


## Refractive and Refractive Cataract Surgery: What can we treat and who don't we want to treat

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### Financial Interest Disclosure



- Alcon – consultant/grants/research/speaker/travel
- Allergan – consultant/grants/research/speaker/travel
- B & L – consultant/travel/speaker
- LaserACE – consultant/MAB
- LenSx – consultant/research/MAB
- Nexus – consultant/research/MAB
- Nidek – consultant/grants/research
- Refocus – consultant/grants/research/speaker/travel
- TLC-medical director
- 1800 Doctors-MAB

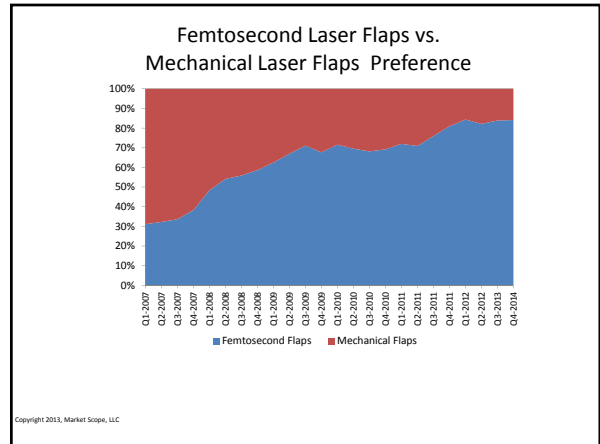
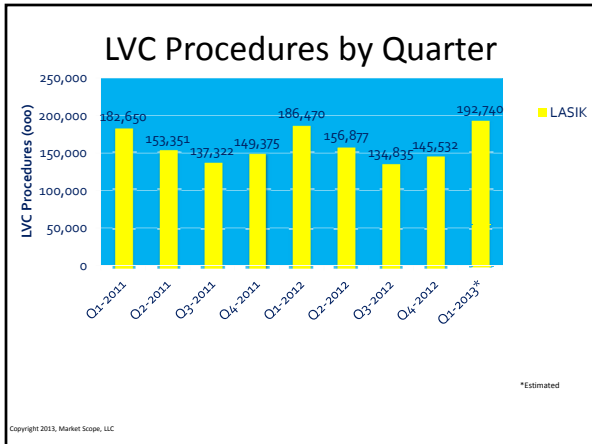
## Refractive Surgery

### Who are our patients?

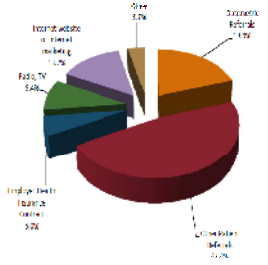


## Where are we with Laser Vision Correction Today?

Life lessons from  
Dr. Karl.....



### Where are the Patients Coming From?



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### Key Take Aways from Current Data

- LVC procedures are on the rise again.
- Femtosecond flaps for LVC surgery are now the most common flaps in the US.
- Satisfied patients are the best source of new patients.

### External Factor Affecting LVC

#### Demographic shift

- Baby Boomers
- Millennials
  - Gen X profile
  - Gen Y profile

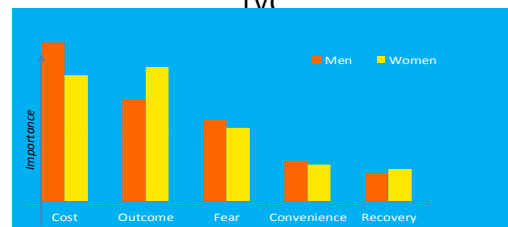
Figure 1: Size of Adult Population (millions) and Age Range (years)

	1988		2010		2020	
	50L	65L	50L	65L	50L	65L
Born Before 1945	62.5M	93+	38.4M	65+	21.8M	75+
Born 1945 - 1964 "Baby Boomers"	77.8M	3-37	77.7M	4-64	69M	16-74
Born 1977 - 1995 "Generation Y"	15M	1-21	64.0M	18-33	70.0M	15-43

Only generation besides the Boomers to have ≥ 4 million births per year

Source: CBST MMA ACCS 2012 Dear Valley Meeting

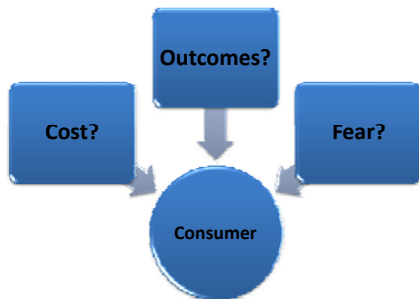
### Cost and the outcome are considered the most important factors in the decision to have LVC



- For women, the outcome was the top factor, followed closely by cost
- For men, however, cost was the top factor by a fairly large margin

Source: Consumer Barrier Research N=73, Data on File

### Consumer Challenges to Consider

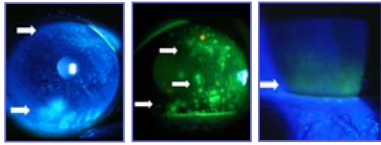


### What are Refractive Patients Looking for?

#### Quality of Life

- Education on their options
- Improvement in their vision
- Spectacle Freedom
- **A surgeon's recommendation**

### What about the ocular surface?



Lid pattern staining    Diffuse staining    Meibomian gland disease  
Aqueous tear deficiency

### Regimen V. NO REGIMEN AND THE EFFECT ON Postoperative day 1 UCVA

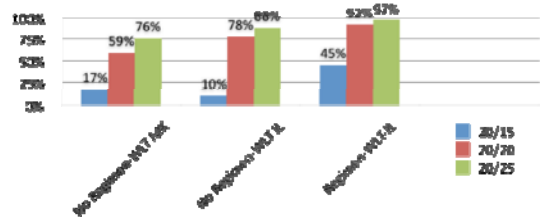
- **Topical Corticosteroid**
  - 4x/day for the days prior to surgery
- **Topical Fluroquinolone**
  - 4x/day for the days prior to surgery
- If you work in a medical environment,
- I add Polytrim or Gentamicin
- (Trust Study)

Stonecipher, K, McMackin, K: Postoperative day 1 visions: Is it the laser or the regimen, how do we improve outcomes, ESCRS, Sept 2009

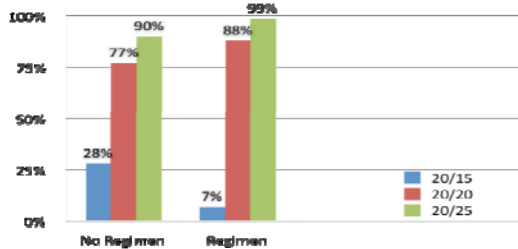
### The Reasons

- Improved **Lid Margin Hygiene**
- Improved Lids promote an improved **Tear Film**
- Improved **Tear Film** allows for better diagnostics on the day of surgery
- What goes in the computer is what comes out
- Better numbers equals **Better Vision** and outcomes as soon as day one
- Better outcomes means **Less Enhancements**

### Final Comparison Myopia



### Final Comparison-Hyperopia



### Conclusions

- There was an improvement in UCVA at the POD 1 level related to the switch from the microkeratome to the femtosecond laser.
- The major improvement in POD 1 UCVA was related to the preoperative regimen of a corticosteroid 4x/day and a fluroquinolone 4x/day for 3 days preoperatively.

## Therapeutics

COULD IT BE WE NEED TO WORK ON THE OCULAR SURFACE?

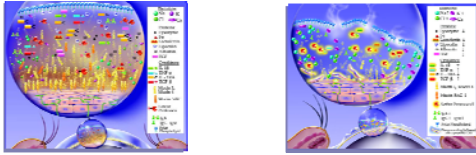


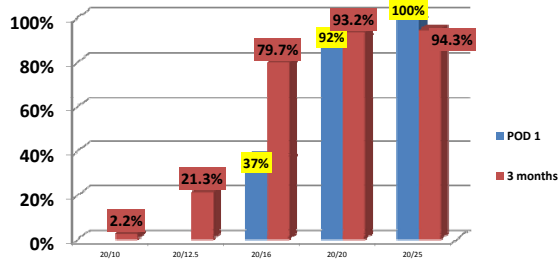
Image from: Dry Eye and Ocular Surface Disorders, 2004

## Dry Eye Following LASIK

- Reported incidence of over 50%, but reports vary widely
  - 21% of LASIK patients seeking consultation for complications complained of dry eye
- Most common within 6 months postsurgery, but may last a year or more
- Reduced incidence with FS laser flaps

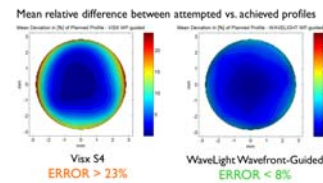
Solomon et al. *J Cataract Refract Surg.* 2002; Albietsz et al. *Adv Exp Med Biol.* 2002; Jabbur et al. *J Cataract Refract Surg.* 2004; Tanaka et al. *J Cataract Refract Surg.* 2004; Toda et al. *Am J Ophthalmol.* 2001. Albietsz et al. *J Refract Surg.* 2002

## Cyclosporine Study

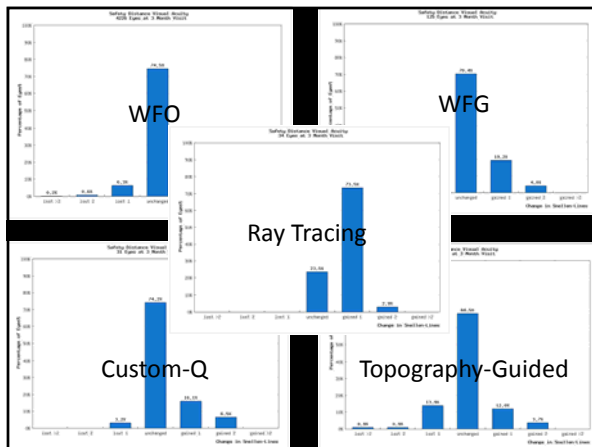


## PROFILE

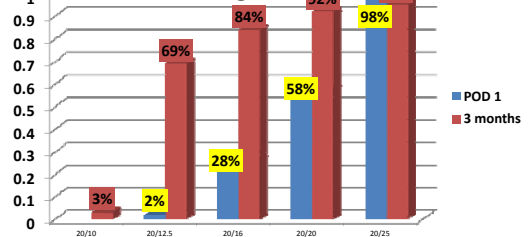
COULD IT BE WE NEED TO WORK ON THE LASER ABLATION PROFILE?



Slide courtesy of PD Dr. Michael Mrochen / IROC - Zurich, Switzerland

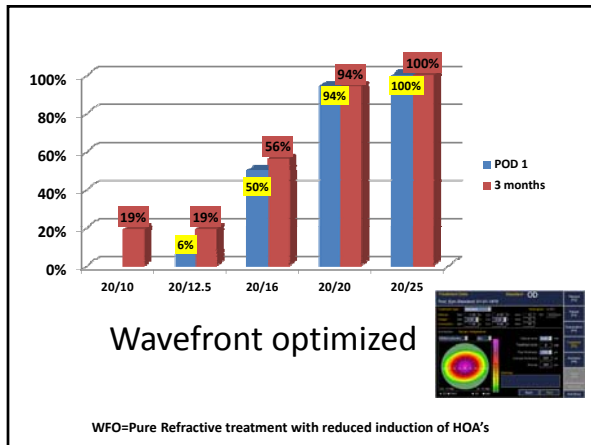
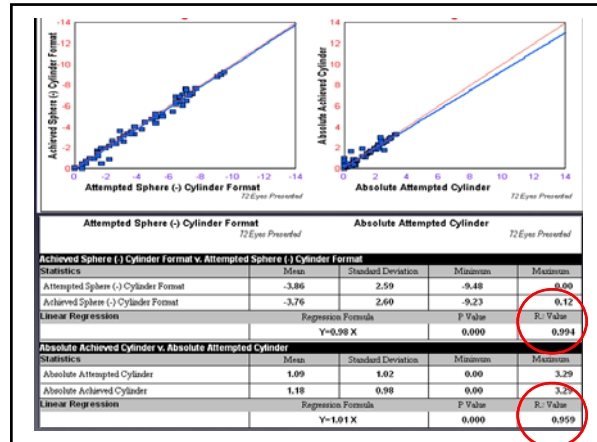
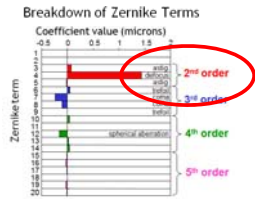


## TCAT



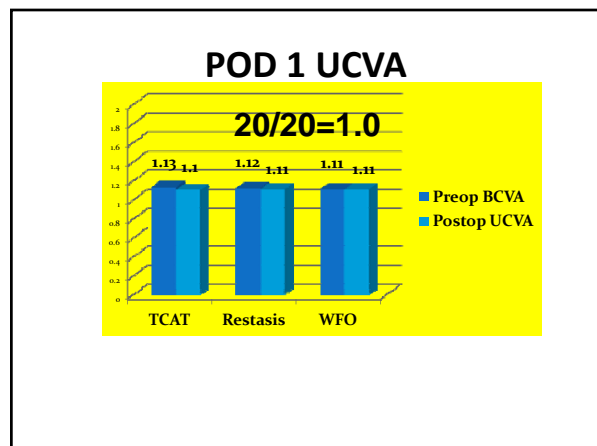
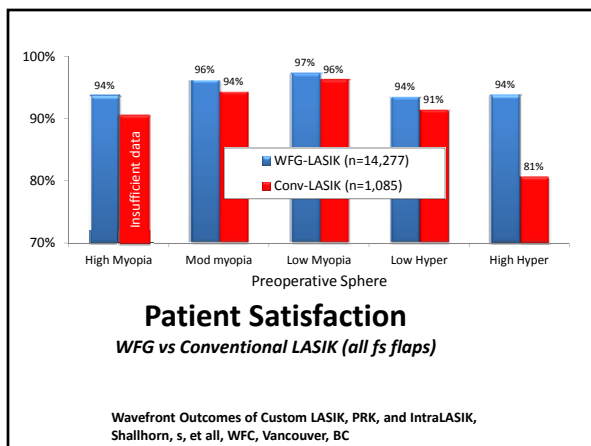
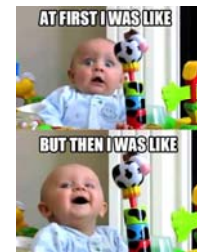
# REFRACTION

COULD IT BE WE NEED  
TO WORK ON THE DATA  
INPUT AND OUTPUT?



## How do you measure success?

Enhancements  
Outcomes  
BCVA=UCVA  
Patient Satisfaction



### Femtosecond and Excimer Lasers



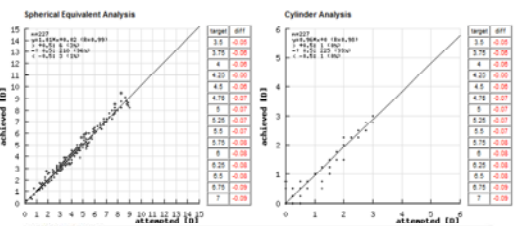
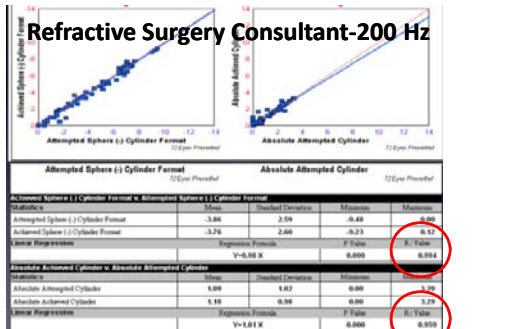
- Combination of femtosecond and excimer laser ablation for 10-12 years.
- Good technologies available by several manufacturers

### Excimer Laser

	VISX Star S4®/IR	WaveLight® Allegretto Wave® Eye-Q
Tracker Speed	60Hz	400Hz
US Rx DFU	Myopia, Hyperopia, Mixed, PTK	Myopia, Hyperopia, Mixed
Wavefront Optimized® Ablation	No	Yes
Wavefront Guided Ablation	Yes	Yes
Iris Registration	Yes	No
Spot Size	Variable 0.65 -5.0mm	0.95mm
Beam Profile	Flat Top	Gaussian
Laser Speed	Variable 6-20 Hz	400 Hz

### Technical Details

### Refractive Surgery Consultant-200 Hz

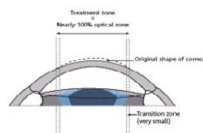


### Internet based refractive analysis-400 Hz

### Optimizing the Optical Zone

- Controlling the peripheral ablation profile allows for:
  - Large, true optical zones
  - Minimized and smooth transition zones
  - And with up to 9-mm treatment diameter, minimal induction of nighttime glare<sup>1</sup>

#### Wavefront Optimized optical zone



1. FDA Clinical Study Supplement #P03000954

Wavefront Optimized® treatments result in a large, true optical zone and a minimized transition zone.

### What About the Laser Technology

Femtosecond Laser


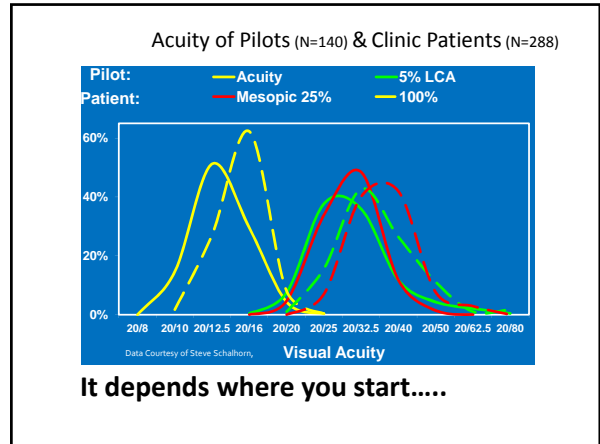


Excimer Laser



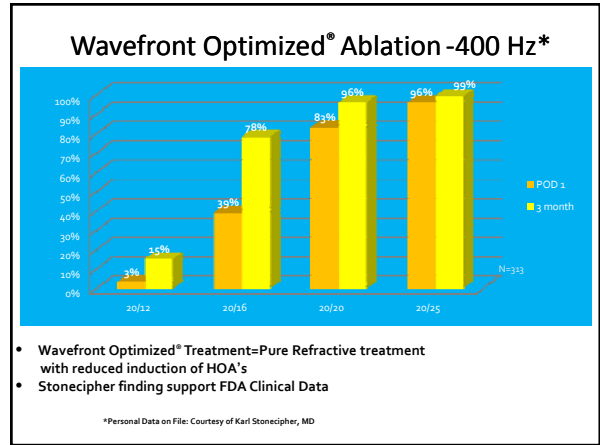
### What about the Data Input

1. Refraction
2. Refraction
3. Refraction
4. Ocular Surface
5. Nomogram


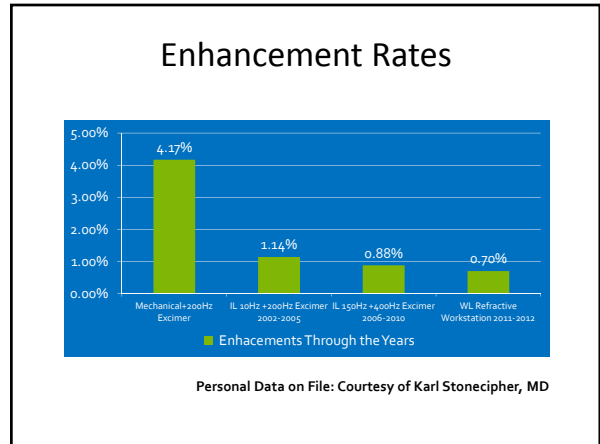
### Nomograms Have Multiple Influences

<ul style="list-style-type: none"> <li>Speed of the Surgeon</li> <li>Technique of the Surgeon</li> <li>Laser Platform</li> <li>Temperature</li> <li>Humidity</li> <li>Ocular Surface Disease</li> <li>Tracking</li> </ul>	<ul style="list-style-type: none"> <li>Manifest Refraction</li> <li>Age</li> <li>Myopia</li> <li>Hyperopia</li> <li>Astigmatism</li> <li>Speed of the laser</li> <li>Registration</li> </ul>
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### Enhancements Cost More than Money

1. Patients think of an enhancement as failure of the procedure
2. Enhancements cost us around \$500.00/case
3. Lost surgery slot and consultation slot
4. Loss of patient referrals because it didn't work
5. Decreased doctor referrals because you had to do it twice
6. Lost play time because your wasting your time doing enhancements.


## Patient Satisfaction

- In our practice patients say:
  - “It went by quickly”
  - “No big deal”
  - “I only remember one laser”
  - “Your staff is awesome”
  - “Your staff treated me like I was part of the family”
- Minimal wait time
- Procedure flow
- Outcomes



## COMPARISON OF POSTOPERATIVE DAY 1 AND MONTH 1 VISUAL OUTCOMES BETWEEN LASER VISION CORRECTION AND FEMTOSECOND CATARACT SURGERY

IS THE FEMTOSECOND LASER REALLY WORTH IT?



## METHODS

- 2 GROUPS (N-103)
  - LENSX
  - CE IOL
- OUR CENTER HAS DONE OVER 1300 CASES (3 SURGEONS)
- THIS SERIES CONSECUTIVE PATIENTS FROM ONE SURGEON (KGS)
- PATIENTS TARGETED FOR PLANO
- 2.7 MM INCISION LENGTH
- PREMIUM IOL CHANNEL PATIENTS
- NO RETINAL OR SYSTEMIC PATHOLOGY
- NO COMPLICATIONS INTROPERATIVELY OR POSTOPERATIVELY

## AXIAL LENGTH

- LENSX
  - AVERAGE 24.2+/-1.3 MM
  - RANGE 20.97 TO 28.46
- CE IOL
  - AVERAGE 23.3+/- .5 MM
  - RANGE 21.25 TO 27.67


## ULTRASOUND TIMES

A 64% REDUCION IN US TIME

Group	Ultrasound Time (Seconds)
LENSX	64.5
CE IOL	133.8

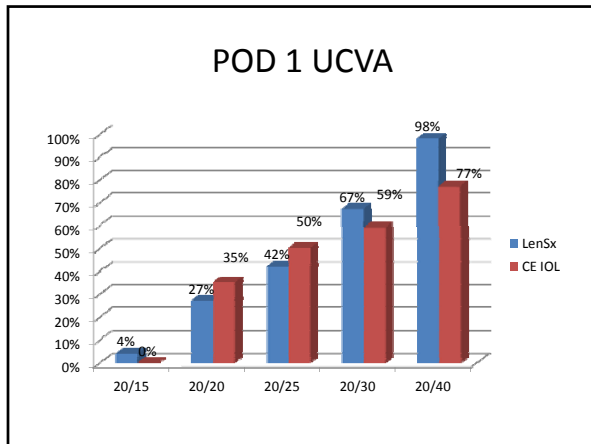
\*Compared to control porcine eyes, femtosecond laser phacoemulsification resulted in a 43% reduction in phacoemulsification power and a 51% decrease in phacoemulsification time.  
Nagy Z, Takacs A, Fikorn T, Sarayba M. Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. J Refract Surg. 2009 Dec;25(12):1053-60.

## POD 1 AVERAGE UCVA




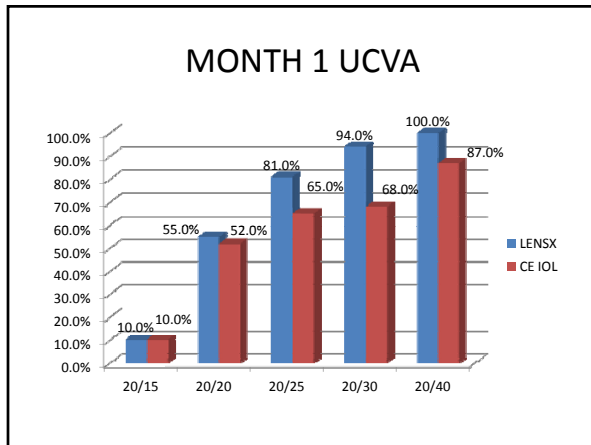
Group	Day 1 Average UCVA
LENSX	0.74+/- .21
CE IOL	0.69+/- .1





### MONTH 1 AVERAGE UCVA

<p><b>LEN SX</b></p> <ul style="list-style-type: none"> <li>• Month 1 Average</li> <li>• 0.9+/-0.19</li> <li>• SE -0.23+/-0.47 D</li> </ul>	<p><b>CE IOL</b></p> <ul style="list-style-type: none"> <li>• Month 1 Average</li> <li>• 0.82+/- .29</li> <li>• SE -0.44+/-0.41 D</li> </ul>
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### WHAT ABOUT LASIK VS FS VS MANUAL?

- Overall 81% of the FS laser group saw 20/30 or better at 1 month compared to 65% of the manual group.
- In a comparative set of LASIK patients, overall 98% of the LASIK group saw 20/20 or better at 1 month and 89% of the group saw 20/20 at POD 1.

### SUMMARY

- 64% REDUCTION IN ULTRASOUND TIME
- POD 1 100%  $\leq$ 20/40 LENSX v 77 % CE IOL
- POD 1 67%  $\leq$ 20/30 v 59% CE IOL
- MONTH 1 100%  $\leq$ 20/40 LENSX v 87% CE IOL
- MONTH 1 94%  $\leq$ 20/30 LENSX v 68% CE IOL

### Enhancements

Is this a dirty word?


**TLC Lifetime Commitment**  
**LIFE** What is the TLC Lifetime Commitment?  
 OT

We have incredible confidence in the stability of the results achieved by patients who have LASIK at a TLC Laser Eye Center, and we stand behind these vision results. The TLC Lifetime Commitment® program helps patients who choose TLC maintain the best possible vision throughout their lives.

**Eligibility for the TLC Lifetime Commitment® Program**  
 The TLC Lifetime Commitment® program covers qualified patients\* who have had laser vision correction at a TLC Laser Eye Center in a participating program. In order to maintain eligibility, patients should keep the following in mind:

- Complete **post-operative** requirements after treatment.
- Complete annual eye exams with your **TLC Laser Eye Center**.
- Ask your TLC Laser Eye Center for complete details.
- Certain changes to your visual system may affect your ability to have an enhancement.

**Benefits of the TLC Lifetime Commitment®**




These are what we do...

## REASONS-LASIK

Poor refractions      Head alignment  
 Poor wavefronts      Regression  
 Dry Eye Disease


## REASONS-CATARACT

Poor biometry      Wrong lens  
 Dry eye disease      Wrong patient  
 Residual Refractive Error      Poor lens alignment



**PEARLS TO LIVE BY**  
 No man left behind...

Doug Katsev



Remember you always get injured on your last run.....

## When to Enhance

- Unhappy with current vision
- No anatomical issues to enhance
- Understands the risks of having a new procedure
- Has the appropriate expectations... this is even **more** important to understand than for the primary procedure.
- UCVA justifies an enhancement
- RX justifies an enhancement

- Aggressive preoperative management of ocular surface disease
- Diagnostics, diagnostics, diagnostics (Know what you have before you start)
- Measure twice cut once
- Monitor your outcomes to help get better results
- Establish patient expectations

How to prevent enhancements


### Incidence of Concomitant Cataract & Dry Eye: A Prospective Health Assessment of Cataract Patients' Ocular surface

William Trattler, MD  
 Damien Goldberg, MD, Charles Reilly, MD, Mark Packer, MD,  
 Parag Majmudar, MD, Eric Donnenfeld, MD, Marguerite  
 McDonald, MD, Jon Vukich, MD, Gregg Berdy, MD,  
 Ranjan Malahotra, MD, and Karl Stonecipher, MD

ePoster Trattler, et al, ASCRS, 2011 71

### Results: Tear Break up Time

- Average TBUT: 4.93 seconds
  - # of eyes with TBUT ≤ 5 seconds: 126 eyes (61.7%)
  - # of eyes with TBUT ≤ 7 seconds: 169 eyes (82.8%)

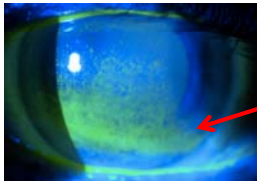


Tear Break up

SLIDE COURTESY OF BILL TRATTLER, MD

### Corneal Staining

- Positive Corneal Staining: 154 eyes (75.5%)
- Central Corneal Staining: 92 eyes (45.1%)



Central Corneal Staining

SLIDE COURTESY OF BILL TRATTLER, MD

### Summary of PHACO Study

- Dry eye signs are very common in patients scheduled for cataract surgery
  - TBUT:
    - More than 60% with very abnormal TBUT (≤ 5 seconds)
      - 83% with TBUT ≤ 7 seconds
  - Corneal Staining
    - 45% with Central staining
  - Schirmer's score
    - 18.6% with very low Schirmer's (≤5mm)

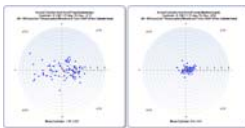
SLIDE COURTESY OF BILL TRATTLER, MD

### A New Approach: WaveTec Vision's Intraoperative Wavefront Technology

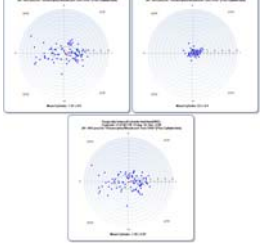


### Standard Toric Cases Cylinder Reduction

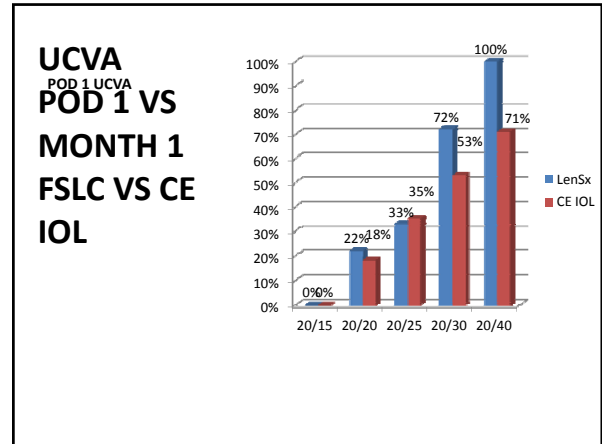
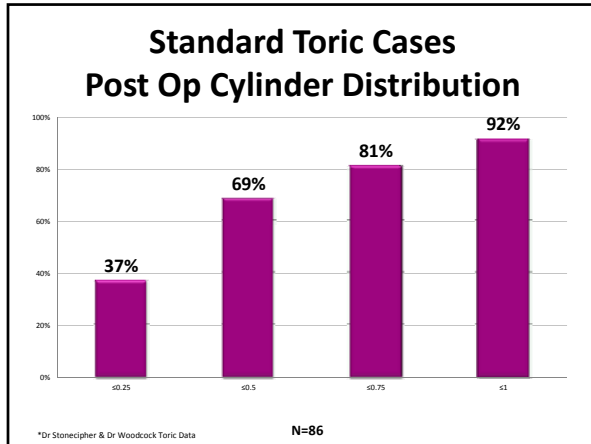
**Pre-op Keratometric Astigmatism**  
N= 86, Mean Cyl 1.91 ± 0.90



**Post-op Refractive Cylinder**  
N= 86, Mean Cyl 0.50 ± 0.40



\*Dr Stonecipher & Dr Woodcock Toric Data



### WHAT WE HAVE DONE.....

- SLIT LAMP LIMBAL RELAXING INCISIONS
- OPERATING ROOM LIMBAL RELAXING INCISIONS

VIDEO COURTESY ERIC DONNENFELD, MD

### The Enhancement

- Primary Procedure was **PRK or LASIK**:
  - Choices for enhancement are PRK, LASIK, Custom (LASIK or PRK), Laser Astigmatic Incisions, AK.
  - +/-MMC
- Primary Procedure was **RK**:
  - May consider RLE or CE IOL depending on age
  - Enhancement procedure can be LASIK or PRK (with MMC)
  - IntraLase is not an option, as the gas can escape through the RK incisions.
- Primary Procedure was **Cataract Surgery**
  - IOL Exchange or Piggyback IOL
  - Choices for enhancement are PRK, LASIK, Custom (LASIK or PRK), Laser Astigmatic Incisions, AK.
  - +/-MMC

### Arcuate Astigmatic Incisions

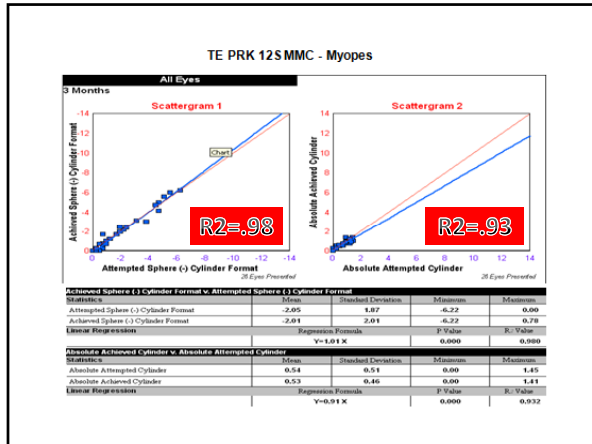
Excellent precision, depth, length, axis

PHOTOS COURTESY OF ROBERT CIONNI, MD

### PRK Enhancements

MYOPIC AND MYOPIC ASTIGMATIC ENHANCEMENTS

CUSTOM, MIXED ASTIGMATISM, HYPEROPIC AND HYPEROPIC ASTIGMATIC ENHANCEMENTS



### Transepithelial PRK

- 50-58 micron PTK
  - 54 micron PTK
    - No previous surgery
  - 58 micron PTK
    - Previous surgery
- PTK diameter 6.5 mm
- Spherical Adjustment
  - 0.66 D
- Standard PRK 6.0 mm
- 12S MMC if indicated
  - Apply in all Enhancements
- Frozen BSS Irrigation
- Medications + BCL

