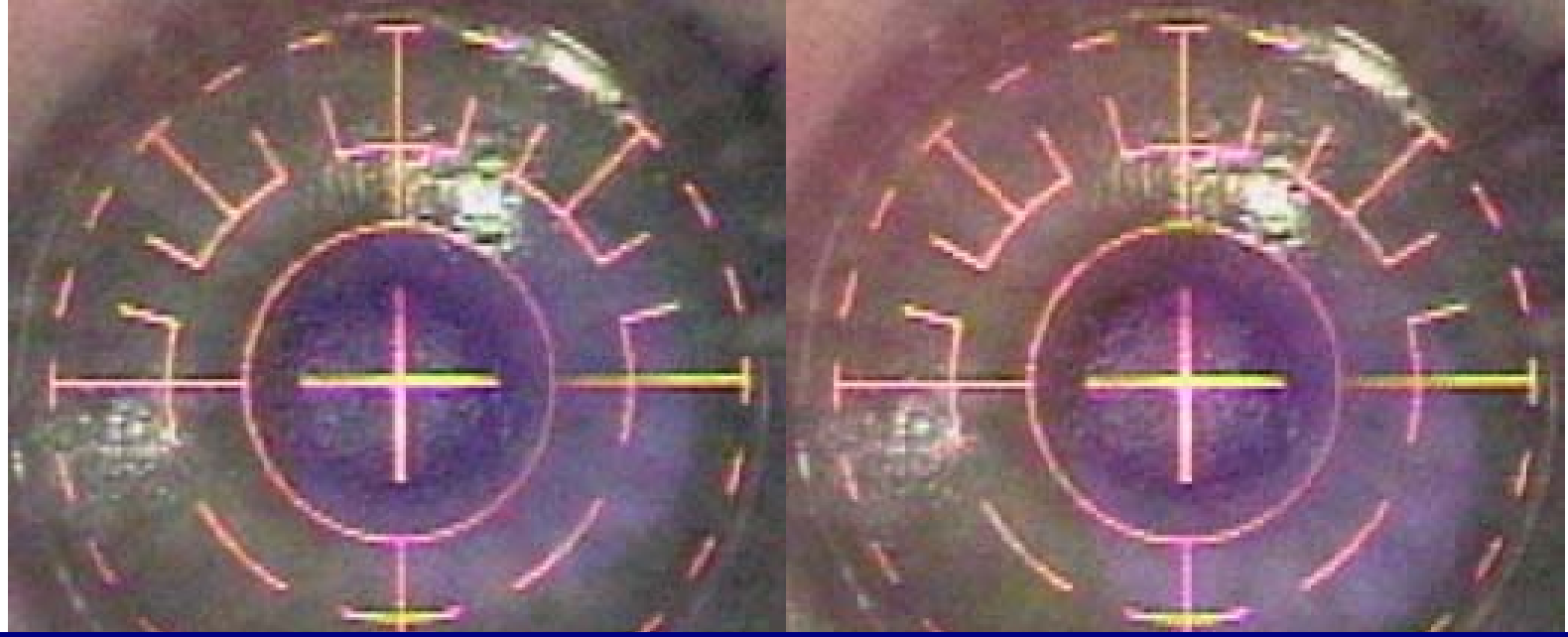
Maximizing clinical outcomes

- For cylinder over -1.50, increasing the treatment zone decreases
  - The spherical overcorrection
- Our present Cylinder Nomogram adjustment for treatment with VISX wavefront
  - decrease the minus sphere ablation by 0.1 for all cylinder over -1.50 and decrease an additional 0.1 for each -0.50 of cylinder over -1.50



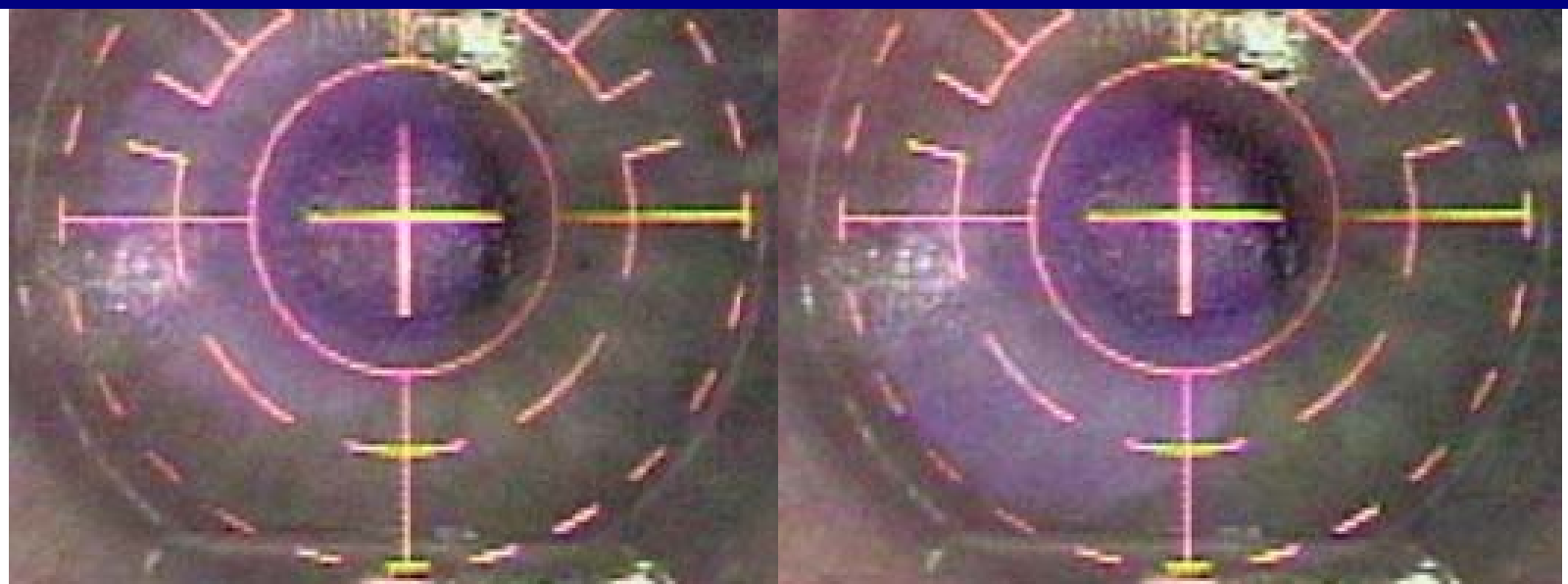



Sphere
Cylinder
Visx High Myopia
with Blend
Spherical aberration
Sphere and
Spherical aberration



Visx Minus Sphere Wavefront Ablation :

Note how sequential laser spot rotate around the central axis



Video

- Attached video shows a wavefront ablation of minus astigmatism
  - Note the treatment at 3 and 9 position is similar to a hyperopic cylinder ablation
  - Note how the central spots are like a minus sphere wavefront ablation
    - except for some dropped spots at the 12 and 6 position