Nebraska Laser Eye Associates

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www.nebraskaeye.com

Question 1

- Is refractive error a disability fully mitigated by glasses or contacts?

Why do our local National Guard members have Lasik just before or after they are posted?

It’s easy to see why firemen have LASIK.

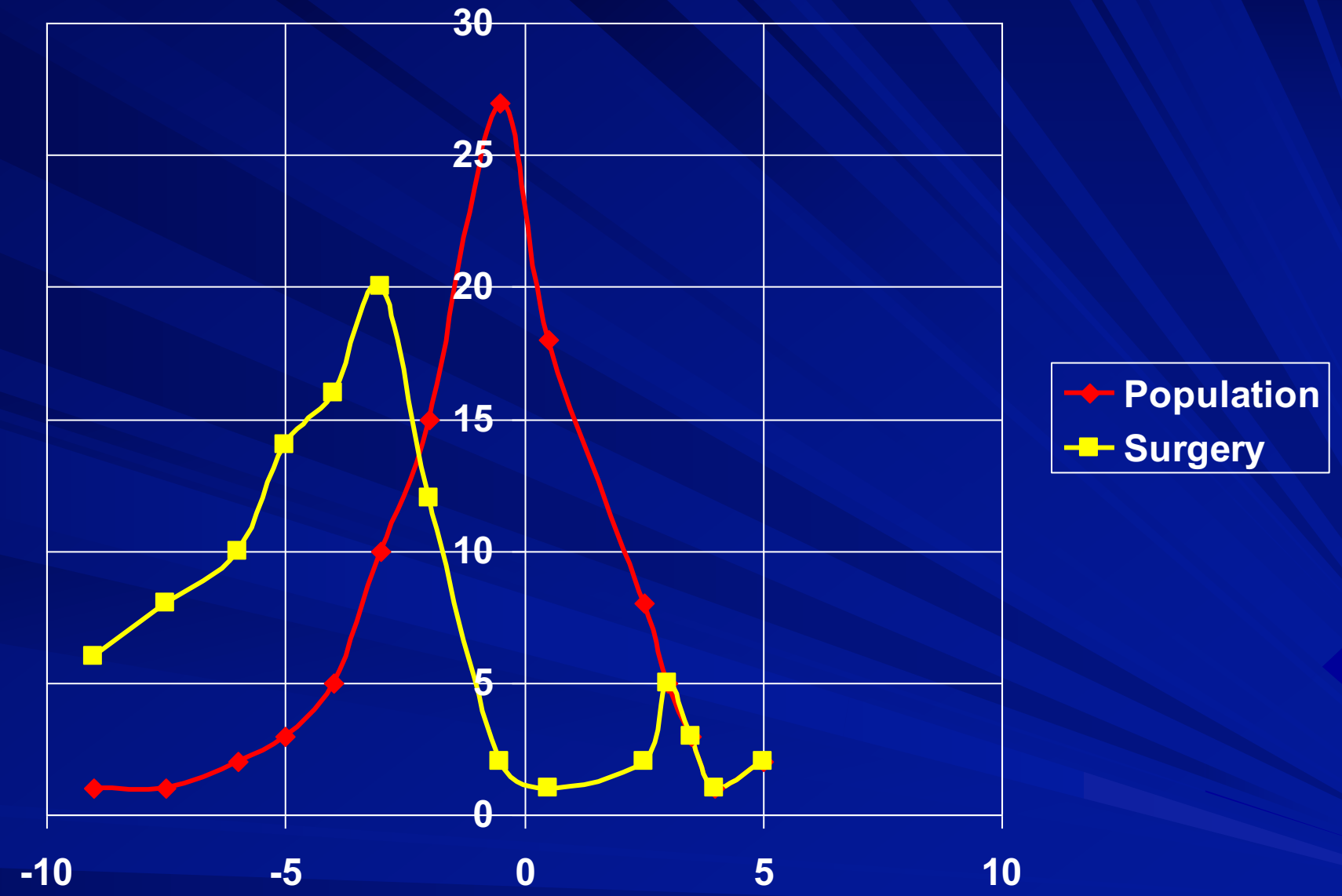
Ask policeman why they have LASIK?

Do glasses give us normal vision?

Do glasses interfere with our play or work ?

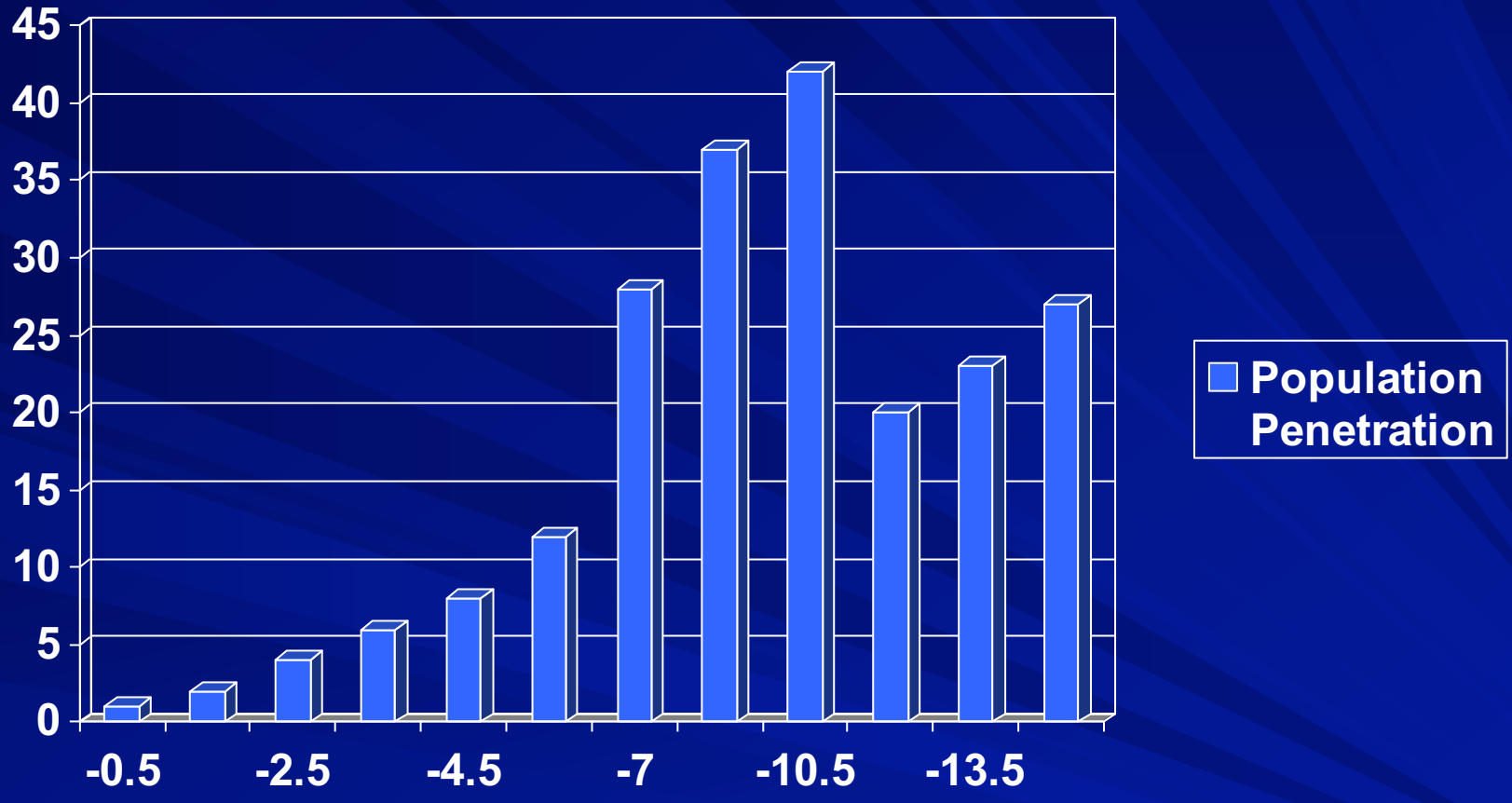
What happens when sand or smoke gets under our contacts?

and we forgot to bring our glasses!



Patients with high myopia seek out refractive surgery in numbers disproportionate to their representation in the general population

Figure: Richard L Lindstrom MD



Twelve to 40% of patients with myopia in the higher ranges undergo surgery compared with 5% to 10% of patients with moderate myopia and less than 5% of patients with low myopia

Figure: Richard L Lindstrom MD

Question 2

- Given that the intent of the law is to make prescription lens, prescriptions, and prosthetic devices more affordable, is the FDA excimer laser system substantially equivalent?

Measure
Prescribe
Dispense

SPECTACLE PRESCRIPTION ONLY

FOR [redacted] DATE 3 OCT 94

ADDRESS

Rx		SPHERICAL	CYLINDRICAL	AXIS	PRISM	BASE
D.V.	O.D.	-3.25	-.25	130		
	O.S.	+.50	-1.00	80		
N.V.	O.D.	+2.00	add			
	O.S.	+2.00				

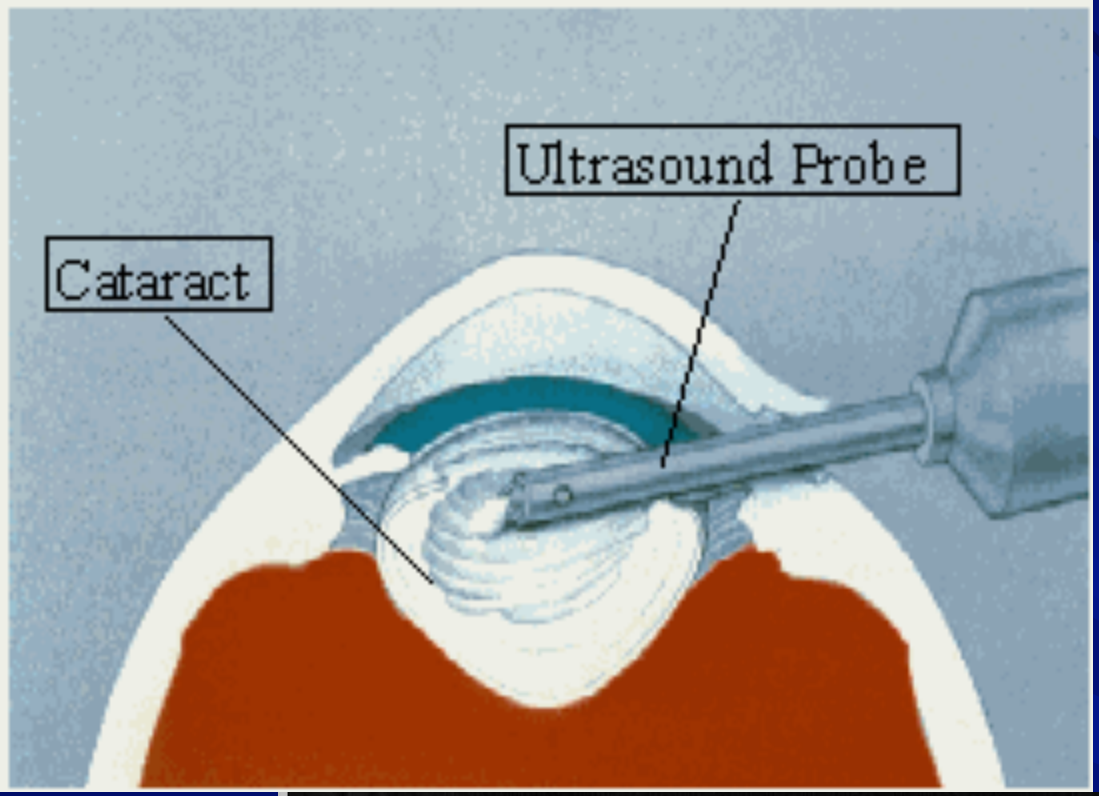
REMARKS P.D. 72, 60

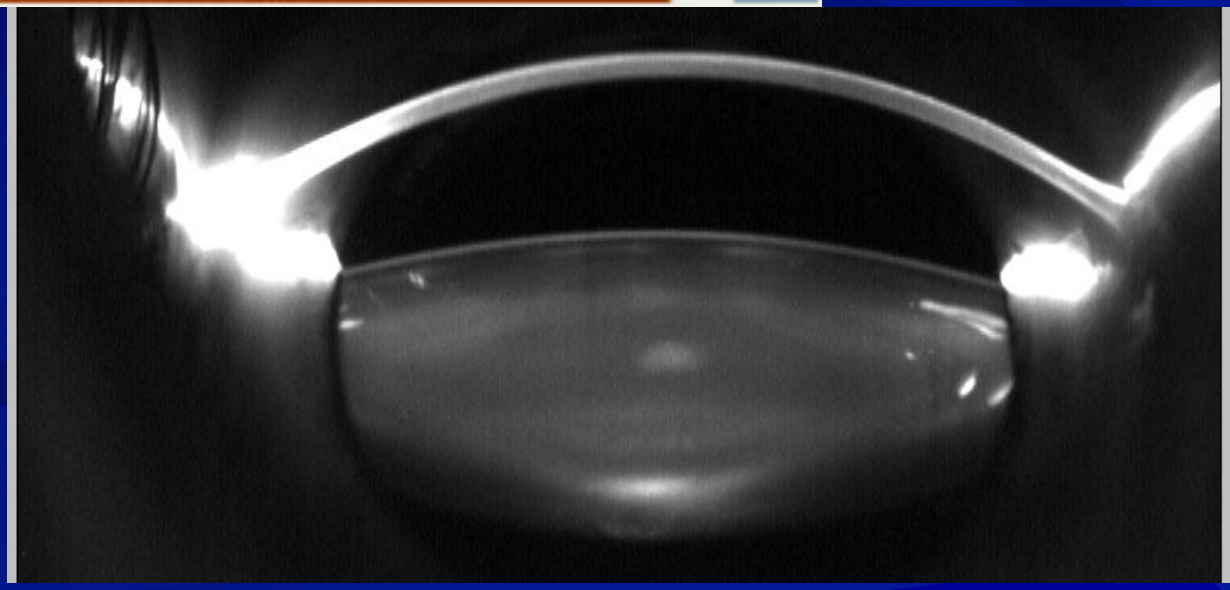
DATE OF EXAM 3 OCT 94 EXPIRATION DATE 3 OCT 95

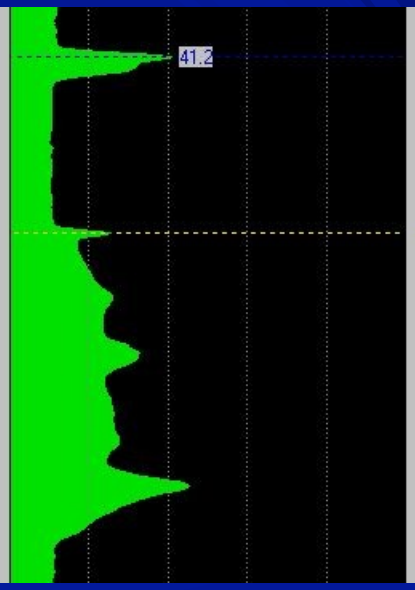
DR. [redacted] LIC. # [redacted]

Measure, Prescribe, Dispense

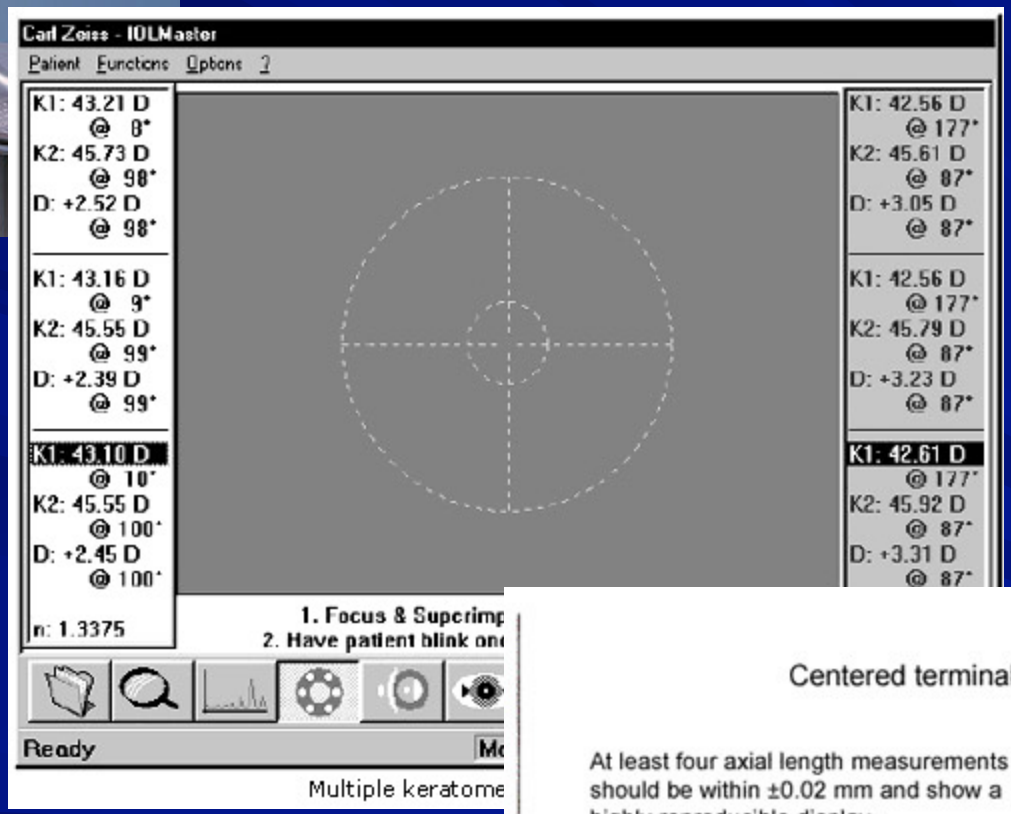
Cataract

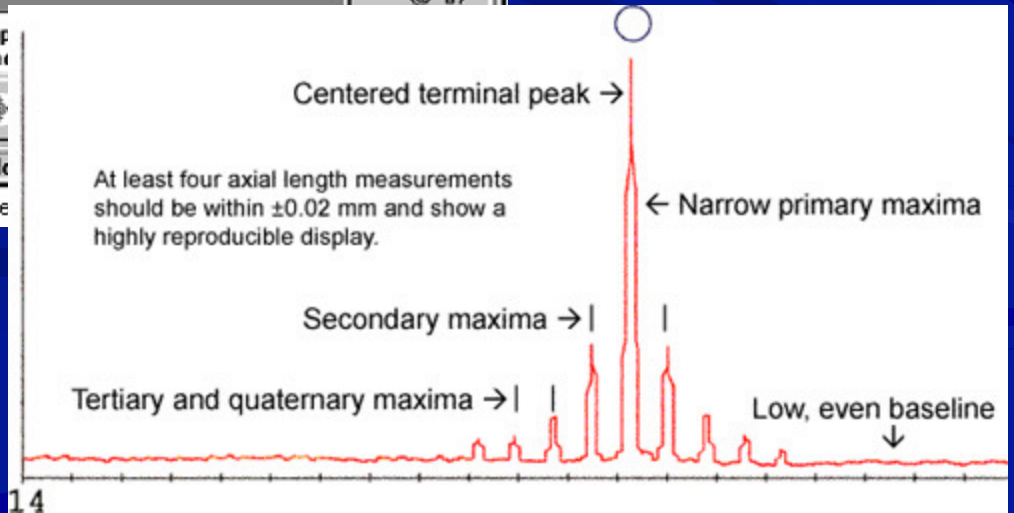






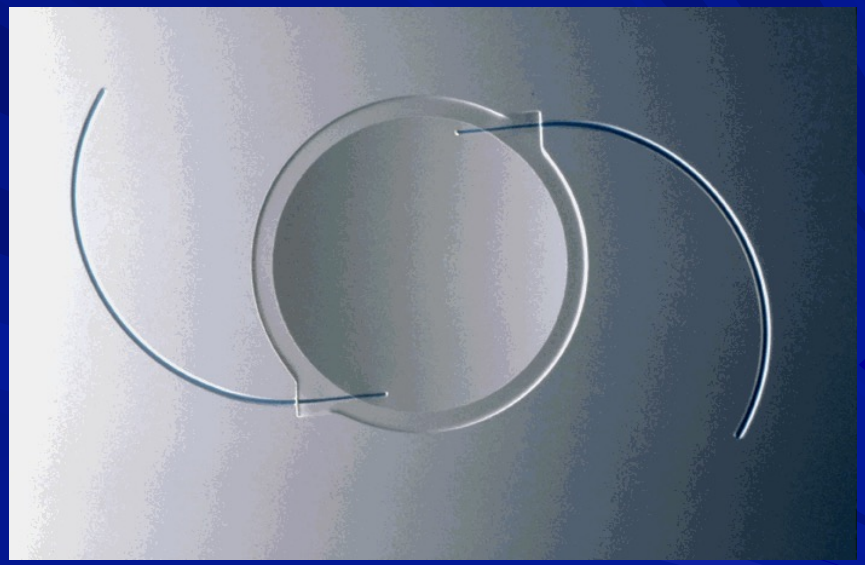
Cataract: Measurements For an Intraocular lens



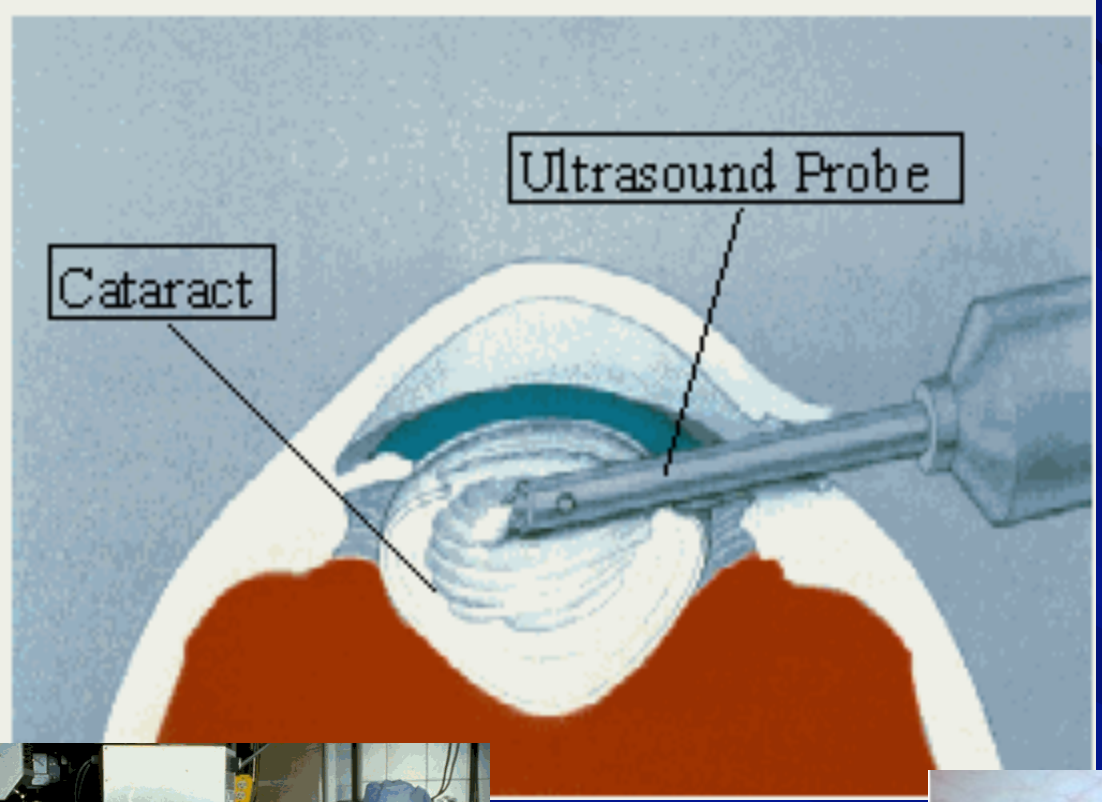


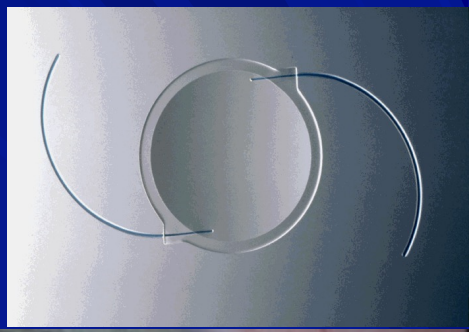
Cataract: Prescription for the Intraocular lens (Hoffer)

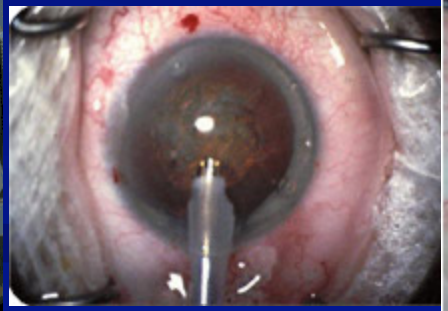
- **Hoffer ProgramsPostop Rx Range**AL
  21.52 Short: use HoffQ
  K1 44.50 K2 43.75 44.2, OK
  TrgRx 0
  IOL Alcon IOL **SAVE** **CLR** SRK/T A
  Con 118.00 25.73
  Holladay 1 SF 1.22 26.10
  HofferQ ACD 4.97 26.34
  26.0 (avg = 26.06)
  CALCULATE **See**
  RangeIOL SRK/T Holl HoffQ
  28.0 -1.73 -1.42 -1.23
  27.5 -1.34 -1.04 -0.85
  27.0 -0.96 -0.67 -0.48
  26.5 -0.58 -0.29 -0.11
  26.0 -0.20 0.08 0.25
  25.5 0.17 0.44 0.61
  25.0 0.54 0.80 0.97
  OKLeft: The main calculation screen using the HofferQ, Holladay 1 and SRK/T formulas. Right: This screen shows refractive results of different IOL powers.

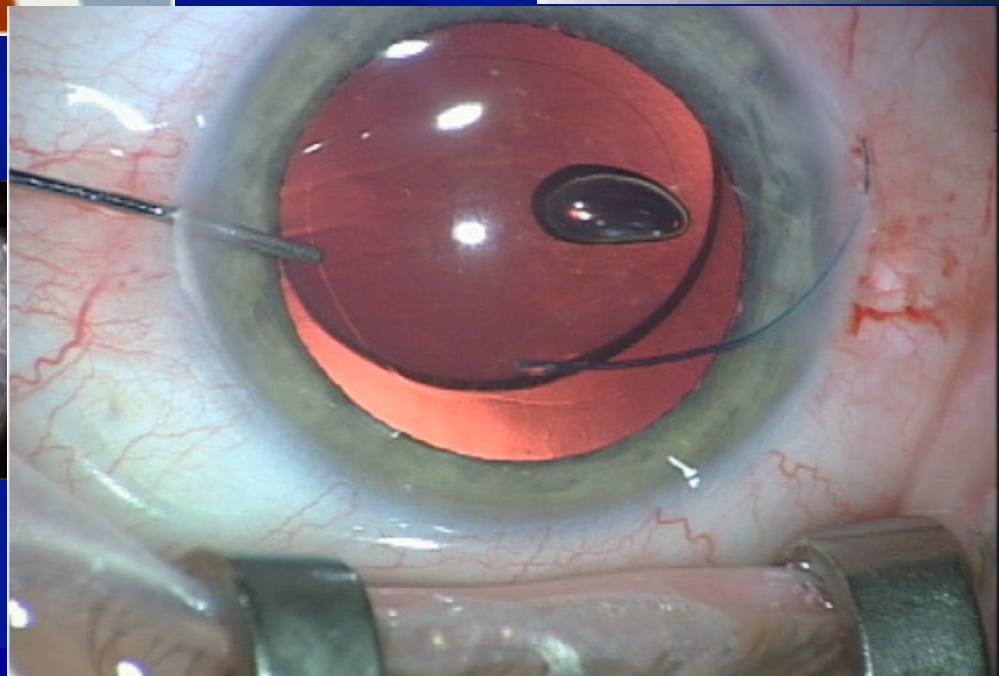


Cataract surgery: Implanting a prosthetic lens









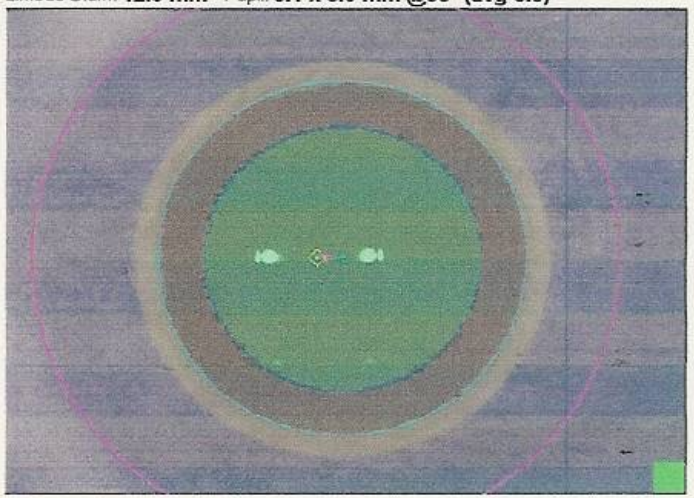
Lasik: Measure

Lasik Prescription

OS +1.12 DS -0.87 DC x 99° @12.5 mm (4.0 Rx Calc)
-02-Sep-2005 12:26:43 W.F. Diam (mm): 6.25 High Order: 11.7 %
Eff. Blur (D): 1.04 Rms Err.(μ): 1.47 Quality: ✓ ✓ ✓ ✓

Manifest: +0.69 DS -0.38 DC x 86° @ 12.50 mm
Cycloplegic:
Auto:
Auto+Cyclo:
K1 (D): 43.60 K2 (D): 44.23 K2 Axis(°): 109
Corneal Thickness (μ): 474
Scotopic Pupil Size (mm): 6.00

Limbus Diam: 12.8 mm Pupil: 8.1 x 8.0 mm @93° (avg 8.0)



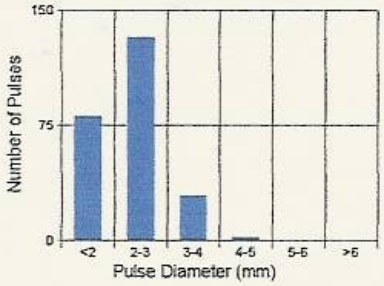
Treatment Type: LASIK Correction Type: CustomVue Nomogram Change: +0%
Physician Adjustments - SPH (D): +0.00 CYL (D): +0.00 Axis(°): VTX(mm): 0.00
Total Correction - SPH (D): +1.14 CYL (D): -0.89 Axis(°): 99 VTX(mm): 0.00

Treatment Parameters
Optical Zone (mm): 6.00
Ablation Zone (mm): 9.00
Max. Ablation Depth (μ): 14.7
No. of Tissue Pulses: 245
Treatment Time (sec): 12

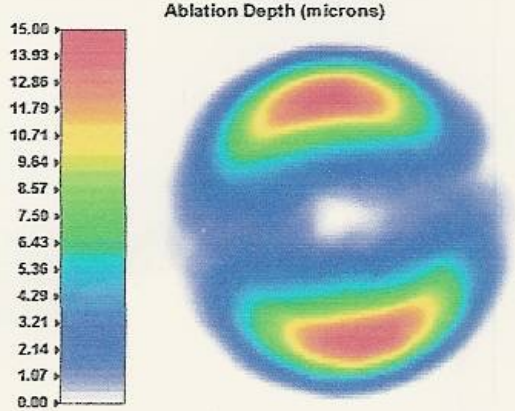
Surgical Parameters
Flap Diameter (mm): 9.50
Flap Thickness (μ): 140
Residual Bed Depth (μ): 319

Additional Information
The Manifest and WaveScan refractions do not match

Distribution of VSS Pulse Diameters

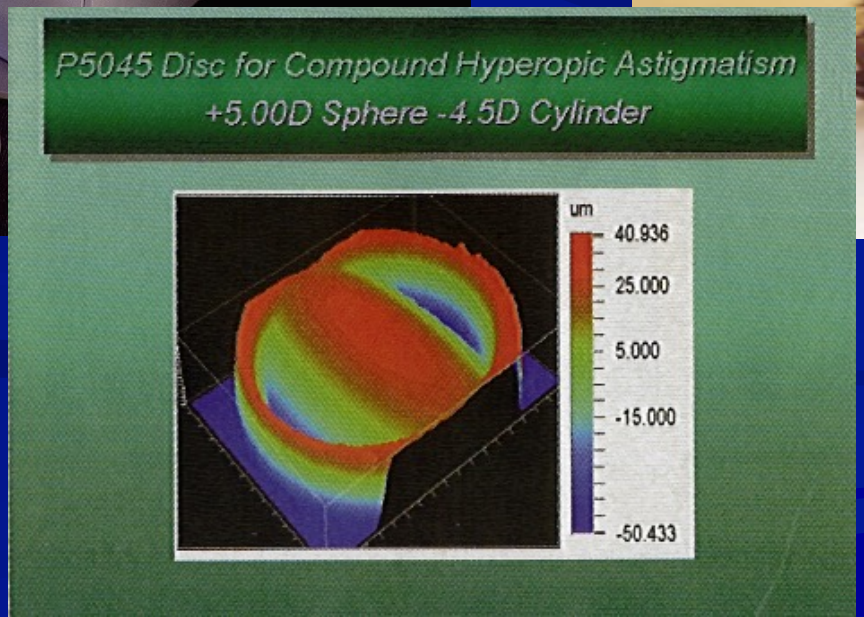


Ablation Depth (microns)

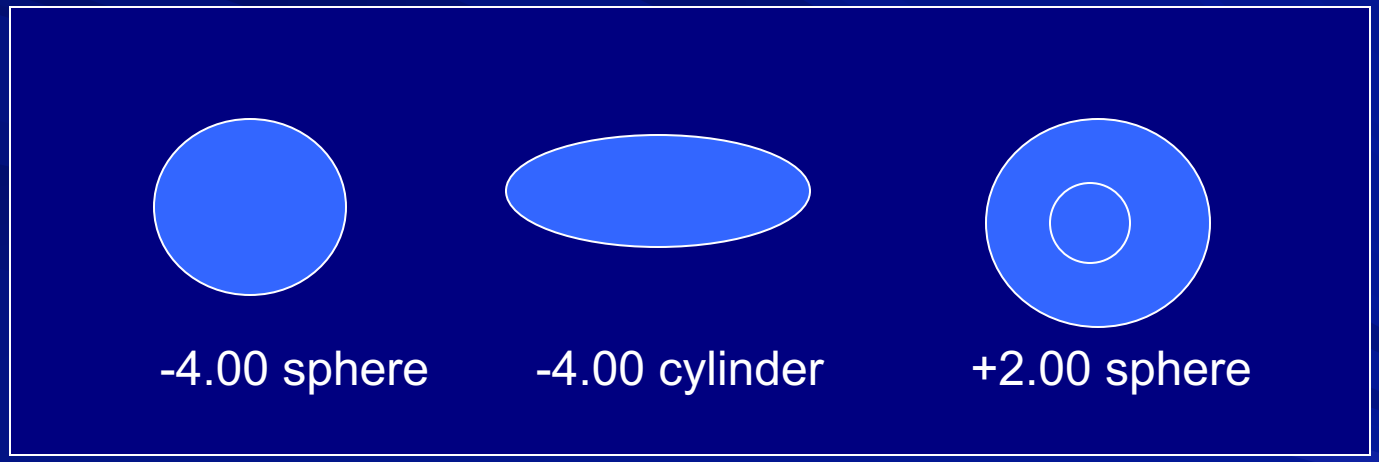


Nebraska Laser Eye Assoc.

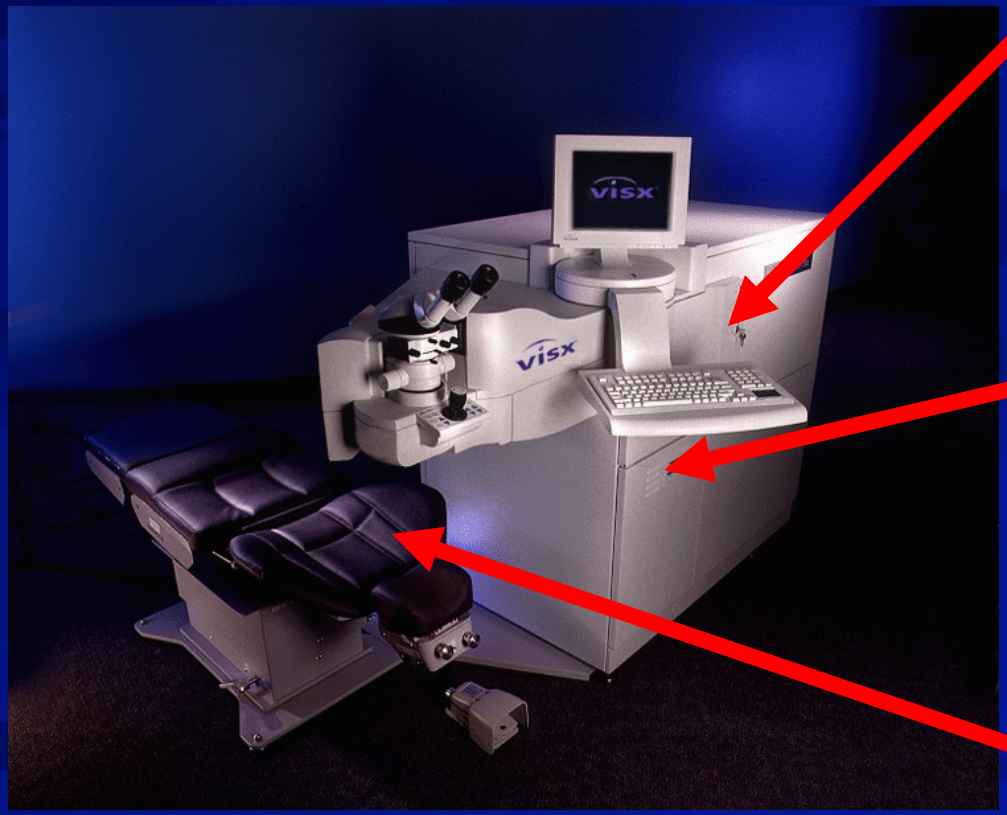
Lasik: Make Trial Lens (optional)



Laser calibration: Standard lens that are verified with a lensometer to assure that the laser is working properly, prior to any patient treatment



Lasik: Preparing for surgery

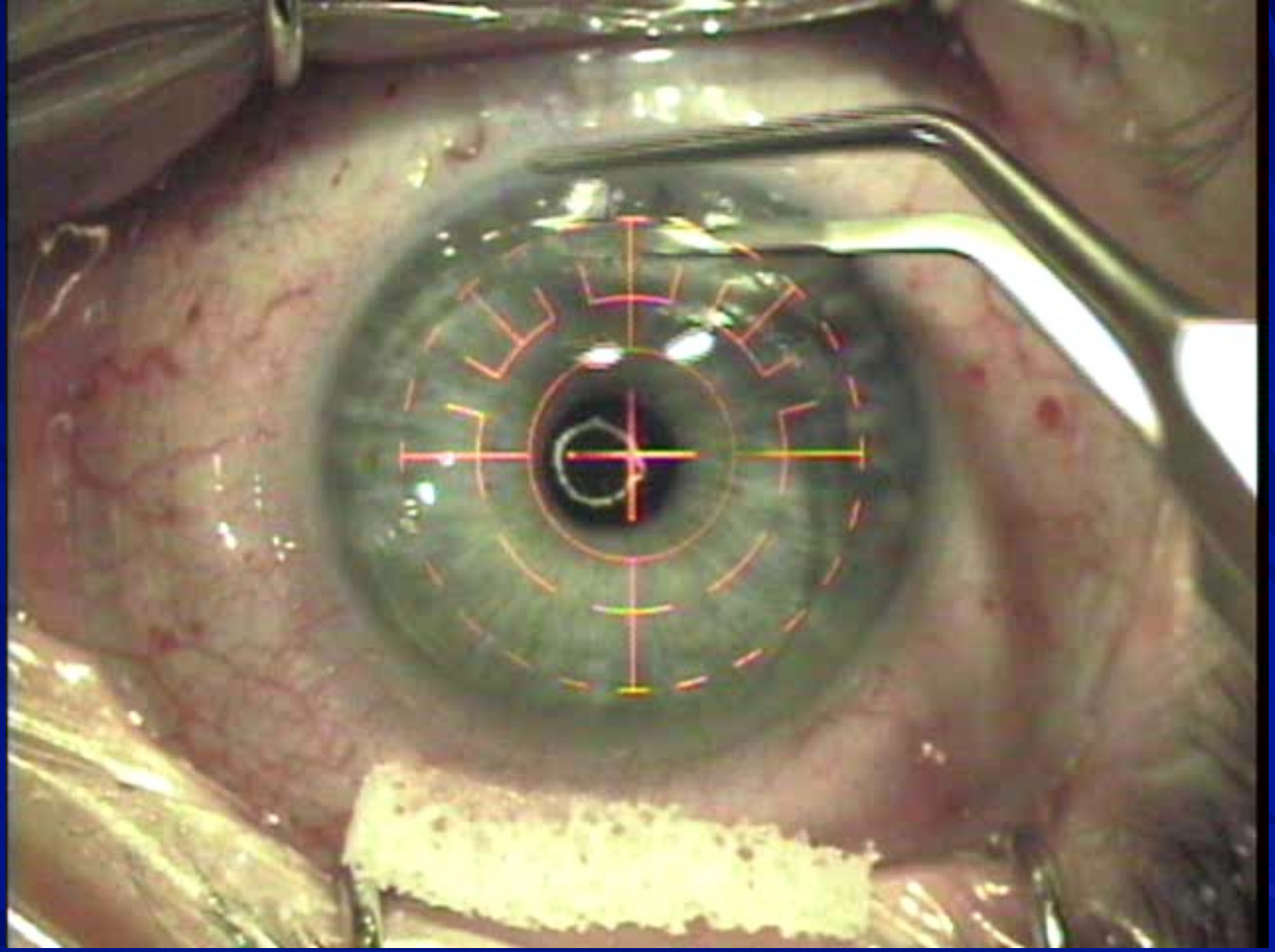


1.Enter VisionKey Card

2. Enter prescription

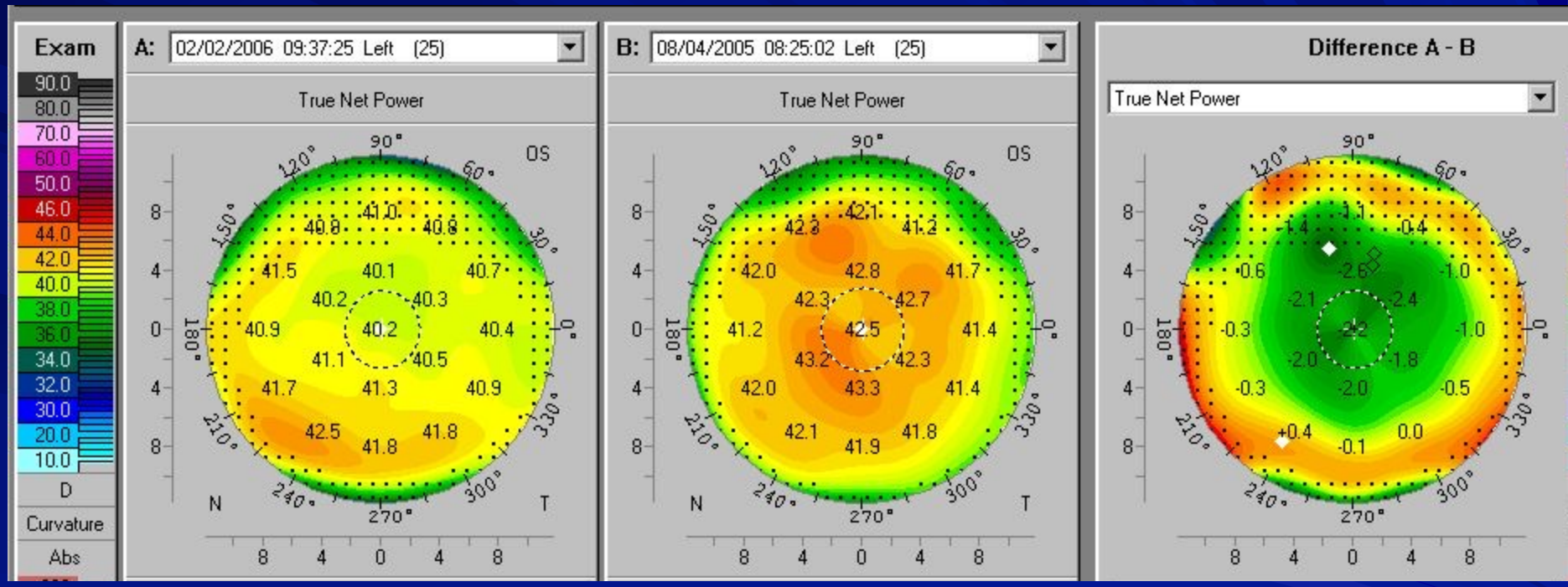
3. Location Photons Will Be Delivered

Lasik: Direct the photons into the eye



Surgeon supervises/directs the delivery of the prescription lens prosthetic device (photons) into the eye

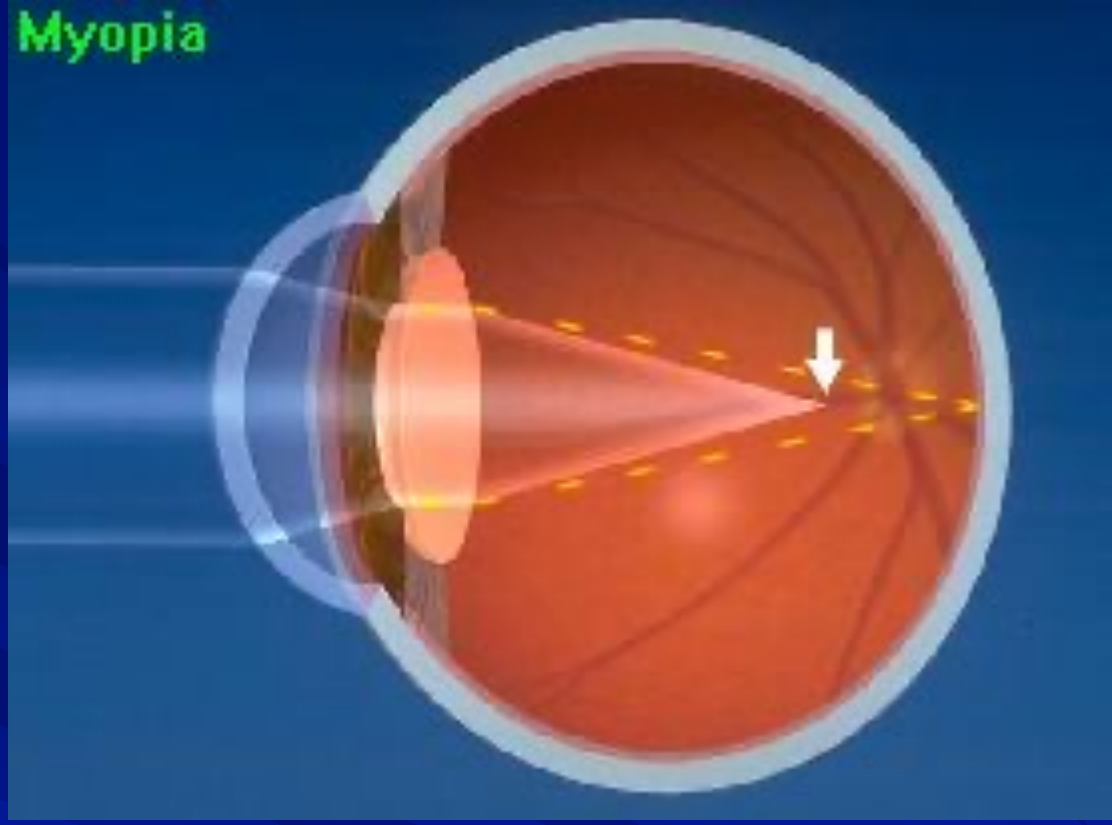
Pre-op minus Post-op= Lasik lens

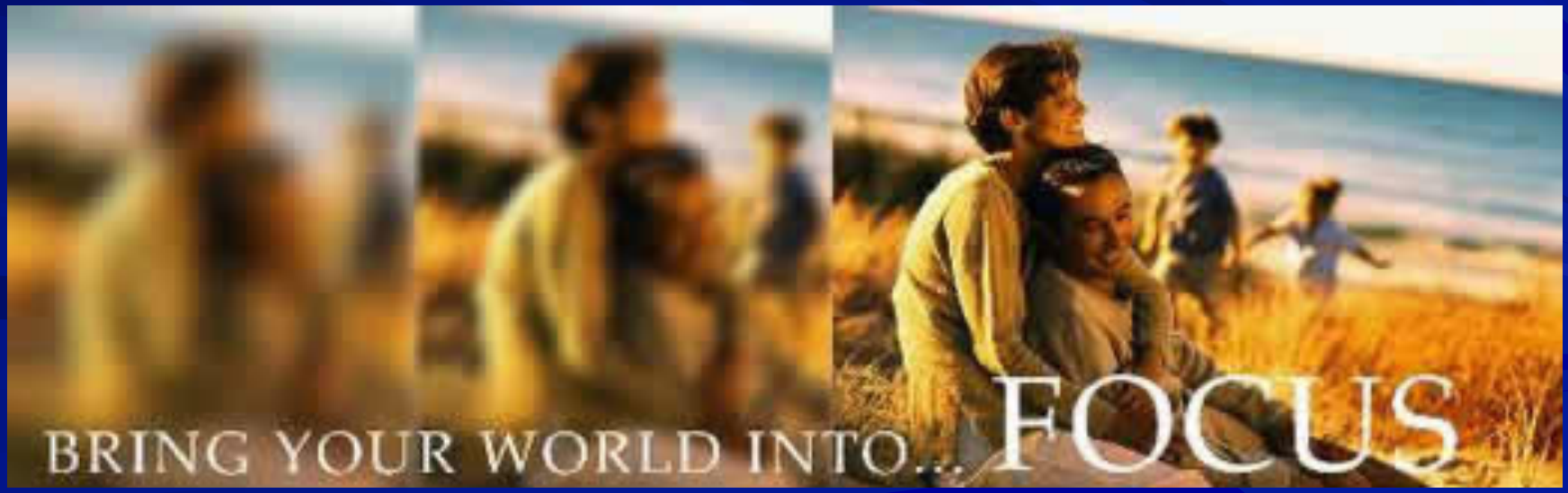


FDA Excimer Laser System

- FDA “Prescription” Device
- Corrects refractive error: “a lens”
- A “Prosthetic Device” that dispenses ultraviolet photons into the cornea to reshape or wear (by photodegradation) the deformed eye into the correct shape

- Lasik uses ultraviolet photodegradation (wear) to reshape the eye and bring objects into focus





FDA Excimer Laser System Regulations (Prescription Device)

- The manufacturer has control of the device
  - The Manufacturer controls the VisionKey card which activates the device
  - The manufacturer delivers the requested prescription to the surgeon , when the surgeon requests the delivery, into an agreed location (focal plane)
  - The surgeon is prohibited by the FDA from “opening” the device
- The physician can
  - Writes the prescription for the treatment
  - On the patient’s behalf, pays the device manufacturer on a per treatment basis
  - Dispenses the treatment into the proper location in the eye
- The patient
  - is the consumer of the prescription device (photons)

CONCLUSION

- The assessed charge is a payment to an FDA approved service provider for Dispensing a proton Prescription, which is Consumed in the patient's eye.