

A Simple LASIK... and Then It Came Astigmatism

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Financial Disclosure

☀ I have no financial interests or relationships to disclose.



2001

- 35 y.o. woman, Physician
- VOD 20/20 -4.00 D
- VOS 20/20 -4.00 D
- OU successful LASIK
- All went well for two years, then...



2003

- Progressive decrease in VA, with return to spectacle use.

2005

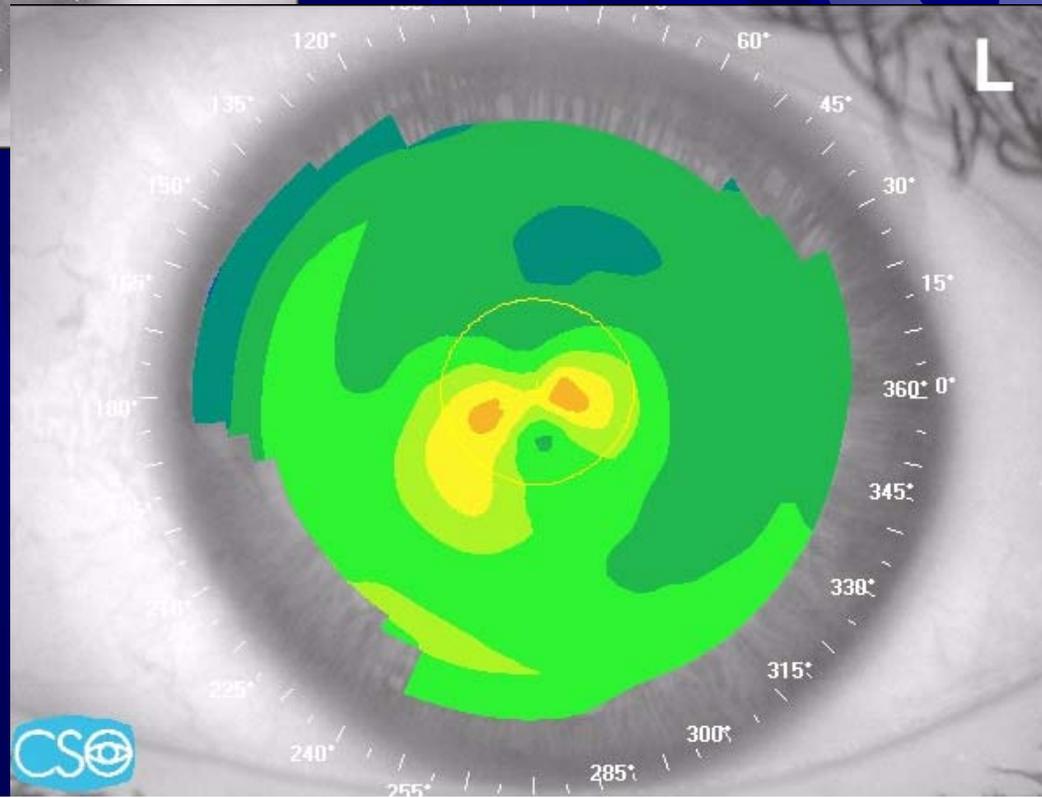
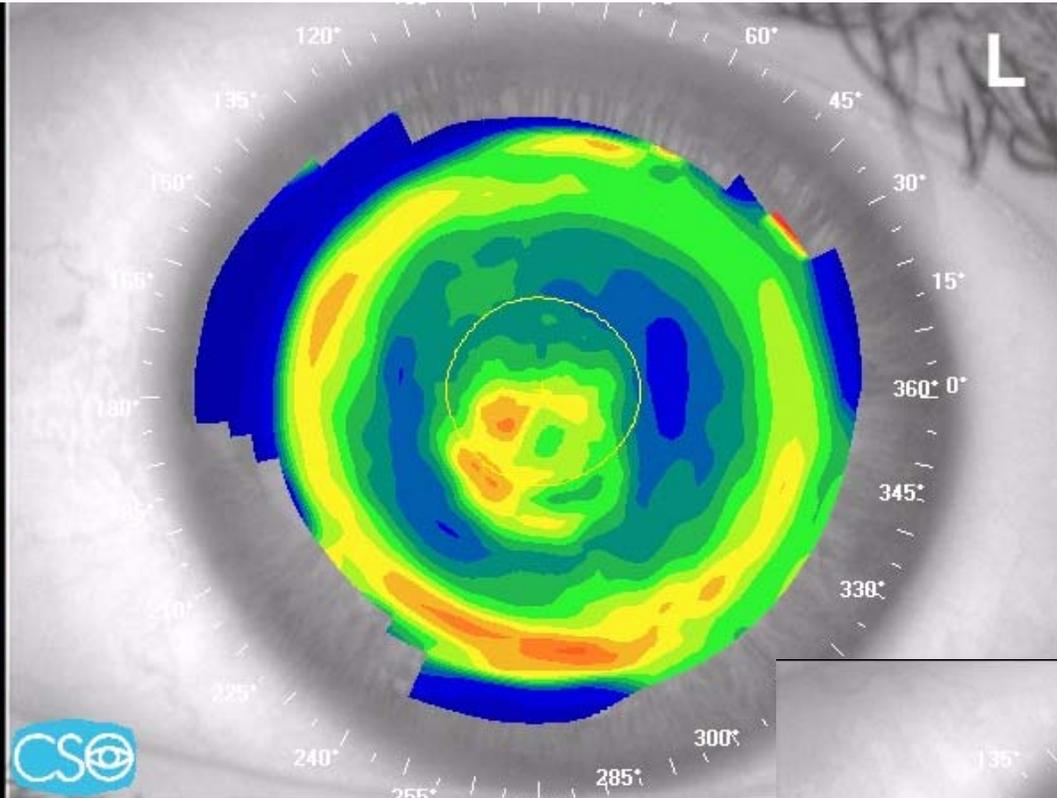
- VOD 20/25 -0.75 -1.00 (65)
- VOS 20/35 -1.50 -3.25 (110)

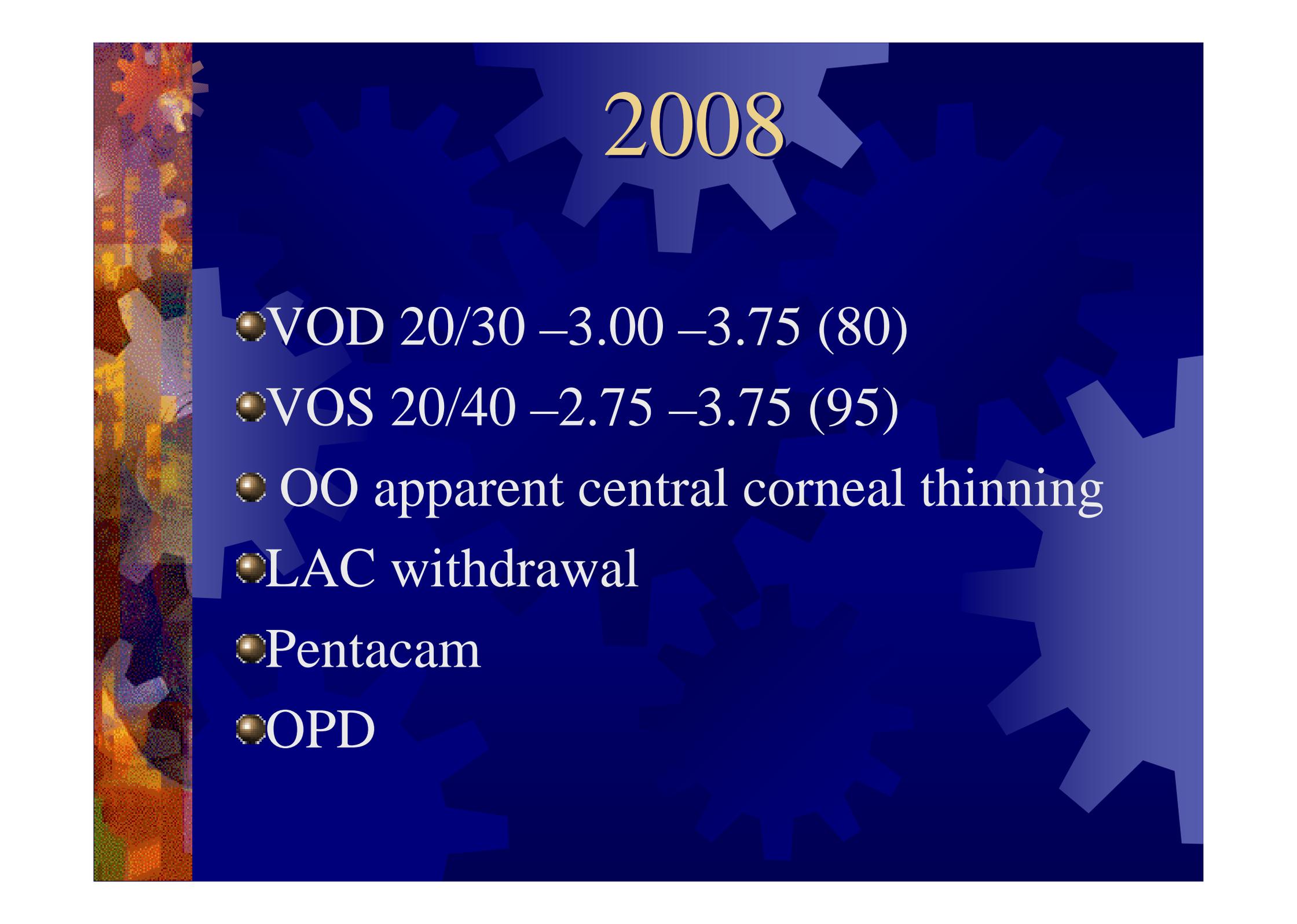
Pentacam:

- 2nd order topographical astigmatism
- Normal pachimetry
- OD 12 mu suspect elevation on altimetric map

Contact lens correction

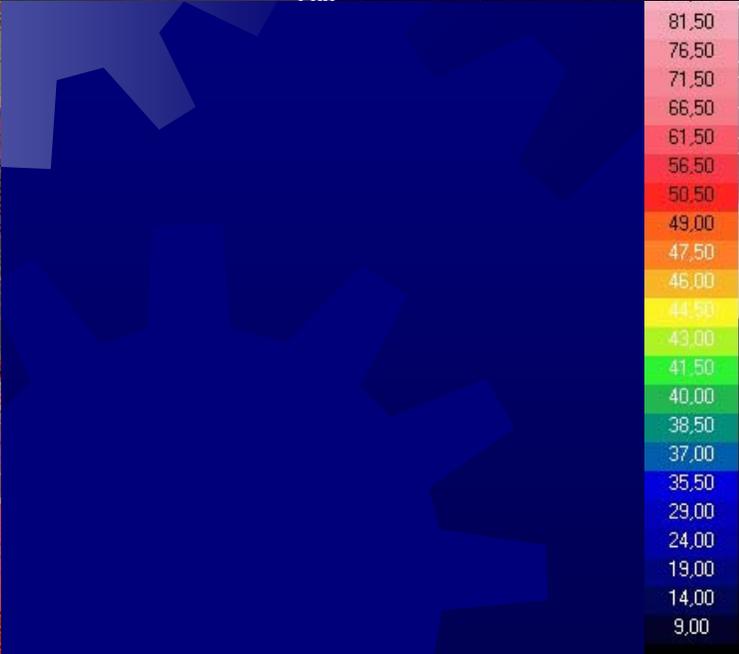
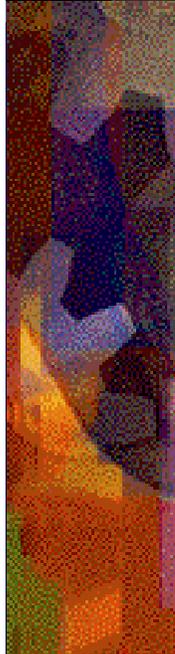
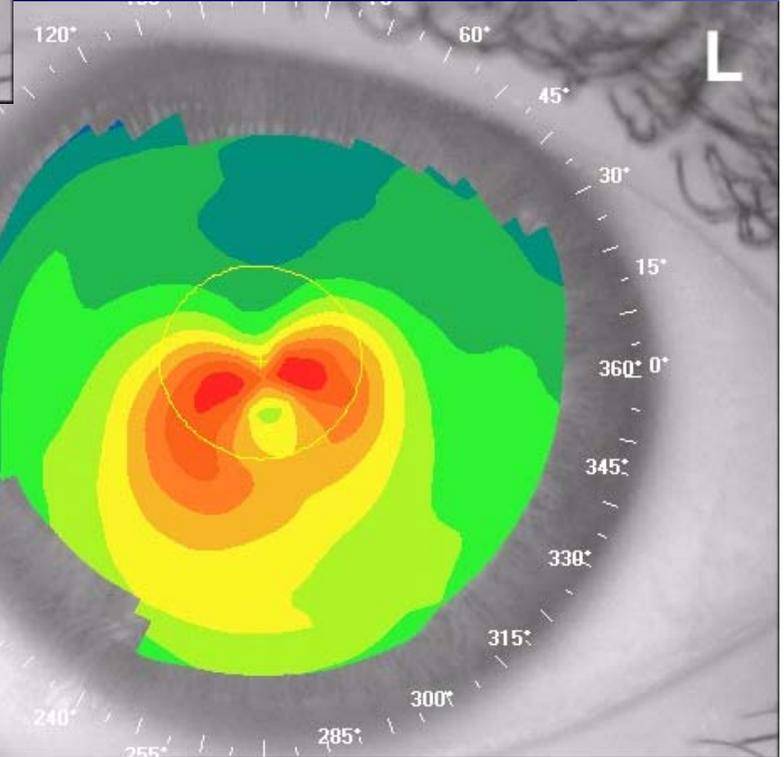
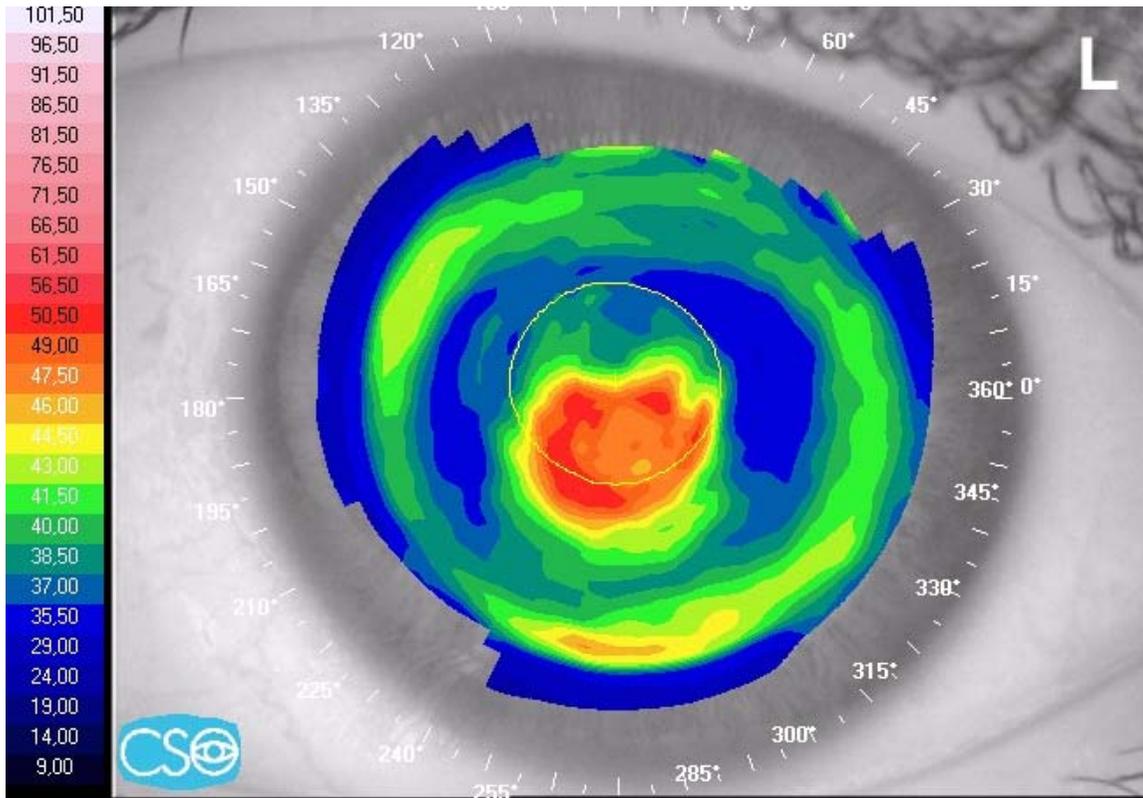
101,50
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9,00





2008

- VOD 20/30 -3.00 -3.75 (80)
- VOS 20/40 -2.75 -3.75 (95)
- OO apparent central corneal thinning
- LAC withdrawal
- Pentacam
- OPD



LE

2008

404 μ

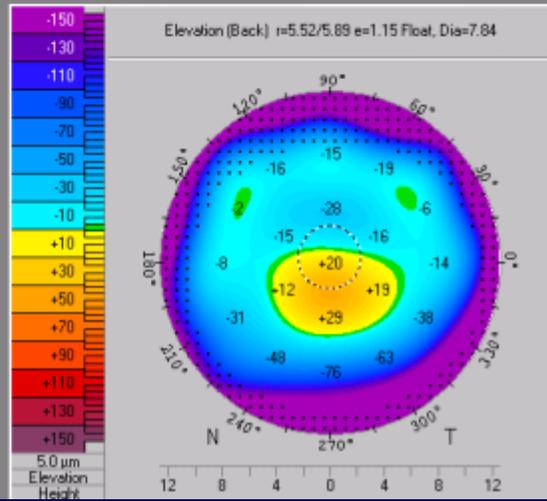
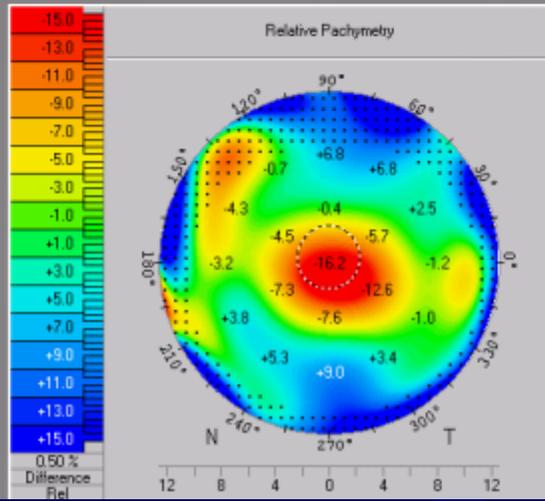
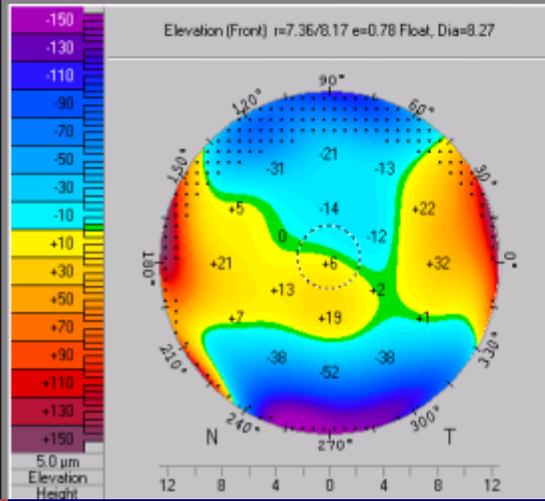
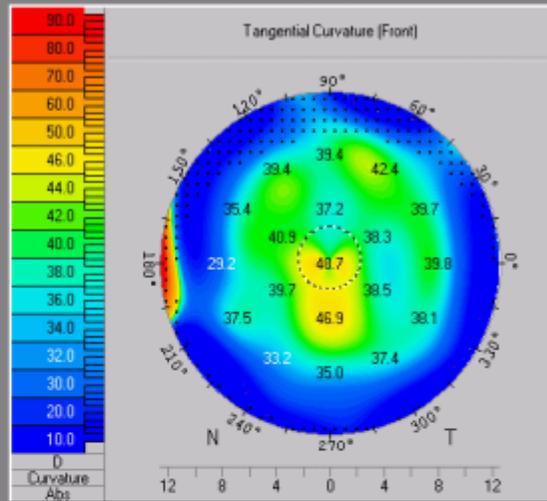
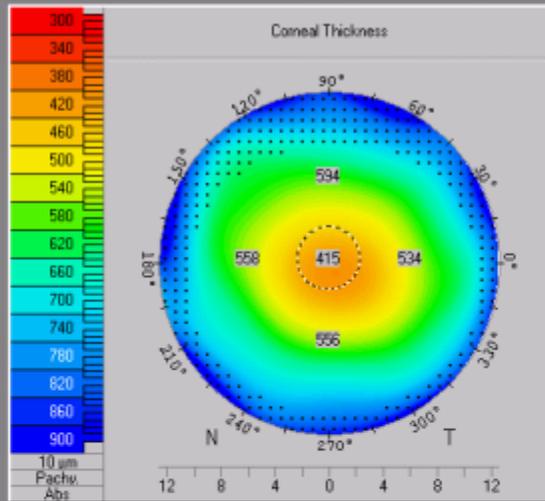
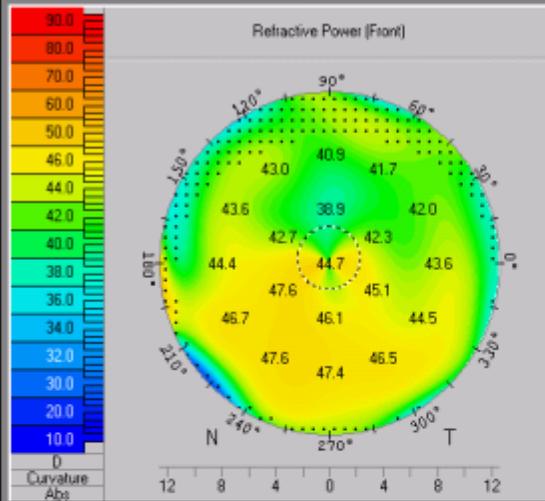
Last Name:
First Name:
ID:
Date of Birth: Eye:
Exam Date: Time:

Equivalent K-Readings (4.5mm Zone)



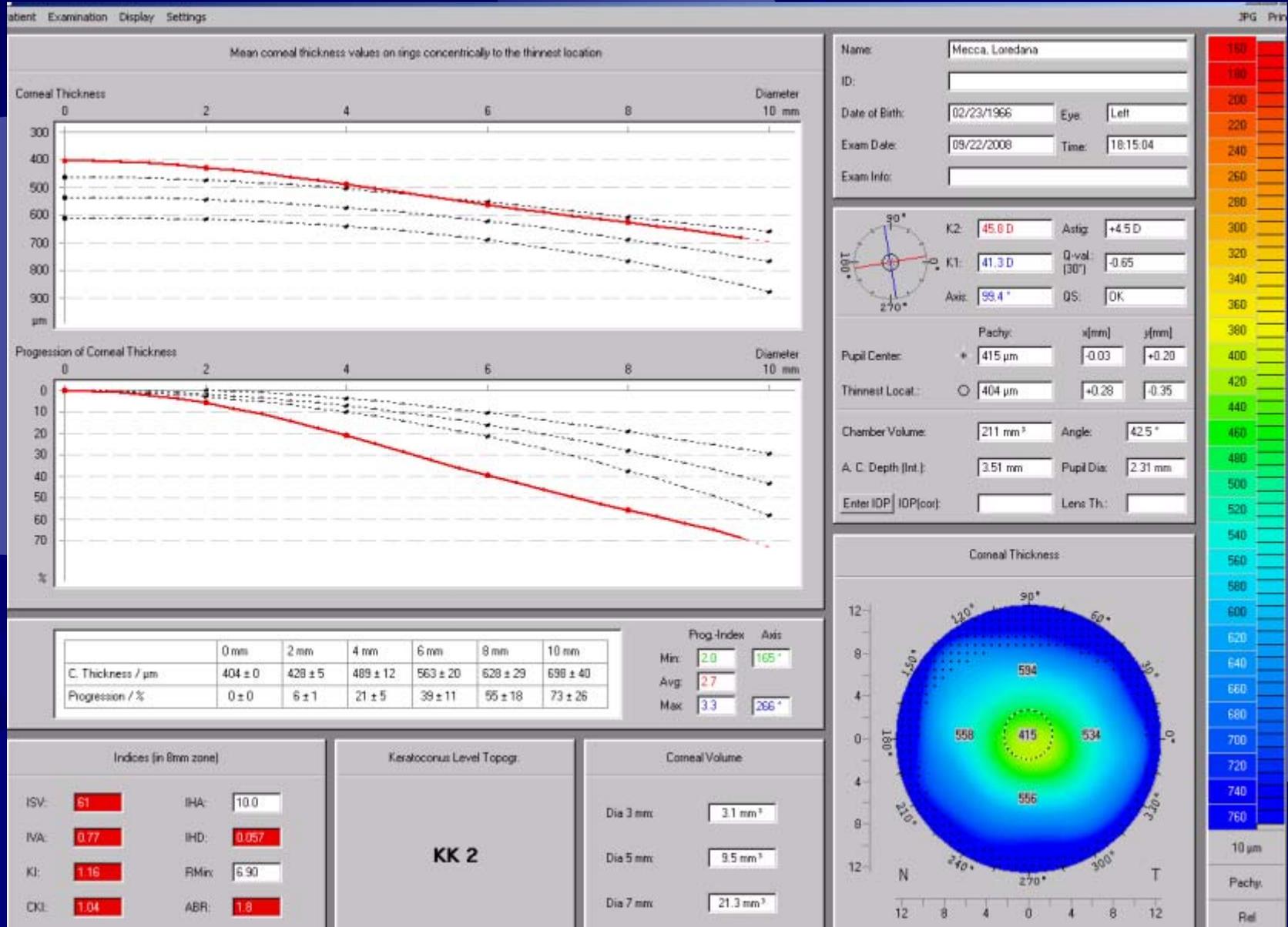
K2: Astig:
K1: Q (4.5mm):
Km: Details

Radii Ratio (B/F): Pupil Dia:
QS: Pachy Min:
Estimated Pre-Refractive SimK (n=1.3375)
Km: Ref Change:



LE

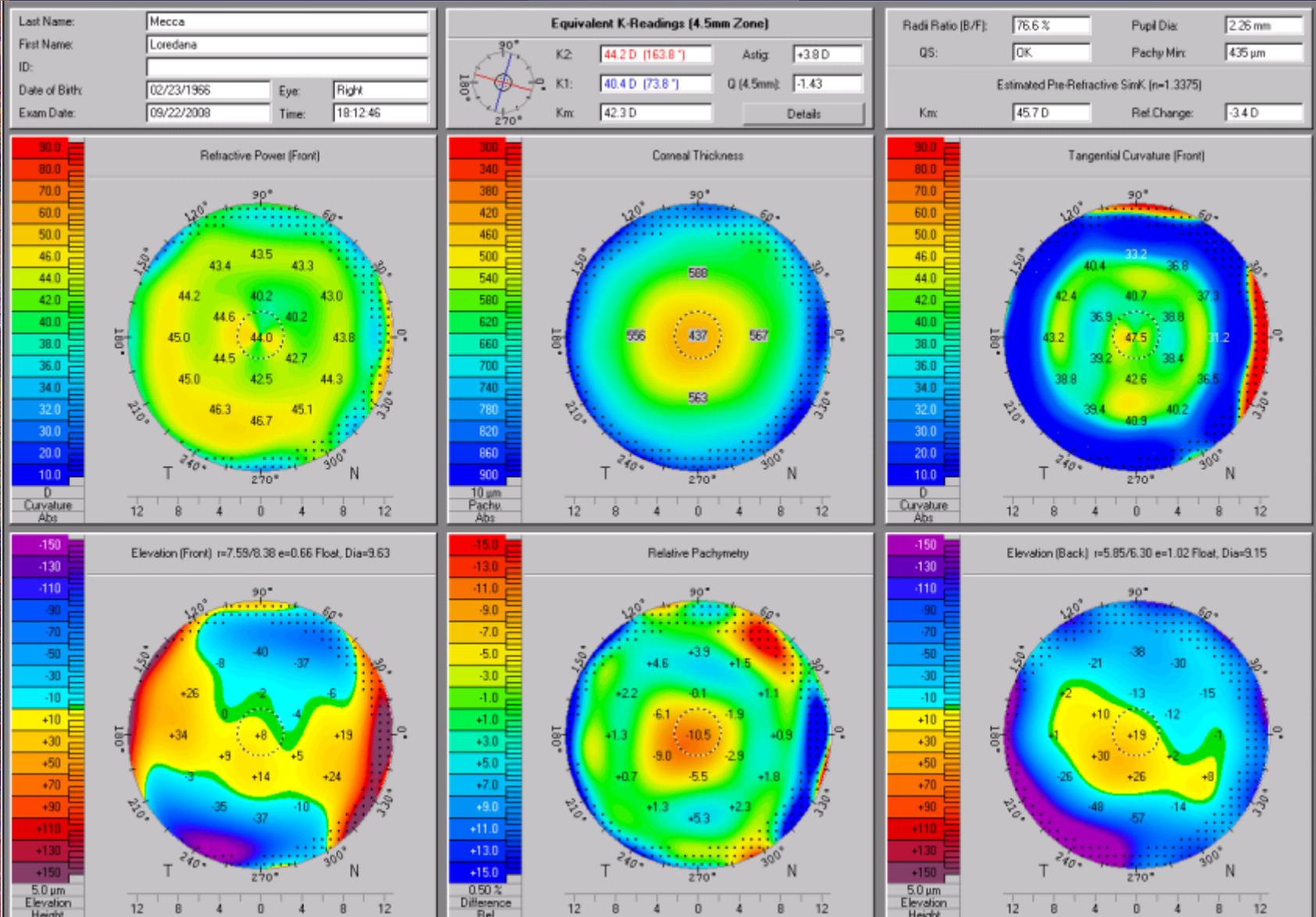
2008



RE

2008

435 μ

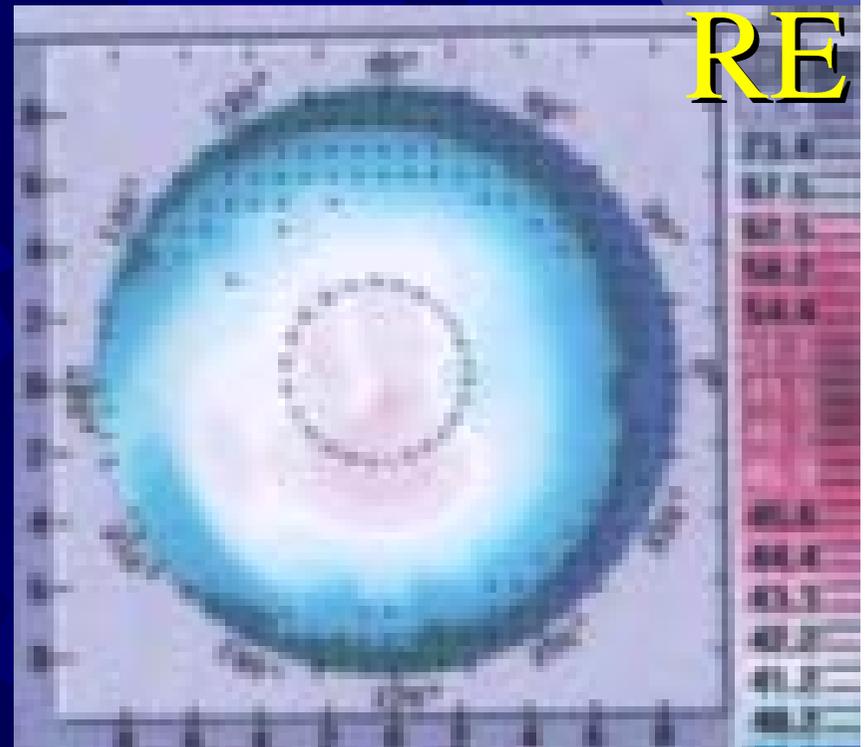


...Patient Selection !

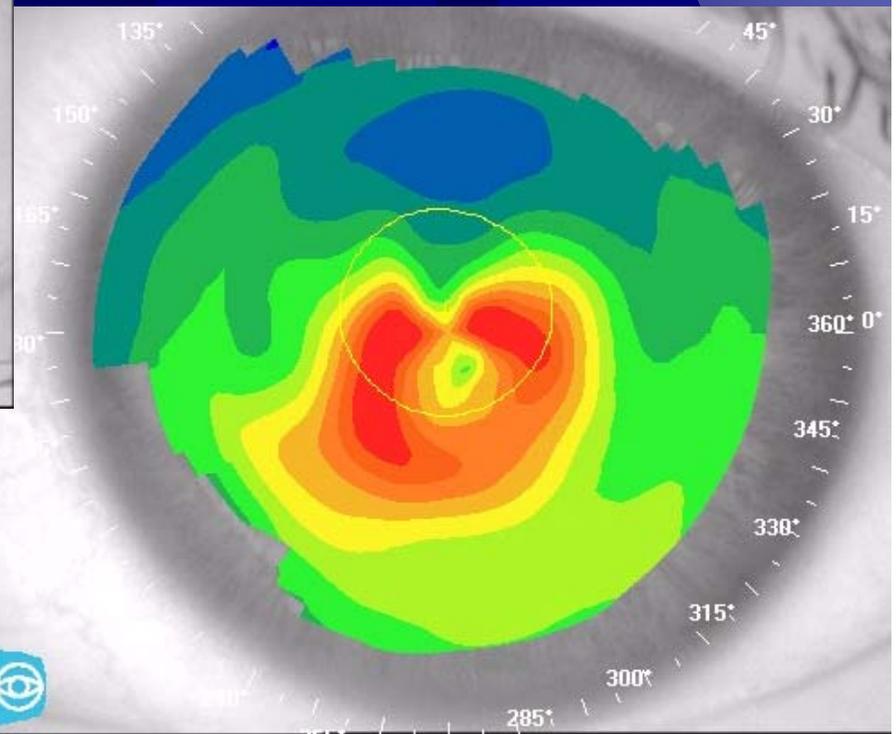
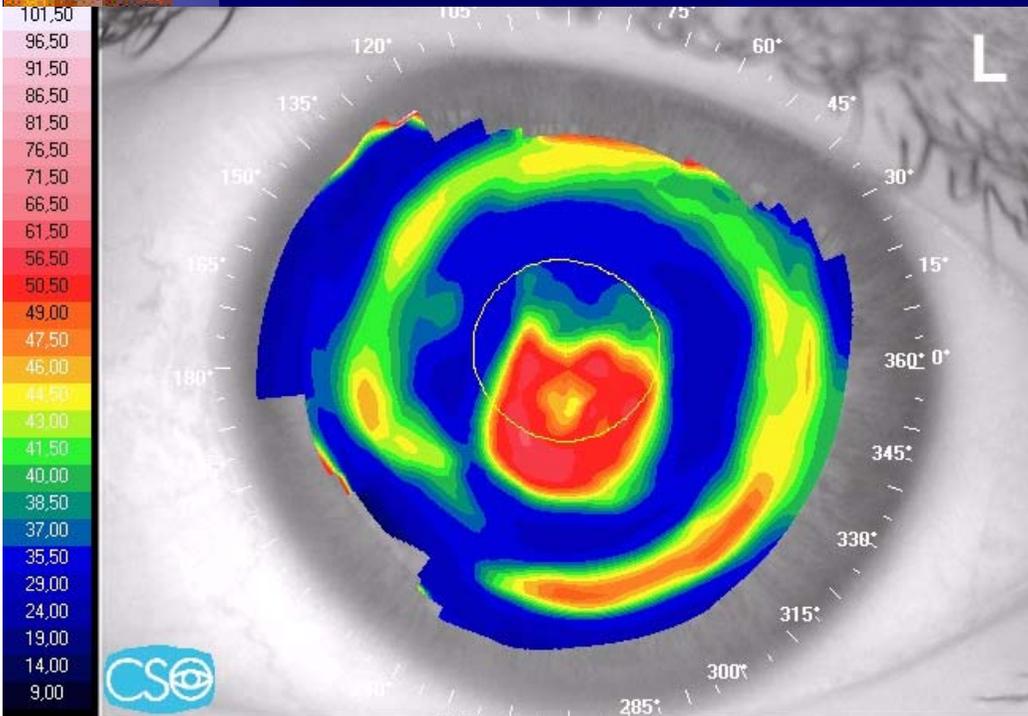
LE



RE



Future PK Candidate ? No... Cross Linking !



Patient Selection, Treatment, And Follow-Up: How Not to End Up In Court

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Refractive Surgery Patients

- a very special breed
- minor refractive defects may not be considered a **disease**
- thus, at times we may not be perceived as physicians treating an illness
- just providers of better life quality...
- ...or simply providers of a service ?

Refractive Surgery Patients

- LASIK:
 - portrayed as a nonessential cosmetic surgery
 - performed as a business
 - not a medical procedure

Abbott RL,

Medical malpractice predictors and risk factors for ophthalmologists performing LASIK and photorefractive keratectomy surgery

Ophthalmology, 2003 Nov; 110

Selection – Eye...

- exhaustive evaluation of ocular health
- exclusion of:
 - defects beyond successful treatment range
 - forme-fruste keratoconus
 - unstable refractive defect
 - ocular diseases
 - etc....

...Patient Selection !

- lifestyle
- profession
- why do you want refractive surgery ?
- expectations
- satisfaction with possible residual defect
- “enhancements”
- patience

Selection - Patient

- ...just talk with the patient, get to know him, if in doubt meet another time and talk again
- limited time spent with patients may mean more lawsuits

Abbott RL, Ophthalmology, 2003; 110

Levinson V, JAMA, 1997; 154

Selection - Patient

Abbott RL, Ophthalmology, 2003; 110

● “The chances for incurring in a malpractice claim or lawsuit correlate significantly with:

- **High surgical volume** (> 100/yr)
 - Physician gender (male)
 - Aggressive marketing
 - Time spent with the patient (55 min or <)
 - Comanagement with optometrists
- **History of a claim or lawsuit**

Selection - Patient

Hickson GB, JAMA, 2002; 287

- The physician's ability to:
 - Establish rapport with patient
 - Provide access to patient
 - Communicate effectively with the patient
- ...are as important as technical competence in protecting against litigation

Selection - Patient

- The odds of a lawsuit increase because the probability of at least one patient being dissatisfied sufficiently to sue increases with the number of surgeries performed
- Furthermore, findings did not imply that high volume surgeons provide inferior care, but that they can expect more liability claims

Abbott RL, Ophthalmology, 2003; 110

Mutti DO, Ophthalmology, 2004; 111

Lindstrom R, Ophthalmology, 2004; 111

Selection - Patients

- Informed Consent
 - In Italy the **same standardized informed consent** is used throughout the nation
 - In Italy all Ophthalmologist member of S.O.I. (5 out of 6) share the **same insurance company**
 - Always give a copy to the Patient

Selection - Patients

- Informed Consent
 - Patient **writes personally** that he has understood about possible residual refractive defect and halos
 - Patient fills personally a **questionnaire** about IC key statements

Treatment

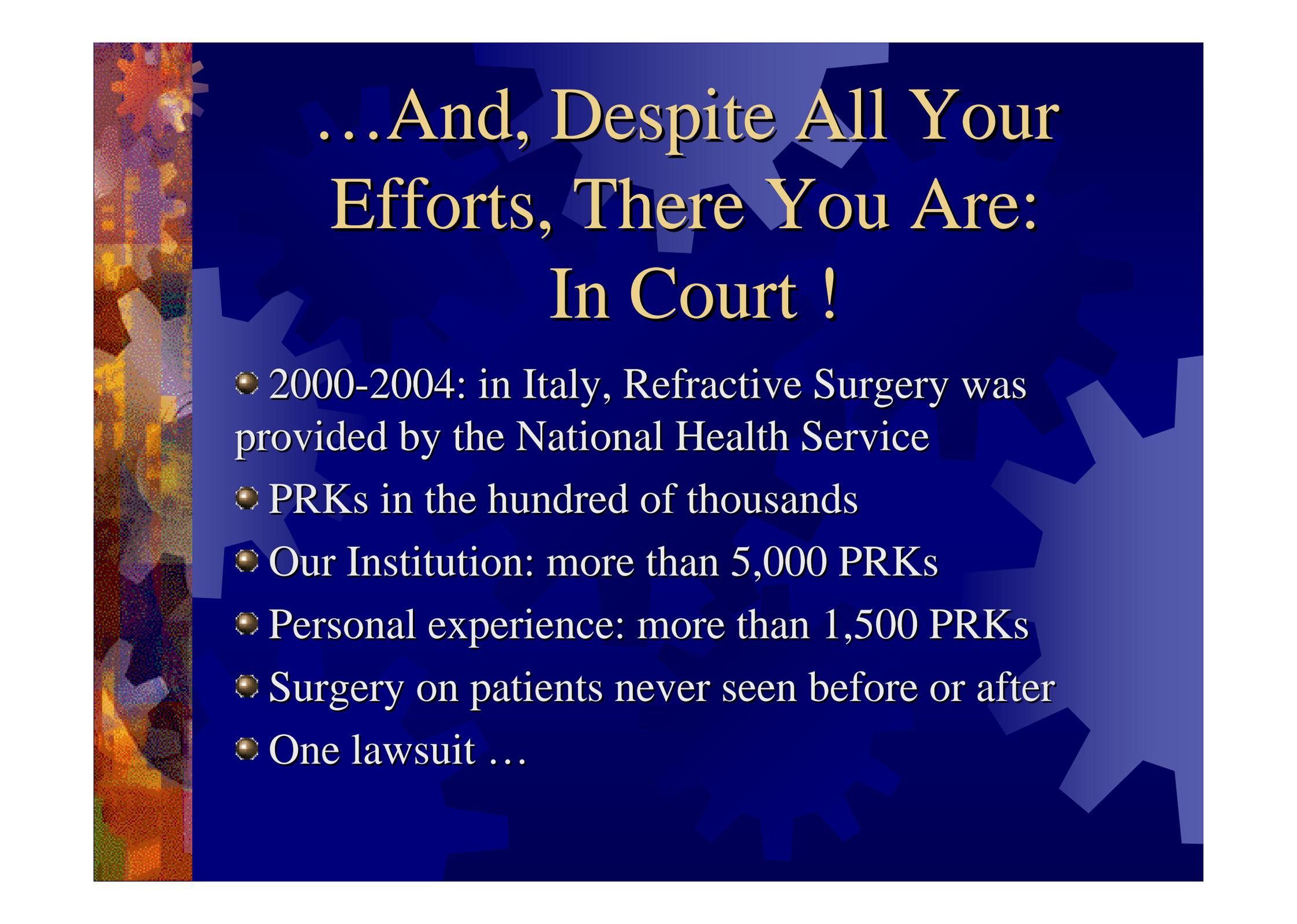
- Visual examination immediately prior to surgery
- Exclusion of patients with incurring infective diseases (i.e, flu, herpes)
- Check comprehension of refractive surgery goals
- Check comprehension of treatment
 - (analgesical prescribed, pharmacist sold per os drops ... patient instilled !!!)

Treatment

- careful monitoring of excimer/femtosecond laser status
- standardized surgical procedures
- obsessive attention to details
 - Call the patient **by name** before and during surgery
 - Check that she/he knows **which eye** is going to receive surgery first

Follow-Up

- define and share all follow-up intervals
 - (1, 3, 6, 12 mos)
- check constant use of **lubricants**
- be **careful** in verbalizing or showing your feeling about an imperfect result
 - -0.50 sph residual may be OK for the Pt
 - But... if **you** look **unhappy**, **she/he** will become **unhappy**
 - -0.50 sph residual may be very handy... when one becomes presbyopic: prolonged spectacle independence



...And, Despite All Your Efforts, There You Are: In Court !

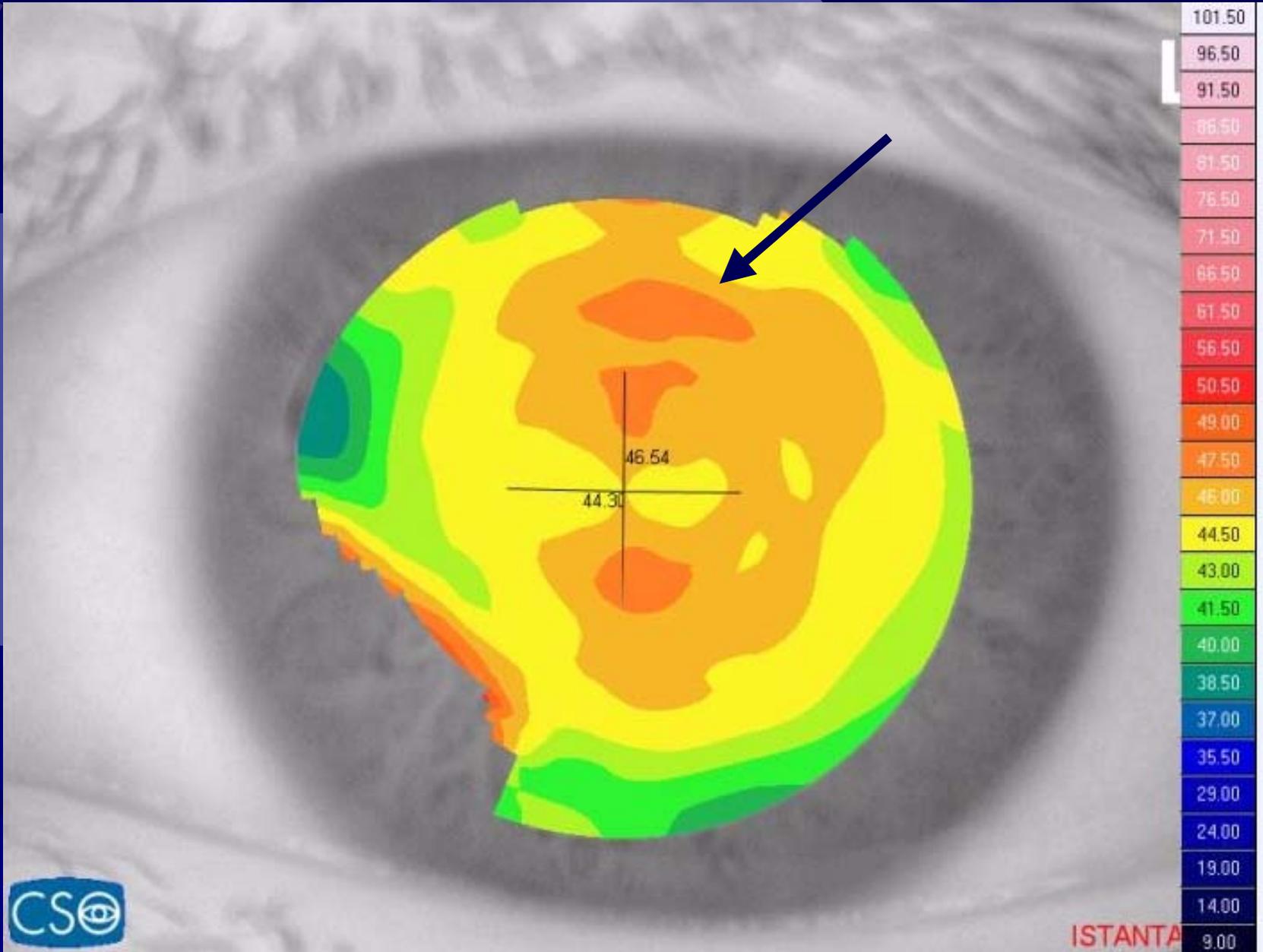
- 2000-2004: in Italy, Refractive Surgery was provided by the National Health Service
- PRKs in the hundred of thousands
- Our Institution: more than 5,000 PRKs
- Personal experience: more than 1,500 PRKs
- Surgery on patients never seen before or after
- One lawsuit ...

...And, Despite All Your Efforts, There You Are: In Court !

- “Free” NHC-provided treatment distorted the perception of refractive disease
- Business pressure ...
- Treatment was perceived as:
 - An occasion to save money
 - Entitlement
 - Recommended when refractive defect was present
 - Essential for aesthetic improvement

One Case in Court

- 32 y.o. woman
- VOD 0.95 -7.50 -2.50 (10)
- VOS 0.9 -7.75 -2.25 (5)
- In LE astigmatic bow-tie was highly asymmetric, with marked curvature in the upper portion (47 D)
- Possible forme-fruste keratoconus and stability of defect studied 1997-2001, then OK for refractive surgery was provided
- In 2001 astigmatism correction with excimer laser was possible only with **symmetrical** corneal remodelling
- symmetrical corneal remodelling on an asymmetrical cornea lead to a **postoperatively asymmetrical cornea**

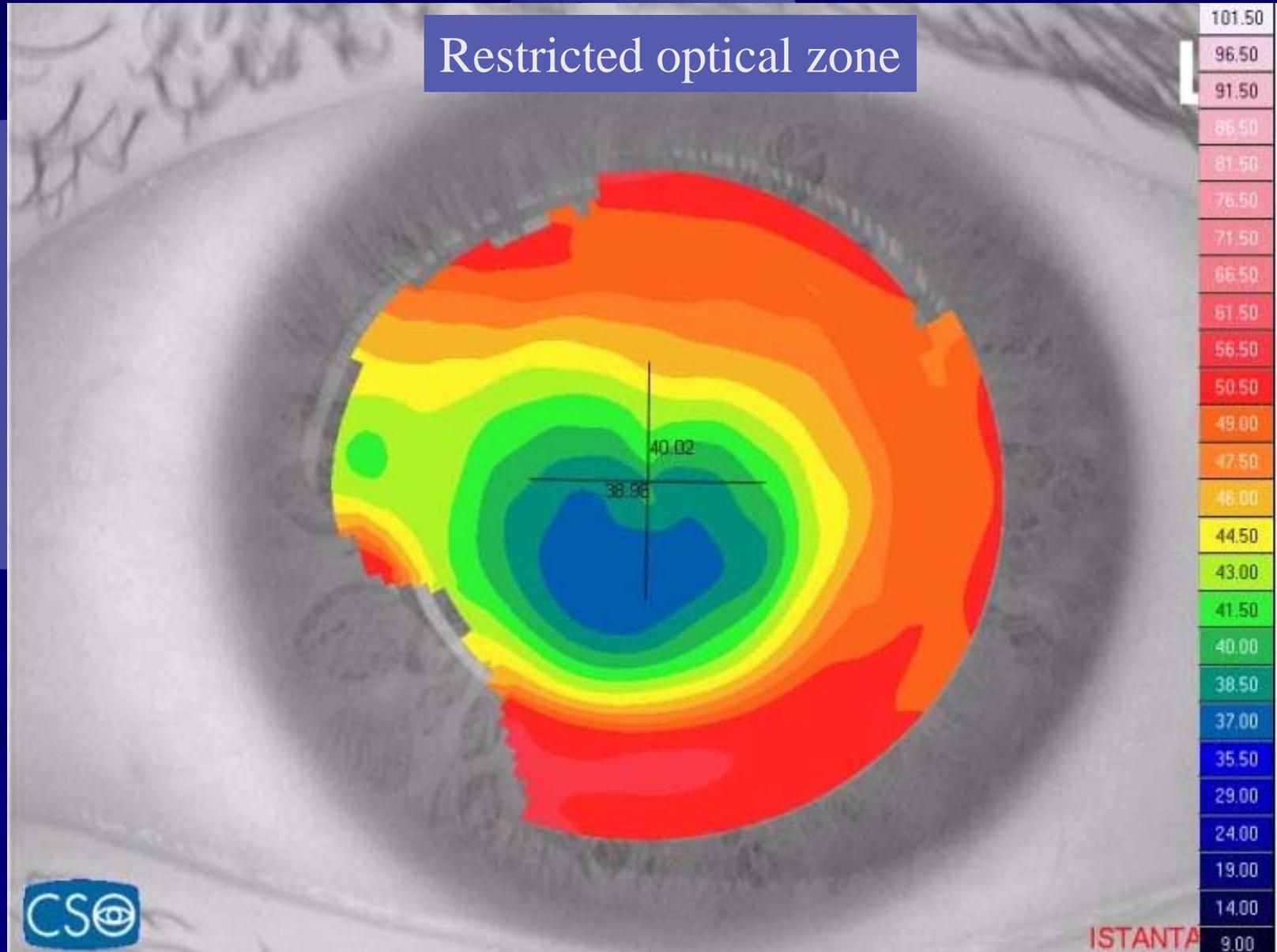


One Case in Court

- **16.01.01 PRK in RE (AP), 23.01.01 PRK in LE (FIC)**
- **02.04.01:**
 - VOD 0.9 -0.75 (180)
 - VOS 0.9 +1.00 -1.00 (175)
- Then Pt **disappeared** for 5 – delicate – months.
- **30.10.01**
 - VOD 1.0 plano
 - VOS 0.4 plano, 0.7 +1.50 -2.50 (180)
- AS : RE haze 0.5 -1, LE haze 1.5-2.0 inferiorly
- Treated with steroids, then simply followed
- **07.07.03**
 - VOD 1.0 plano, 1.0 +0.25 cycloplegia
 - VOS 0.95 plano, 0.85 +2.75 cycloplegia
- AS: OD normal, LE haze 1 -2 inferiorly, crescent-moon shaped, optical zone preserved

Decentration ?

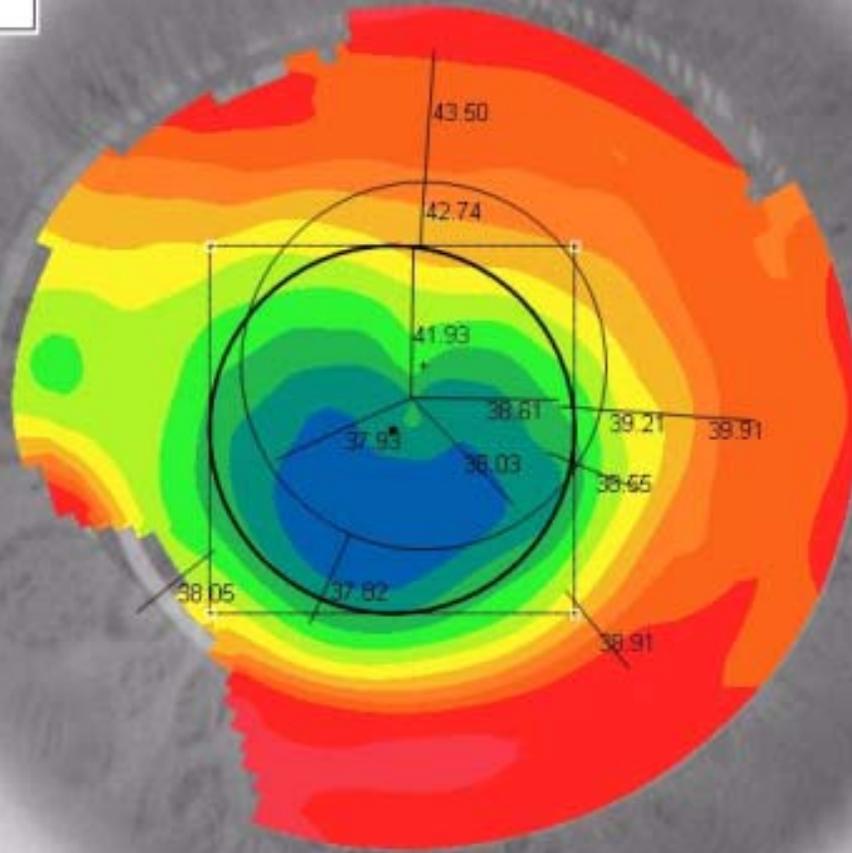
Restricted optical zone



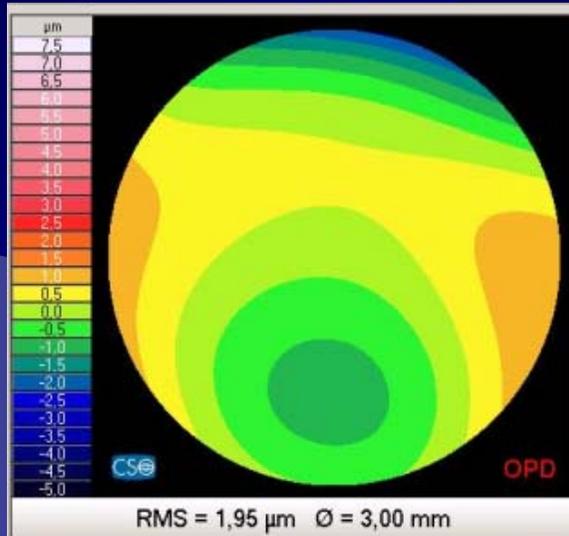
Decentration

Tipo Scala
Assoluta
D
101.50
96.50
91.50
86.50
81.50
76.50
71.50
66.50
61.50
56.50
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49.00
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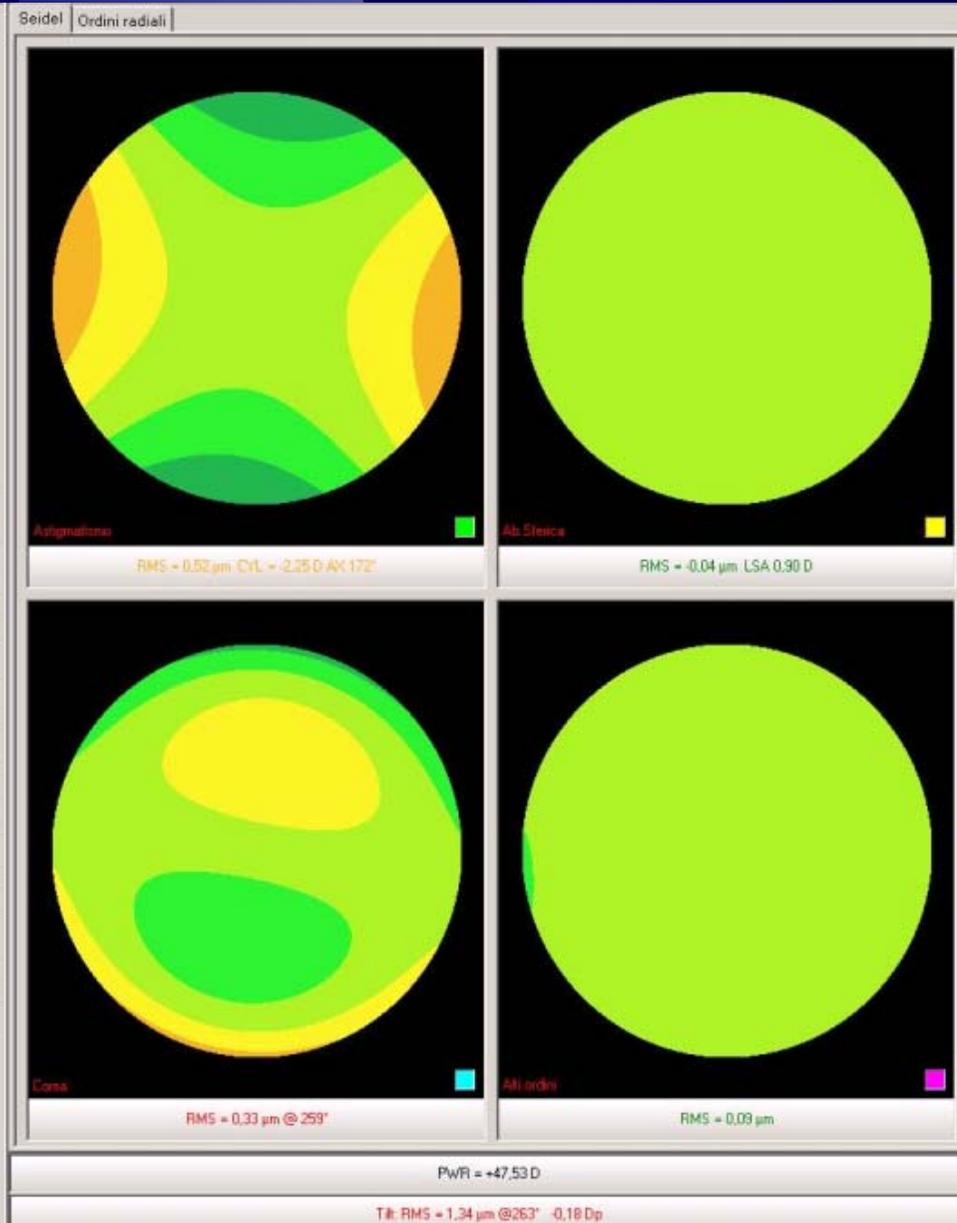
Vertice (xc,yc) = (-0.20 mm,0.32 mm)
Vertice (pc,pc) = (0.37 mm,2°)
Pupilla (xc,yc) = (-0.32 mm,0.64 mm)
Pupilla (pc,pc) = (0.71 mm,2°)
Max = 1.85
Min = 1.85



Aberrations



	Descrizione	Valore (RMS)	Fondoscala = 0,57
Z(0,0)	Pistone	-1,09 μm	
Z(1,±1)	Tilt	1,34 μm @ 263°	
Z(2,±2)	Astigmatismo	0,52 μm @ 172°	<input checked="" type="checkbox"/>
Z(2,0)	Defocus	-0,65 μm	
Z(3,±3)	Trifoglio	0,08 μm @ 118°	<input type="checkbox"/>
Z(3,±1)	Coma	0,33 μm @ 259°	<input checked="" type="checkbox"/>
Z(4,±4)	Quadrifoglio	0,02 μm @ 78°	<input type="checkbox"/>
Z(4,±2)	Astigmatismo II	0,03 μm @ 101°	<input type="checkbox"/>
Z(4,0)	Ab. Sferica	-0,04 μm	<input type="checkbox"/>
Z(5,±5)	Pentafoglio	0,01 μm @ 7°	<input type="checkbox"/>
Z(5,±3)	Trifoglio II	0,01 μm @ 41°	<input type="checkbox"/>
Z(5,±1)	Coma II	0,01 μm @ 158°	<input type="checkbox"/>
Z(6,±6)	Esafoglio	0,01 μm @ 25°	<input type="checkbox"/>
Z(6,±4)	Quadrifoglio II	0,01 μm @ 35°	<input type="checkbox"/>
Z(6,±2)	Astigmatismo III	0,00 μm @ 7°	<input type="checkbox"/>
Z(6,0)	Ab. Sferica II	0,00 μm	<input type="checkbox"/>
Z(7,±7)	Epitafoglio	0,01 μm @ 13°	<input type="checkbox"/>
Z(7,±5)	Pentafoglio II	0,00 μm @ 4°	<input type="checkbox"/>
Z(7,±3)	Trifoglio III	0,00 μm @ 81°	<input type="checkbox"/>
Z(7,±1)	Coma III	0,00 μm @ 65°	<input type="checkbox"/>



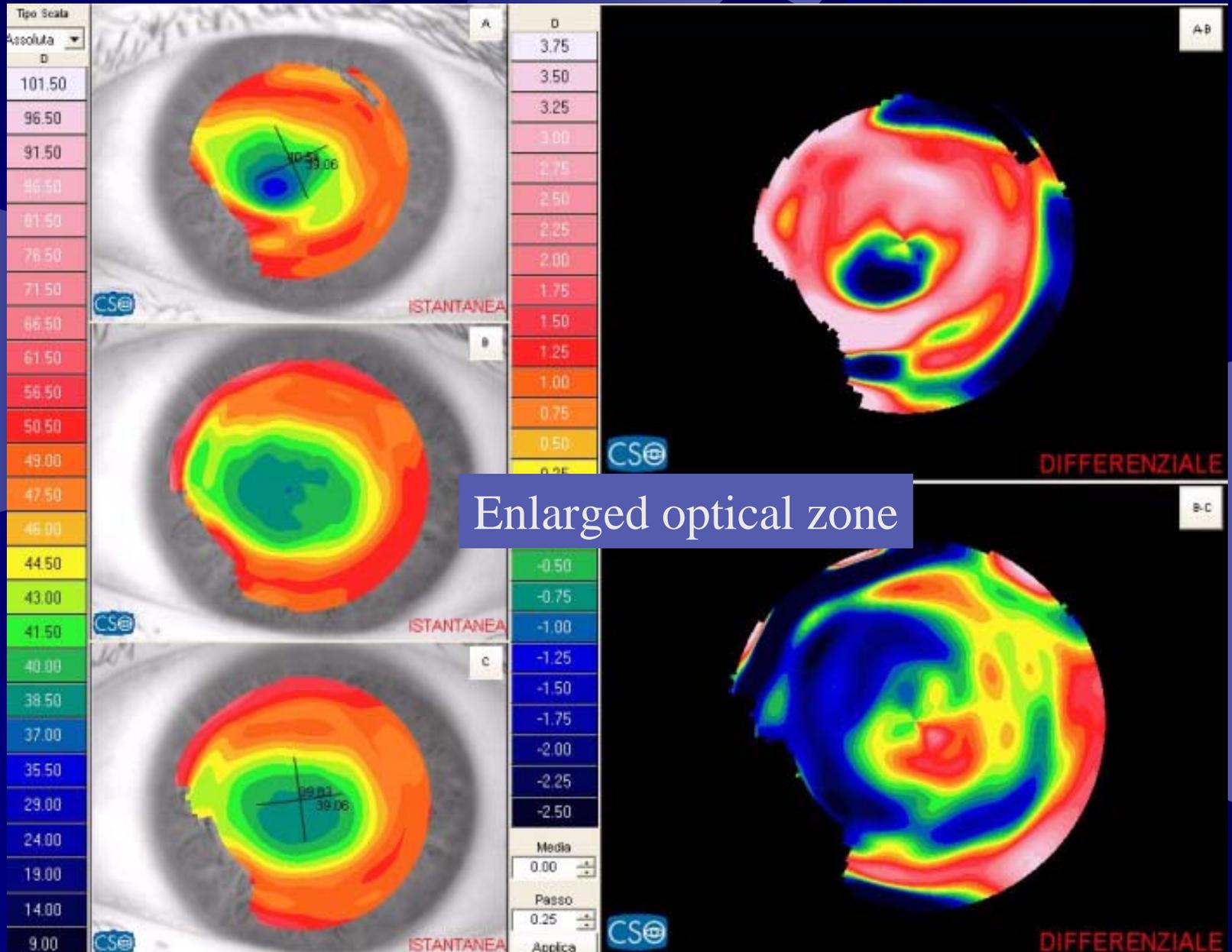
One Case in Court

- High preoperative corneal curvature and asymmetry + **no-show** and consequent inadequate therapy, resulted in increased collagen deposition with consequent **restriction of optical zone**
- Possible intraoperative head tilt
- **Decentration** and **hypercorrection**
- Patient **complained** of fatigue in near vision and fluctuating visual acuity
- Follow-up was tight, totally free and supportive for 1.5 yrs
- Waited for the availability of **custom ablation**

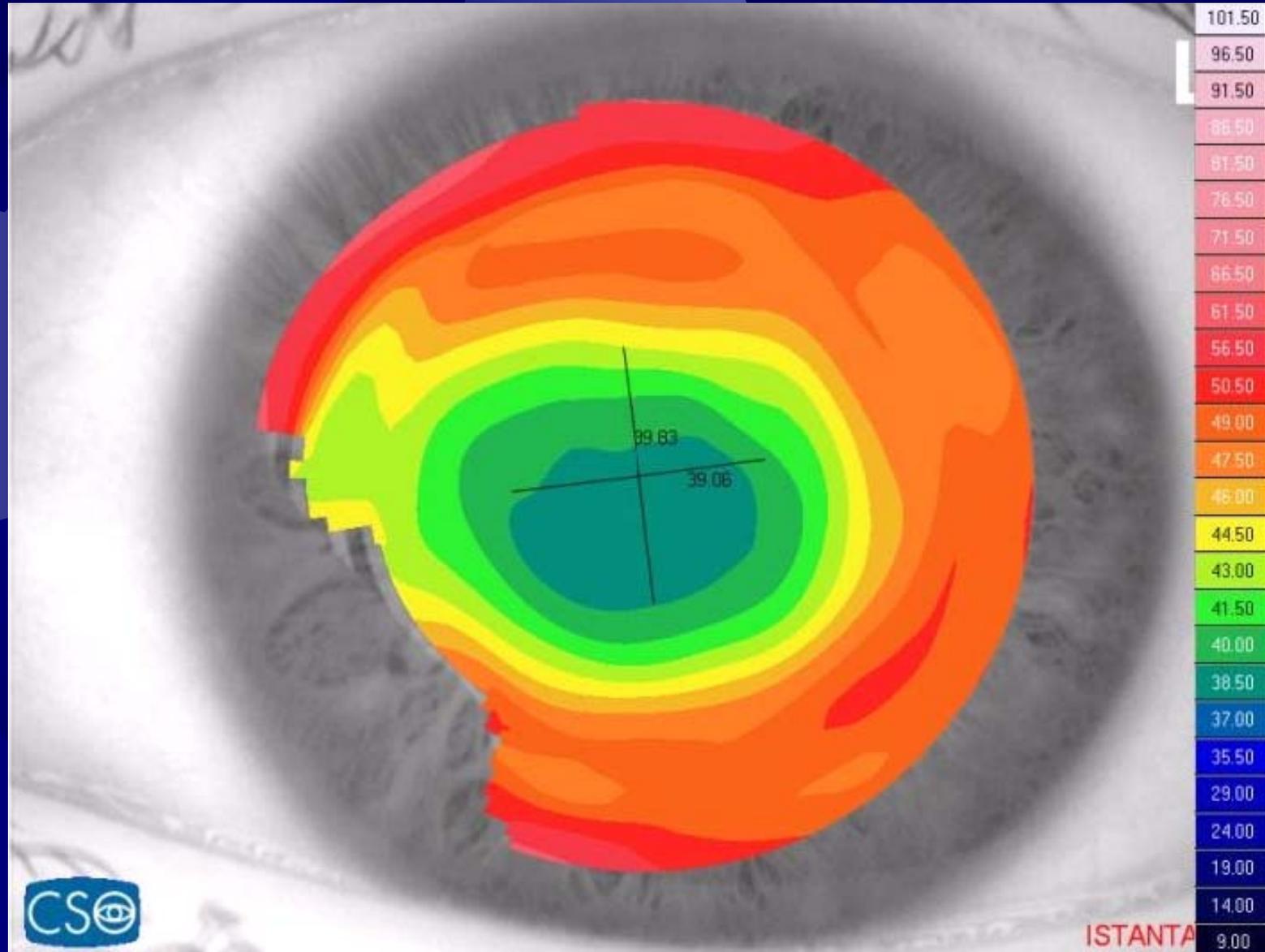
One Case in Court

- **16.07.03**: Pt underwent **customized PTK** with NIDEK EC 5000
- **04.09.03** VOS 0.95 plano, NV I DW +1.50
- PTK eliminated optical zone restriction and reduced haze
- Pt interrupted follow-up and **filed suit...**

PTK

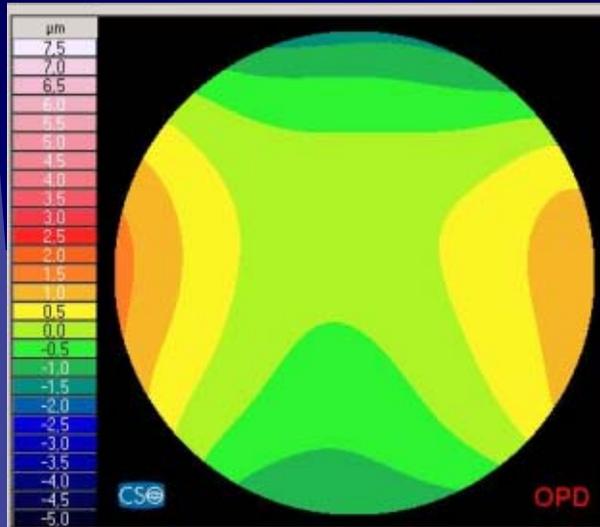


Post - PTK



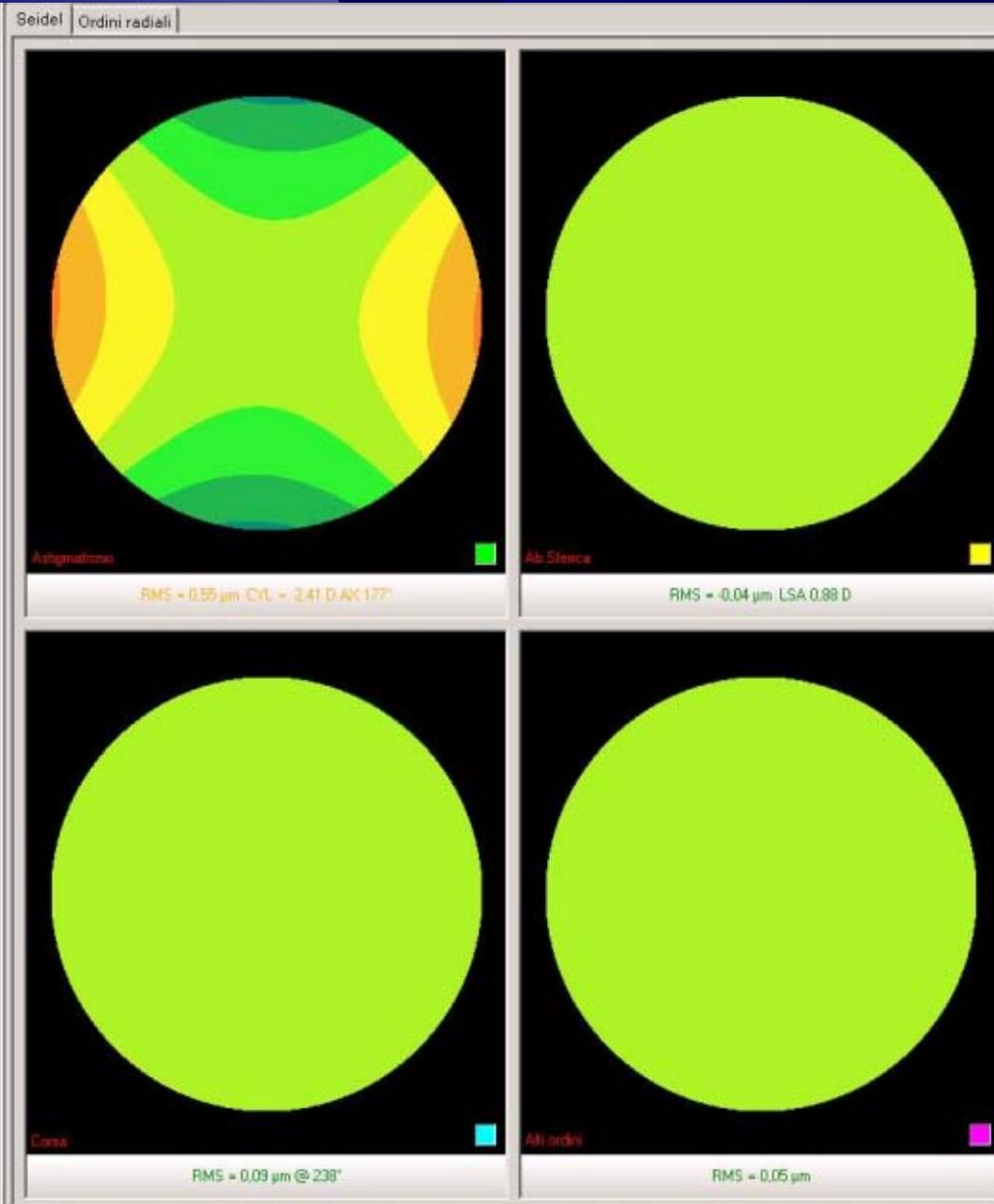
ISTANTA

Aberrations - Postop



RMS = 0,68 μm $\varnothing = 3,00 \text{ mm}$

	Descrizione	Valore (RMS)	Fondoscala = 0,57
Z[0,0]	Pistone	0,17 μm	
Z[1, \pm 1]	Tilt	0,34 μm @ 267°	
Z[2, \pm 2]	Astigmatismo	0,55 μm @ 177°	
Z[2,0]	Defocus	0,04 μm	
Z[3, \pm 3]	Tritoglio	0,03 μm @ 74°	
Z[3, \pm 1]	Coma	0,09 μm @ 238°	
Z[4, \pm 4]	Quadrifoglio	0,01 μm @ 6°	
Z[4, \pm 2]	Astigmatismo II	0,00 μm @ 163°	
Z[4,0]	Ab. Sferica	-0,04 μm	
Z[5, \pm 5]	Pentafoglio	0,02 μm @ 21°	
Z[5, \pm 3]	Tritoglio II	0,00 μm @ 28°	
Z[5, \pm 1]	Coma II	0,01 μm @ 58°	
Z[6, \pm 6]	Esafoglio	0,02 μm @ 27°	
Z[6, \pm 4]	Quadrifoglio II	0,01 μm @ 53°	
Z[6, \pm 2]	Astigmatismo III	0,00 μm @ 48°	
Z[6,0]	Ab. Sferica II	0,00 μm	
Z[7, \pm 7]	Eptafoglio	0,02 μm @ 23°	
Z[7, \pm 5]	Pentafoglio II	0,01 μm @ 20°	
Z[7, \pm 3]	Tritoglio III	0,01 μm @ 51°	
Z[7, \pm 1]	Coma III	0,01 μm @ 223°	



One Case in Court

- **09.01.08. Medico-Legal evaluation, Ophthalmological Consultant for the Judge:**

- VOS 0.85 plano, 1.0 +0.75
- AS LE small paracentral corneal opacity

- **Consultant's Conclusions:**

- Correct information
- Correct surgical technique in PRK and PTK
- Known possible complication of PRK
- No functional damage
- 1- 1.5% biological damage
- Waiting for the Judge now...

Conclusions

- Always show attention and dedication
- Have a positive attitude, but...be cautious
- Never promise too much
- Surgeons must strive to develop the strongest doctor/patient relationship possible with their patients

(Lindstrom R, Ophthalmology, 2004; 111)

- Thorough and obsessive documentation

You Can't Fix Crazy

■ Schizophrenia:	1.3%
■ Bipolar:	1.2%
■ Panic Disorder: ★	1.7%
■ Obsessive Compulsive Disorder: ★★	2.4%
■ Generalized Anxiety Disorder: ★★	2.8%
■ Depression: ★	5.3%
■ Borderline Personality Disorder	2.0%
■ Alcoholism ★	<u>5.5%</u>

Total 22.2%

(significant overlap, so not really)

Some patients will never
be happy

From National Institute of Mental Health



Courtesy of Stephen Dell, MD