

17TH INTERNATIONAL CONFERENCE OF THE
RESEARCH INSTITUTE OF OPHTHALMOLOGY

RIO 2025

*Anterior Segment Eye Diseases
Current Status & Future Directions*



Post LVC Ectasia and CXL Xtra

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A. Professor of Ophthalmology

The Speaker Has No Financial Interest



Post LVC Ectasia

- Biomechanical Failure!!

Why

- Preop: Preexisting Ectasia susceptibility
- Intraop: Tissue removal +/- Flap cut
- Postop: Rubbing and sleeping Pattern !!

Post PRK Ectasia

PRK

- At least 57 eyes founded in literature.

Antonio Leccisotti Graefe's. Corneal ectasia after photorefractive keratectomy. Arch Clin Exp Ophthalmol 2007;245:869-75.

Reinstein Dan Z, Sabong Srivannaboon, Archer Timothy J, Dip Comp Sci, Silverman Ronald H, Hugo Sutton, Coleman Jackson D. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk of ectasia after LASIK (Part II): Quantifying population risk. Journal of Refractive Surgery November 2006;22(9):861-70.

Randleman JB, Caster AI, Banning CS, Stulting RD. Corneal ectasia after photorefractive keratectomy. J Cataract Refract Surg Aug 2006;32(8):1395-98.

Kim, Hyojin, Choi, Jun-Sub, Joo, Choun-Ki Cornea. Corneal ectasia after PRK: Clinicopathologic case report. August 2006; 25(7):845-48.



10.5005/jp-journals-10025-1014

CASE REPORT

Corneal Ectasia after PRK

Jes Nørsgaard Mortensen

ABSTRACT

It is well known that iatrogenic ectasia is lower in PRK compared to LASIK. The true incidence of post-LASIK and post-PRK ectasia remains unknown according to Dr Marguerite B McDonald. Corneal ectasia after PRK was reported to start after 3 to 5 years and after LASIK 6 to 18 months. The author reports of a case with corneal ectasia after PRK in both eyes that started after 16 years. In spite of corneal cross-linking the progression of the ectasia progressed in both eyes.

Keywords: Ectasia, LASIK, PR

How to cite this article: Mortensen JN. Corneal Ectasia after PRK. Int J Keratoco Ectatic Corneal Dis 2012;1(1):73-74.

Source of support: Nil

Conflict of interest: None declared

INTRODUCTION

McDonald only 32 cases of post-PRK were reported in international literature, but that the number was growing, possibility due to the late onset of the post-PRK ectasia.

There is a difference in the start of the iatrogenectasia. After PRK the onset is postponed till 3 to 5 years and after LASIK 6 to 18 months.

Professor Theo Seiler pointed out the different major risk factors most important to consider when performing LASIK: Thickness of the flap, thickness of the residual stroma, forme fruste keratoconus, the tensile strength of the cornea. Professor Marguerite B McDonald agreed on that but even pointed out that an abnormal topography should warn not to perform PRK.

Corneal ectasia after PRK was reported to start after 3 to 5 years, but even later start has been reported, Kim Hyojin⁵ reports of a case after 9 years after PRK.

Post LASIK Ectasia

Post LASIK Ectasia

- Prof Theo Seiler 1998: first case of Iatrogenic Ectasia after Lasik
- At least 1500 case reports



LASIK Case

A twenty three year old male patient

Preoperative refraction OD -2,50 sph -1,00x170 CDVA 1.2
OS -2,50 sph -1,00x25 CDVA 1.2

N.B. the vision and refraction were stable for at least 5 years (documented in his file from previous visits)

Max ablation depth OD 63 um
OS 63 um

Optical zone for OD and OS: 7 mm

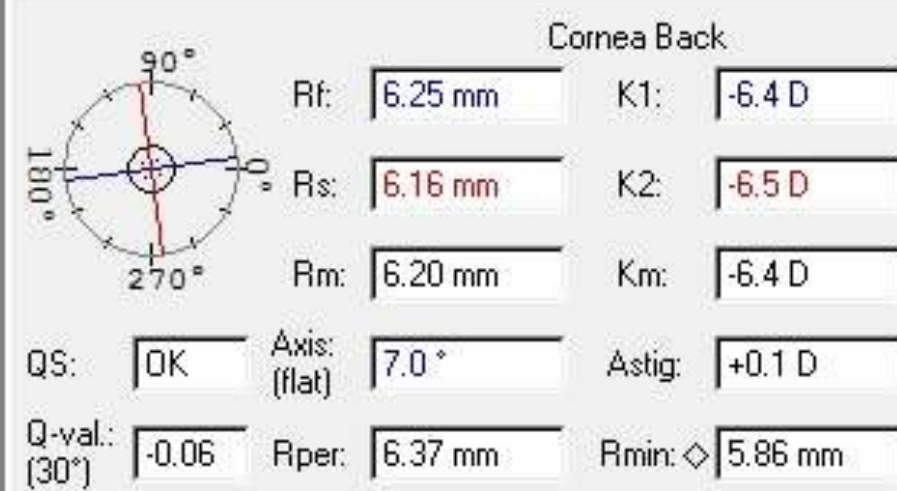
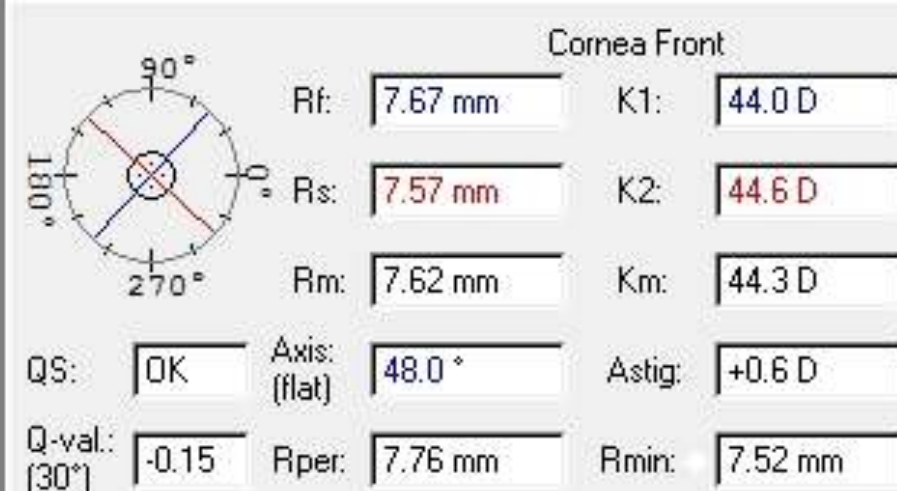
conventional LASIK with Moria M2 microkeratome with 130 head

Pre LASIK

OCULUS - PENTACAM 4 Maps Refractive

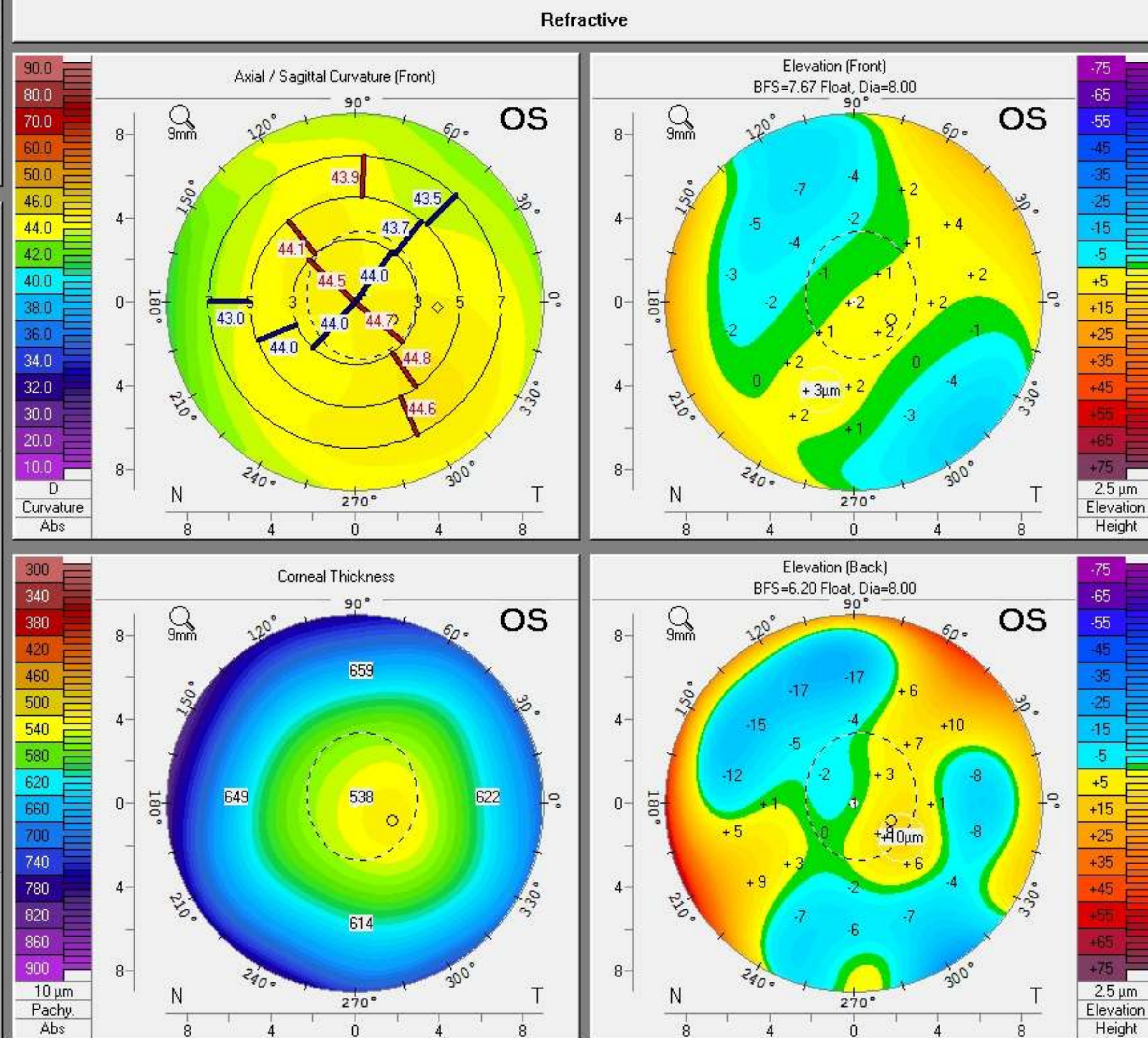
1.22:01

Last Name:
First Name:
ID:
Date of Birth: 07/10/1987 Eye: Left
Exam Date: 03/27/2016 Time: 14:41:52
Exam Info:



Pupil Center:	Pachy:	x(mm)	y(mm)
+	538 µm	+0.17	+0.16
Pachy Apex:	539 µm	0.00	0.00
Thinnest Locat.:	530 µm	+0.88	-0.41
K Max. (Front):	44.9 D	+1.90	-2.17

Cornea Volume:	62.5 mm ³	KPD:	+1.1 D
Chamber Volume:	211 mm ³	Angle:	43.0°
A. C. Depth (Int.):	3.39 mm	Pupil Dia:	2.83 mm
Enter IOP IOP(corr):		Lens Th.:	



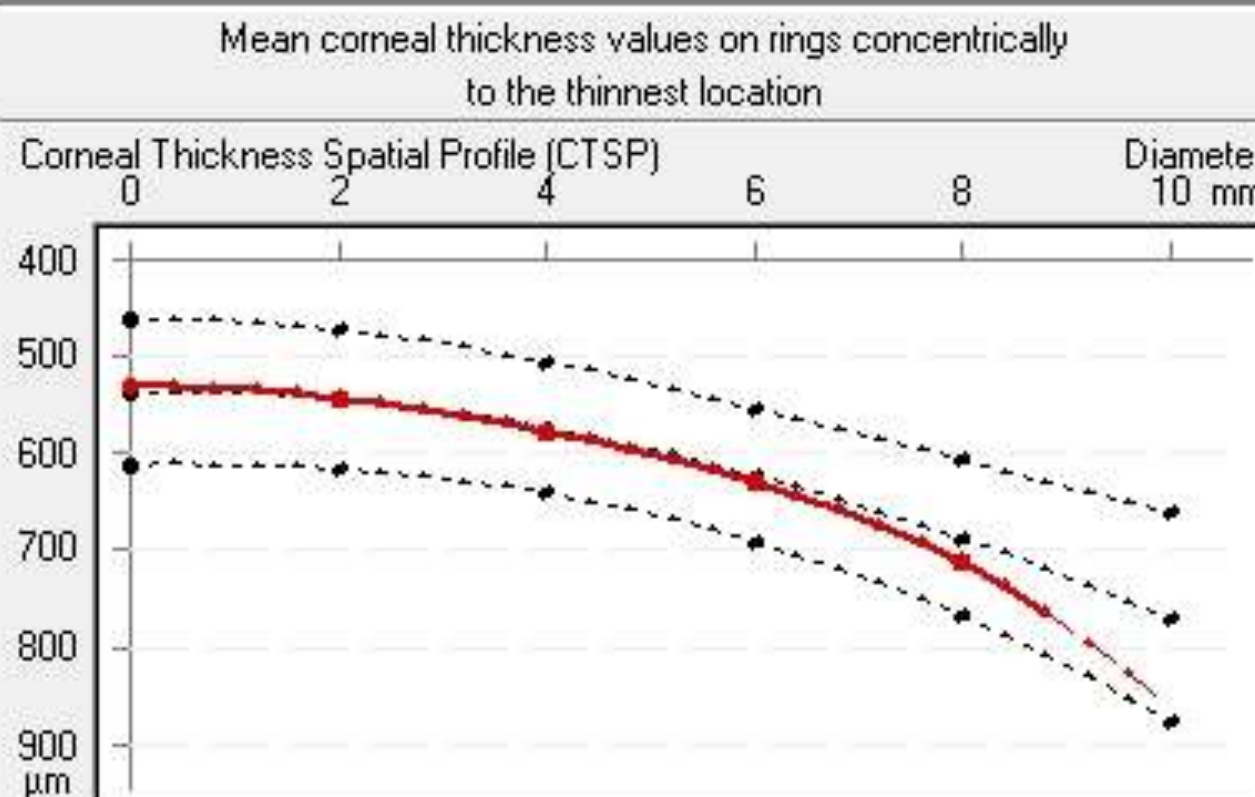
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 First Name:
 ID:
 Date of Birth: 07/10/1987 Eye: Left
 Exam Date: 03/27/2016 Time: 14:41:52

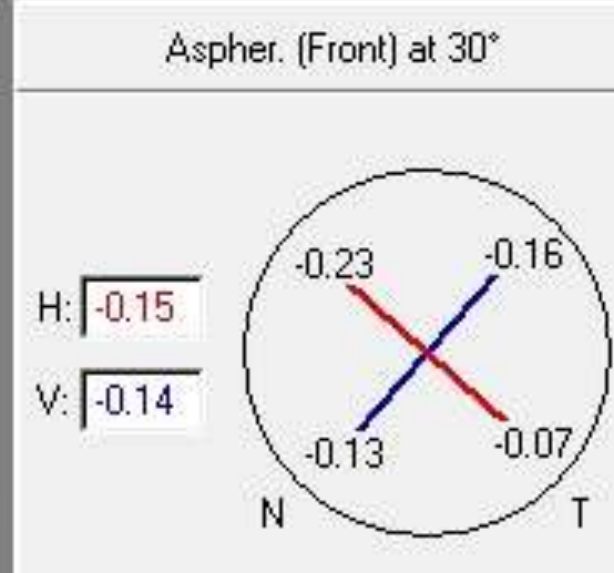


Pupil Center: + 538 μ m x[mm] +0.17 y[mm] +0.16
 Thinnest Locat.: O 530 μ m x[mm] +0.88 y[mm] -0.41
 A. C. Depth (Int.): 3.39 mm Pupil Dia: 2.83 mm
 Angle: 43.0° Lens Th.:



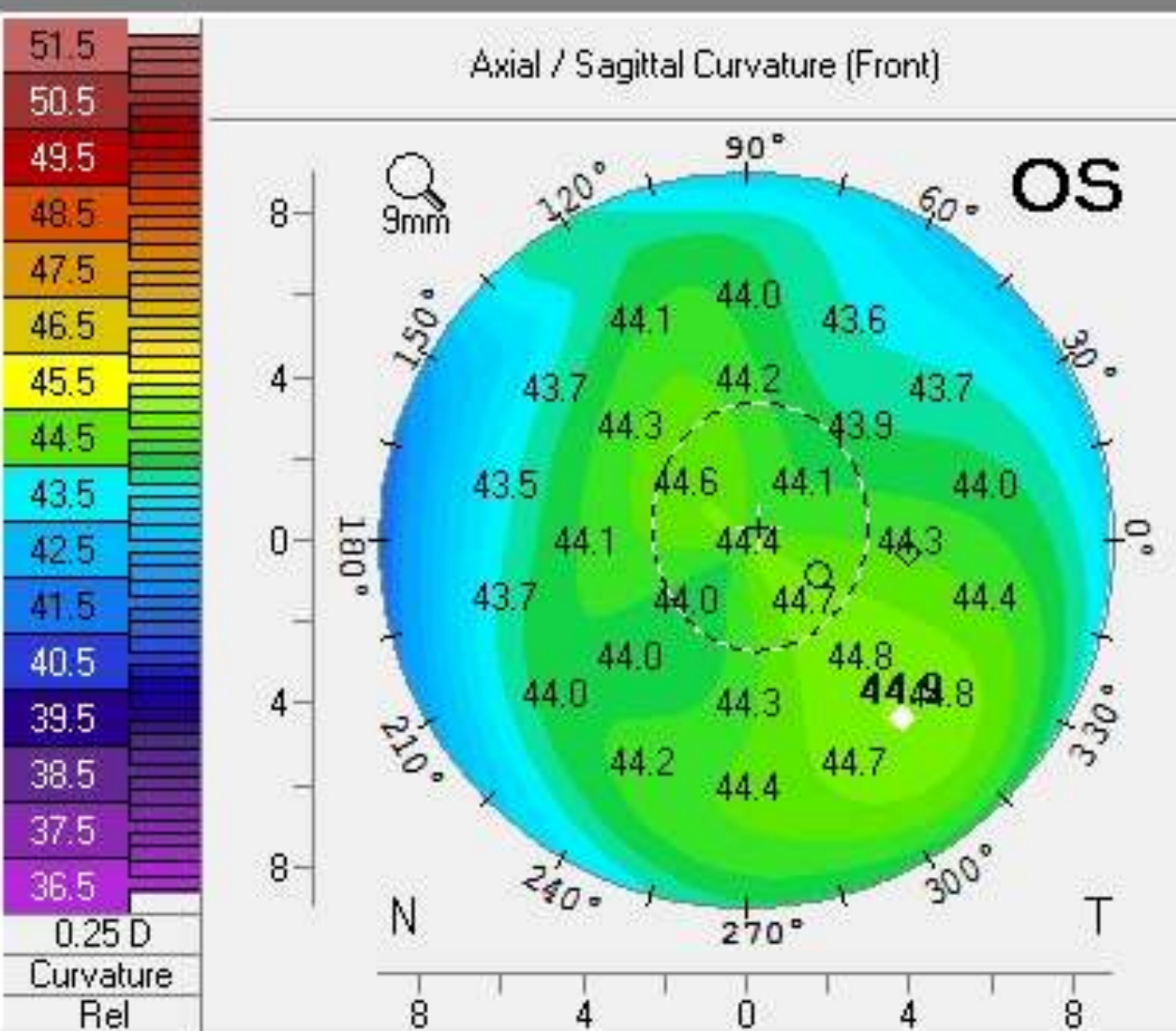
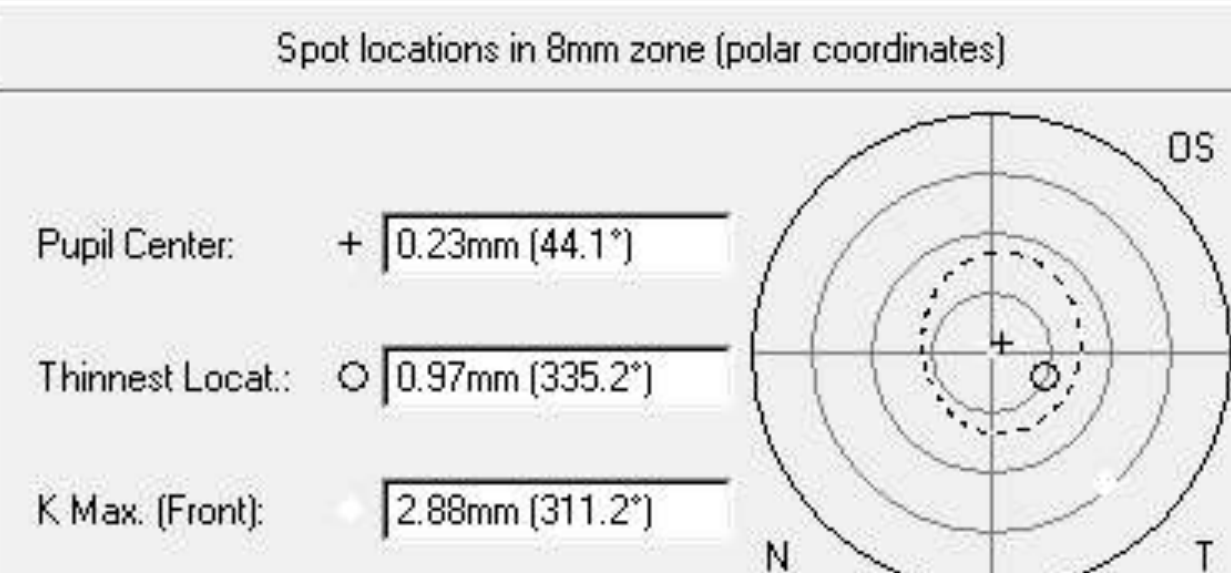
Indices (in 8mm zone)

ISV: 10 IHA: 8.4
 IVA: 0.08 IHD: 0.010
 KI: 1.01 RMin: 7.52
 CKI: 1.00 TKC: -
 KISA: 0.800 IS: 0.59



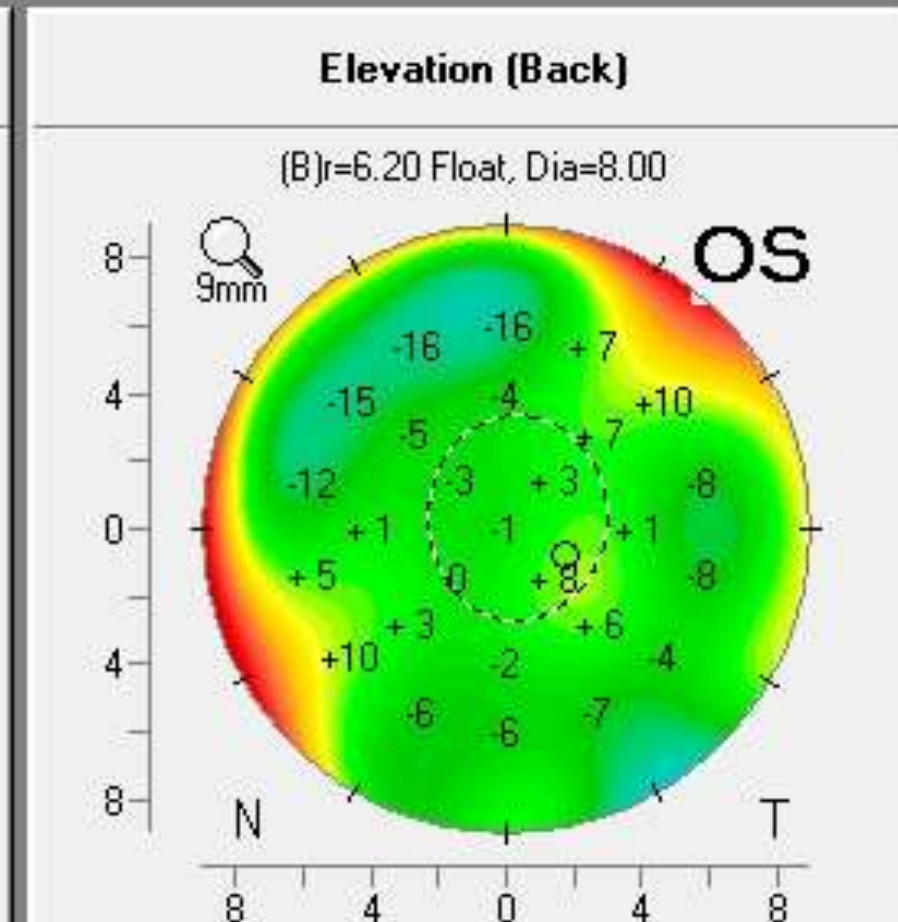
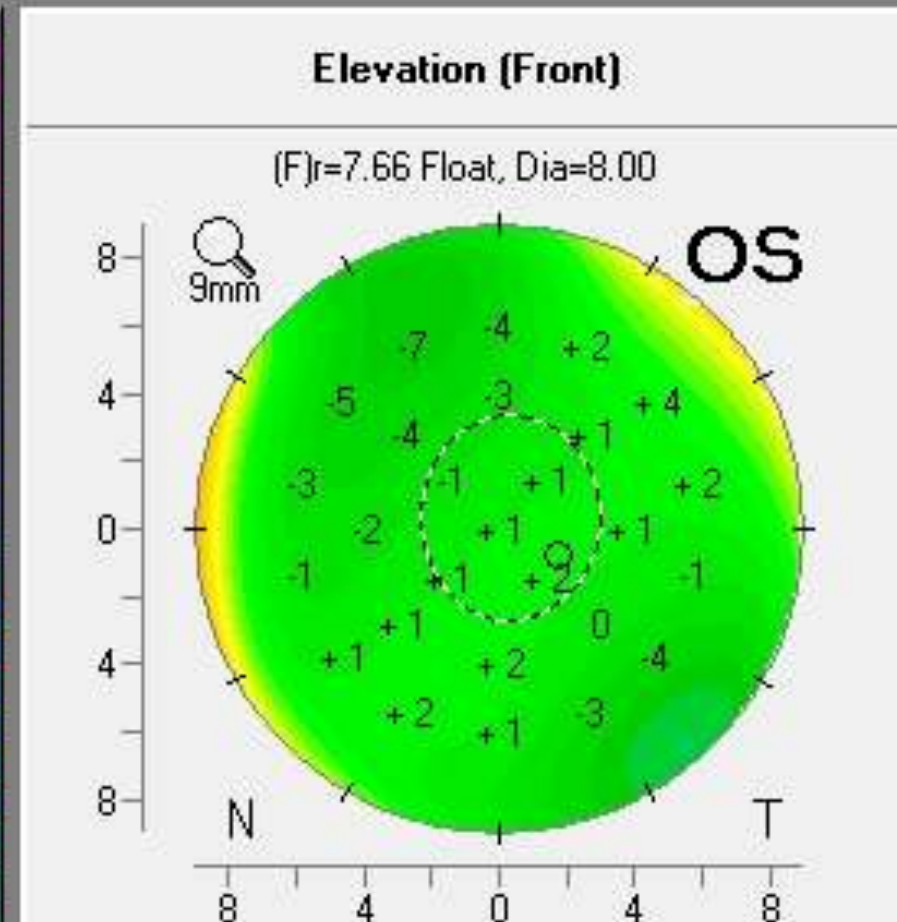
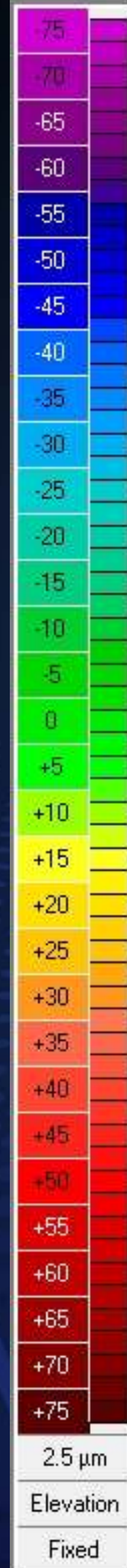
Asphericity (Front) of Major Meridians

(Q-val.)	20°	25°	30°	35°	40°
Nas	-0.29	-0.27	-0.23	-0.25	-0.50
Temp	0.03	-0.02	-0.07	-0.14	-0.19
Inf	-0.00	-0.07	-0.13	-0.16	-0.30
Sup	-0.15	-0.14	-0.16	-0.17	-0.22
Mean	-0.11	-0.12	-0.15	-0.18	-0.31



OCULUS - PENTACAM Belin/Ambrósio Enhanced Ectasia Display

1.22r01



Last Name:

First Name:

ID:

Date of Birth: 07/10/1987 Eye: Left

Exam Date: 03/27/2016 Time: 14:41:52

Exam Info:

K1:	44.0D	Axis:	48.0°
K2:	44.6D	Q-val.:	-0.15
KMax:	44.9D	QS:	OK

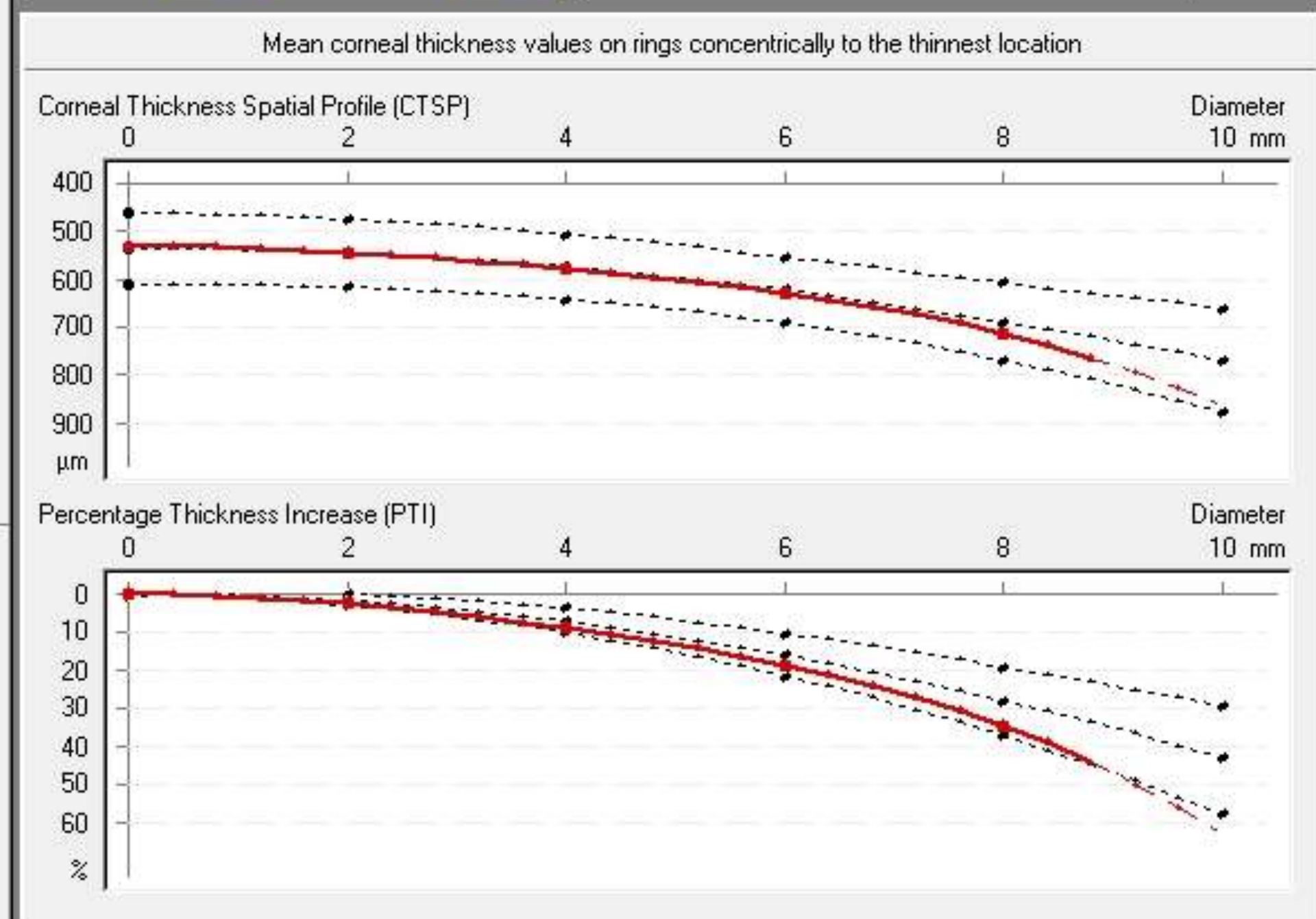
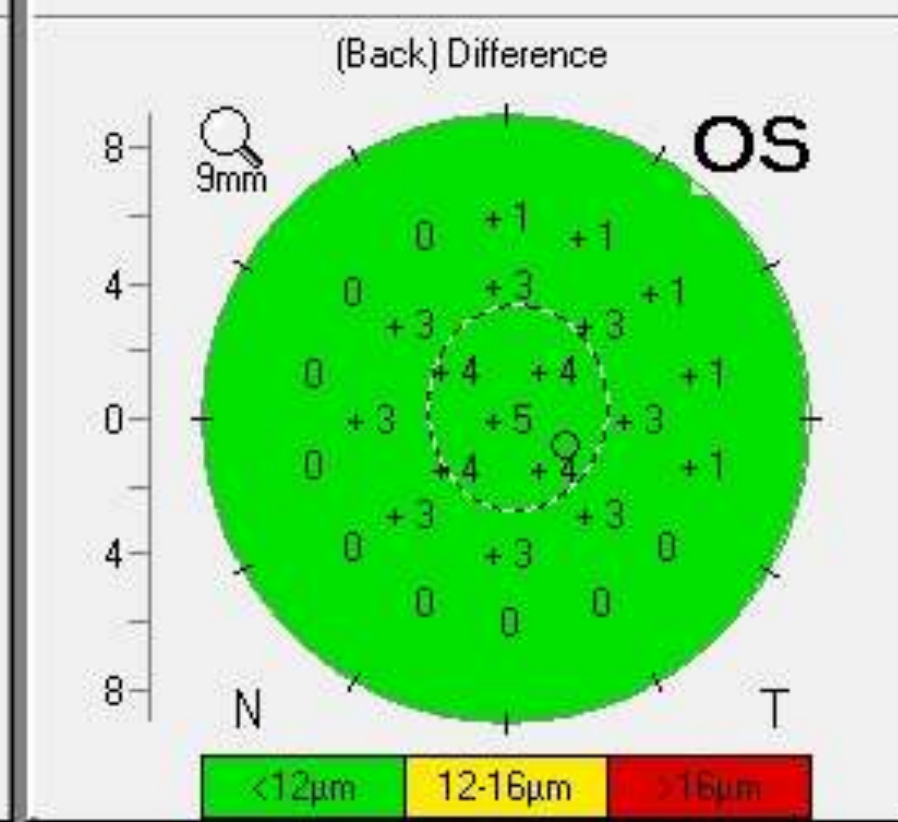
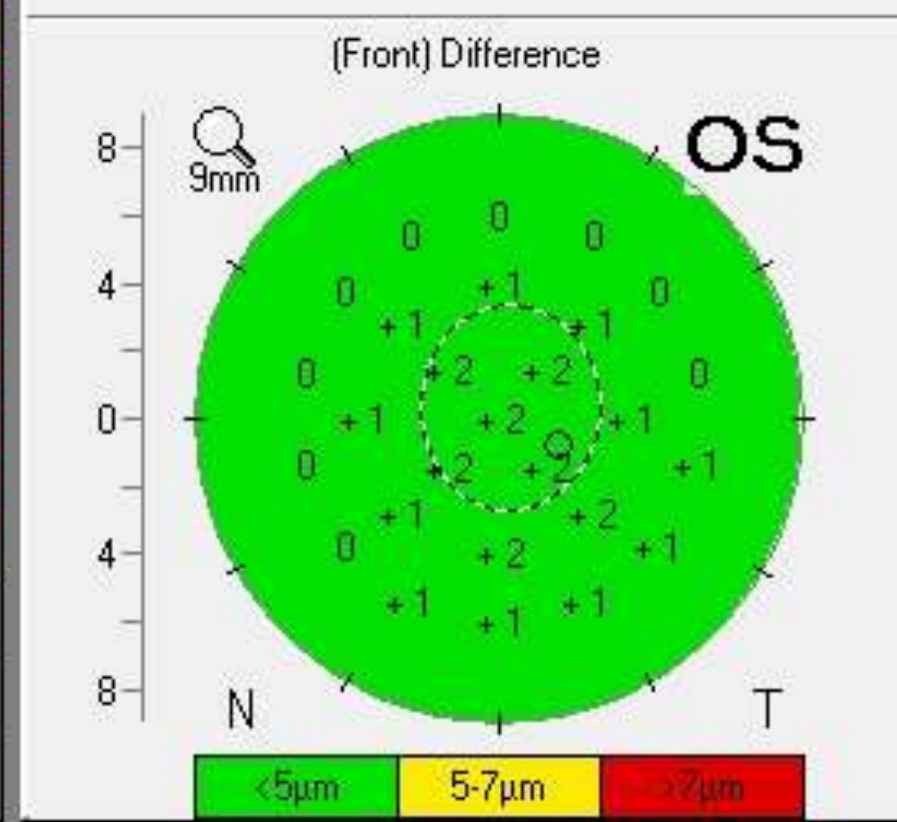
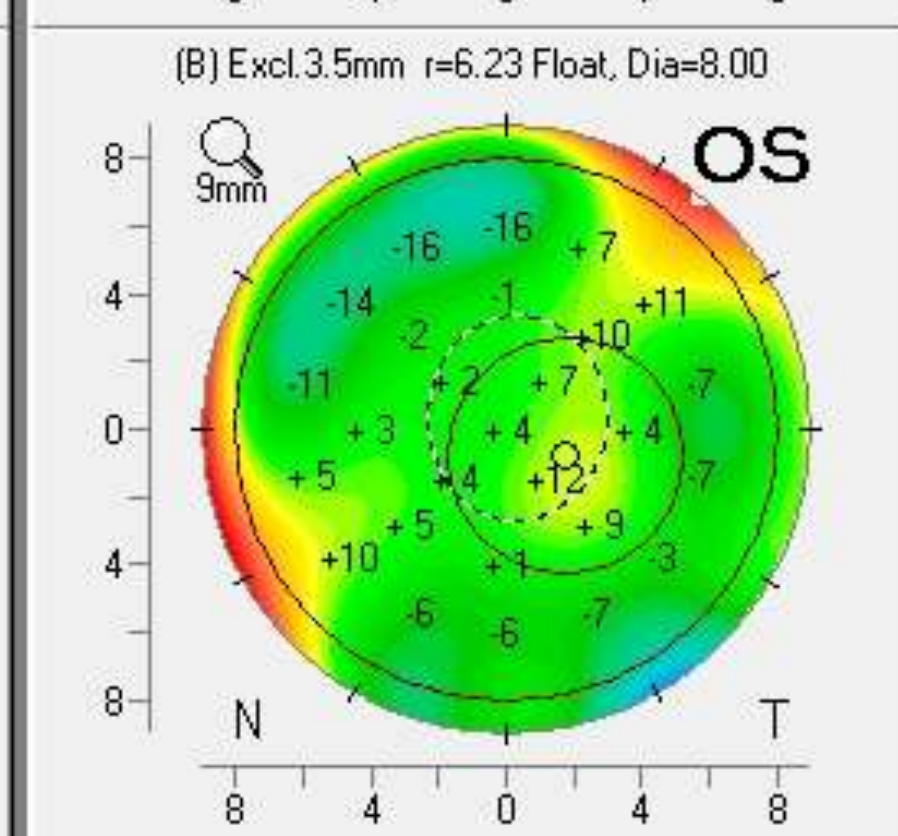
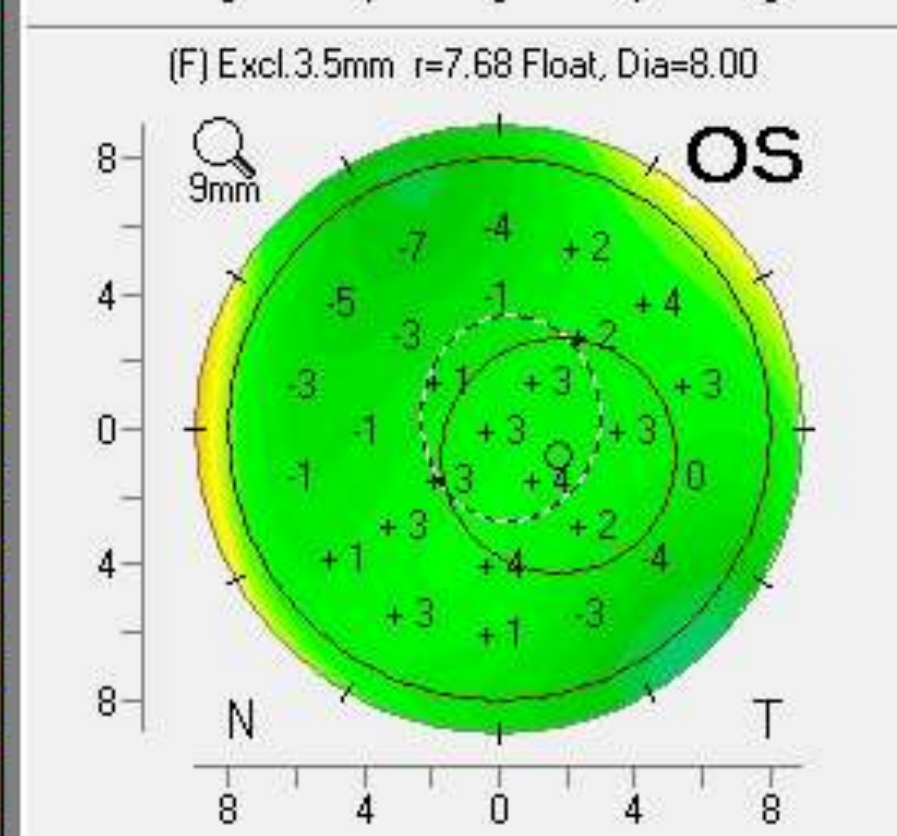
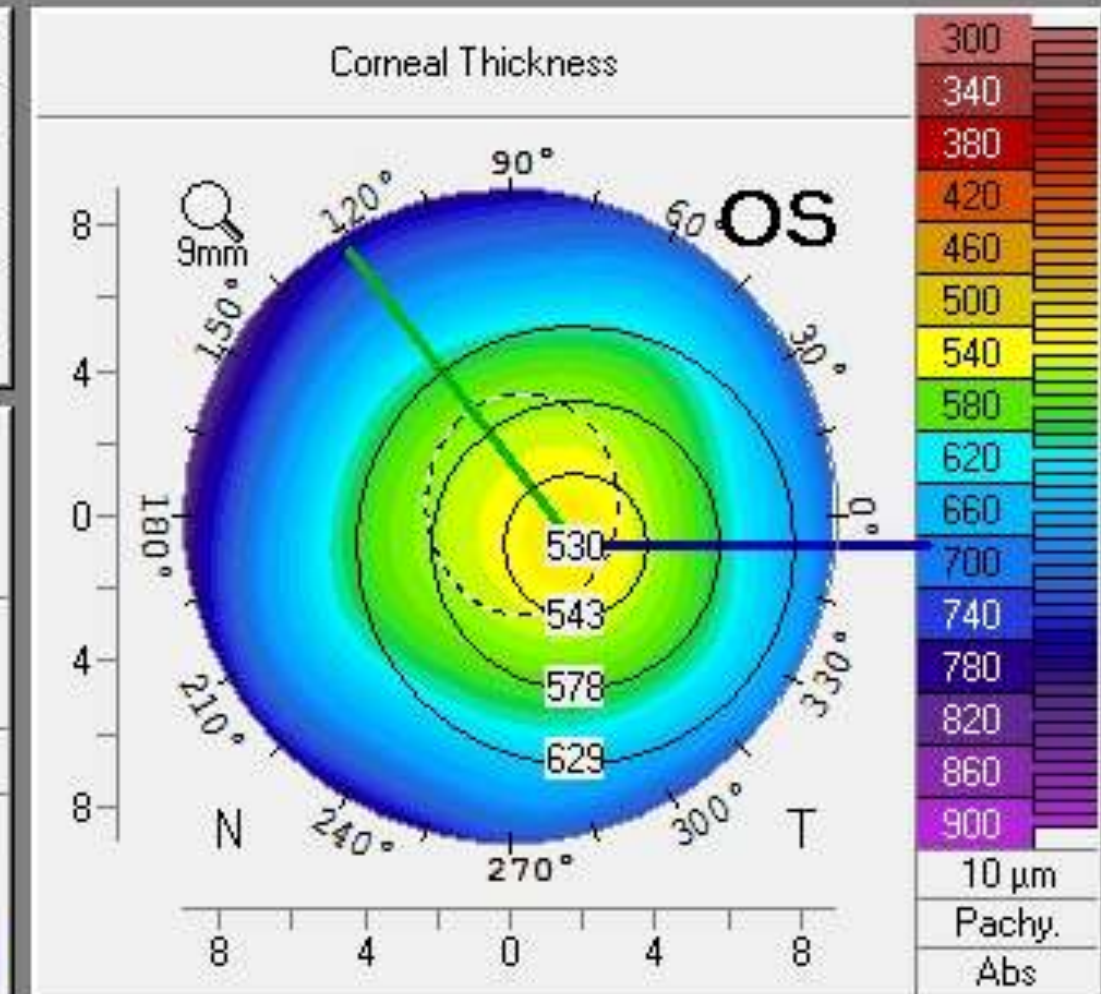
Pachy Thin. Locat.: ☐ 530µm

Dist. Apex-Thin.Loc.: ☐ IT 0.97mm

F.Ele.Th: 2µm B.Ele.Th: 8µm

Progression Index:

Min:	0.85	Max:	1.81
Avg:	1.24	ARTmax:	293



Reference Database: ☒ Myopic/Normal ☐ Hyperopic/Mixed Cyl.

Df: -0.42 Db: -0.31 Dp: 2.24 Dt: 0.23 Da: 1.78 D: 1.56

OCULUS - PENTACAM 4 Maps Refractive

1.22x01

Last Name:
First Name:
ID:
Date of Birth: 07/10/1987 Eye: Left
Exam Date: 12/31/2019 Time: 12:05:00
Exam Info:

Cornea Front

90°
180°
270°

Rf: 7.99 mm K1: 42.2 D
Rs: 7.01 mm K2: 48.1 D
Rm: 7.50 mm Km: 45.0 D
QS: OK Axis: (flat) 79.7° Astig: +5.9 D
Q-val: (30°) -0.24 Rper: 7.88 mm Rmin: 6.36 mm

Cornea Back

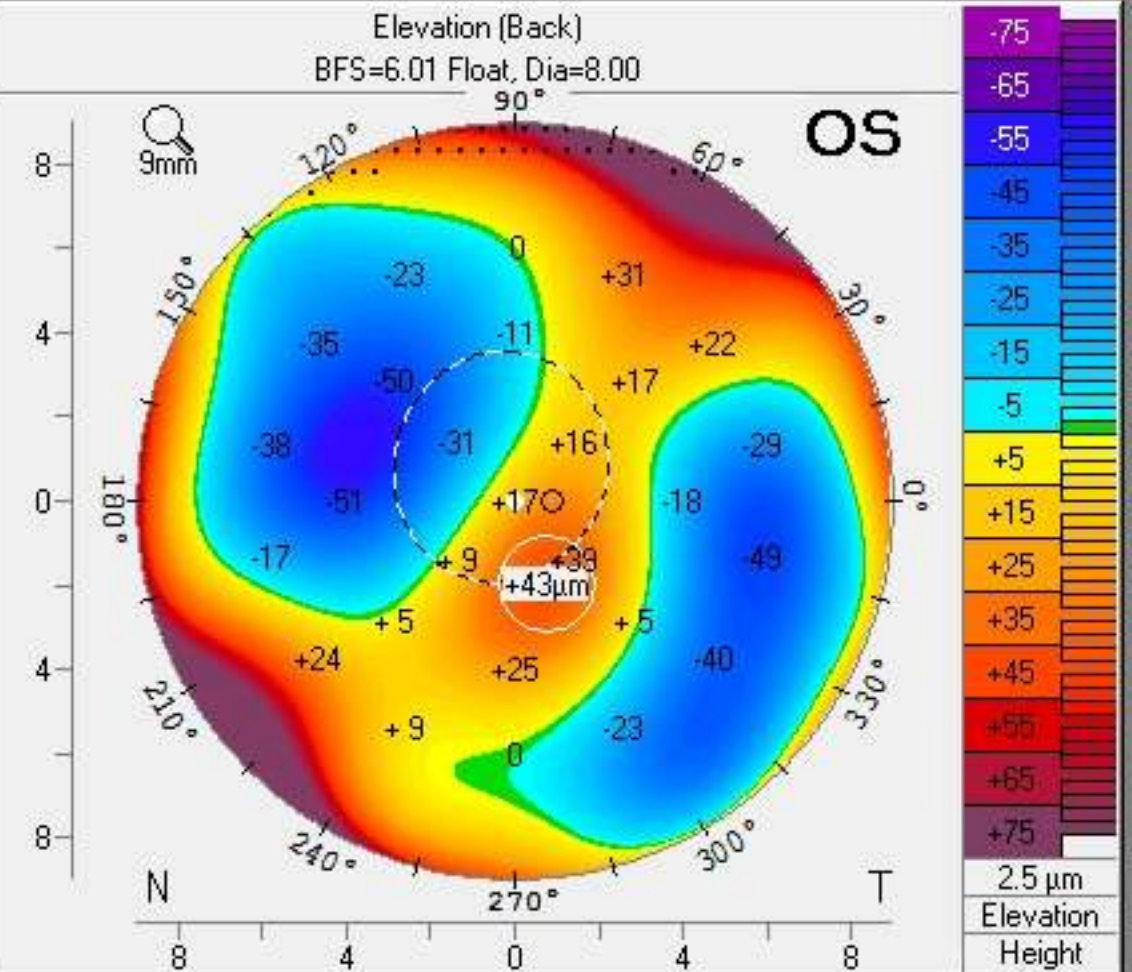
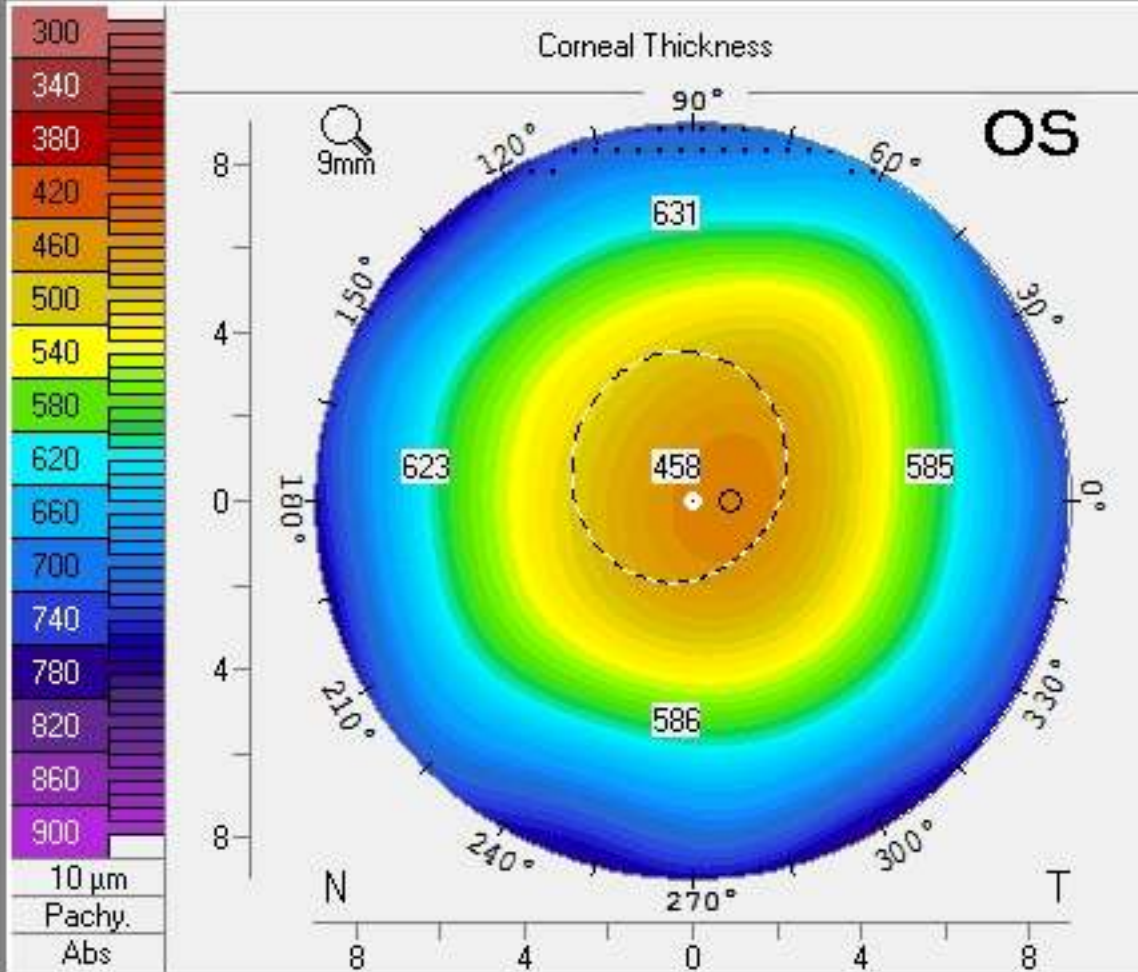
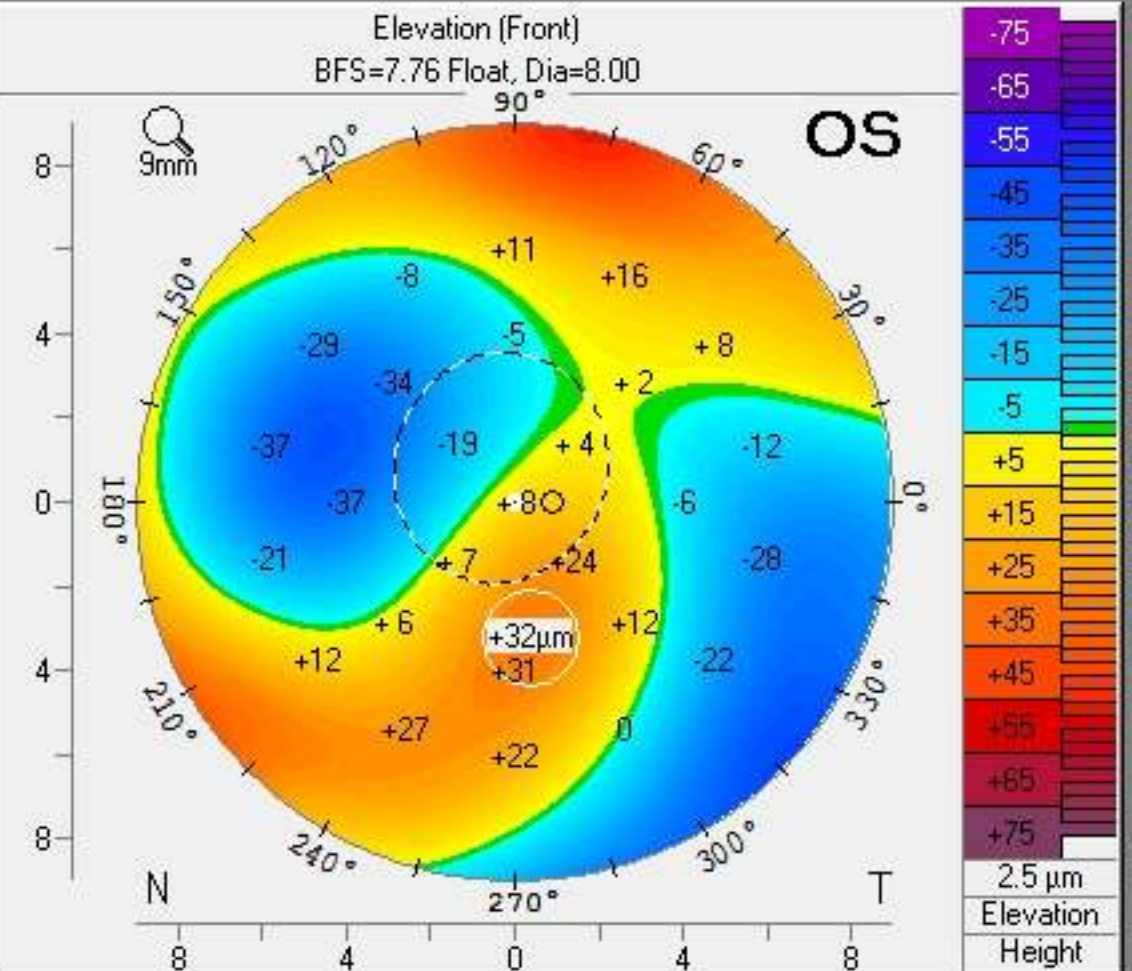
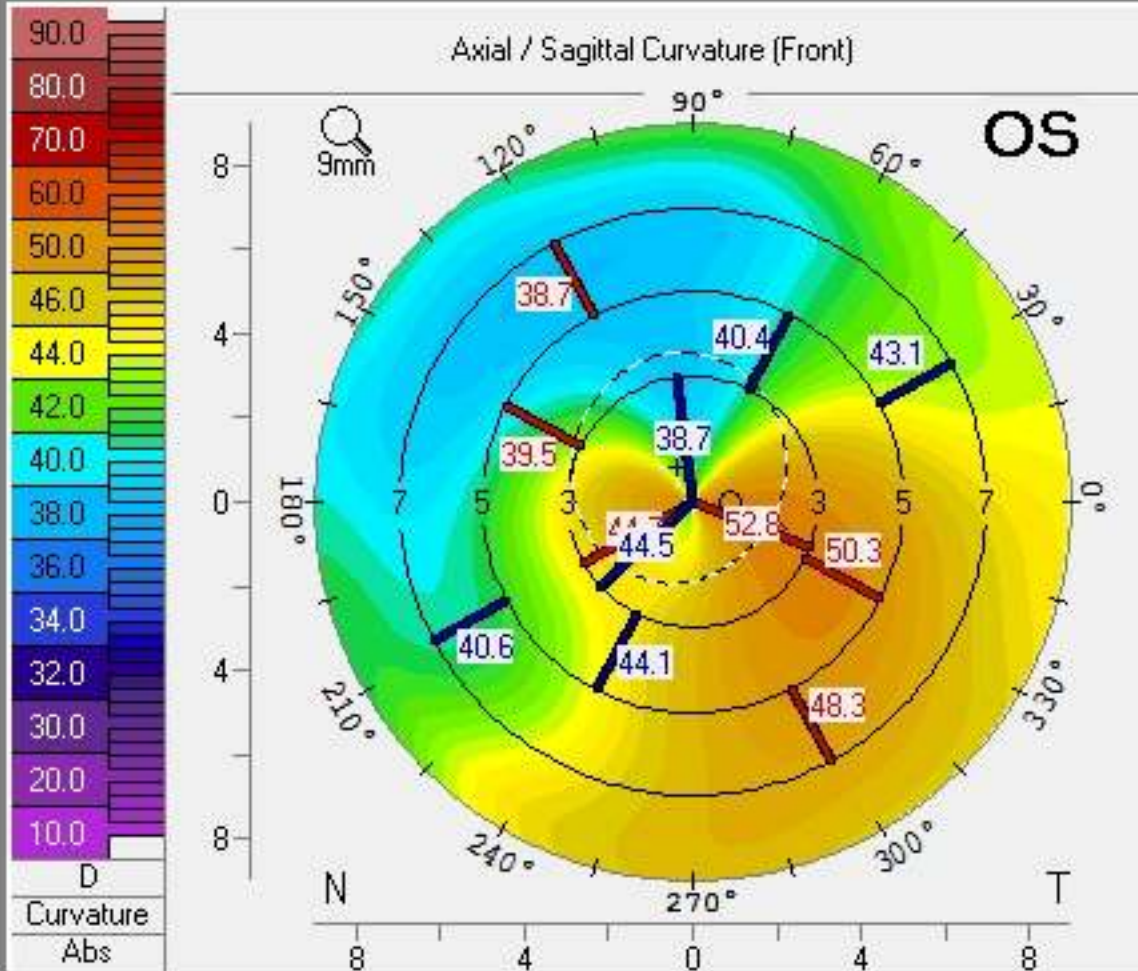
90°
180°
270°

Rf: 6.02 mm K1: -6.7 D
Rs: 5.40 mm K2: -7.4 D
Rm: 5.71 mm Km: -7.0 D
QS: OK Axis: (flat) 73.0° Astig: -0.8 D
Q-val: (30°) -0.55 Rper: 6.34 mm Rmin: 4.38 mm

Pupil Center: + 458 μ m x[mm] -0.18 y[mm] +0.41
Pachy Apex: - 450 μ m 0.00 0.00
Thinnest Locat.: O 445 μ m +0.45 0.00
K Max. (Front): 53.1 D +1.03 -0.32

Cornea Volume: 60.3 mm³ HWTW: 11.4 mm
Chamber Volume: 204 mm³ Angle: 37.9°
A. C. Depth (Int.): 3.40 mm Pupil Dia: 2.64 mm
Enter IOP IOP(cor): Lens Th.:

Refractive



Assessment of Preoperative Risk Factors for Post-LASIK Ectasia Development

Mohamed Tarek El-Naggar¹, Rania Serag Elkitkat²⁻⁵, Hossam El-din Ziada⁶, Louise Pellegrino Gomes Esporcatte⁷⁻⁹, Renato Ambrósio Jr⁷⁻¹¹

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Purpose: To evaluate preoperative risk factors (mainly those related to corneal topography/tomography) for post-LASIK ectasia development.

Methods: A retrospective case review for post-LASIK ectasia for myopia or myopic astigmatism. The evaluated data included preoperative subjective refraction, method of flap creation, and topometric/tomographic parameters from Oculus Pentacam, including subjective curvature pattern, topometric, elevation, and pachymetric indices from the Belin Ambrosio display “BAD”, and the Pentacam Random Forest Index (PRFI). Moreover, preoperative ectasia detection indices were calculated (including Percentage of Tissue Altered “PTA” index, Randleman Ectasia Risk Score System “ERSS”, and Navarro Index for Corneal Ectasia “NICE”).

Results: Twenty-four eyes of 15 patients were enrolled. Concerning the risk factors, age was lower than 25 in 19 eyes (79%); flaps were created using a microkeratome in 17 eyes (70.8%); thinnest pachymetry was lower than 510µm in eight eyes (33%); total deviation from BAD was higher than 1.6 in 50%; Ambrósio’s relational thickness (ART) max was lower than 340 in 45.83%; PTA index was higher than 40% in 16%; ERSS was more than 3 points in 62.5%; NICE was higher than 8 points in three eyes (12.5%); PRFI index was more than 0.125 in 87.5%; two eyes (8%) had no identifiable risk factors.

Conclusion: Current ectasia risk assessment criteria were insufficient for detecting a relatively large number of cases. There is an unequivocal need for more information, which may be derived from biomechanical assessment and epithelial thickness mapping. Novel corneal tomography indices derived from artificial intelligence may increase accuracy in characterizing ectasia susceptibility.

Keywords: cornea ectasia, preoperative ectasia risk assessment, LASIK screening, Pentacam

Introduction

Laser in situ keratomileusis (LASIK) is the most frequently performed refractive surgery worldwide, with recognizable efficiency and safety.¹ Post-LASIK corneal ectasia has been regarded as one of the most feared complications since the first report by Seiler in 1998.^{2,3} It is considered in patients who develop keratometric steepening, elevated values of posterior corneal elevation, with or without central and paracentral corneal thinning, and/or topographic evidence of asymmetric inferior corneal steepening following LASIK procedure.⁴ Its prevention has always been a significant concern for refractive surgeons.^{5,6}

In the published literature, the prevalence of post-LASIK ectasia ranges between 0.04% and 0.9%.^{7,8} Over the last two decades, the incidence of ectasia has reduced from moderately high levels of 0.66%⁹ and 0.57%,¹⁰ down to 0.2%,¹¹ 0.05%,¹² and 0.033%.¹³ Such reduction in this severe complication has resulted from considerable efforts to develop advanced and meticulous preoperative screening strategies.^{12,14}

topometric/tomographic parameters including subjective curvature pattern, topometric, elevation, pachymetric indices, BAD-D and PRFI
Preoperative ectasia detection indices: PTA, ERSS and NICE

Conclusion: Current ectasia risk assessment criteria were insufficient for detecting a relatively large number of cases. There is an unequivocal need for more information, which may be derived from biomechanical assessment and epithelial thickness mapping.

Post SMILE Ectasia

Table 1. Studies analyzing corneal biomechanics after laser refractive surgery techniques.

Study* and Year	Instrument(s)	Technique(s)	Conclusions
LASIK vs LASEK/PRK			
Kirwan 2008 ⁶¹	ORA	LASIK, LASEK	No differences between techniques
Kamiya 2009 ⁶²	ORA	LASIK, PRK	More effect after LASIK
Hassan 2014 ⁶³	Corvis	LASIK, PRK	More effect after LASIK
Shen 2014 ⁶⁴	Corvis	FS-LASIK, LASEK	More effect after FS-LASIK
SMILE vs LASIK			
Shen 2014 ⁶⁴	Corvis	SMILE, FS-LASIK	No differences between techniques
Pedersen 2014 ⁶⁵	ORA; Corvis	SMILE, FS-LASIK	No differences between techniques
Wang 2014 ⁶⁶	ORA	SMILE, FS-LASIK	Differences for myopia >6 D in favor of SMILE
Wu 2014 ⁶⁷	ORAA	SMILE, FS-LASIK	More effect after FS-LASIK
Agca 2014 ⁶⁸	ORA	SMILE, FS-LASIK	No differences between techniques
Sefat 2016 ⁶⁹	Corvis	SMILE, FS-LASIK	No differences between techniques
Osman 2016 ⁷⁰	ORA	SMILE, FS-LASIK	More effect after FS-LASIK
Wang 2016 ^{69,71}	ORA	SMILE, FS-LASIK	More effect after FS-LASIK
Zhang 2016 ⁷²	ORA	SMILE, FS-LASIK WF	No differences between techniques
SMILE vs LASEK/PRK			
Shen 2014 ⁶⁴	Corvis	SMILE, LASEK	No differences between techniques
Dou 2015 ⁷³	ORA	SMILE, LASEK	Regarding per unit tissue removed, SMILE had less effect on corneal biomechanics than LASEK
Yildirim 2016 ⁷⁴	ORA	SMILE; PRK	More effect after SMILE
Chen 2016 ⁷⁵	ORA	SMILE; LASEK	More effect after LASEK
Al-Nashar 2017 ⁷⁶	ORA	SMILE; PRK	No differences between techniques
Technique variations			
Kamiya 2014 ⁷⁷	ORA	SMILE, FLEx	Presence or absence of flap lifting had no significant affect on biomechanical parameters
Shen 2014 ⁷⁸	Corvis	SMILE	Differences pre/post from extraction of lenticule and not its sculpting
Mastropasqua 2014 ⁷⁹	Corvis	SMILE	No significant modifications in biomechanical properties after SMILE
El-Massry 2015 ⁸⁰	ORA	SMILE	Less biomechanical affectation with 160 µm vs 100 µm
Leccisotti 2016 ⁸¹	Corvis	FS-LASIK	Changes in biomechanical properties after femtosecond creation of LASIK flap
Fernández 2016 ⁸²	Corvis	SMILE	No differences between low, medium, and high myopia after considering removed CCT

CCT = central corneal thickness; FLEx = femtosecond lenticule extraction; FS-LASIK = femtosecond laser-assisted; laser in situ keratomileusis; LASEK = laser-assisted subepithelial keratectomy; LASIK = laser in situ keratomileusis; ORA = Ocular Wavefront Analyzer; PRK = photorefractive keratectomy; SMILE = small-incision lenticule extraction; WG = wavefront guided

*P < 0.05.



Tissue Removal

6mm Optical Zone			
	SMILE	Excimer	%
-2.00	37	27	37%
-3.00	50	39	28%
-5.00	75	63	19%
-8.00	110	97	13%

6.5mm Optical Zone			
	SMILE	Excimer	%
-2.00	43	32	34%
-3.00	59	47	25%
-5.00	89	75	18%
-8.00	130	116	12%

Comparison of changes in corneal volume and corneal thickness after myopia correction between LASIK and SMILE

Anna Schuh¹, Carolin M. Kolb², Wolfgang J. Mayer¹, Efstathios Vounotrypidis¹, Thomas Kreutzer¹, Thomas Kohnen², Siegfried Priglinger¹, Mehdi Shajari^{1,2*}, Daniel Kook^{1,3}

¹ Department of Ophthalmology, Ludwig-Maximilians-University, Munich, Germany, ² Department of Ophthalmology, Goethe University, Frankfurt, Germany, ³ SMILE Eyes Eye Clinic Munich Airport, Munich, Germany

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Abstract

Myopia is the most common refractive error. Surgical correction with laser is possible. LASIK and SMILE are the techniques currently most used. Aim of the study was to compare changes in corneal volume and thickness after the respective laser treatment. 104 eyes of 52 patients were matched based on refractive error into two equally sized groups, either treated with LASIK or SMILE. Measurements were obtained from the Scheimpflug camera (Pentacam) preoperatively and at 3 and 12 months postoperatively. 3 months postoperatively, the flapless SMILE procedure resulted in a significant overall greater loss of corneal volume ($P < 0.01$) and corneal thickness ($P < 0.01$) compared to LASIK. No significant difference was found when comparing the 3 to 12-months values in each group. Within the currently used ranges of refractive error correction, loss in central corneal thickness and corneal volume with SMILE is higher in comparison to LASIK. As greater loss in corneal volume and thickness might contribute to higher level of corneal instability maximum ranges of refractive error correction with SMILE should not supersede those set currently for LASIK until more long-term results on corneal ectasia are available for SMILE.

Loss in central corneal thickness and corneal volume with SMILE is higher in comparison to LASIK. As greater loss in corneal volume and thickness might contribute to higher level of corneal instability maximum ranges of refractive error correction with SMILE should not supersede those set currently for LASIK until more long-term results on corneal ectasia are available for SMILE.

April 2015

CASE REPORT

Bilateral ectasia after femtosecond laser-assisted small-incision lenticule extraction



Mohamed Tarek El-Naggar, MD, FRCS

This case report describes clinical and topographic features of bilateral corneal ectasia after femtosecond laser-assisted small-incision lenticule extraction. The case suggests that patients with preoperative forme fruste keratoconus or early keratoconus might develop significant progression of corneal ectasia after the small-incision lenticule extraction procedure and shows that the procedure can affect the corneal biomechanics.

Financial Disclosure: The author has no financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:884–888 © 2015 ASCRS and ESCRS

Corneal ectasia after laser in situ keratomileusis (LASIK) is a well-described, relatively rare complication of corneal refractive surgery.^{1,2} Several reports of ectasia after photorefractive keratectomy (PRK) have been published.^{3–5} To my knowledge, this is the first report of ectasia after femtosecond laser-assisted small-incision lenticule extraction (SMILE, Carl Zeiss

and associated bilateral relative anterior and posterior surface elevation using a best-fit sphere of 8.0 mm diameter. Although the keratometry (K) readings on the anterior corneal surface sagittal map were relatively flat (right eye, 40.4 diopters [D] and 41.6 D; left eye, 40.8 D and 41.6 D), sub-clinical keratoconus/forme fruste keratoconus was diagnosed and LASIK surgery was not considered an option.

Because the patient had a documented stable refraction for the past four years and considering his age and eye health,

Case Report

- A 33-year-old Caucasian male patient came to our clinic seeking LASIK surgery
- Manifest refraction:
 - -2.00 -1.00 x 65 OD
 - -2.25 -1.25 x 105 OS
- CDVA: 20/15 in both eyes, separately.
- The patient had no significant ocular history, including trauma, amblyopia, or strabismus; and has no family history of keratoconus.
- After careful full ophthalmological examination, nothing significant was detected.

Initial Pentacam exam of the right eye

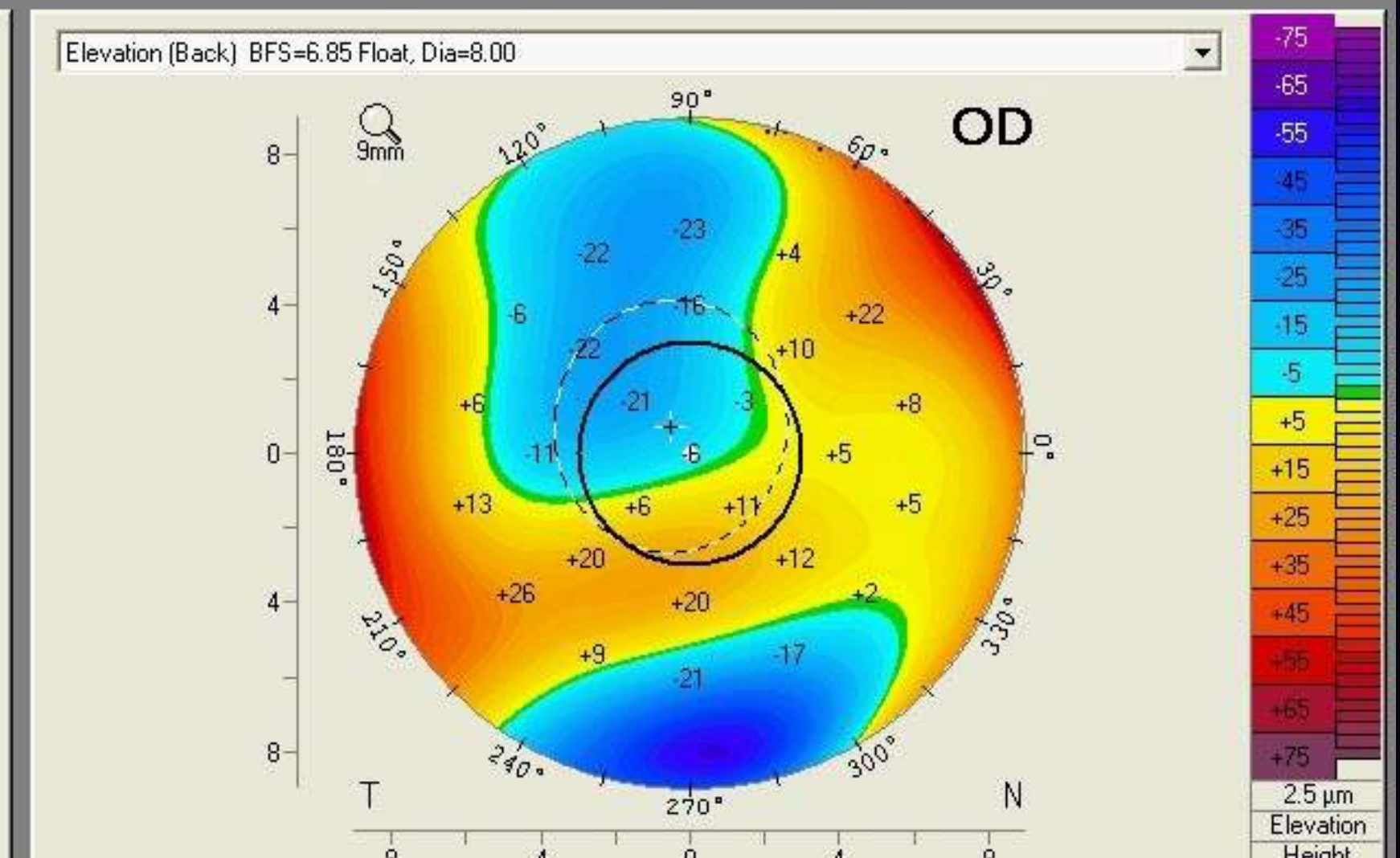
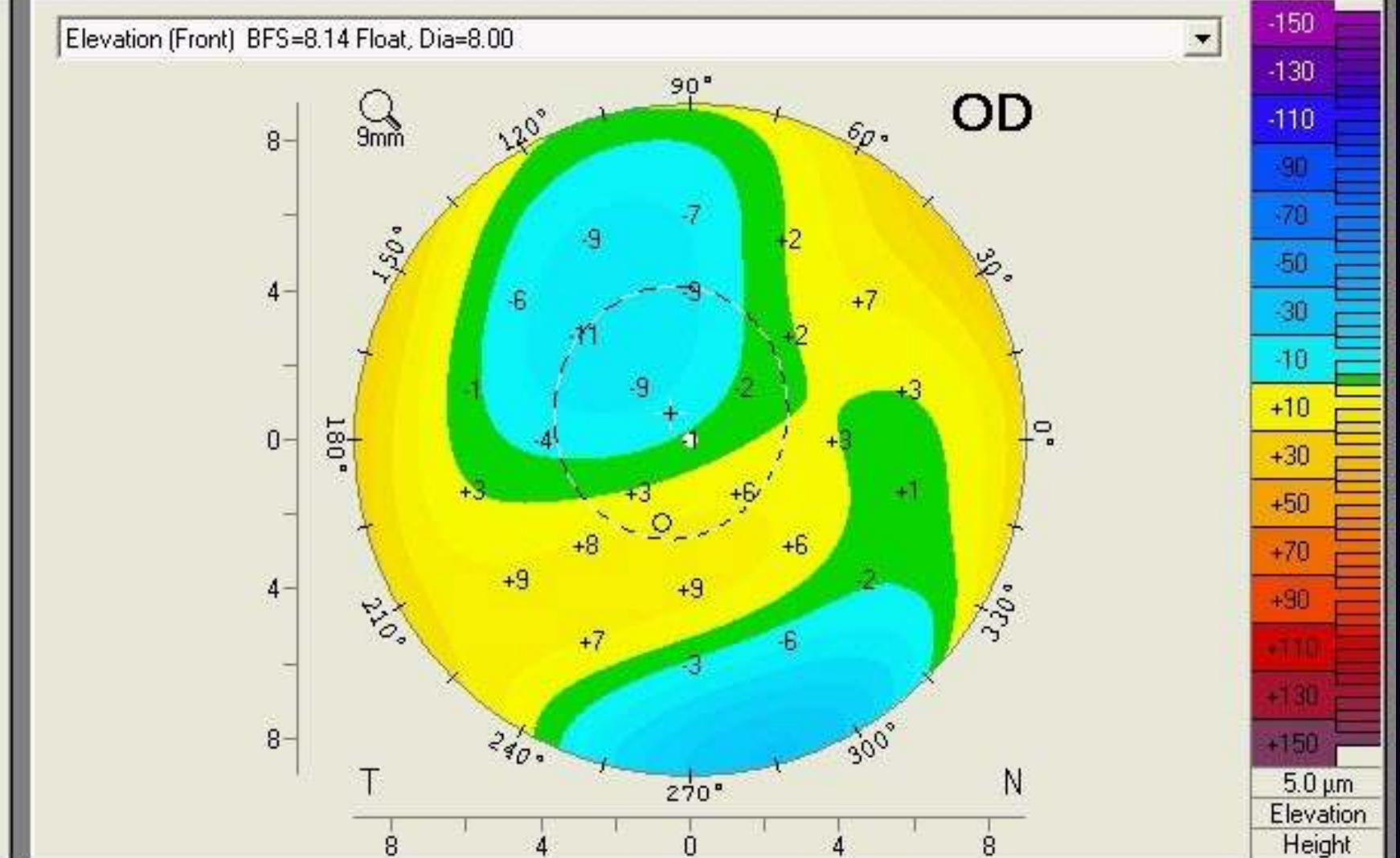
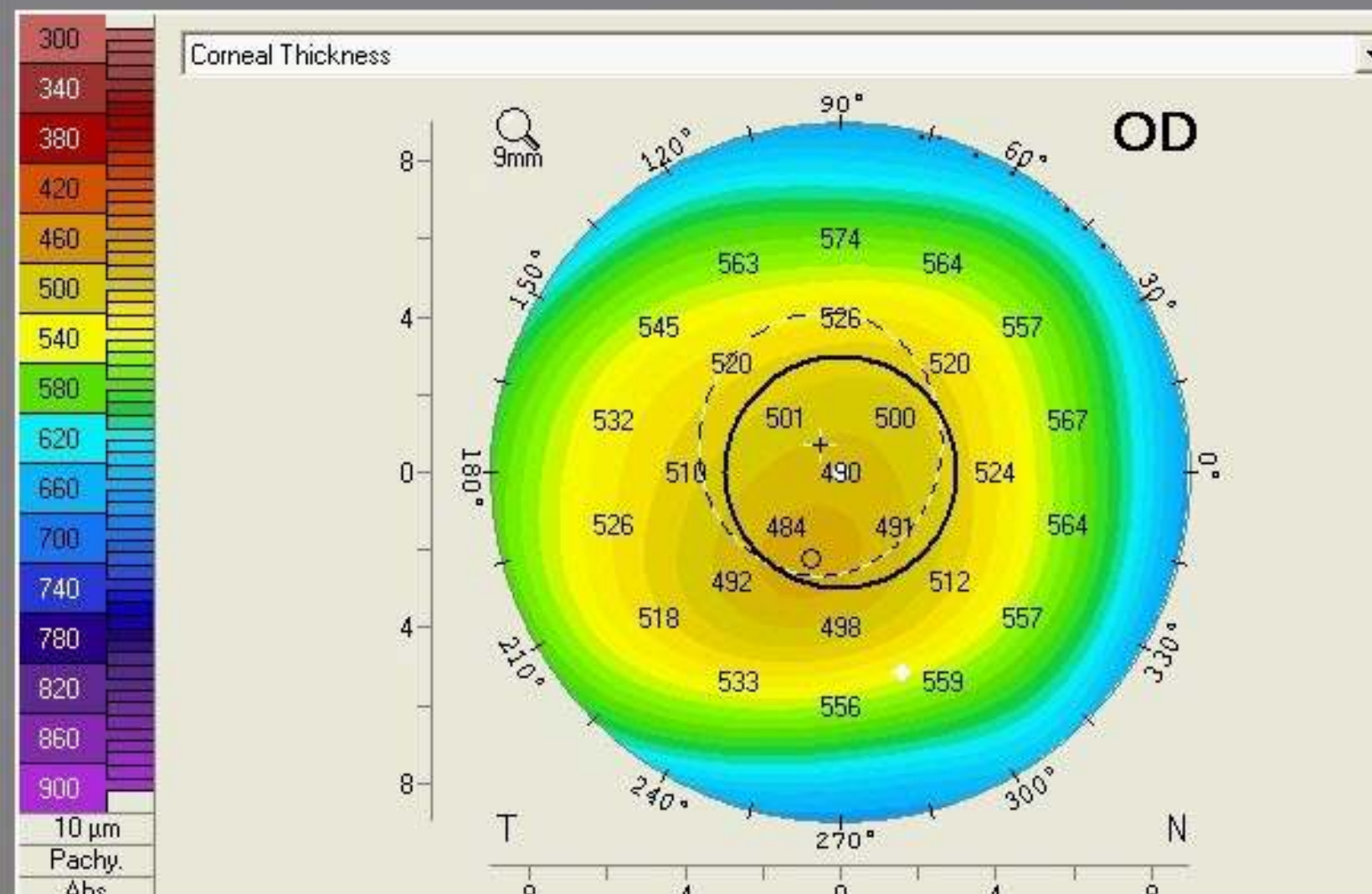
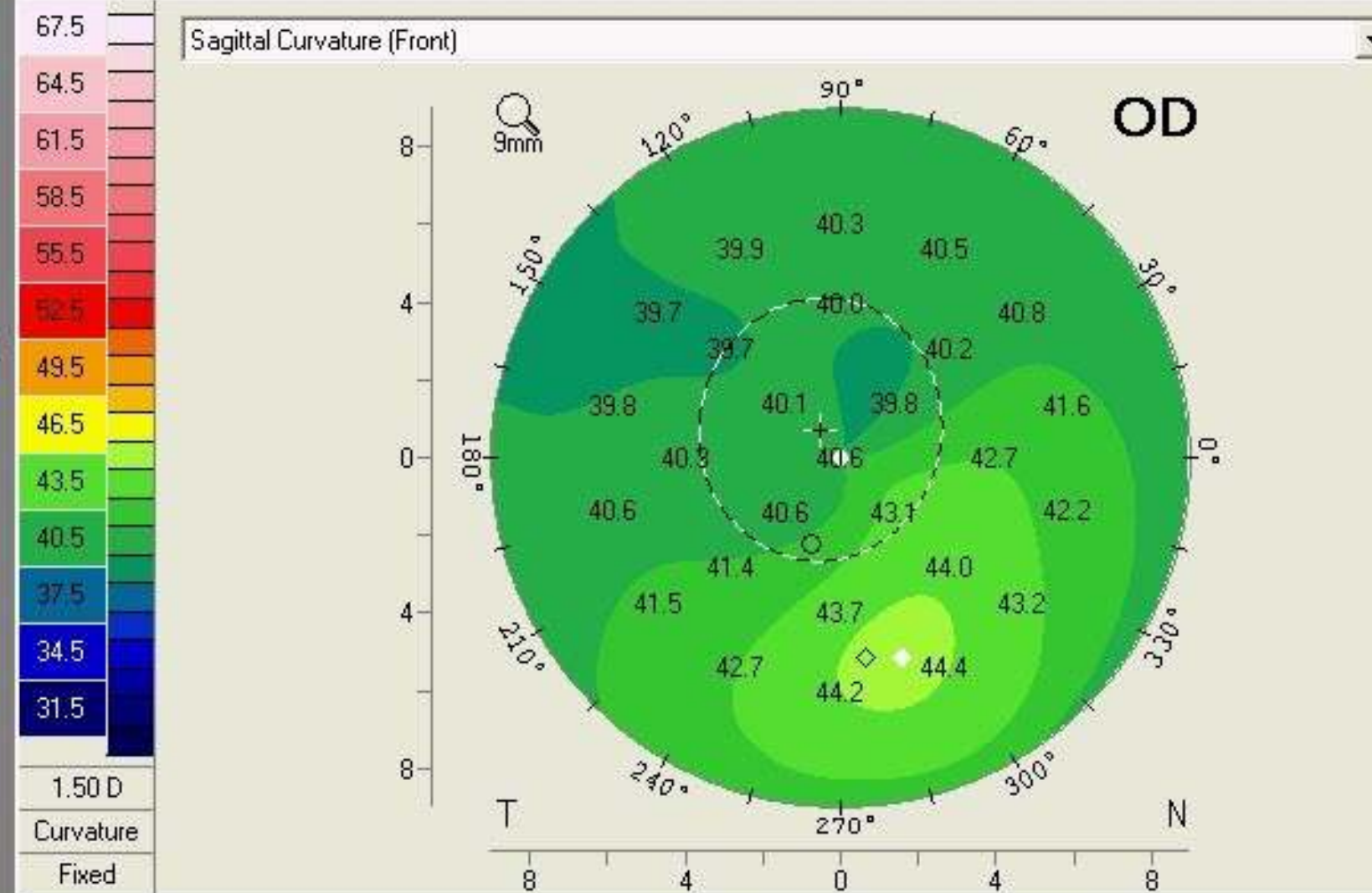
OCULUS - PENTACAM

Last Name: /
First Name: /
ID: /
Date of Birth: 11/30/1980 Eye: Right
Exam Date: 05/29/2013 Time: 17:20:32
Exam Info: /



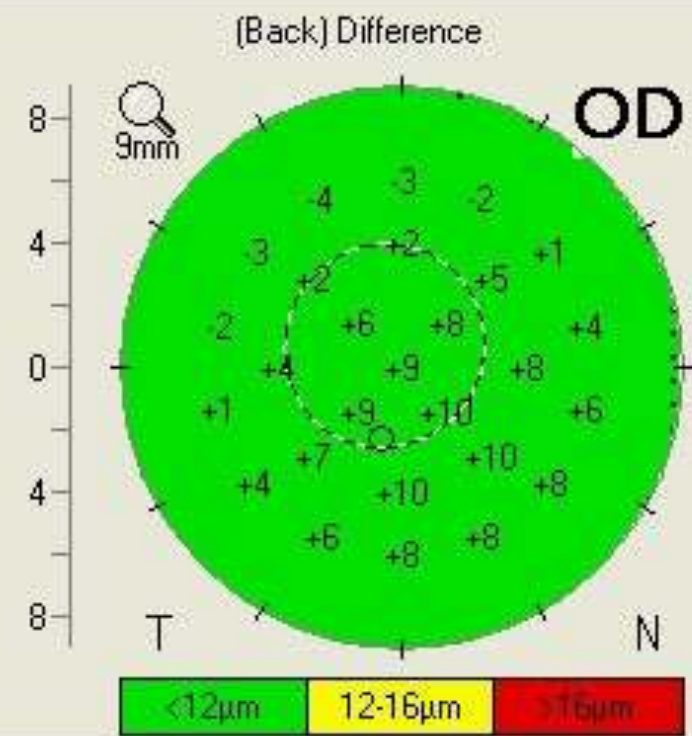
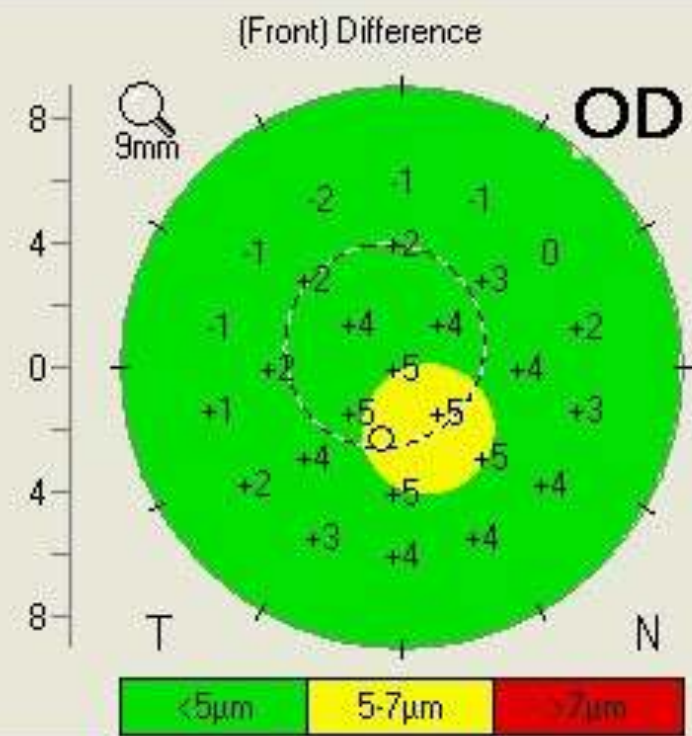
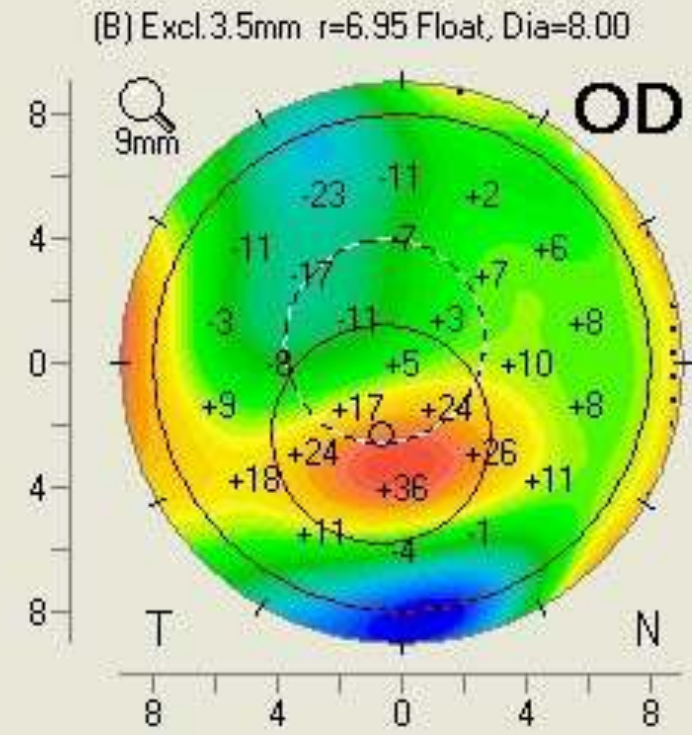
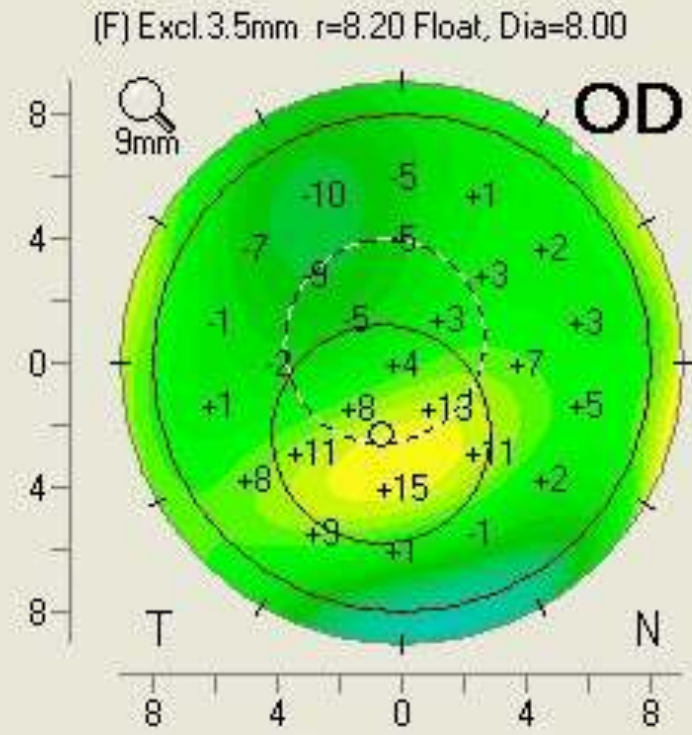
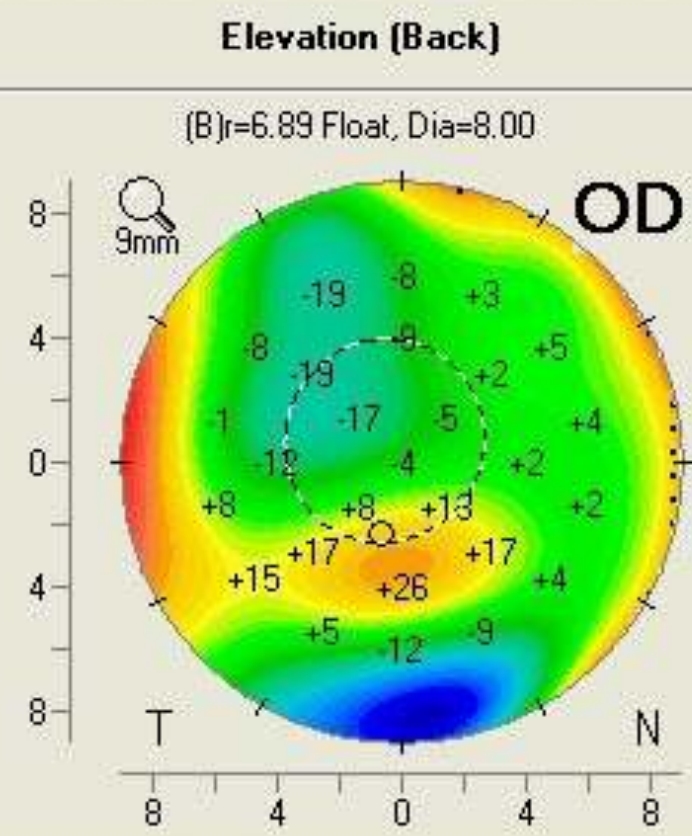
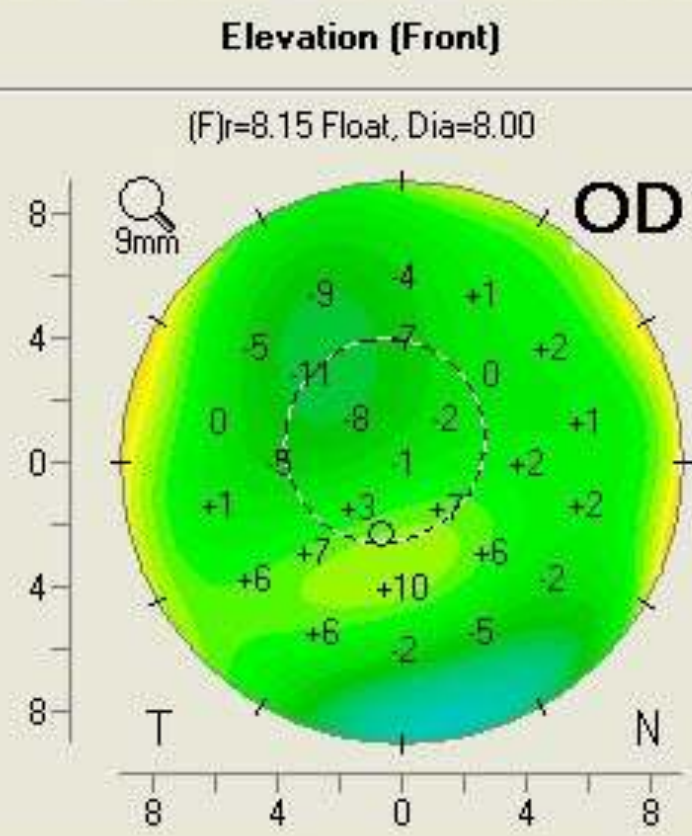
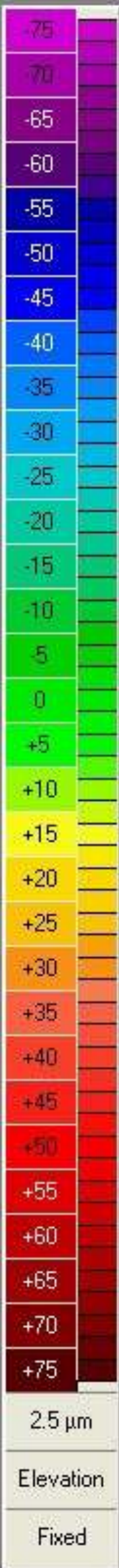
Pupil Center:	+	Pachy:	494 µm	x[mm]	-0.27	y[mm]	+0.36
Pachy Apex:	•		490 µm		0.00		0.00
Thinnest Locat.:	○		481 µm		-0.39		-1.12
K Max. (Front):	•		44.6 D		+0.79		-2.56

Cornea Volume: 52.3 mm³ Ø Cornea: /
Chamber Volume: 247 mm³ Angle: 38.1°
A. C. Depth (Int.): 3.76 mm Pupil Dia: 3.25 mm
Enter IOP IOP(Sum): +2.4 mmHg Lens Th: /



OCULUS - PENTACAM

Belin / Ambrósio Enhanced Ectasia

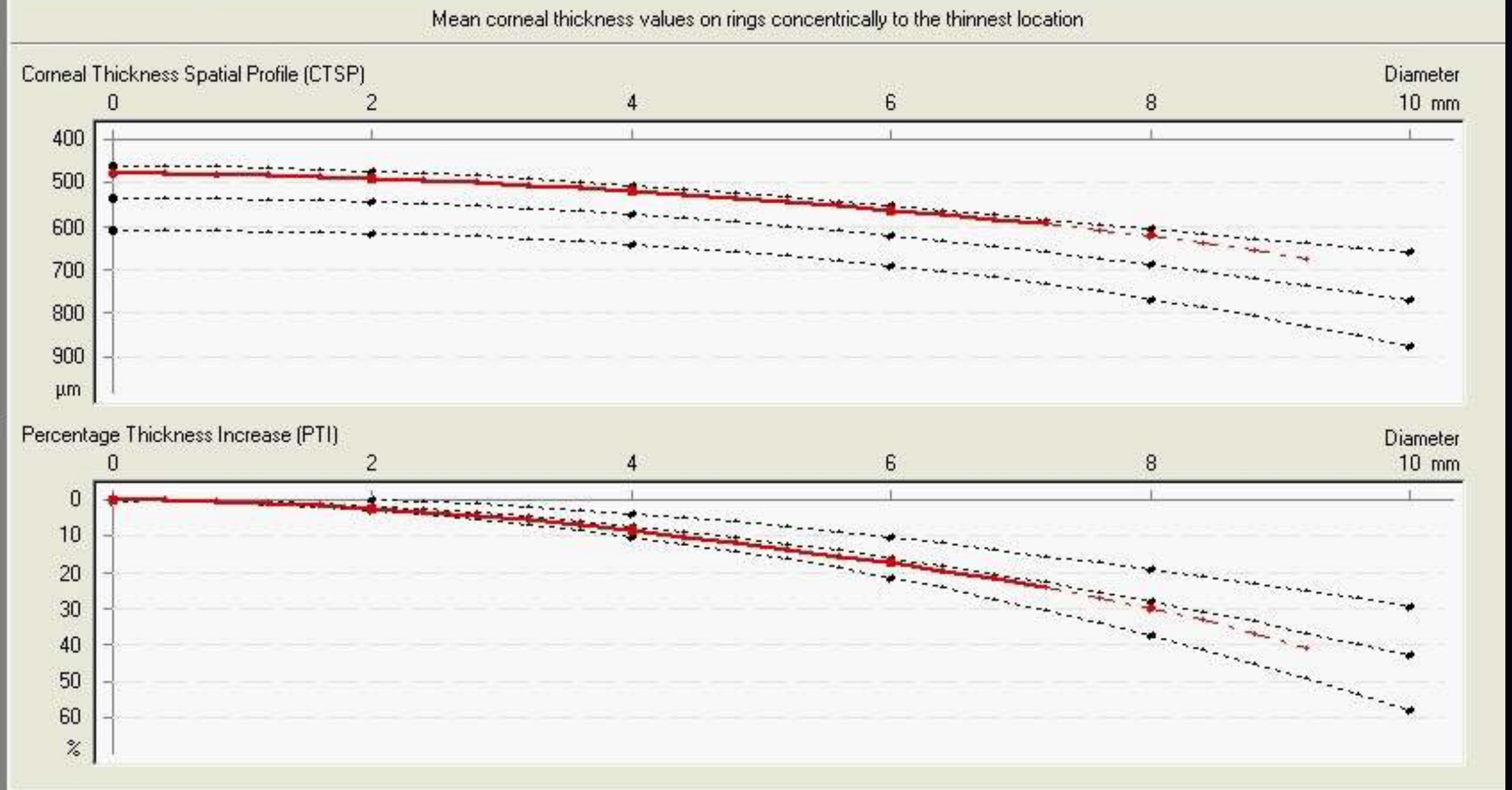
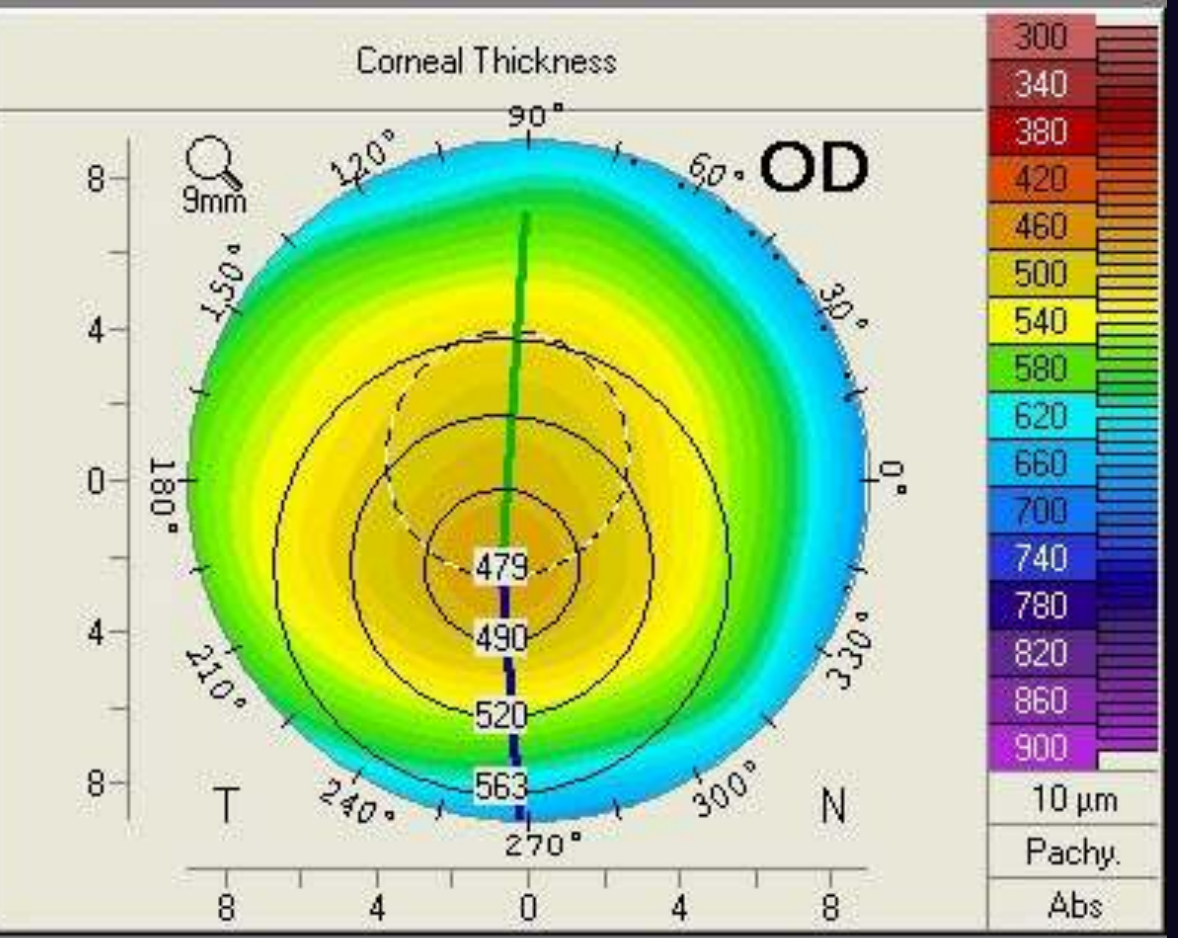


Last Name: / First Name: ID: Date of Birth: 11/30/1980 Eye: Right Exam Date: 05/29/2013 Time: 17:21:16 Exam Info:

K1: 40.6D Axis: 63.9° K2: 41.6D Q-val.: -0.15 (8mm)

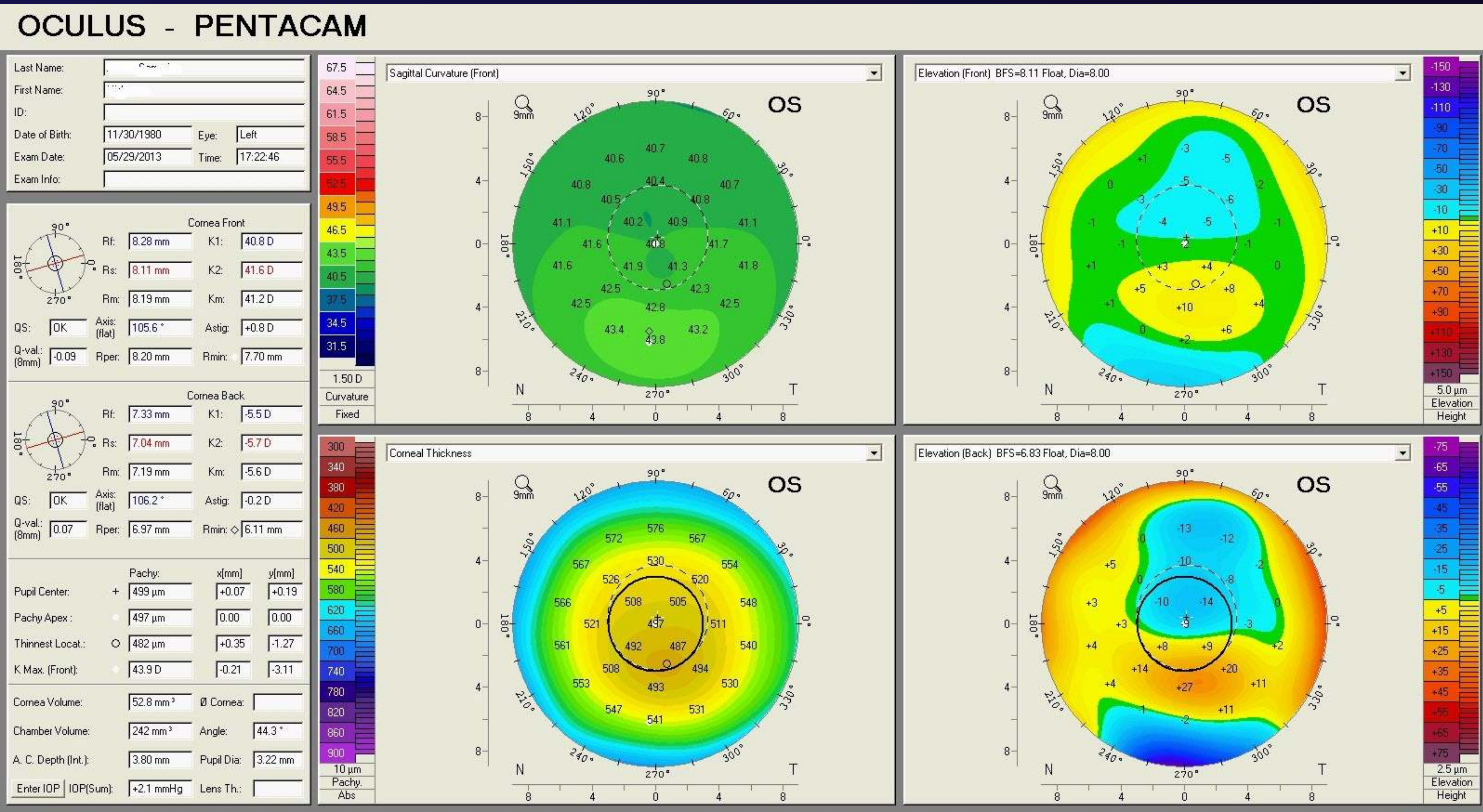
Pachy Apex: 489µm Pachy Thin. Loc.: 479µm Dist. Apex-Thin. Loc.: IT 1.19mm

Progression Index: Avg: 1.16 QS: OK Min: 0.75 Max: 2.03



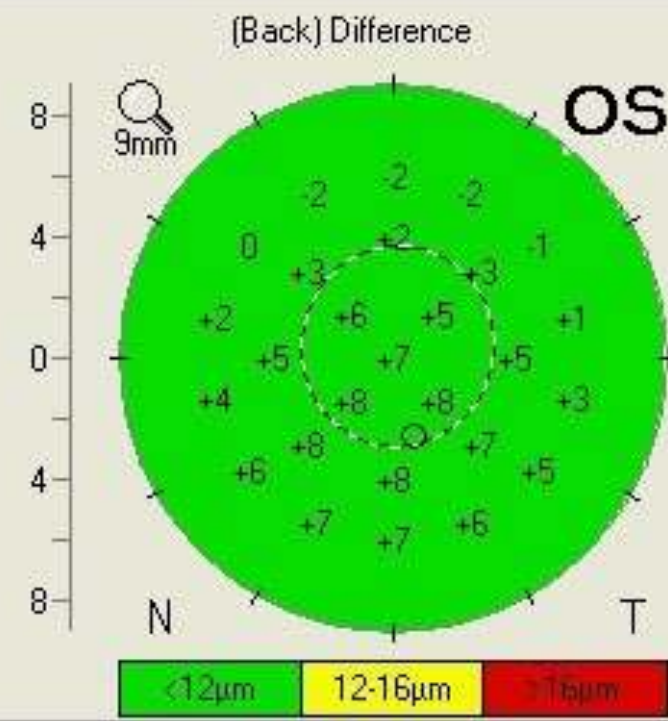
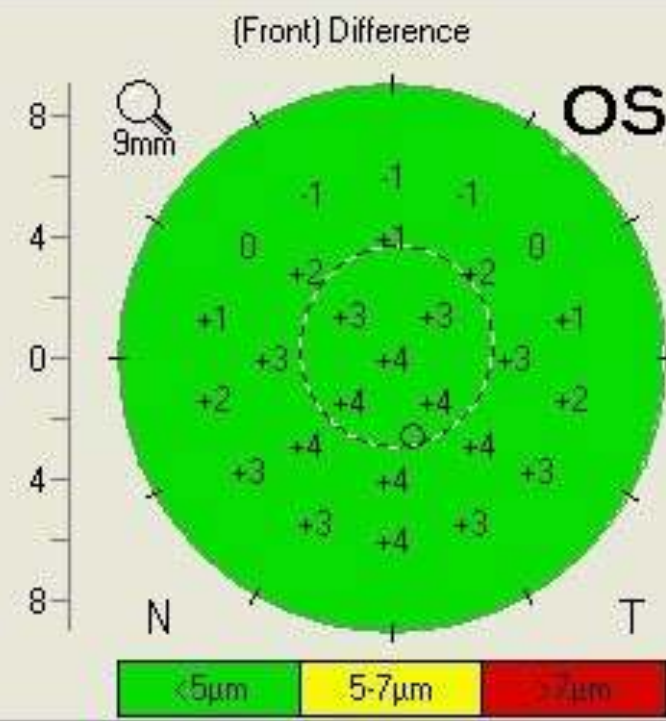
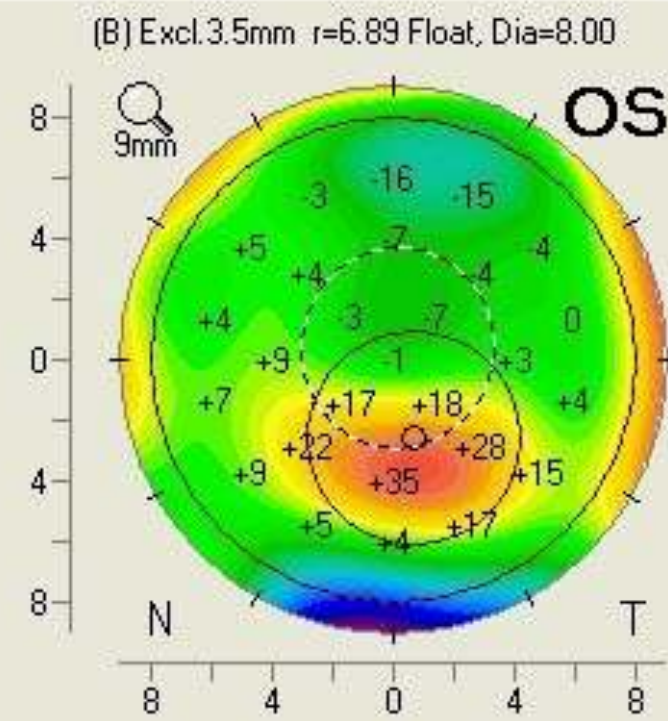
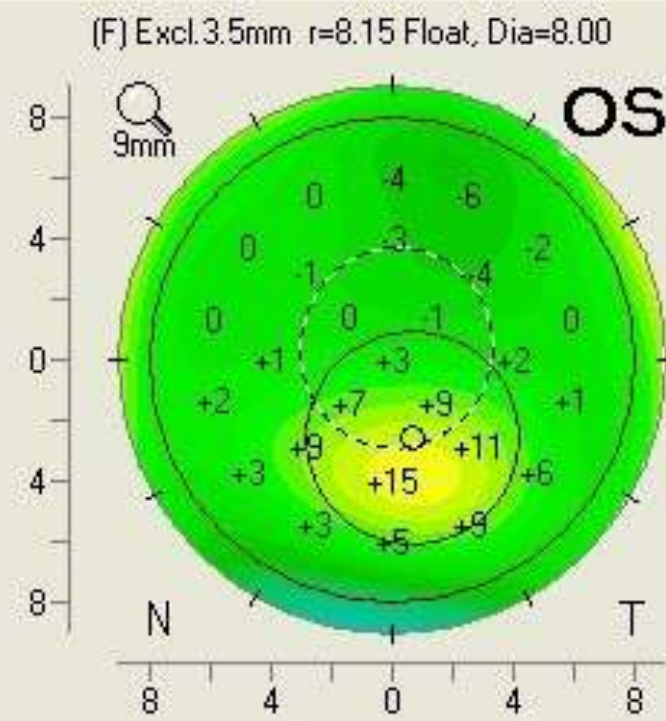
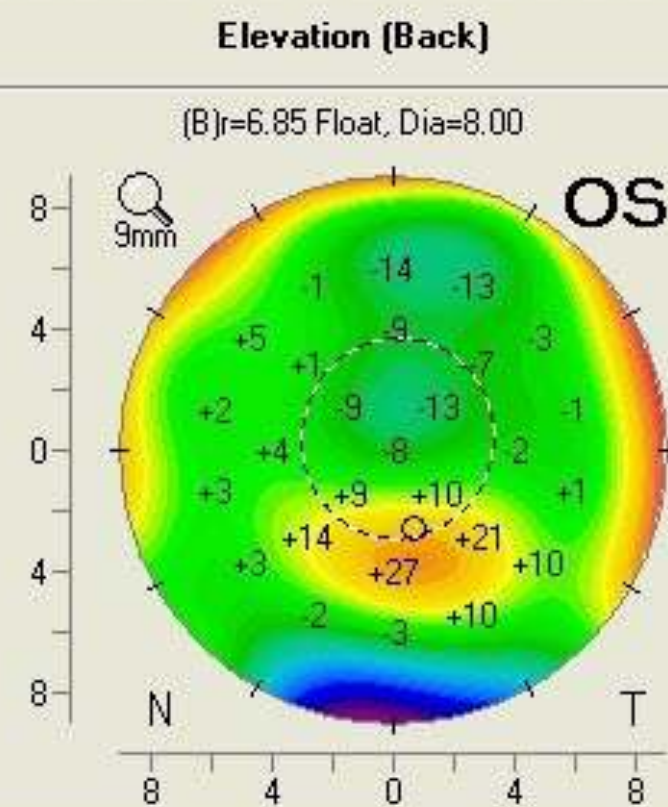
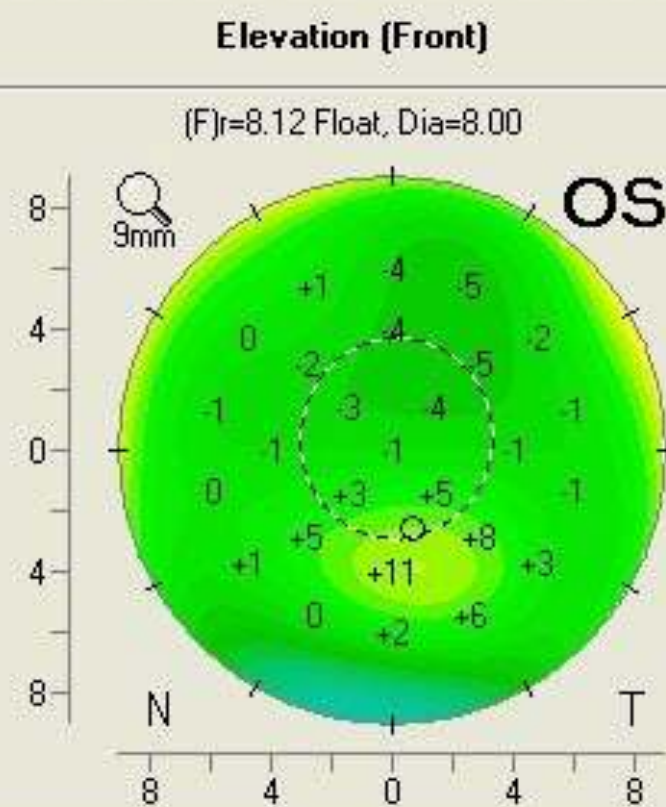
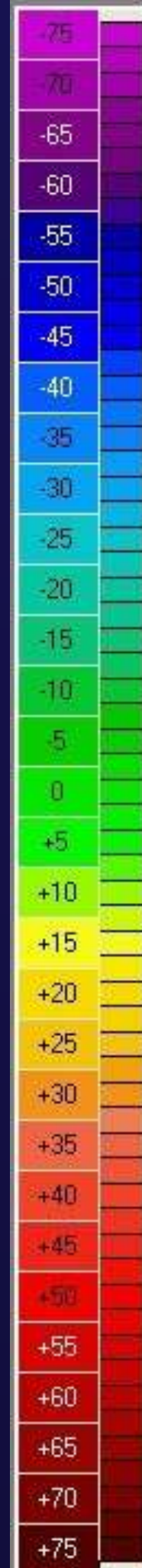
Df: 1.88	Db: 1.15	Dp: 1.75	Dt: 1.90	Dy: 3.49	D: 3.27
----------	----------	----------	----------	----------	---------

Initial Pentacam exam of the left eye



OCULUS - PENTACAM

Belin / Ambrósio Enhanced Ectasia



Last Name: _____

First Name: _____

ID: _____

Date of Birth: 11/30/1980 Eye: Left

Exam Date: 05/29/2013 Time: 17:22:46

Exam Info: _____

K1: 40.8D Axis: 105.6°

K2: 41.6D Q-val: -0.09 (8mm)

Pachy Apex: 497µm

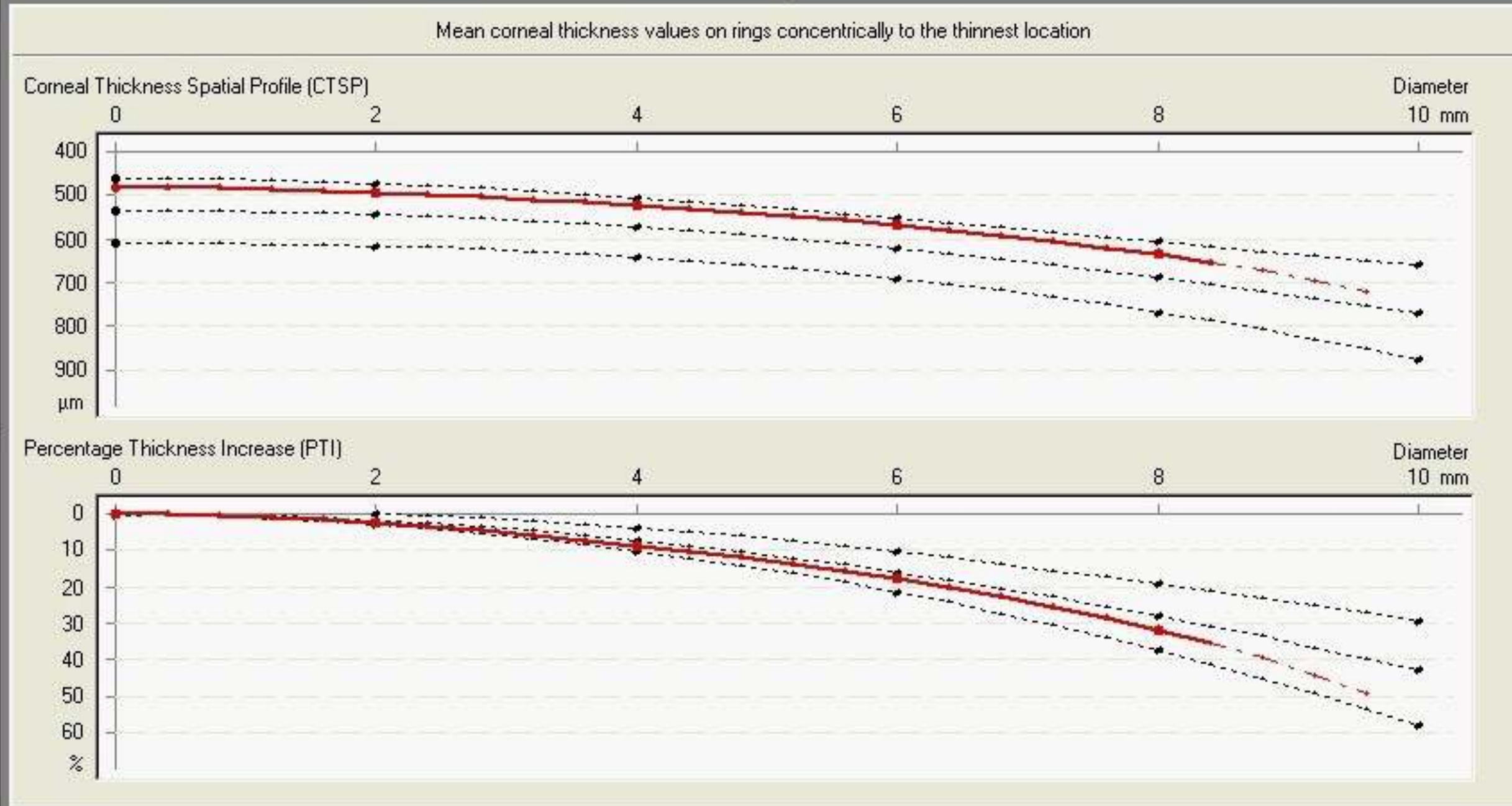
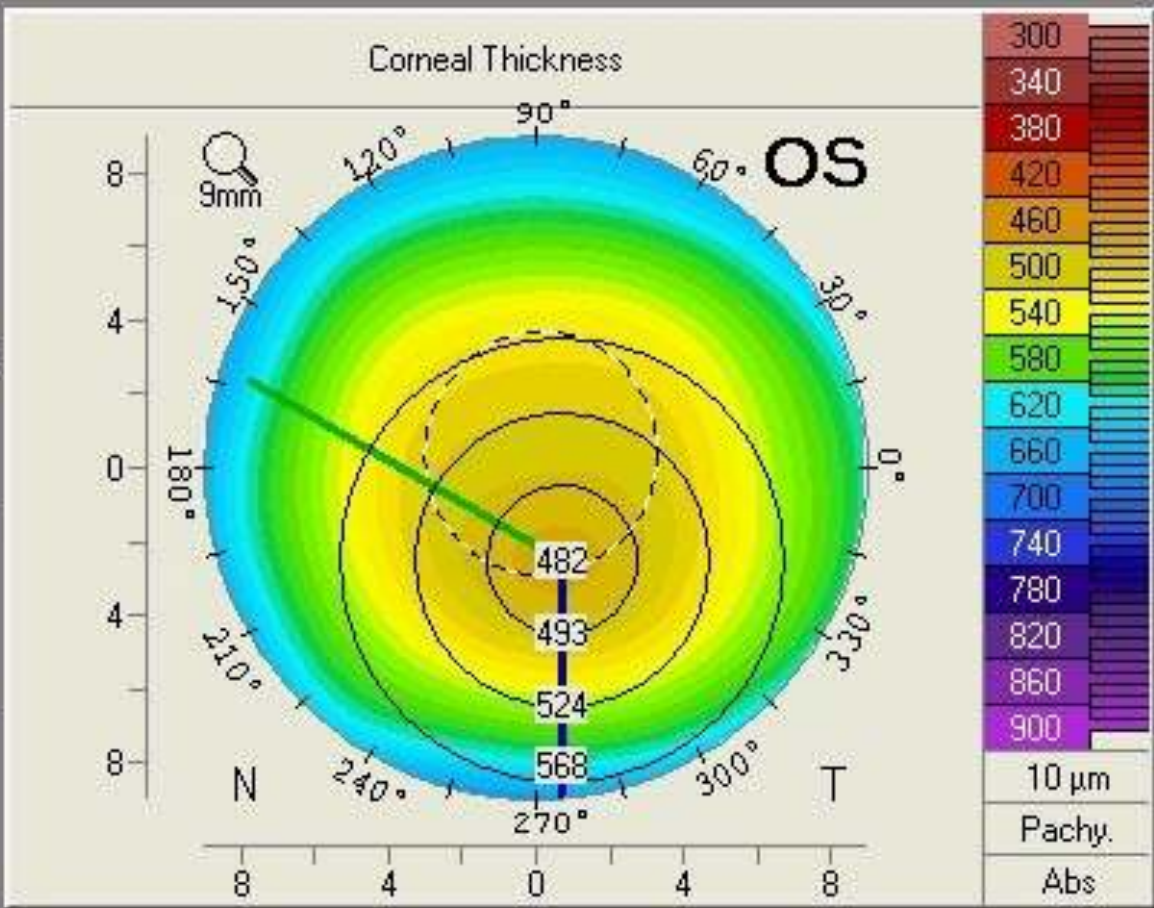
Pachy Thin. Loc.: 482µm

Dist. Apex-Thin. Loc.: IT 1.32mm

Progression Index:

Avg: 1.18 QS: OK

Min: 0.73 Max: 2.15

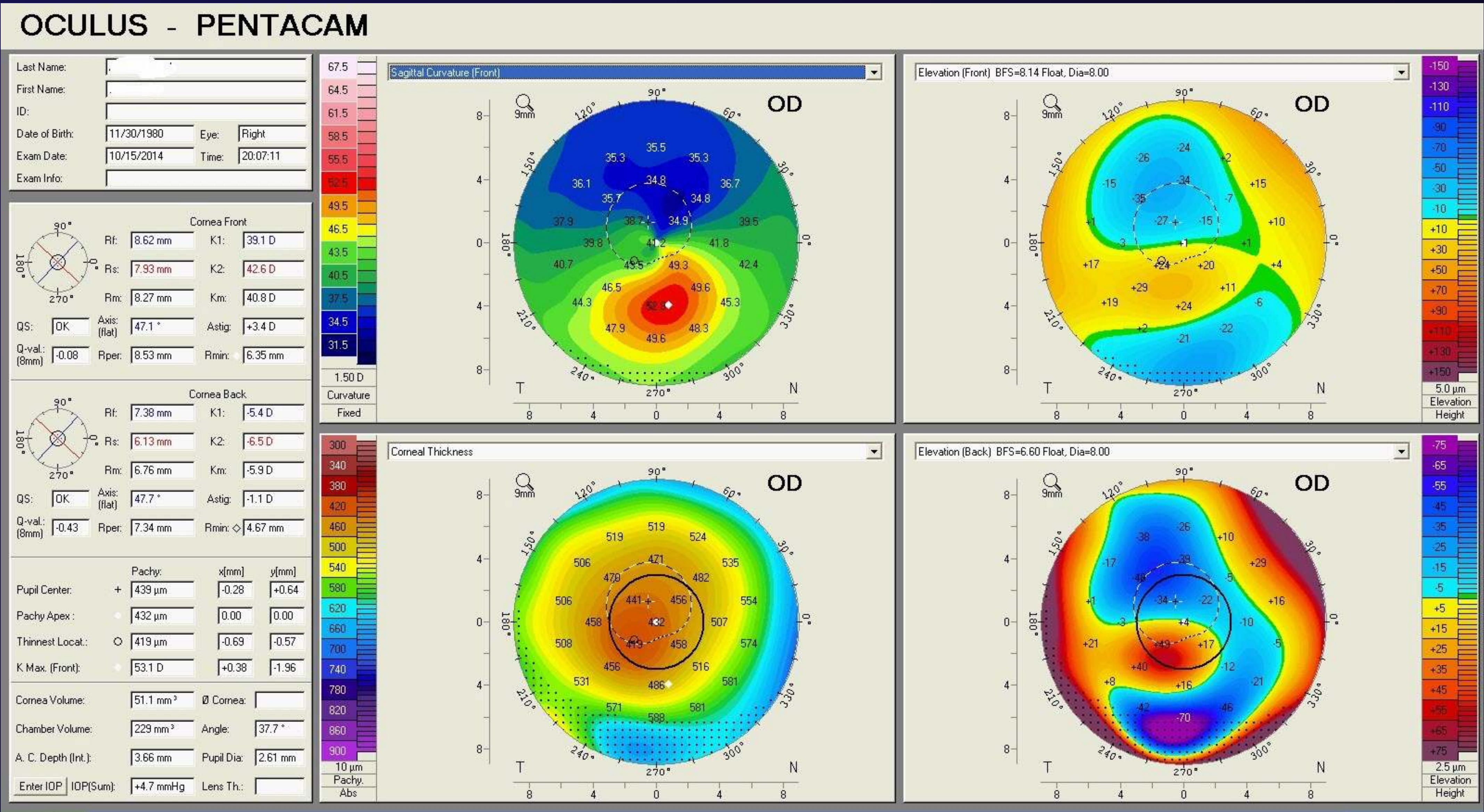


Df: 1.05 Db: 0.63 Dp: 1.84 Dt: 1.78 Dy: 3.98 D: 2.89

One and a half year later

- The patient came complaining of diminution of vision
- He reported that he underwent a Femtosome procedure 6 months before
- Manifest refraction:
 - OD: -0.50 -2.75 x 35 correcting to 20/30
 - OS: -2.00 -3,00 x 120 correcting to 20/30
- The cornea was centrally clear apart from superior faint scar related to the operation and circumferential faint opacity related to the operation in both eyes

OD Post-SMILE



OS Post-SMILE

OCULUS - PENTACAM

Last Name:

First Name:

ID:

Date of Birth: 11/30/1980 Eye: Left

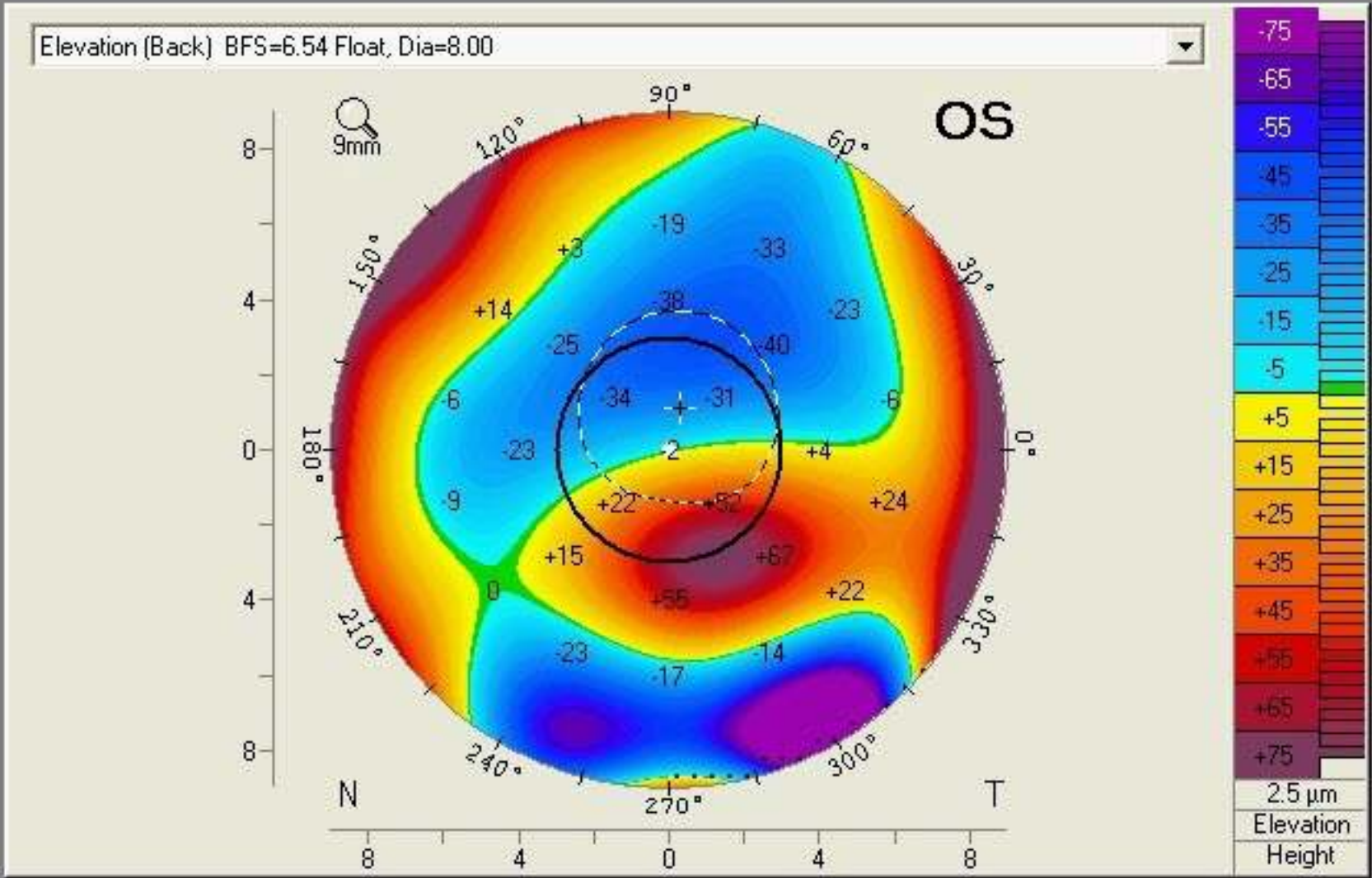
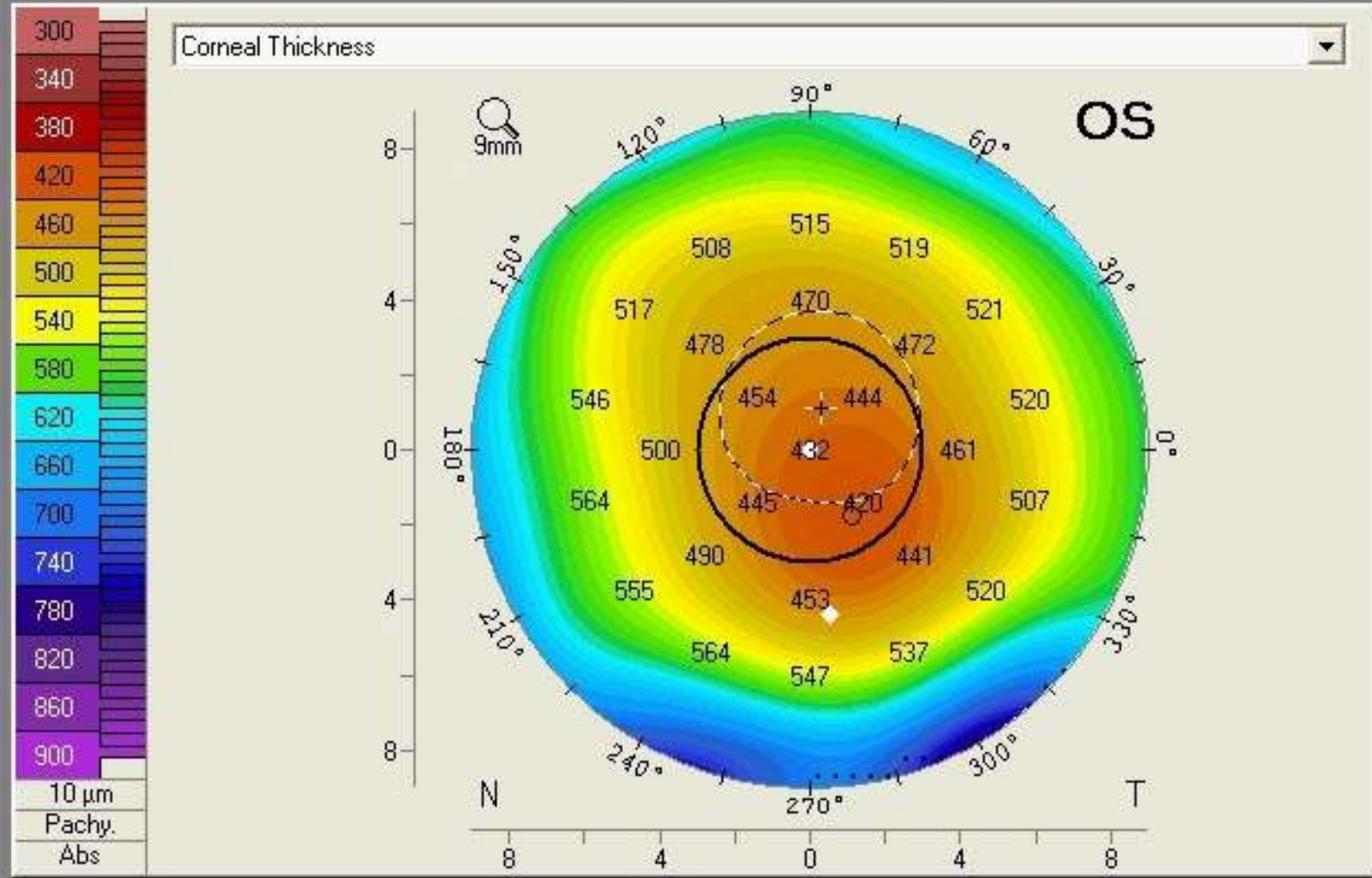
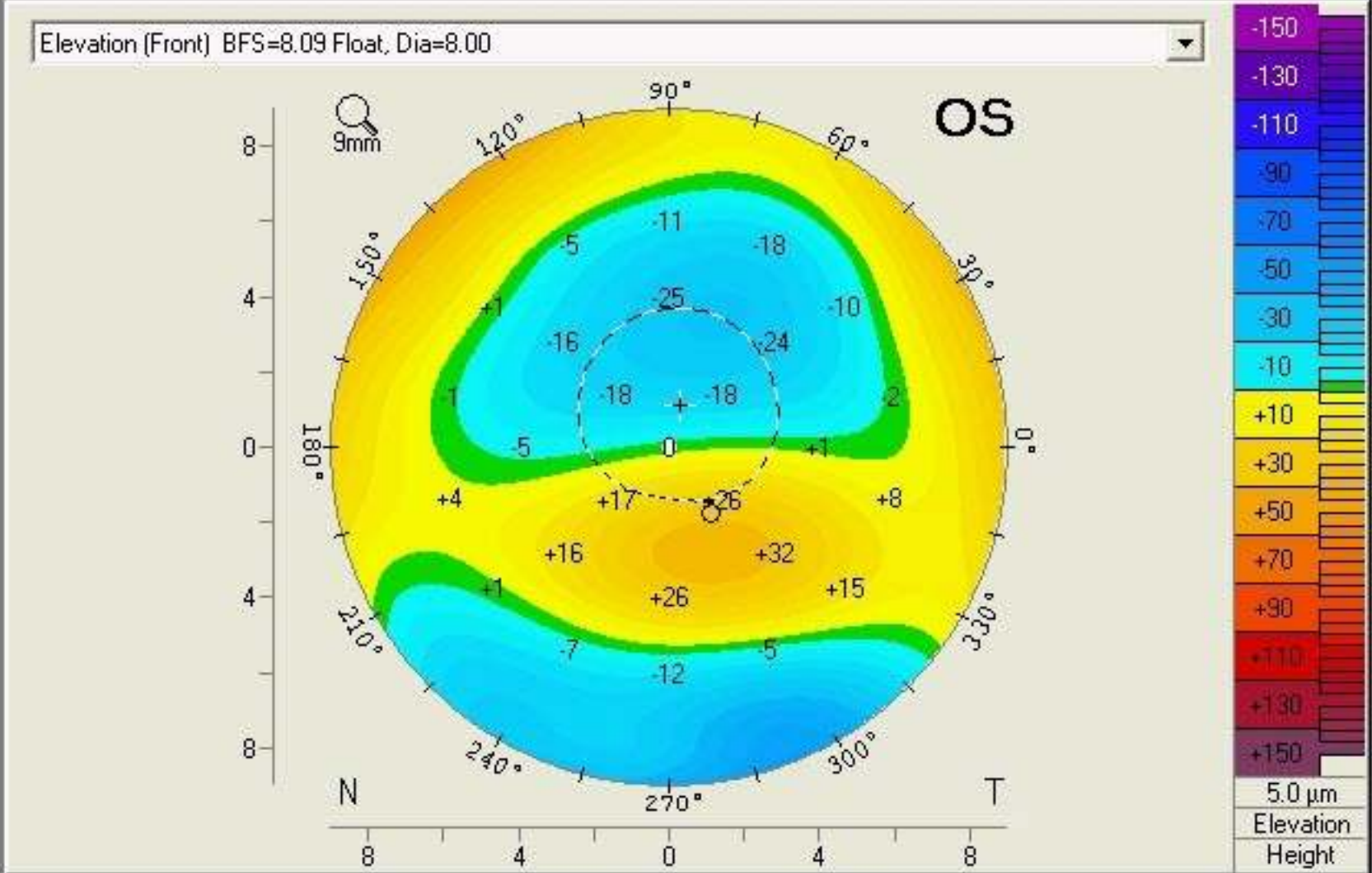
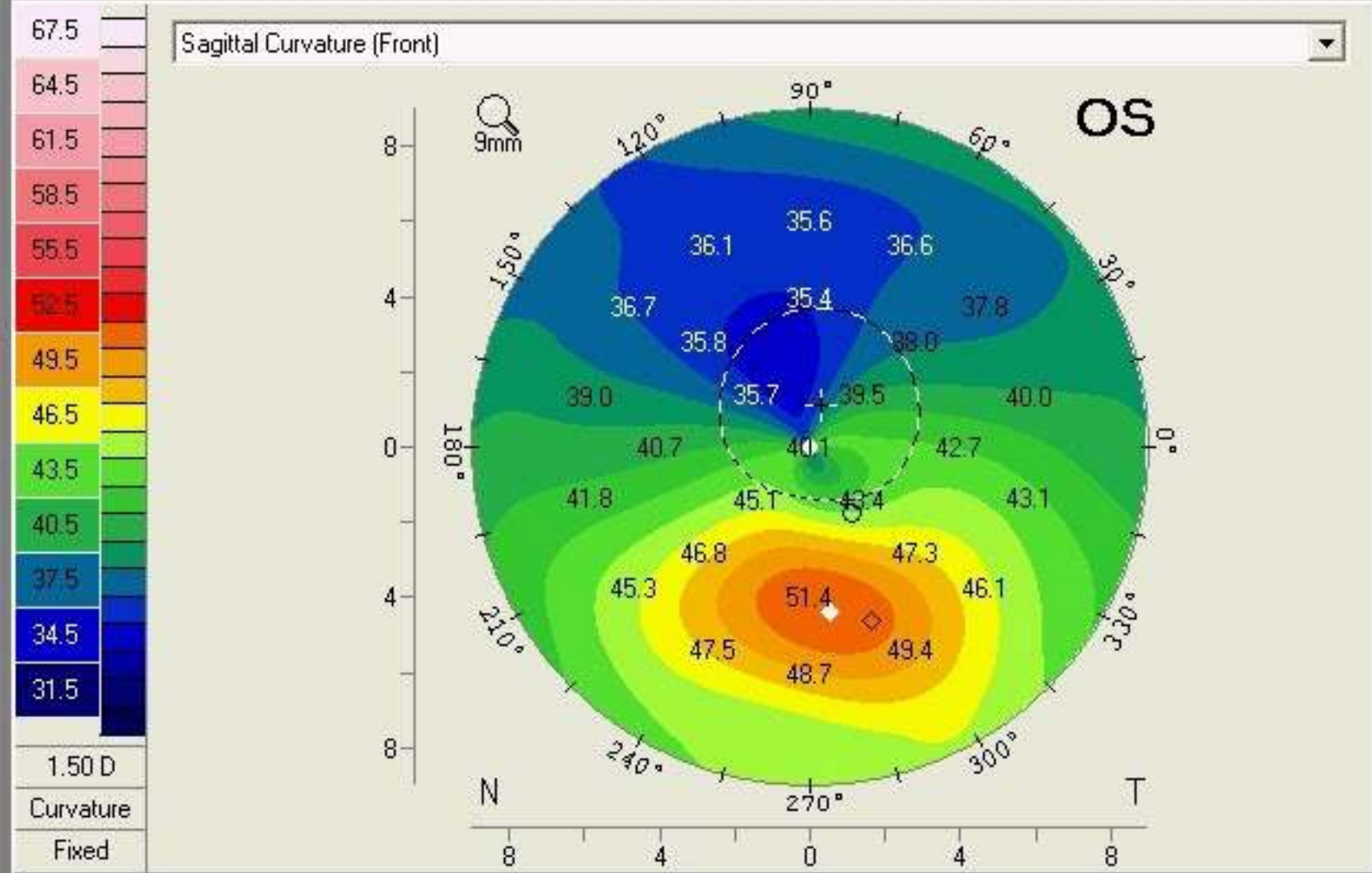
Exam Date: 10/15/2014 Time: 20:09:53

Exam Info:



Pupil Center:	Pachy:	x[mm]	y[mm]
	+ 440 µm	+0.13	+0.57
Pachy Apex:	432 µm	0.00	0.00
Thinnest Locat.:	419 µm	+0.54	-0.89
K Max. (Front):	51.6 D	+0.27	-2.18

Cornea Volume:	51.5 mm ³	Ø Cornea:	
Chamber Volume:	234 mm ³	Angle:	41.2°
A. C. Depth (Int.):	3.74 mm	Pupil Dia:	2.63 mm
Enter IOP IOP(Sum):	+4.7 mmHg	Lens Th.:	



OCULUS - PENTACAM

Name: ID: Date of Birth: 11/30/1980

Exam

67.5

66.0

64.5

63.0

61.5

60.0

58.5

57.0

55.5

54.0

52.5

51.0

49.5

48.0

46.5

45.0

43.5

42.0

40.5

39.0

37.5

36.0

34.5

33.0

31.5

30.0

1.50 D

Curvature

Fixed

A: 10/15/2014 20:08:19 Left (25) 3D-Scan HR

K1: 39.9 D
K2: 42.4 D
Axis: (flat) 121.9°
Q-val: (8mm) -0.16
QS: Data Gaps!

Pachy: x[mm] y[mm]

Pupil Center: + 438 μm +0.05 +0.56

Thinnest Locat.: O 419 μm +0.54 -0.87

Chamber Volume: 234 mm³ Angle: 44.3°

A. C. Depth (Int.): 3.74 mm Pupil Dia: 2.70 mm

IOP(cor): Lens Th.:

Sagittal Curvature (Front)

OS

N 8 4 0 4 8 T

B: 05/29/2013 17:22:46 Left (25) 3D-Scan HR

K1: 40.8 D
K2: 41.6 D
Axis: (flat) 105.6°
Q-val: (8mm) -0.09
QS: OK

Pachy: x[mm] y[mm]

Pupil Center: + 499 μm +0.07 +0.19

Thinnest Locat.: O 482 μm +0.35 -1.27

Chamber Volume: 242 mm³ Angle: 44.3°

A. C. Depth (Int.): 3.80 mm Pupil Dia: 3.22 mm

IOP(cor): Lens Th.:

Sagittal Curvature (Front)

OS

N 8 4 0 4 8 T

Difference A - B

K1: -0.8 D
K2: +0.8 D
Axis: (flat) +16.3°
Q-val: (8mm) -0.07
QS:

Pachy: x[mm] y[mm]

Pupil Center: + -61 μm -0.02 +0.36

Thinnest Locat.: O -63 μm +0.18 +0.40

Chamber Volume: -8 mm³ Angle: 0.0°

A. C. Depth (Int.): -0.06 mm Pupil Dia: -0.53 mm

IOP(cor): Lens Th.:

Sagittal Curvature (Front)

OS

N 8 4 0 4 8 T

+21.0

+19.5

+18.0

+16.5

+15.0

+13.5

+12.0

+10.5

+9.0

+7.5

+6.0

+4.5

+3.0

+1.5

0.0

-1.5

-3.0

-4.5

-6.0

-7.5

-9.0

-10.5

-12.0

-13.5

-15.0

-16.5

1.50 D

Curvature

Fixed

Ectasia risk: A multifactorial conundrum



Ectasia after corneal refractive surgery remains one of the most insidious and perplexing problems in the day-to-day practice of the refractive surgeon. Although the incidence of ectasia is low, it is the *raison d'être* for most of the measurements and history obtained in the course of screening patients for refractive surgery.

In this issue of the journal, Ziaei and a group of coauthors representing the Cornea Committee of the American Society of Cataract and Refractive Surgery (ASCRS) present a major review of surgical approaches to managing ectasia (pages 842–872). They summarize key advances in treatment, including combinations of treatments aimed at improving corneal optics and stabilizing progressive disease. Although great progress continues to be made on the therapeutic side of this problem, reliable characterization of ectasia risk remains a challenge. And from every vantage point, avoidance or prevention of ectasia at the preoperative planning stage is much preferred to treating it later.

Clinicians can easily assess predisposition for a disorder when a single highly predictive marker is available, such as a specific genetic mutation in a hereditary disease with high expressivity and high penetrance. Unfortunately, refractive surgeons do not have access to a single high-probability marker for ectasia. Ectasia in the setting of refractive surgery is a multifactorial problem, as Randleman et al.¹ illustrated through their landmark retrospective analysis of patient- and procedure-specific risk factors. This reality complicates efforts to quantify risk in the setting of the screening examination, where our ability to both measure and synthesize the major components of risk for a given patient is still incomplete.

Acknowledging the multivariate nature of the problem and appealing to structural principles are critically important for properly conceptualizing risk. From the vantage point of the cornea as a structure, material failure is the final common pathway of ectasia.^{2–5} The cor-

The key challenge, then, is to determine—with a limited amount of information and proxy variables—just where on the spectrum of structural behavior a given eye currently resides and how surgical intervention will change that.

The Case Reports section of this issue features a cautionary example of this process and the clinical stakes of different interpretations of apparent risk. El-Naggar (pages 884–888) presents what might be the first reported cases of corneal ectasia in a patient who had femtosecond small-incision refractive lenticule extraction, an intrastromal procedure that largely preserves the integrity of the anterior stromal collagen structure. Previous publications^{8,9} have presented a biomechanical rationale for the potential structural advantages of this approach, and at first glance, the case report could be taken as an indictment of this claim. However, the preoperative tomography showed bilateral evidence of ectatic predisposition suggested by asymmetric inferior topographic steepness, posterior corneal elevation, decentered thinnest corneal points, and low overall corneal thickness. The patient was advised by the author that he was not a laser in situ keratomileusis (LASIK) candidate but then had small-incision refractive lenticule extraction performed elsewhere and returned to the author's clinic 6 months later with evidence of marked progression of inferior steepening and manifest ectasia.

This case offers several learning points. First, ectasia risk assessment is currently sufficiently imprecise that the presence of even 1 perceived risk factor (particularly a topographic risk factor such as inferior steepness) should bias the surgical decision toward observation or tissue-sparing procedures. In the reported case, the patient's older age, low absolute corneal curvatures, refractive stability, and low level of myopic refractive error might have been factored into the decision to proceed with surgery despite the concerns apparent on tomography. This point is

CASE REPORT

Corneal ectasia 6.5 months after small-incision lenticule extraction

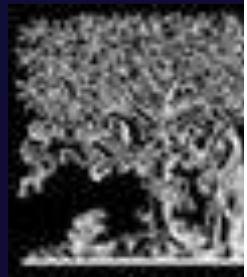


Yumeng Wang, MM, Chuanbo Cui, MD, Zhiwei Li, PhD, Xiangchen Tao, MD, Chunxiao Zhang, MM,
Xiao Zhang, MM, Guoying Mu, MD

Our case involves a 19-year-old patient with forme fruste keratoconus. Small-incision lenticule extraction was performed, and 6.5 months after surgery, corneal ectasia was diagnosed. Preoperatively, the minimum central corneal thickness was 546 μm in the right eye and 542 μm in the left eye; the refractive correction was $-6.75 -1.00 \times 45$ and $-6.75 -0.75 \times 140$, respectively; the lenticular thickness was 137 μm and 135 μm , respectively. At 6.5 months, ectasia was diagnosed based on anterior and posterior surface keratometry of 38.4/39.5 diopters (D) and $-6.3/-6.8$ D, respectively, in the right eye and 38.6/40.8 D and $-7.1/-6.6$ D, respectively, in the left eye. The keratometry increased gradually and the corneal thickness decreased after surgery, and these trends continued during the 13-month follow-up. This report documents corneal ectasia as a complication of small-incision lenticule extraction and highlights the importance of preoperative evaluation and the need for long-term follow-up.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:1100–1106 © 2015 ASCRS and ESCRS



Unilateral corneal ectasia following small-incision lenticule extraction



Gitansha Sachdev, MS, FICO, Mahipal S. Sachdev, MD, Ritika Sachdev, MS, Hemlata Gupta, MS, DNB, FAICO

We describe a case of unilateral corneal ectasia in a 26-year-old man following small-incision lenticule extraction. The preoperative corneal topography was normal, with a minimum corneal thickness of 511 μm and 513 μm in the right eye and left eye, respectively. Lenticules of 85 μm and 82 μm were fashioned to offer a refractive correction of $-3.75 -1.50 \times 180$ and $-3.50 -1.50 \times 165$ in the right eye and left eye, respectively. Twelve months after small-incision lenticule extraction, the patient presented with early signs of ectasia in the left eye on corneal topography, which had worsened at the 18-month examination. Intrastromal corneal ring segment implantation with corneal collagen crosslinking was performed to arrest further progression and to improve uncorrected distance visual acuity. On the last examination, the corrected distance visual acuity was 20/20⁻².

Financial Disclosure: Dr. Mahipal S. Sachdev receives travel grants from Carl Zeiss Meditec AG. No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:2014–2018 © 2015 ASCRS and ESCRS

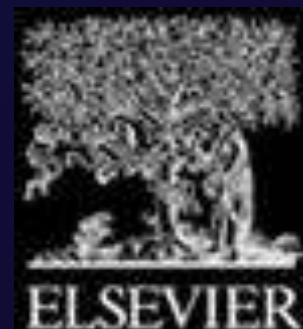
Iatrogenic corneal ectasia, although rare, is possibly the most dreaded complication following refractive surgery. It has been reported after laser in situ keratomileusis (LASIK) and photorefractive keratectomy.^{1–4} Two cases of bilateral ectasia following small-incision lenticule extraction (SMILE, Carl Zeiss Meditec AG) were reported in patients with forme fruste keratoconus.^{5,6} We report a case of unilateral ectasia following small-incision lenticule extraction in a patient with normal corneal topography.

CASE REPORT

A 26-year-old man presented to our cornea clinic requesting

(CDVA) was 20/20 in both eyes. The patient had no family history of keratoconus. The complete preoperative workup was within normal limits. Scheimpflug imaging (Pentacam, Oculus Optikgeräte GmbH) revealed a normal topography with a maximum keratometry (K) value of 44.9 diopters (D) in the right eye and 45.1 D in the left eye, with minimal thickness of 511 μm and 513 μm , respectively. The anterior and posterior elevation maps were also unremarkable (Figure 1). No significant inferior-superior asymmetry was noted on the curvature maps (Figure 2).

Uneventful femtosecond laser small-incision lenticule extraction was performed. The cap thickness was 110 μm with an optical zone of 6.0 mm and a corneal side cut of 3.0 mm. The lenticule thickness in the right eye and left eye was 85 μm and 82 μm , respectively, with a residual stromal bed (RSB) of 304 μm and 305 μm , respectively (Figure 3).



Bilateral Ectasia After Femtosecond Laser-Assisted Small Incision Lenticule Extraction (SMILE)

Jaakko S. Mattila, MD; Juha M. Holopainen, MD, PhD

Journal of Refractive Surgery. 2016;32(7):497-500 <https://doi.org/10.3928/1081597X-20160502-03>

Posted July 13, 2016

[ABSTRACT](#)[FULL TEXT](#)[FIGURES/TABLES](#)[REFERENCES](#)[VIEW PDF](#)

Abstract

PURPOSE:

To describe a case of bilateral ectasia after small incision lenticule extraction (SMILE) in a patient with early keratoconus.

METHODS:

Case report.

RESULTS:

Bilateral SMILE was performed on a patient even though preoperative topographies showed changes indicating early keratoconus. The right eye underwent further photorefractive keratectomy enhancement 18 months later. The patient developed a bilateral corneal ectasia.

CONCLUSIONS:

This case underlines the importance of thorough preoperative assessment for possible keratoconus suspect changes with corneal topography to avoid postoperative ectasia.

[J Refract Surg. 2016;32(7):497–500.]

July 2016

Ectasia After Corneal Refractive Surgery: Nothing to SMILE About

J. Bradley Randleman, MD



Since the first reports in 2011,^{1,2} small incision lenticule extraction (SMILE) has dramatically entered the landscape of corneal refractive surgical procedures. With offerings of a single laser system, less disruption of the corneal surface, and relative preservation of the anterior lamellar fibers, SMILE has promised excellent refractive outcomes and possible advantages over previous iterations of laser refractive surgery.

One of the postulated advantages is biomechanical. Through maintenance of the anterior lamellae, SMILE in theory maintains a stronger cornea postoperatively. Mathematical modeling³ and finite element analysis⁴ lend some support to this view. Clinically, the extent of this biomechanical benefit remains to be determined.

Postoperative ectasia remains a feared complication of corneal refractive surgery and has driven the development of technology and patient screening protocols for more than a decade. Although there remains controversy in some aspects of screening,⁵⁻⁸ there are many identified topographic and tomographic patterns that have been shown to place patients at higher risk for postoperative ectasia and that are recognized as at least relative contraindications for excimer laser procedures, including LASIK and surface ablation.^{9,10}

Although a relatively new procedure, there are already a handful of reports of ectasia developing after SMILE.¹¹⁻¹⁴ In this issue, the Journal is contributing an additional case to the literature.¹⁵ To date, all of these cases have exhibited abnormal preoperative topographic patterns, and most if not all would have been excluded from LASIK during screening by most surgeons. *And that is the point of this editorial.*

From Emory Eye Center and Emory Vision, Atlanta, Georgia.

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doi:10.3928/1081597X-20160613-01

LESSONS FROM THE PAST

Corneal refractive surgery has provided immense benefit to our patients worldwide for more than 50 years, with greatest adoption of a few procedures: radial keratotomy, followed by photorefractive keratectomy (PRK), followed by LASIK. Each of those procedures offered unique benefits to patients, and each came with unique risks. With each technique, initial treatment parameters proved too broad and each saw a narrowing of their scope. There were several patients with 16 or more radial keratotomy incisions until surgeons realized that eight cuts or less proved significantly more stable over time. There are many early reports of outcomes for PRK or LASIK up to -20.00 diopters or more, whereas today's excimer lasers are not approved for that range and most surgeons stop well short of treating that degree of myopia. And topographic patterns that placed patients at risk for ectasia were clarified in part through evaluating cases with these patterns that developed the complication.^{16,17}

We now have amassed extensive knowledge about how the cornea responds to laser surgical alteration, how preoperative corneal biomechanics, determined through screening topography and tomography, affect candidacy and long-term stability, and how the amount of tissue altered through surgery affects risk.¹⁸ So, let us use this information to our advantage as we perform and study the novel surgical approach that is SMILE.

STARTING CONSERVATIVELY

With SMILE we have an opportunity to do things a better way from the outset, during the phase of possible widespread use of the procedure. This better way includes using a cautious, conservative, and scientific approach relying on evidence-based medicine to drive surgical decision-making. We can use the information from screening patients for 20 years for PRK and LASIK, especially what we've learned in the past 10 years, and apply those standards to SMILE.

We have identified many abnormal topographic patterns as contraindications for LASIK. We know from

Misinterpretation of topographic early keratoconus, with consequent post small-incision lenticule extraction ectasia

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Received 1 January 2017

Accepted 27 April 2017

Delta Journal of Ophthalmology
2017, 18:182–184

The purpose of this paper is to describe an infrequent complication of small-incision lenticule extraction. Bilateral corneal ectasia that was discovered 6 months postoperatively is described here. The case has shown that the procedure can aggravate early keratoconus cases without any advantage over laser in-situ keratomileusis or surface ablation procedures. Placido disk imaging with correct scaling and color coding of Scheimpflug images is essential in the preoperative assessment of small-incision lenticule extraction patients.

Keywords:

ectasia, keratoconus, placido, Scheimpflug, SMILE

DJO 18:182–184

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1110-9173

Introduction

Femtosecond lenticule extraction and small-incision lenticule extraction (SMILE) have not been thoroughly investigated. However, they have shown encouraging results in the treatment of myopia and myopia with mild to moderate astigmatic error [1,2]. SMILE represents a less invasive alternative to laser in-situ keratomileusis (LASIK) for the correction of myopic error, without disruption of the Bowman's layer. However, microdistortions have been observed in the Bowman's layer in patients who had SMILE, which resulted from unavoidable tissue compression from shortening of the cap's arc length, without adversely affecting vision [3].

Case history

A 26-year old Egyptian male patient presented with a history of previous SMILE (Carl Zeiss Meditec AG, Jena, Germany) procedure in Egypt 5 months earlier. He complained of progressively decreasing vision in his left eye with glare and halos in both eyes (OU). His visual acuity was 20/30 in the right eye that corrects to 20/25 with $-0.75/-0.75 \times 10$. Left eye visual acuity was 20/400

Corneal thickness spatial profile showed normal pattern both eyes. Keratometry readings on the anterior corneal surface sagittal map were relatively flat (right eye: 41.9 and 42.5 D and left eye: 43.0 and 43.6 D), which tempted the surgeon to proceed with SMILE, especially with cold color code and wrong scaling on the posterior elevation map ($5 \mu\text{m}$). However, the surgeon overlooked suspicious indices, especially in the absence of placido disk imaging on preoperative assessment. Suspicious findings included posterior elevation of $+20 \mu\text{m}$ in both eyes at the border of the central 5 mm circle, high index of height decentration and index of height asymmetry, especially in the left eye, and high I-S ratio on sagittal map left eye, with an early vortex pattern.

Discussion

Although Wu and Wang [4] have found a statistically significant elevation in corneal hysteresis and corneal resistance factor in SMILE, compared with femtosecond laser-assisted LASIK, the superiority of biomechanical stability with SMILE has not been convincingly demonstrated and future analysis should clarify this aspect [4].

April 2017

Ectasia following small-incision lenticule extraction (SMILE): a review of the literature

Sep 2017

This article was published in the following Dove Press journal:
Clinical Ophthalmology
15 September 2017
[Number of times this article has been viewed](#)

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Purpose: Four cases of corneal ectasia after small-incision lenticule extraction (SMILE) have been reported. In this review, we provide an overview of the published literature on corneal ectasia after SMILE and risk factors associated with this complication.

Methods: Case reports were identified by a search of seven electronic databases for pertinent heading terms between 2011 and July 2017. We identified patient characteristics and surgical details including preoperative topography, central corneal thickness, and anterior keratometry (Km). Residual stromal bed (RSB) values not reported were computed using VisuMax ReLEx SMILE software Version 2.10.10. Preoperative ectasia risk was measured using the Randleman Ectasia Risk Score System (ERSS). Percent tissue alteration was calculated for each patient as described by Santhiago et al.

Results: Seven eyes of four patients developed corneal ectasia post SMILE. Two patients had abnormal topography in both eyes. One patient had abnormal topography in one eye. Only one patient was noted to have normal topography in both eyes and later developed ectasia in one eye in the absence of any known risk factors. The mean Randleman ectasia risk score was 4 ± 3 (range: 1–8). The mean calculated percent tissue altered (PTA) was $38\% \pm 6\%$ (range: 30%–47%).

Conclusion: A majority of reported ectasia cases occurred in patients with subclinical keratoconus. These conditions may be exacerbated by SMILE and should be considered abso-



Unilateral corneal ectasia after small-incision lenticule extraction in a 43-year-old patient

Jean Christophe Gavrillov, MD, Raphael Atia, MD, Vincent Borderie, MD, PhD,
Laurent Laroche, MD, Nacim Bouheraoua, MD, PhD

Unilateral corneal ectasia developed after small-incision lenticule extraction for mild myopia in a 43-year-old man with preoperative asymmetric astigmatism. The ectasia was diagnosed 4 years postoperatively. Preoperative data showed asymmetric astigmatism with no signs of forme fruste keratoconus. Inferior anterior curvature steepening exceeded 2.00 diopters without bulging of

the posterior curvature, and pachymetric thickness exceeded 515 μm . Corneal ectasia can occur after small-incision lenticule extraction in patients older than 40 years with preoperative asymmetric astigmatism.

J Cataract Refract Surg 2018; 44:403–406 © 2018 ASCRS and ESCRS

Since the first description of small-incision lenticule extraction (SMILE, Carl Zeiss Meditec AG) in 2011 by Sekundo et al.,¹ the number of procedures performed to correct myopia and astigmatism with this new technique has steadily increased. The incidence of corneal ectasia after laser in situ keratomileusis (LASIK) has been estimated at 1 in 2500.² Because small-incision lenticule extraction is a flapless procedure, it has been suggested that the risk for corneal ectasia after small-incision lenticule extraction is lower than after LASIK.³ To date, 4 reports of corneal ectasia have been published.^{4–8} We report a case of unilateral corneal ectasia 4 years after small-incision lenticule extraction for mild myopia in a patient older than 40 years with preoperative asymmetric

eyes, representing a steepening of more than 2.00 diopters (D) in the right eye and 1.80 D in the left eye. Moreover, Scheimpflug camera images showed an absence of posterior curvature bulging and no correspondence between the steeper anterior curvature and the thinner points of the cornea.

Small-incision lenticule extraction was performed uneventfully with the Visumax femtosecond laser system (Carl Zeiss Meditec AG). The caps were 7.30 mm in diameter and 120 μm thick in both eyes. The diameter of the optical zone was 6.50 mm in both eyes. The maximum and minimum lenticule thicknesses were 94 μm and 15 μm , respectively, in the right eye and 109 μm and 15 μm , respectively, in the left eye, with a residual stromal bed (RSB) of 308 μm in the right eye and 286 μm in the left eye. The immediate postoperative course was uneventful, with an uncorrected distance visual acuity of 20/20 in both eyes at the 1-month examination.

Four years after the initial small-incision lenticule extraction,

March 2018

FULL ARTICLE

Corneal tomographic features of postrefractive surgery ectasia

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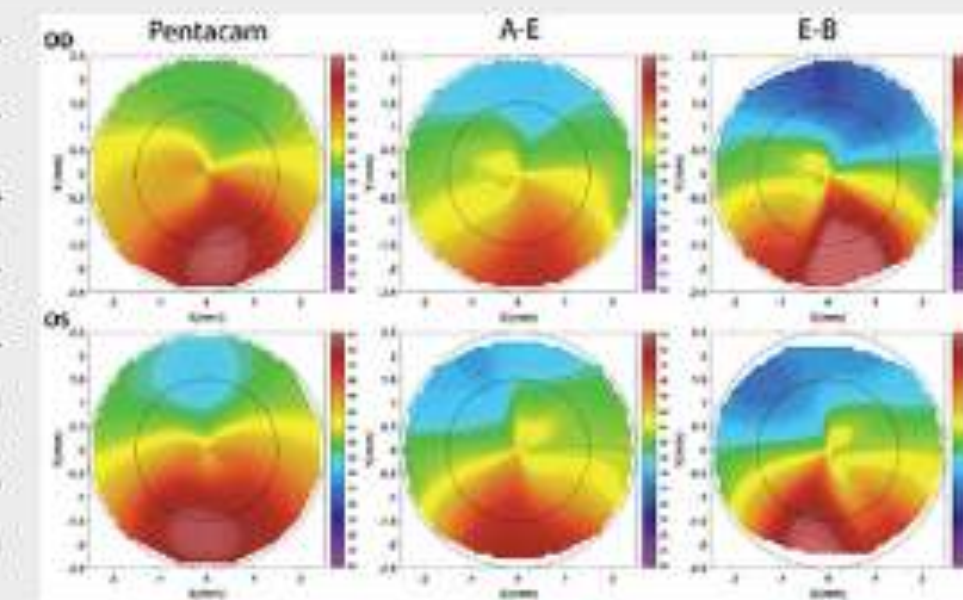
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Funding information

Indo-German Science and Technology Center,
Grant/Award Number: SIBAC

The purpose of this study was to evaluate the tomographic features of post-refractive surgery eyes. This was a retrospective evaluation of clinical data. Three patients with post-LASIK (laser-assisted in situ keratomileusis) and two patients with post-SMILE (small incision lenticule extraction) ectasia were imaged with Scheimpflug imaging (SI, Pentacam) and optical coherence tomography (OCT, RTVue). Curvature and wavefront aberrations of the air-epithelium interface (A-E) and epithelium-Bowman's layer interface (E-B) were derived. OCT of normal and keratoconic eyes from an earlier study were compared with the data of the ectasia eyes. Curvature and aberrometry of the A-E interfaces were statistically similar between SI and OCT. However, OCT revealed a steeper and more aberrated E-B interface than A-E though correlation between them was inferior to the correlation for keratoconic eyes. Furthermore, the magnitude of differences between the A-E and E-B interfaces was greater in the ectasia eyes than the keratoconic eyes. OCT could possibly assist better in selecting appropriate treatment plan for postrefractive surgery ectasia eyes than conventional tomographers.



KEYWORDS

ectasia, cornea, SMILE, LASIK, tomography, OCT, Bowman's layer

September 2018

CASE REPORT

Unilateral ectasia after small-incision lenticule extraction

Eric E. Pazo, MSc, MD, PhD, Richard N. McNeely, BSc, PhD, Samuel Arba-Mosquera, MSc, PhD, Christoph Palme, MD, Jonathan E. Moore, PhD, FRCOphth

December 17, 2018

A 23-year-old man developed unilateral corneal ectasia after bilateral small-incision lenticule extraction (SMILE). The preoperative corneal topography was normal, with a minimum corneal thickness of 582 μm and 586 μm in the right eye and left eye, respectively. The refractive correction was -3.00 diopters (D) sphere in the right eye and -3.50 D sphere in the left eye. At the 12-month postoperative visit, corneal topography showed early signs of ectasia in the right

eye; the ectasia had deteriorated by the 15-month examination. Corneal crosslinking was performed to arrest further progression. At the last examination, the uncorrected distance visual acuity in the right eye was 0.1 logarithm of the minimum angle of resolution (logMAR) and the corrected distance visual acuity, -0.1 logMAR.

J Cataract Refract Surg 2018; ■:■-■ © 2018 ASCRS and ESCRS

At present, the prevalence of ectasia after laser in situ keratomileusis (LASIK) has been estimated to be between 0.04% and 0.6%.¹ A review article by Moshirfar et al.² found that at the time of publication, only 4 cases of corneal ectasia after small-incision lenticule extraction (SMILE, Carl Zeiss Meditec AG) had been documented and reported.³⁻⁶ A proposed advantage of small-incision lenticule extraction is a stronger postoperative biomechanical effect as a result of the anterior stromal lamellae being maintained. This theory is supported by mathematical modeling⁷ and finite element analysis⁸; however, the practicality of this benefit remains to be proven clinically.

CASE REPORT

A 23-year-old man presented to the clinic requesting corneal refractive surgery for myopic correction. He had no history or symptoms of dry eye, atopy, or allergies of which he was aware. The preoperative refractive error was -3.00 diopters (D) sphere in the right eye and -3.50 D

family history of keratoconus and had a stable refraction for more than 2 years. A complete preoperative ophthalmologic examination was performed and all parameters were within normal limits. Scheimpflug imaging (Pentacam, Oculus Optikgeräte GmbH) showed normal topography with a maximum keratometry (K) value of 44.9 D in the right eye and 45.0 D in the left eye and a minimum thickness of 582 μm and 586 μm , respectively. The anterior and posterior elevation maps were also unremarkable (Figure 1). No significant inferior-superior asymmetry was noted on the curvature maps. The fluorescein tear breakup time (TBUT) was 15 seconds in the right eye and 14 seconds in the left eye.

Uneventful bilateral small-incision lenticule extraction was performed. The cap thickness was 135 μm with an optical zone of 6.50 μm and a corneal side cut of 2.41 mm. The lenticule thickness was 63 μm in the right eye and 71 μm in the left eye with a residual stromal bed (RSB) of 384 μm and 380 μm , respectively (Figure 2).

The immediate postoperative course was uneventful.

Bilaterally Asymmetric Corneal Ectasia Following SMILE With Asymmetrically Reduced Stromal Molecular Markers

January 14, 2019

Rohit Shetty, MD, FRCS, PhD; Nimisha Rajiv Kumar, MSc; Pooja Khamar, MS; Matthew Francis, M.Tech; Swaminathan Sethu, PhD; J. Bradley Randleman, MD; Ronald R. Krueger, MD; Abhijit Sinha Roy, PhD; Arkasubhra Ghosh, PhD

ABSTRACT

PURPOSE: To evaluate extracellular matrix regulators and inflammatory factors in a patient who developed ectasia after small incision lenticule extraction (SMILE) despite normal preoperative tomographic and biomechanical evaluation.

METHODS: The SMILE lenticules from both eyes of the patient with ectasia and three control patients (5 eyes) matched for age, sex, and duration of follow-up were used for gene expression analysis of lysyl oxidase (LOX), matrix metalloproteinase 9 (MMP9), collagen types I alpha 1 (COLIA1) and IV alpha 1 chain (COLIVA1), transforming growth factor-beta (TGF-beta), bone morphogenetic protein 7 (BMP7), interleukin-6 (IL-6), cathepsin K, cluster of differentiation 68, integrin beta-1, and tissue inhibitor of metalloproteinase-1 (TIMP1). Furthermore, the functional role of LOX was assessed in vitro by studying the collagen gel contraction efficiency of LOX overexpressing in primary human corneal fibroblast cells.

RESULTS: Preoperatively, manifest refraction was -9.25 diopters (D) in the right eye and -10.00 D in the left eye. Corneal thickness, Pentacam (OCULUS Optikgeräte GmbH, Wetzlar, Germany) tomography, and Corvis biomechanical indices (OCULUS Optikgeräte GmbH) were normal. The ectatic eye lenticule (left) had reduced expression of LOX and COLIA1 compared to controls without ectasia. Increased mRNA fold change expression of TGF-beta, BMP7, IL-6, cathepsin K, and integrin beta-1 was noted in the ectatic left eye compared to controls; however, MMP9 and TIMP1 levels were not altered. Ectopic LOX expression in human corneal fibroblast induced significantly more collagen gel contraction, confirming the role of LOX in strengthening the corneal stroma.

CONCLUSIONS: Reduced preexisting LOX and collagen levels may predispose clinically healthy eyes undergoing refractive surgery to ectasia, presumably by corneal stromal weakening via inadequately cross-linked collagen. Preoperative molecular testing may reveal ectasia susceptibility in the absence of tomographic or biomechanical risk factors.

[J Refract Surg. 2019;35(1):6-14.]

Reduced LOX

Incidence of Ectasia After SMILE From a High-Volume Refractive Surgery Center in India

Sheetal Brar, C R Roopashree, Sri Ganesh

PMID: 34914554 DOI: [10.3928/1081597X-20210812-03](https://doi.org/10.3928/1081597X-20210812-03)

Abstract

Purpose: To report the incidence of ectasia after small incision lenticule extraction (SMILE) in a high-volume refractive surgery center in India.

Methods: To derive the incidence of ectasia after SMILE, all eyes that underwent SMILE or SMILE Xtra (SMILE combined with prophylactic accelerated corneal cross-linking) from November 2012 to August 2019 were retrospectively analyzed. Furthermore, these cases were classified as being "normal" or "borderline" based on certain predefined criteria. Only eyes with a minimum follow-up of 12 months were included.

Results: Of the total 7,024 eyes analyzed, 6,619 eyes underwent SMILE, of which 10 eyes developed ectasia at a mean interval of 21.3 months, making the incidence of ectasia after SMILE 0.15%. Of these 10 eyes with ectasia, 2 eyes had normal preoperative topography, whereas the remaining 8 eyes were borderline as per the predefined criteria. Retrospective data analysis revealed that 6,025 of 7,024 eyes were normal and thus suitable for a standard SMILE procedure, whereas 999 eyes were borderline, of which 594 eyes underwent SMILE and 405 eyes underwent SMILE Xtra. The incidence of ectasia in borderline eyes undergoing SMILE was 0.80% (8 of 999) versus 0% (none) for borderline eyes undergoing SMILE Xtra (chi square, $P < .05$).

Conclusions: The incidence of ectasia after SMILE in the early postoperative period was 0.15%, with borderline eyes accounting for most cases. Borderline eyes treated with SMILE Xtra did not progress to ectasia, potentially suggesting a protective role of simultaneous CXL. [*J Refract Surg.* 2021;37(12):800-808.].

2021

Ectasia After SMILE, Revisited

J. Bradley Randleman, MD



Small incision lenticule extraction (SMILE) has seen dramatic growth in its utilization in refractive surgery during the past decade. With more than 4 million SMILE procedures performed worldwide and a recent expanded approval range in the United States, the procedure has become an important option for patients who desire refractive surgery. In this issue, Brar et al¹ tackle a contentious topic: the development of postoperative ectasia after SMILE. I first editorialized on this topic 5 years ago,² after a series of case reports were published with patients developing ectasia after SMILE. At that time I asked "...why not use the same preoperative topographic and tomographic screening criteria [for SMILE] that we have developed for [laser in situ keratomileusis] LASIK and [photorefractive keratectomy] PRK?" Now there is greater evidence to support this contention.

SMILE has been theorized to have some biomechanical benefit in normal corneas when compared to LASIK.³⁻⁵ This advantage is thought to be directly related to the preservation of the anterior-most corneal stromal fibers, which are known to impart the greatest tensile strength in the normal cornea.⁶ So, why does this advantage not translate to reduced ectasia rates after SMILE in susceptible corneas? Many groups have found significant differences in the anterior corneal stroma between keratoconic or postoperatively ectatic and normal corneas, with redistribution of collagen fibers resulting from interlamellar and interfibrillar

evidence for the focal weakening that occurs primarily in the anterior corneal stroma in ectatic eyes. Therefore, the preservation of these anterior-most fibers in SMILE appears at best to be inconsequential, and more likely to be detrimental to postoperative corneal integrity by preserving the tissue most negatively impacted by the ectatic disease process. This point is stated particularly clearly in an editorial by Dupps published in 2018.¹⁴

In this issue, Brar et al¹ state what many others have thought, namely that they initially believed that SMILE had perceived biomechanical advantages over LASIK that might make it suitable for borderline cases. That theory has now been tested and found to be incorrect. I applaud the authors for being so forthcoming on this critical point. In their cohort, borderline cases had surgery and developed ectasia at an unacceptably high rate. The primary message, to avoid SMILE in borderline eyes, is clear.

There is a second message in this article: SMILE combined with a modified, rapid corneal cross-linking approach (called SMILE Xtra) may be safely performed in borderline eyes. To this point, the authors report their outcomes of SMILE Xtra, with no cases of ectasia presenting within the follow-up period. Although this finding is encouraging, I have significant concerns about this conclusion based on the data available to date.

First, the definition Brar et al used for "borderline

2021

Bilateral Corneal Ectasia 3 Years After Small Incision Lenticule Extraction in a Borderline Case

César Hernández-Chavarría, MD,* Mónica Benedetti S, MD,* Gonzalo García de Oteyza, MD,†
Ana Mercedes García-Albisua, MD,* and Everardo Hernández-Quintela, MD, MSc*‡

Purpose: The purpose of this study was to report a case of bilateral ectasia 3 years after small incision lenticule extraction (SMILE) in a patient with normal preoperative topography of the right eye and abnormal topography of the left eye.

Methods: This study was a case report.

Results: A 22-year-old man developed bilateral corneal ectasia after SMILE. The preoperative corneal topography of the right eye was unremarkable, with a minimum corneal thickness of 511 μm in the right eye, and the abnormal corneal topography of the left eye revealed a risk factor for developing ectasia, with a minimum corneal thickness of 514 μm in the left eye. The refractive error was -4.50 to 3.50×10 degrees in his right eye and -4.25 to 3.50×0 degrees in his left eye with a best-corrected visual acuity of 20/20. An uncomplicated SMILE was performed; after his last follow-up visit at 1 month, the patient was lost to follow-up for 3 years. After that time, he presented with visual loss with left predominance. Bilateral ectasia was diagnosed through corneal topography, and crosslinking was performed in both eyes.

Conclusions: There are a very few reports of corneal ectasia after SMILE with normal preoperative topography.

Key Words: cornea, ectasia, SMILE, refractive surgery

(*Cornea* 2022;41:359–362)

Laser-assisted in situ keratomileusis (LASIK) has been popular for more than 2 decades and is the most commonly performed refractive surgery. Despite its popularity, LASIK is not exempt from complications such as dry eye, flap-related, and iatrogenic ectasia with a reported prevalence of 0.04% to 0.05%.¹ In a series by Randleman et al,² of 171

eyes that developed ectasia after refractive surgery, only 4% were induced after photorefractive keratectomy (PRK) and 96% after LASIK. To reduce those surgery-related complications, a less invasive technique, small incision lenticule extraction (SMILE), appeared into the refractive surgeries portfolio in the hopes of reducing complications. Because SMILE preserves the collagen network of the anterior stroma, it was initially believed to imply almost no risk of iatrogenic ectasia.³ However, at least 5 cases of iatrogenic ectasia associated with SMILE have been reported in the literature.⁴ Of these 5 cases, only 2 were noted to have normal preoperative corneal topographies. We report a case of bilateral iatrogenic ectasia in an apparently healthy patient with normal preoperative topography of the right eye and abnormal corneal topography with higher risk for developing ectasia in the left eye. Our motivations are 2-fold: to share diagnostic criteria for bilateral ectasia and to raise awareness of the need for more in-depth studies of SMILE's impact on corneal biomechanics.

CASE REPORT

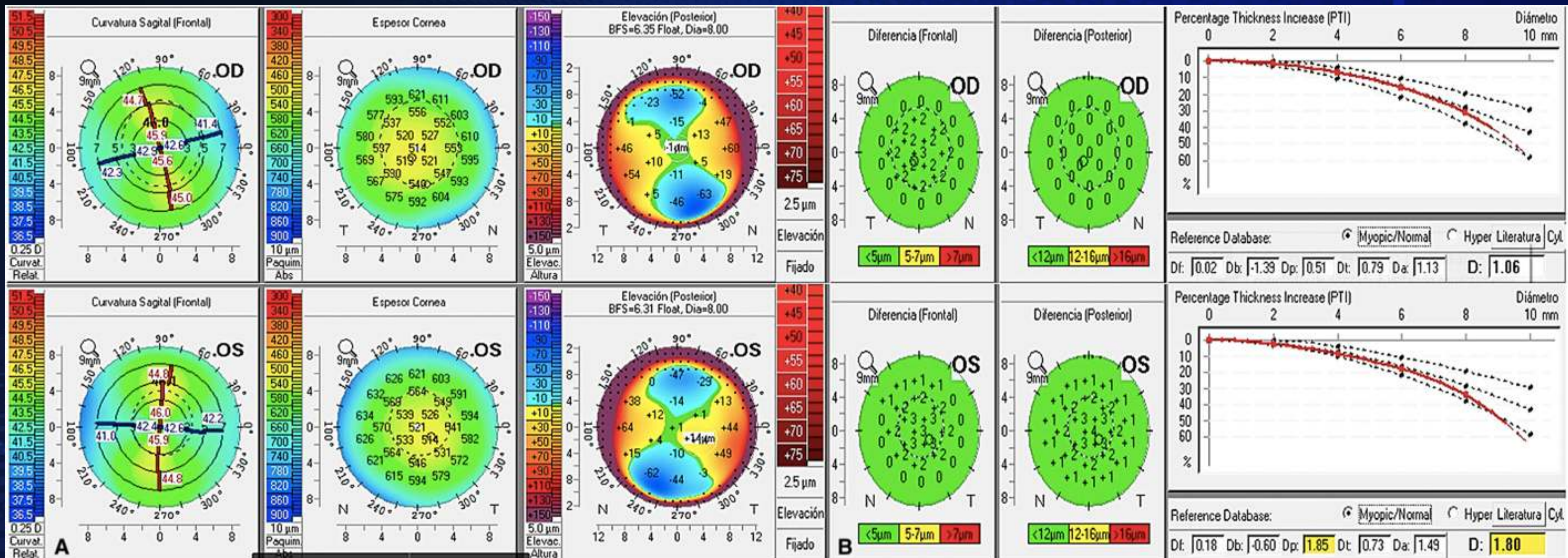
A 22-year-old male patient came to our clinic requesting refractive surgery. The preoperative refraction was -4.50 to 3.50×10 degrees in the right eye and -4.25 to 3.25×174 degrees in the left eye. The best-corrected visual acuity was 20/20 in both eyes, and he had a cycloplegic refraction of -4.50 to 3.50×10 degrees in the right eye and -4.25 to 3.50×0 degrees in the left eye. The patient had no significant ocular history, such as trauma, amblyopia, or strabismus, and no family history of keratoconus. The SMILE procedure was performed instead of laser-assisted in situ keratomileusis (LASIK) because the patient was a contact sports athlete, and we wanted to avoid a flap dislocation or other flap complications.

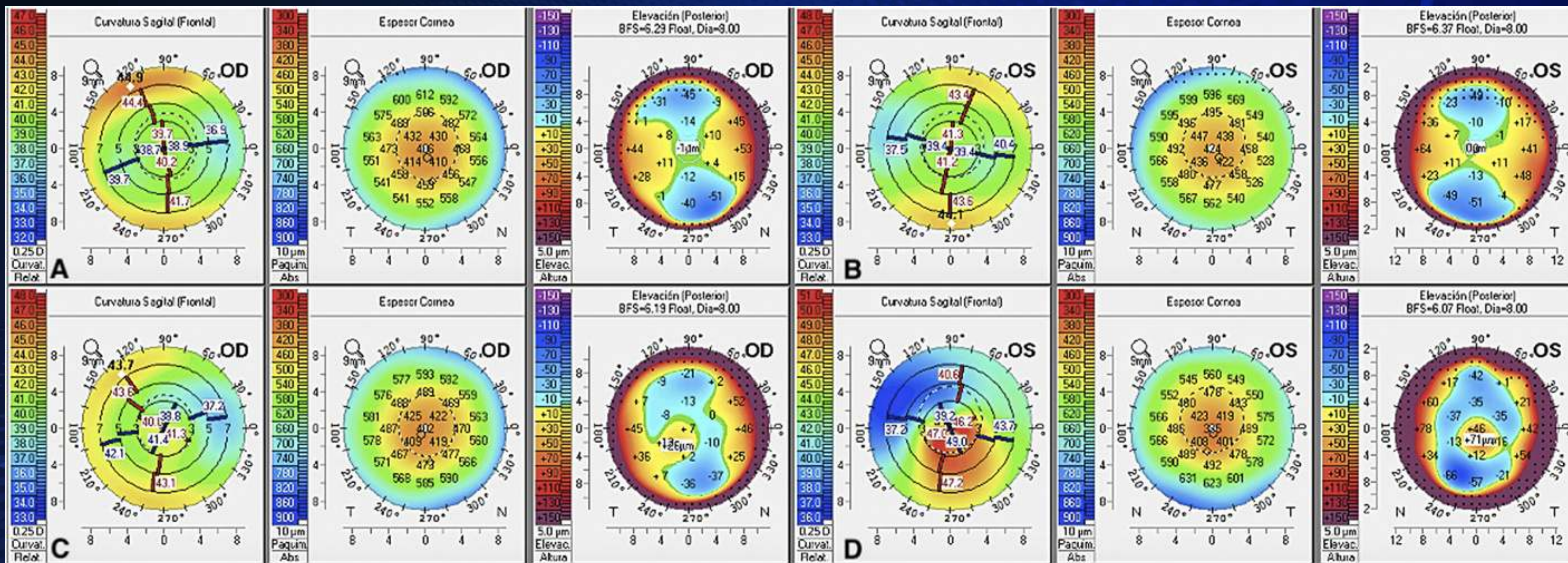
A complete ophthalmologic and topographic evaluation was performed. The ophthalmologic evaluation and dry eye assessment were unremarkable with a tear break-up time greater than 10 seconds and an Oxford staining score of 0. A Scheimpflug-based corneal topography (Pentacam; OCULUS, GmbH, Germany) was performed on both eyes, showing a maximum keratometry value of 45.80 D in

2022

Notes

Received for publication December 15, 2020; revision received August 30, 2021; accepted October 24, 2021. Published online ahead of print February 2, 2022.





Ectasia After SMILE Lacking Perceivable Risk Factors

Norma Morales Flores, MD; Sofía Pérez-Solórzano, MD; Nicolás Kahuam-López, MD, PhD; Arturo Ramirez-Miranda, MD; Enrique O. Graue-Hernández, MD, MSc; Alejandro Navas, MD, PhD

ABSTRACT

PURPOSE: To describe 3 eyes from 2 patients who had corneal ectasia after small incision lenticule extraction (SMILE) without tangible risk factors.

METHODS: A 27-year-old woman and a 24-year-old man with compound myopic astigmatism and normal corneal topographies underwent uneventful SMILE in both eyes.

RESULTS: The first patient complained of decreased visual acuity 6 months after SMILE. She presented with uncorrected distance visual acuity (UDVA) of 20/60 and 20/200 in the right and left eyes, respectively. Topography revealed decreased

thickness and inferior steepening in both eyes. The second patient presented at 5 years after SMILE with UDVA of 20/400 and 20/100 in his right and left eyes, respectively. Tomography revealed an inferior steepening in the right eye. These findings were compatible with post-refractive surgery ectasia.

CONCLUSIONS: Even though SMILE is considered a safe procedure, it is not exempt from developing corneal ectasia even without evident risk factors, which implies the need for a strict preoperative evaluation.

[*Journal of Refractive Surgery Case Reports*. 2022;2(3):e63-e67.]

Small incision lenticule extraction (SMILE) is a safe, effective, and predictive refractive procedure. It has been postulated to have some advantages over laser in situ keratomileusis (LASIK). Because a flap is unneeded, the strength of the anterior stroma is better preserved, so corneal biomechanical stability may be greater.¹

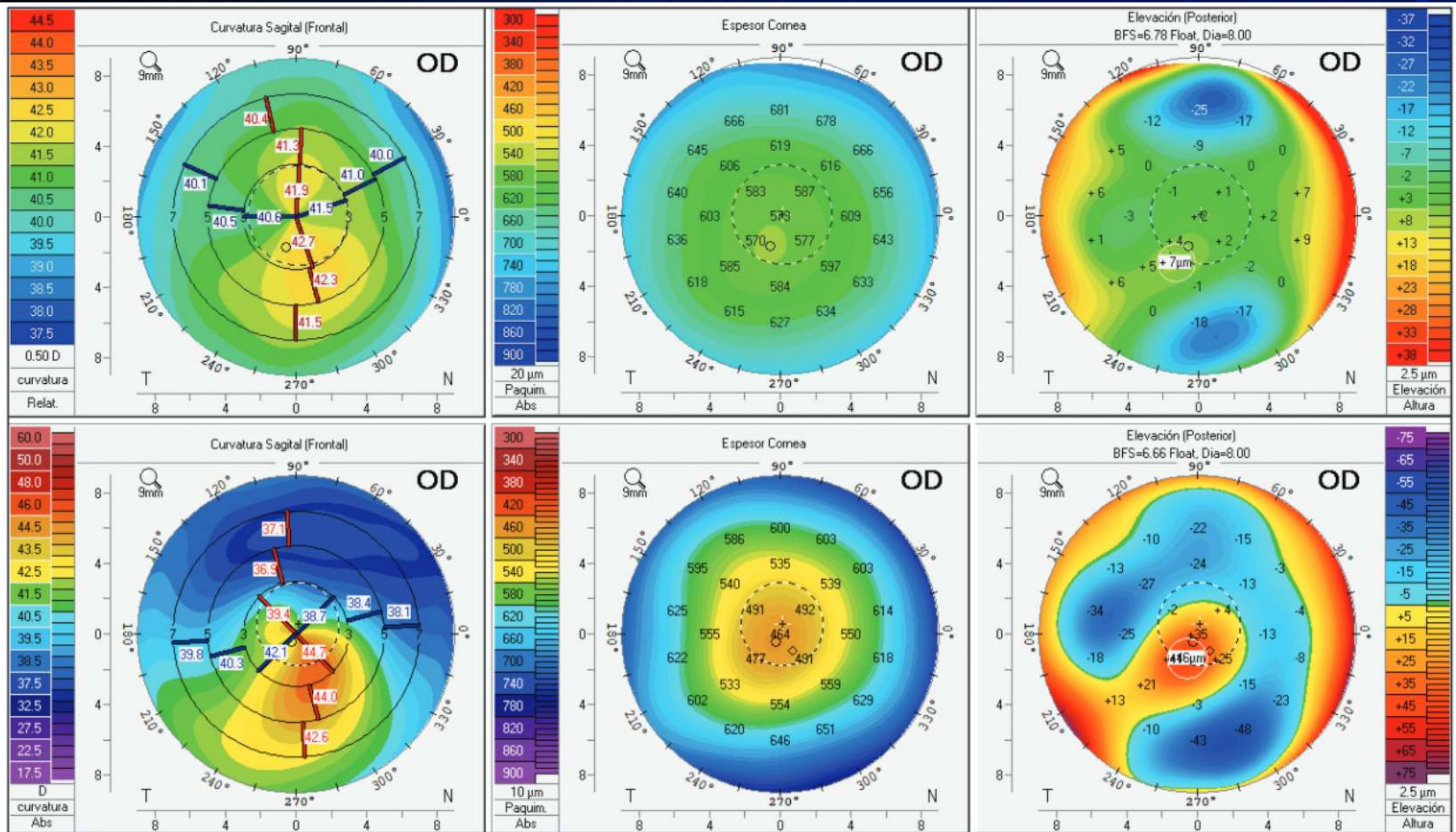
Corneal ectasia is one of the most feared complications after refractive surgery. Ectasia occurs when the biomechanical integrity of the cornea is compromised beyond a safe threshold required to maintain its shape and curvature and there is consequent, irreversible corneal thinning and steepening.¹ The purpose of this report is to describe 3 eyes of 2 patients with corneal ectasia after SMILE who did not have tangible risk factors.

CASE REPORTS

CASE 1

A 27-year-old female weightlifter had an uncorrected distance visual acuity (UDVA) of 20/400 and a corrected distance visual acuity (CDVA) of 20/25 in both eyes. The preoperative refractive error was -6.00 -4.00 × 30° and -5.75 -4.00 × 150°, respectively. At preoperative evaluation, there was no history of keratoconus, stable refraction, no eye rubbing, no atopy, and a normal slit-lamp examination. Without any relevant clinical findings, Scheimpflug topography (SIRIUS; CSO) was performed (**Figure 1**) and was programmed for SMILE. For the procedure, in the left eye the cap thickness was 140 μm and the lenticule thickness was 137 μm, leaving a residual stromal bed of 260 μm.

2022



Preop MR= -4.75 -1.00 $\times 5^\circ$

CT=568 μm Cap T=160 μm Lenticule T =102 μm RSB 306 μm

Corneal Ectasia after Laser-Assisted Small-Incision Lenticule Extraction: The Case for an Enhanced Ectasia Risk Assessment

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Abstract

Purpose: To present a case of asymmetric progressive corneal ectasia following femtosecond laser-assisted small-incision lenticule extraction.

Methods: After obtaining a patient's consent, preoperative and postoperative findings were represented in this case report.

Results: A 29-year-old woman presented with normal preoperative Placido disk-based corneal topography and tomographic findings. The corrected refractive error was -4.00 and $-4.50 -1.00 \times 177$ in the right and left eye, respectively, with a maximal lenticule thickness of 87 and 115 μm OD/OS. Twenty months postoperatively, the patient presented with decreased vision in the left eye and mild ectatic changes in corneal shape in both eyes. The retrospective evaluation of the integrated rotating Scheimpflug tomography (Pentacam; Oculus, Wetzlar, Germany) and corneal biomechanical (Corvis ST) assessment revealed moderate susceptibility for corneal ectasia in the right eye and a significant corneal ectasia in the left eye.

Conclusion: This case corroborates the need for an enhanced multimodal approach to characterize the risk for postoperative corneal ectasia after laser vision correction.

Keywords: Biomechanics, Corneal ectasia, Small-incision lenticule extraction

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Submitted: 01-Mar-2022; **Revised:** 26-Mar-2022; **Accepted:** 05-Apr-2022; **Published:** 30-Nov-2022

INTRODUCTION

Excellent safety and efficacy have been reported for the small-incision lenticule extraction (SMILE) technique as a flapless procedure.¹ Although the SMILE procedure may theoretically reduce the risk of corneal ectasia, it is not eliminated due to corneal alterations by tissue removal and biomechanical weakening of the cornea.^{2,3} This report describes a case of asymmetric progressive corneal ectasia following

CASE REPORT

A 29-year-old woman seeking refractive surgery presented in our clinic in 2019. Baseline refractive characteristics are presented in Table 1. An informed consent was obtained from the patient. The patient had no ocular disease and no family history of keratoconus. The corrected distance visual acuity (CDVA) was 20/20 in both eyes. A full ophthalmologic assessment and diagnostic imaging including Placido

2022

- A 29-year-old woman
- Normal preoperative topography and tomographic findings.
- MR $-4.50 -1.00 \times 177$ OS
- Maximal lenticule thickness = 115 μm OS

OCULUS - PENTACAM Compare 2 Exams

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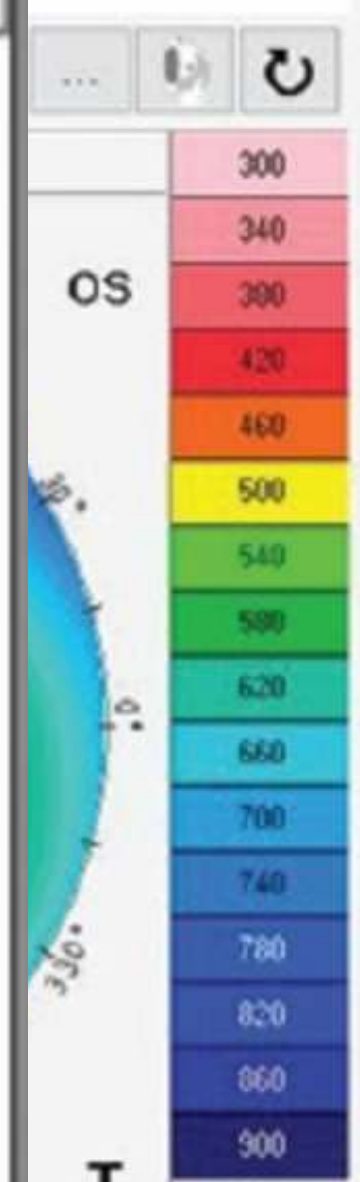
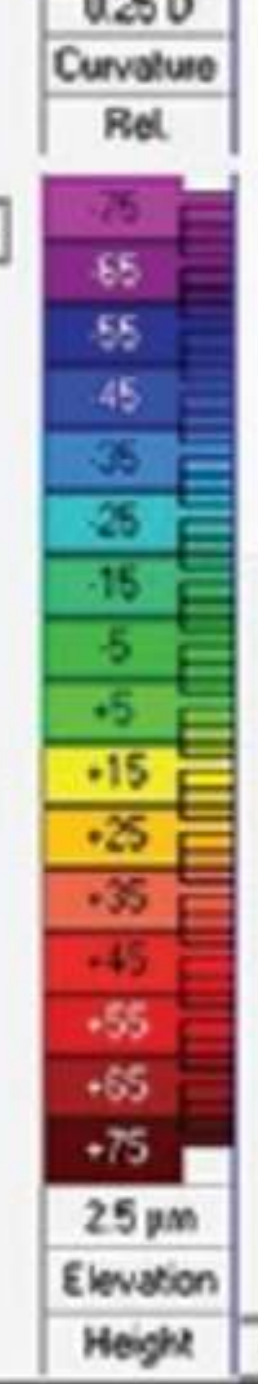
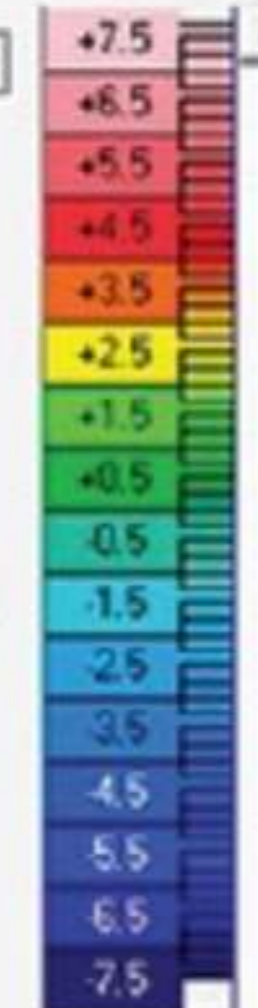
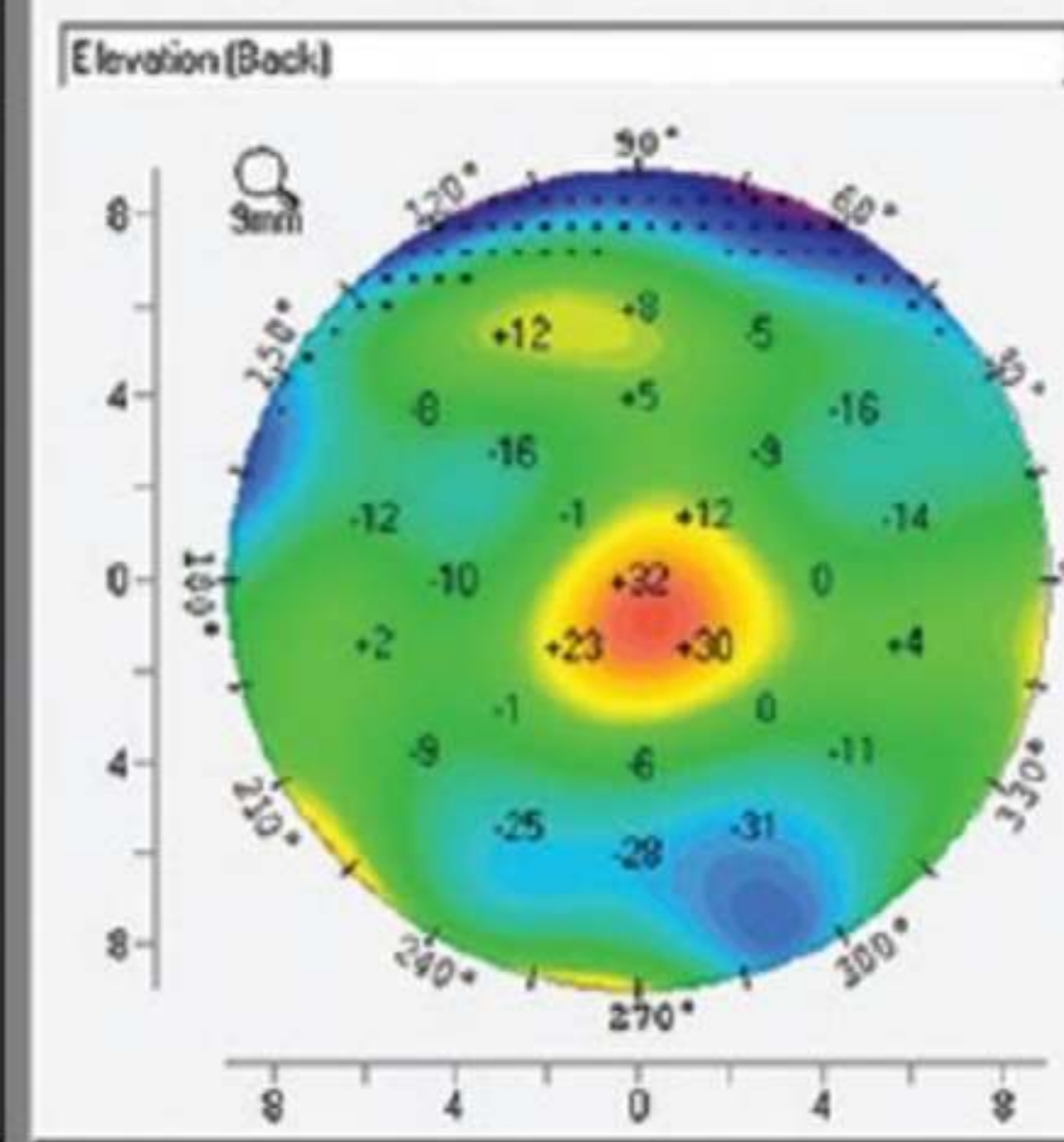
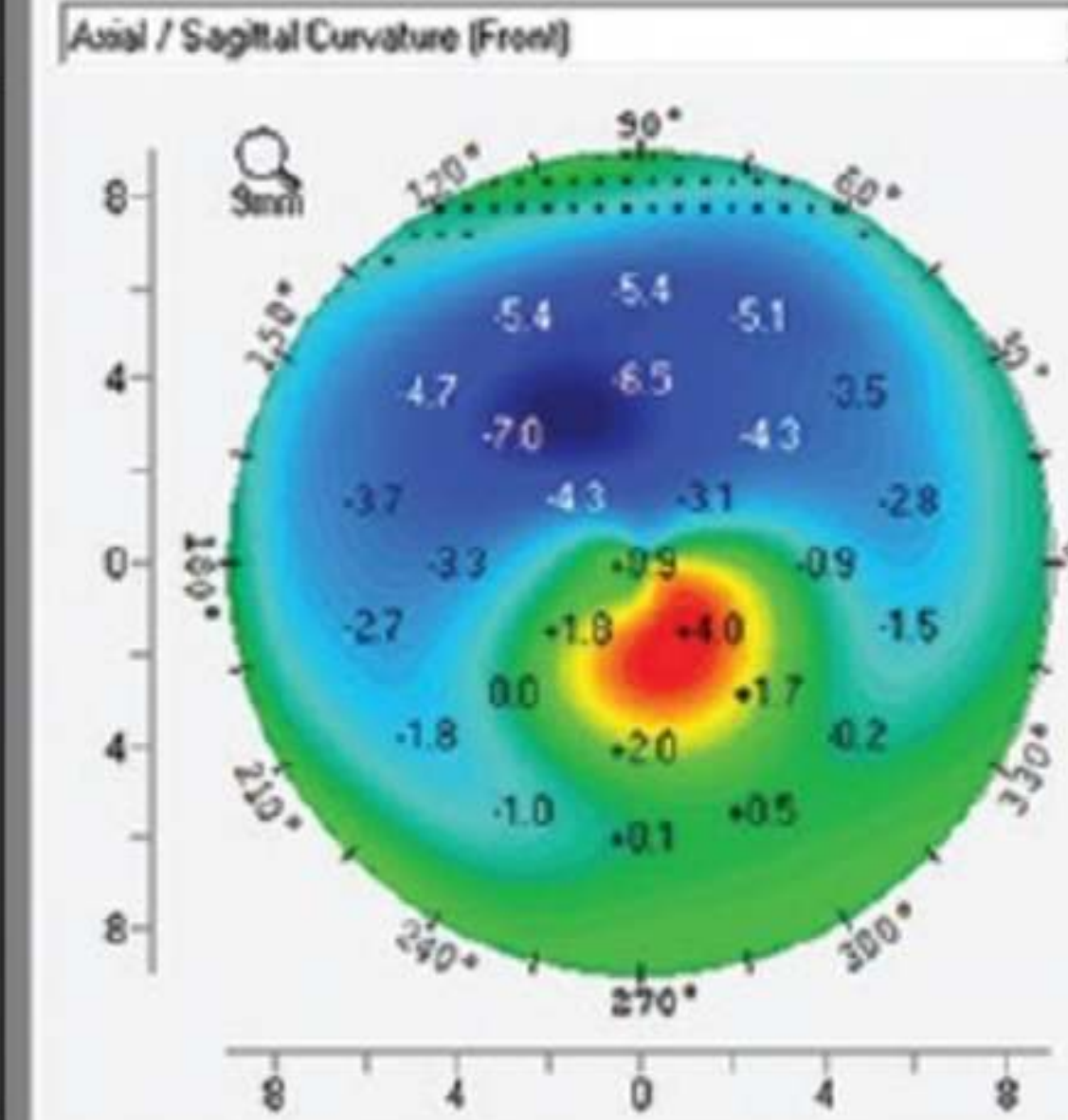
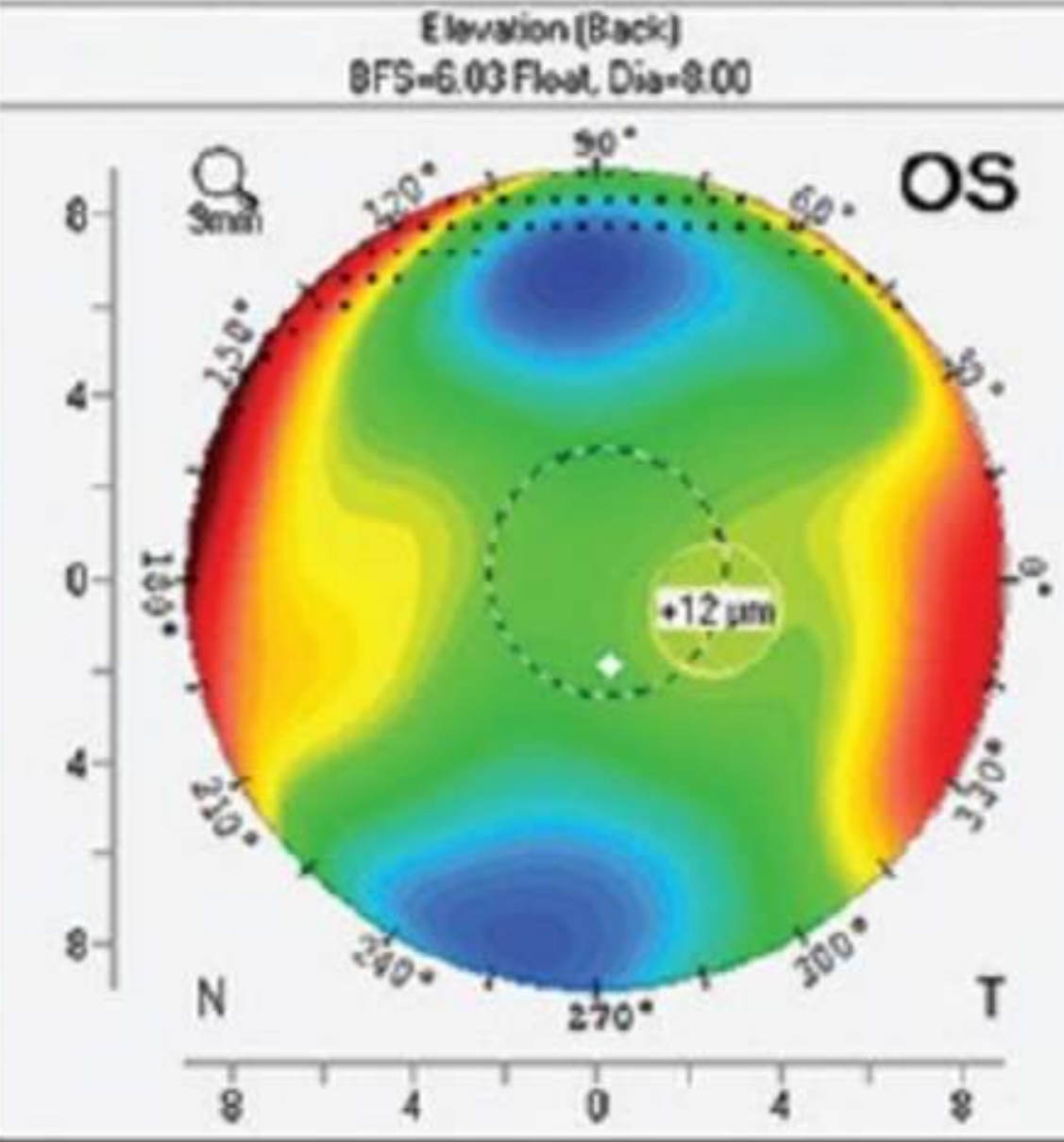
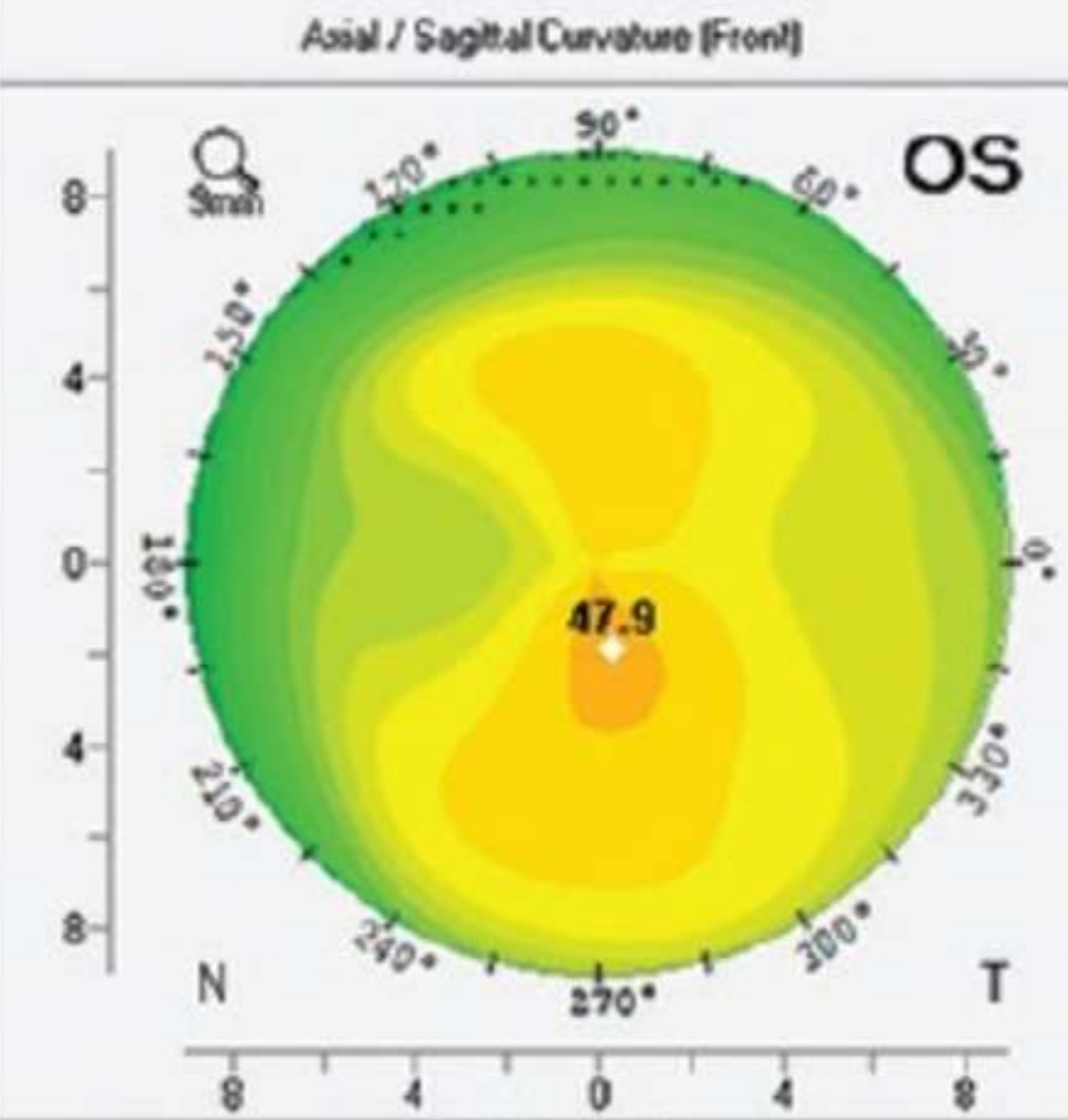
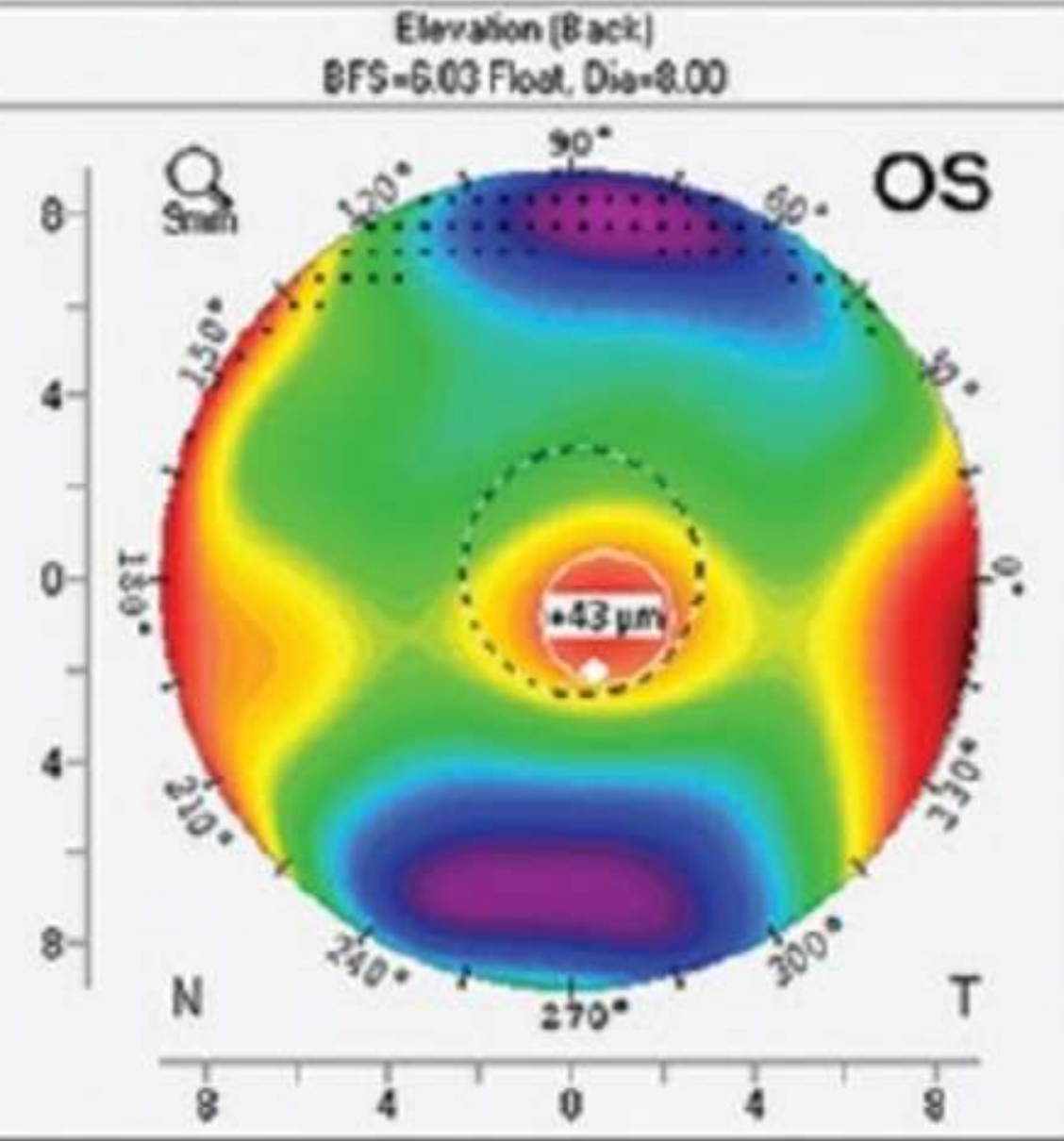
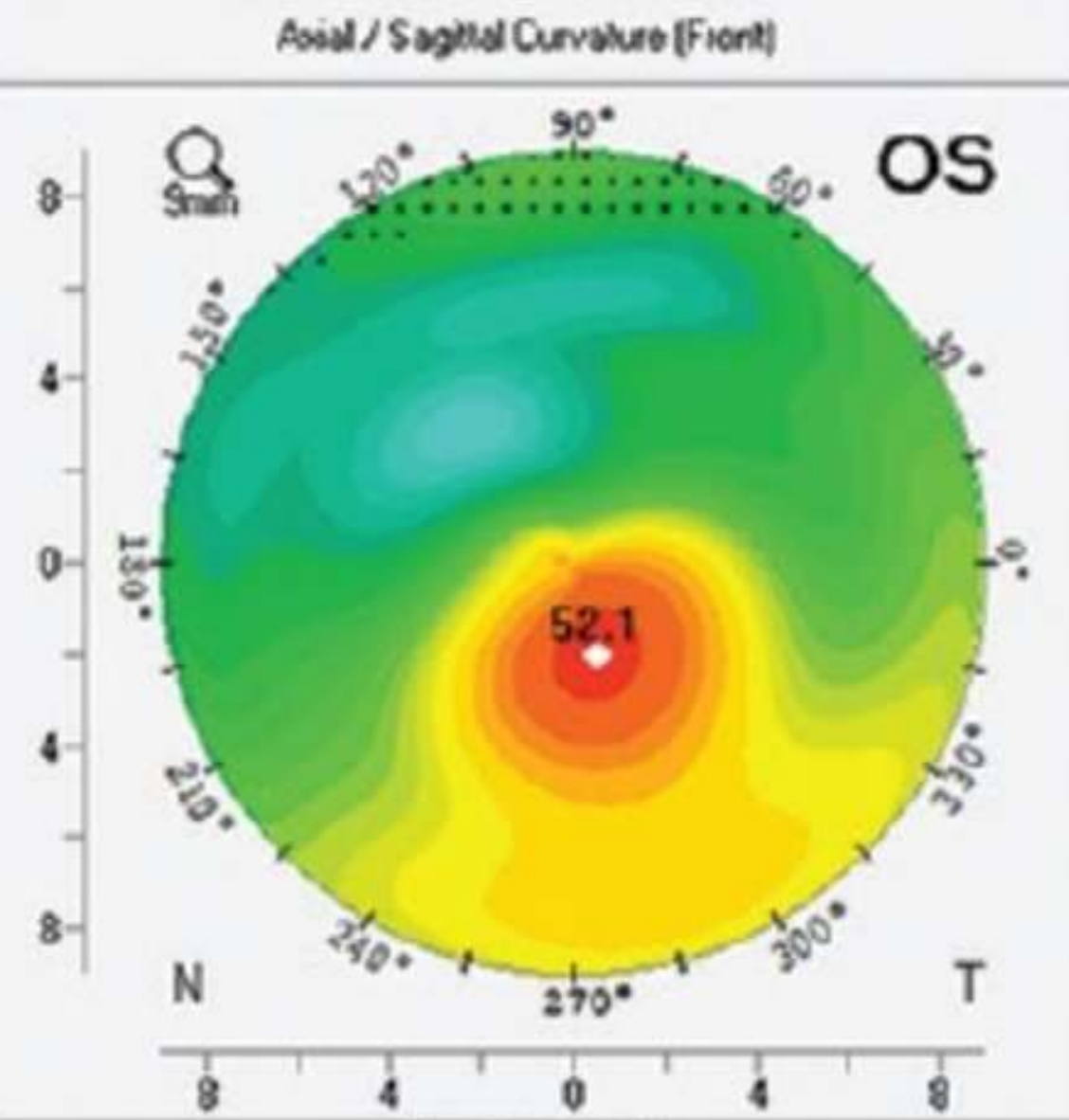
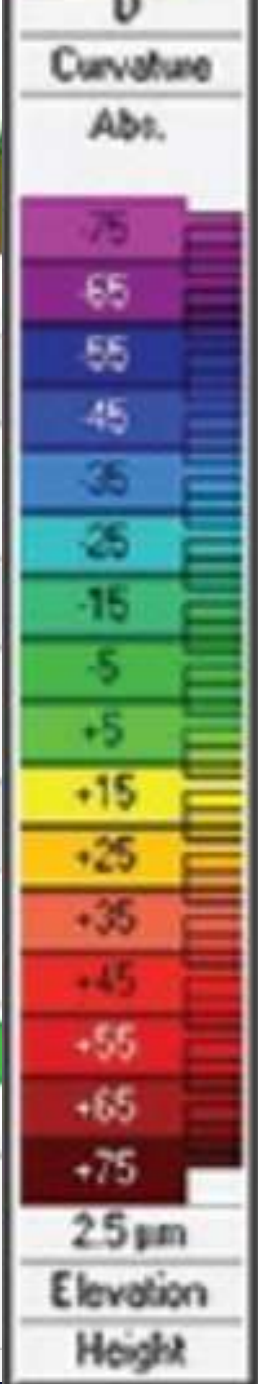
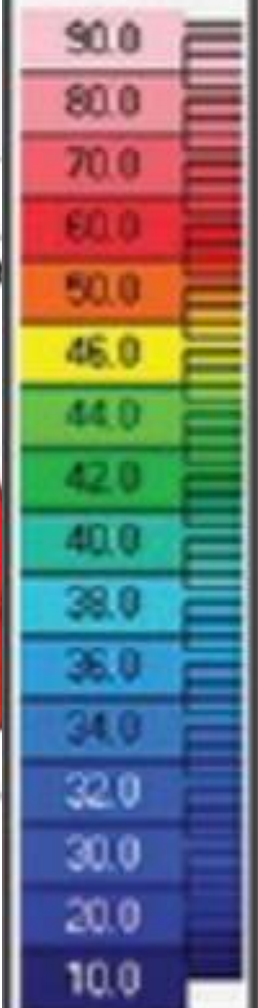
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Exam

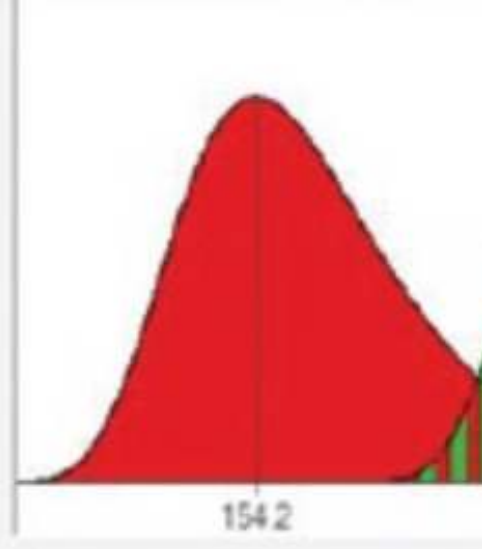
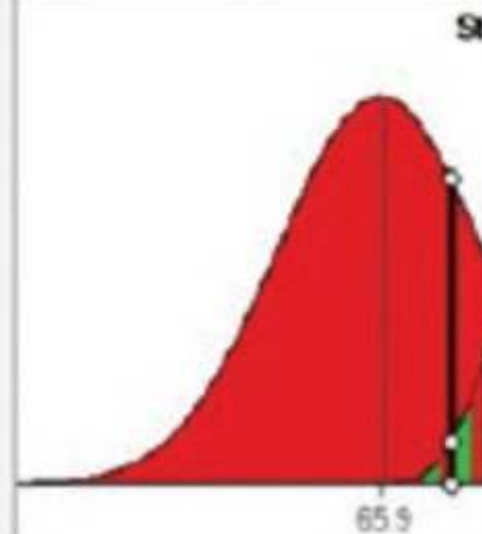
A: A: 06/19/2021 16:41:15 Left (25) 3D-Scan HR

B: B: 05/15/2019 19:28:58 Left (25) 3D-Scan HR

Difference A - B

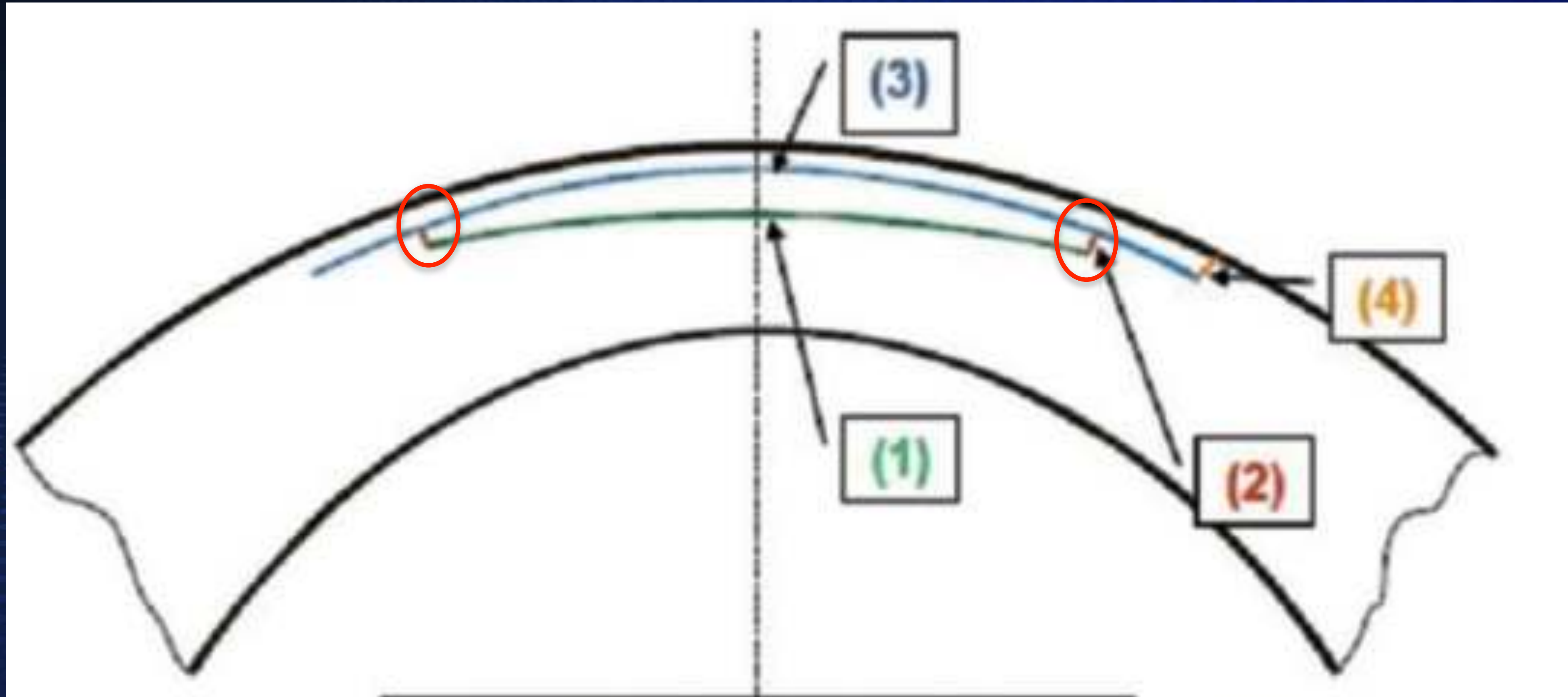


Distributions:



2.09

Why?



Vertical sidecuts/Empty space/Eye rubbing



John Kanellopoulos 2009 “Prophylactic CXL”

LVC “Xtra”

- Simultaneous accelerated CXL and refractive surgery
- “Borderline Cases” ?????
- Is it effective?
- Reported complications: Haze, DLK, CTK..etc

PRK Xtra??

PRK Xtra

- Epithelial debridement + Laser
- 0.1% riboflavin with HPMC or 0.22 or 0.25% without dextran applied for 90s-15 mins and subsequently rinsed off with BSS
- UV-A irradiation of:
 - 30 mW/cm² for 90s (2.7 J/cm²)
 - 9 mW/cm² for 10 mins (5.4 J/cm²)

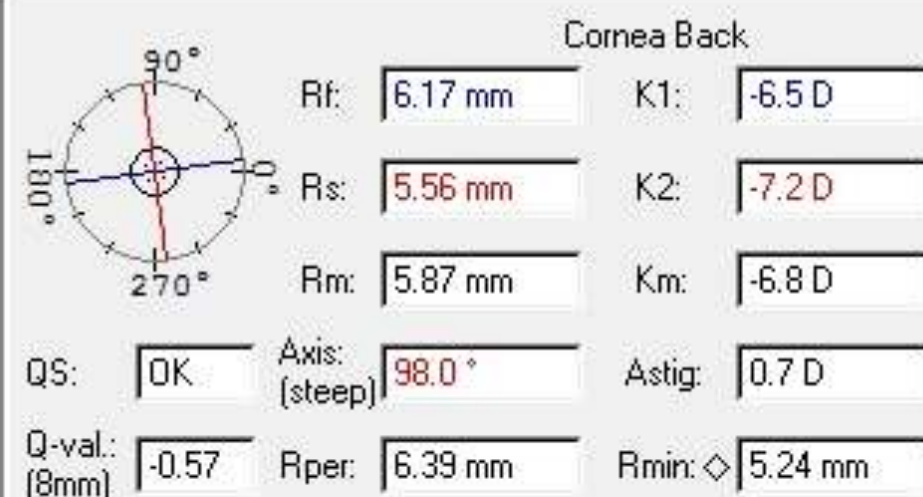
Ectasia after PRK Xtra !!!

A 41-year-old male Patient
MR= +1.25 -1.75x13 CDVA 1.0 (20/20)

OCULUS - PENTACAM 4 Maps Refractive

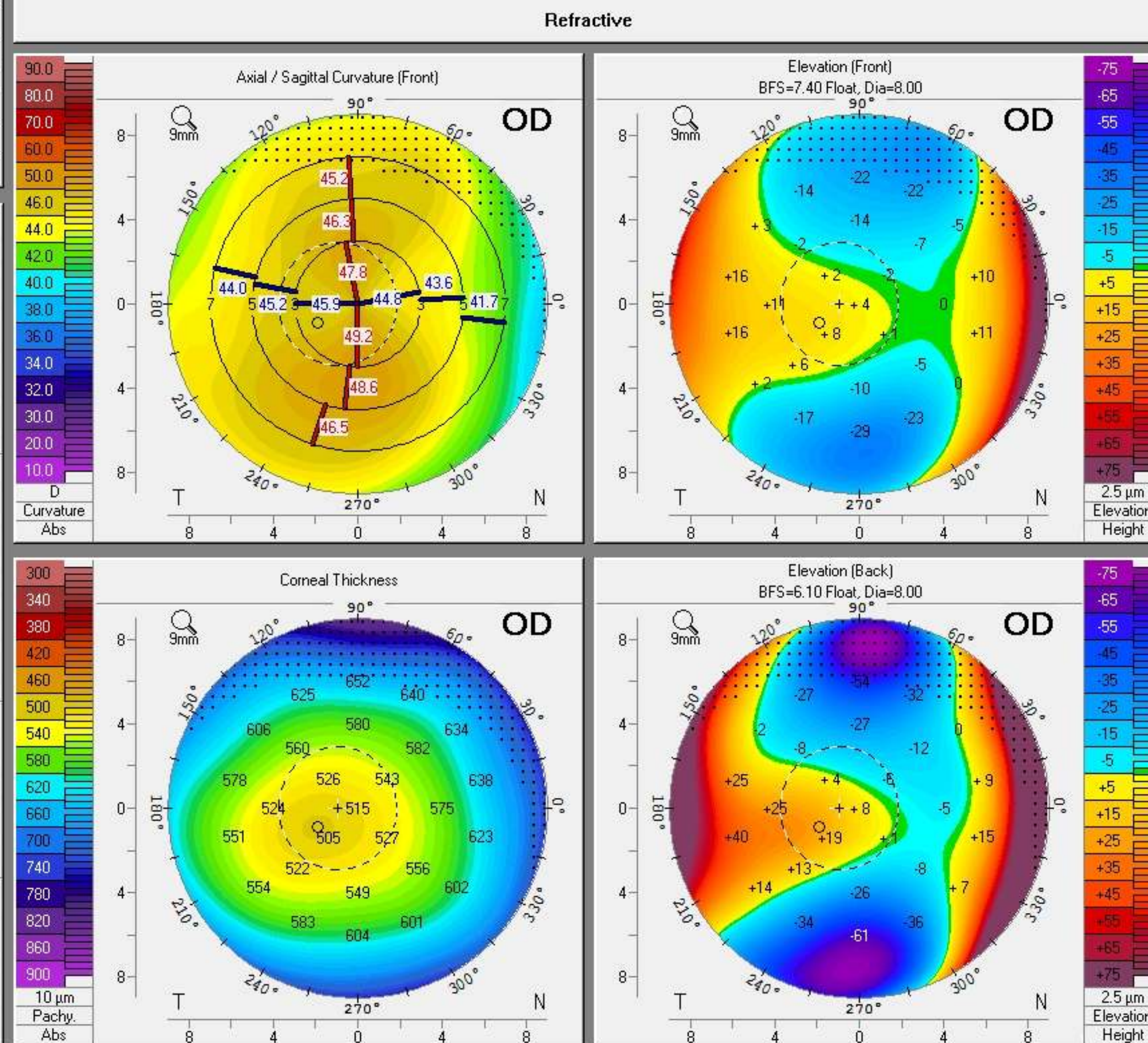
1.21r43

Last Name:
 First Name:
 ID:
 Date of Birth: 05/23/1975 Eye: Right
 Exam Date: 10/06/2016 Time: 01:55:25
 Exam Info:



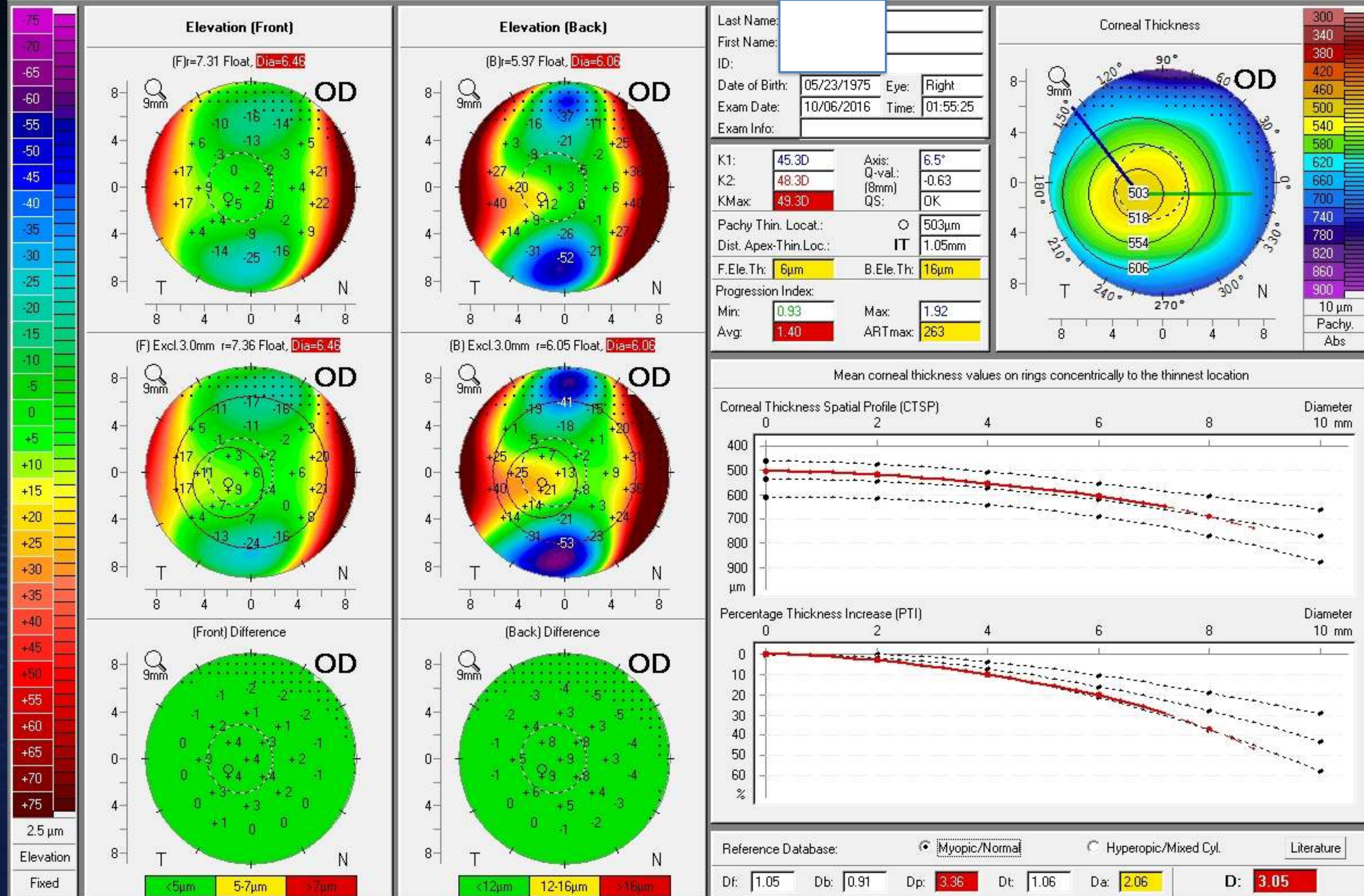
Pupil Center: + 509 μ m x[mm] -0.48 y[mm] 0.00
 Pachy Apex: · 515 μ m 0.00 0.00
 Thinnest Locat.: ○ 503 μ m -0.95 -0.44
 K Max. (Front): · 49.3 D +0.13 -1.78

Cornea Volume: 60.0 mm³ Ø Cornea: 11.6 mm
 Chamber Volume: 110 mm³ Angle: 28.9°
 A. C. Depth (Int.): 2.59 mm Pupil Dia: 2.85 mm
 Enter IOP IOP(Sum): +1.4 mmHg Lens Th.:



OCULUS - PENTACAM Belin / Ambrósio Enhanced Ectasia

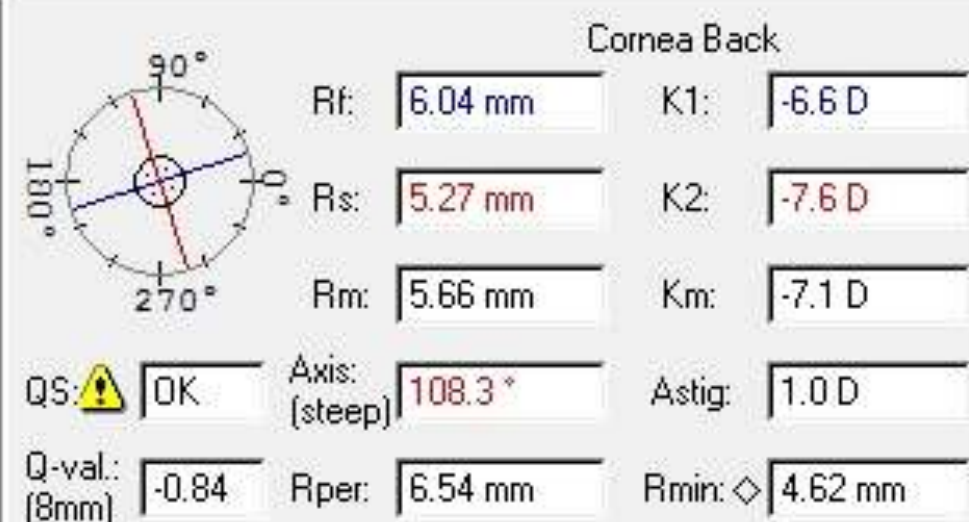
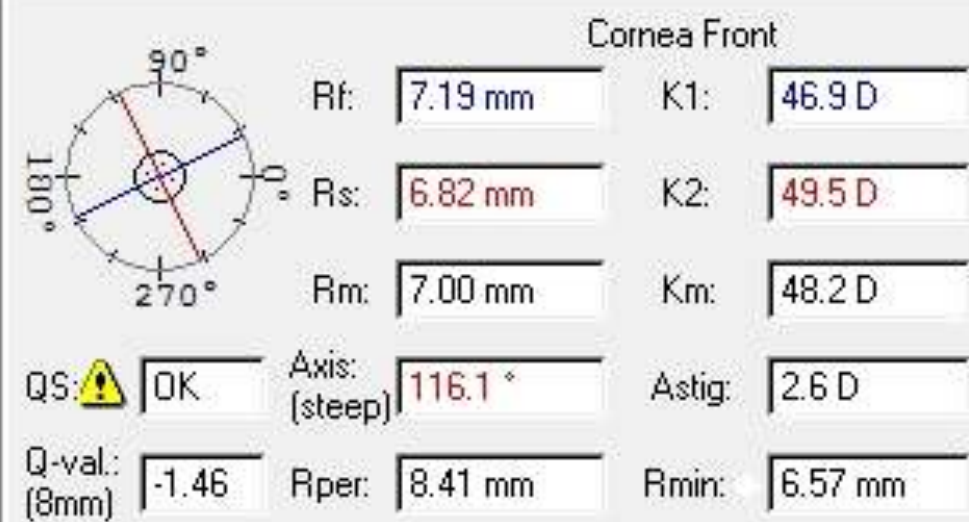
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OCULUS - PENTACAM 4 Maps Refractive

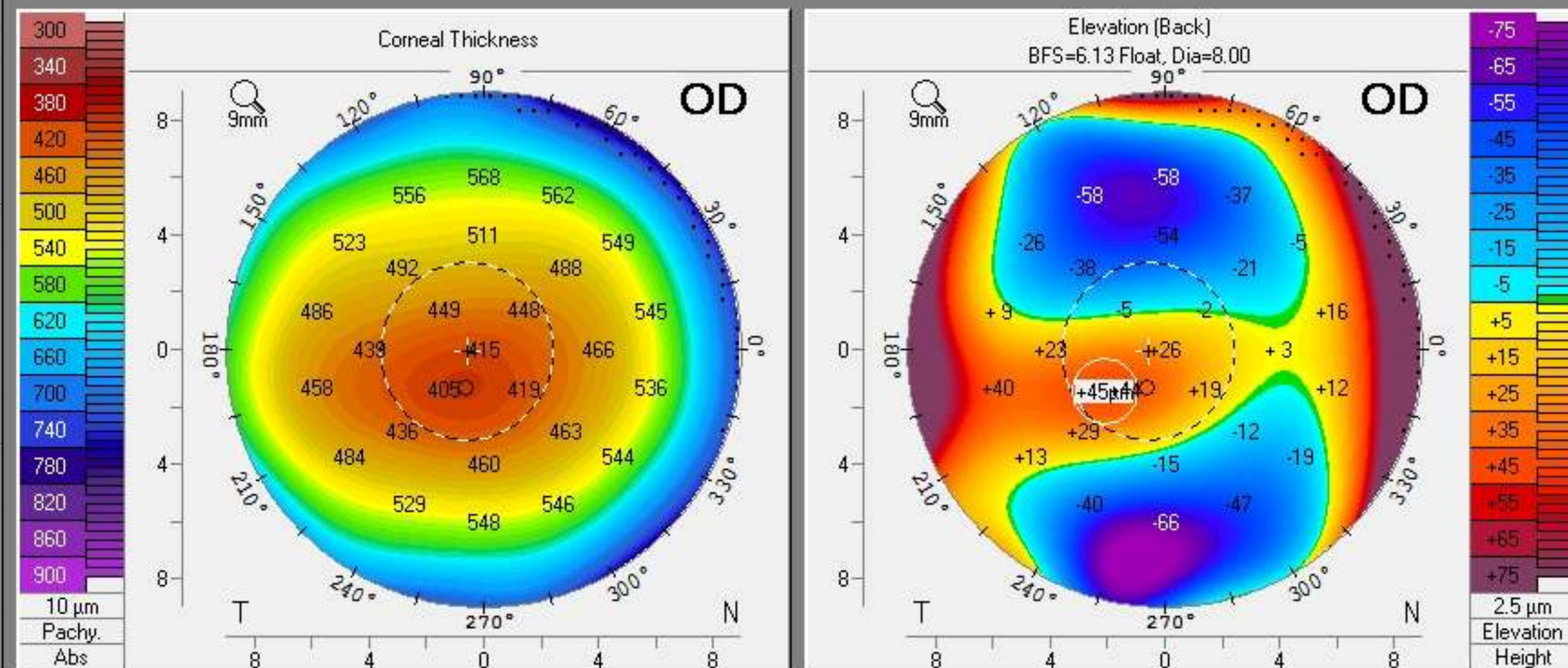
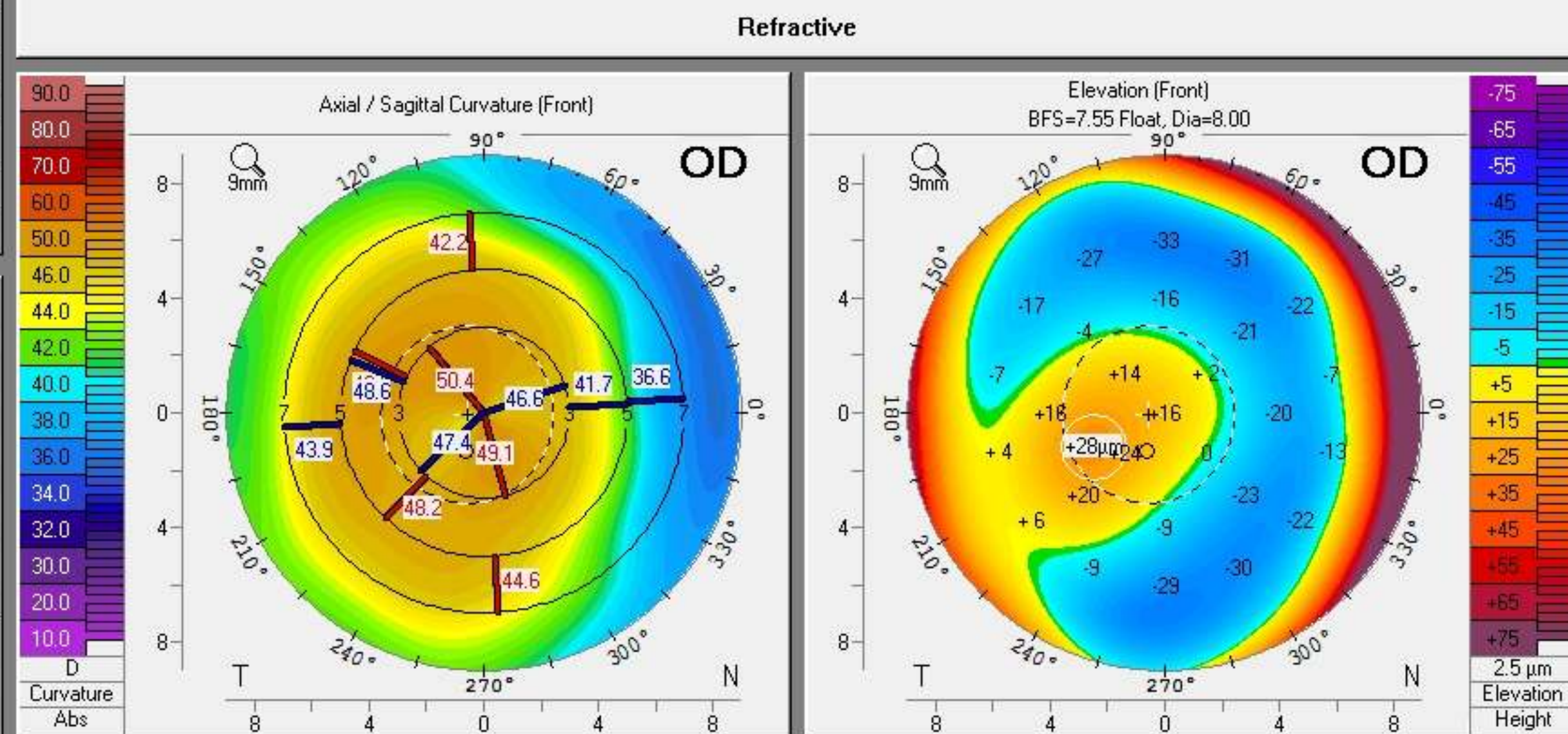
1.21r43

Last Name:
 First Name:
 ID:
 Date of Birth: 05/23/1975 Eye: Right
 Exam Date: 02/06/2020 Time: 02:44:25
 Exam Info:



Pupil Center: + Pachy: 413 µm x[mm] -0.29 y[mm] -0.03
 Pachy Apex: · 415 µm 0.00 0.00
 Thinnest Locat.: ○ 403 µm -0.33 -0.66
 K Max. (Front): · 51.3 D -0.07 +0.13

Cornea Volume: 54.5 mm³ Ø Cornea: 11.6 mm
 Chamber Volume: 107 mm³ Angle: 25.7°
 A. C. Depth (Int.): 2.58 mm Pupil Dia: 3.05 mm
 Enter IOP IOP(Sum): +5.4 mmHg Lens Th.:



OCULUS - PENTACAM Compare 2 Exams

1.30r04

Name:

ID:

Date of Birth:

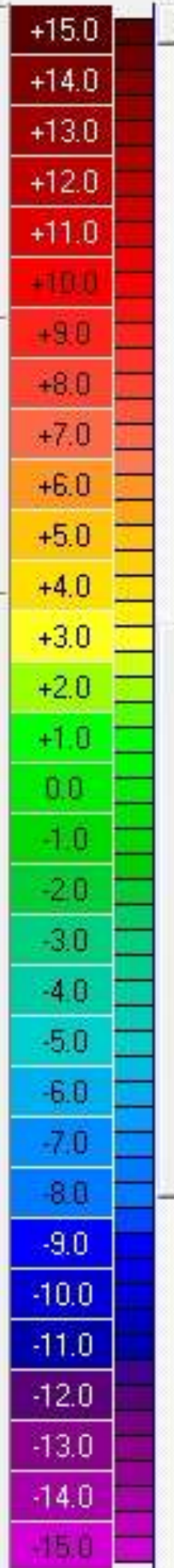
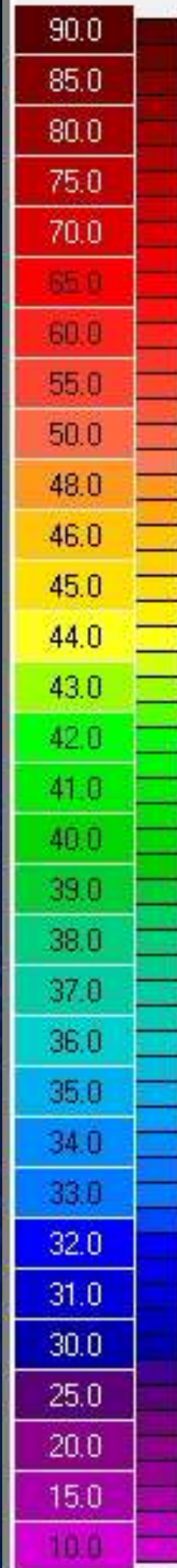
05/23/1975

Exam

A: A: 02/06/2020 02:44:25 Right (25) 3D-Scan

B: B: 10/06/2016 01:56:34 Right (25) 3D-Scan

Difference A - B



	Pachy:	x[mm]	y[mm]
Pupil Center:	+ 413 μm	-0.29	-0.03
Thinnest Locat.:	○ 403 μm	-0.33	-0.66

	Pachy:	x[mm]	y[mm]
Pupil Center:	+ 508 μm	-0.48	+0.03
Thinnest Locat.:	○ 502 μm	-0.78	-0.52

	Pachy:	x[mm]	y[mm]
Pupil Center:	+ 95 μm	+0.19	-0.06
Thinnest Locat.:	○ 99 μm	+0.45	-0.14

Chamber Volume:	107 mm ³	Angle:	25.7°
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Chamber Volume:	110 mm ³	Angle:	27.2°
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Chamber Volume:	-3 mm ³	Angle:	-1.5°
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A. C. Depth (Int.):	2.58 mm	Pupil Dia:	3.05 mm
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A. C. Depth (Int.):	2.62 mm	Pupil Dia:	2.85 mm
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A. C. Depth (Int.):	-0.04 mm	Pupil Dia:	+0.19 mm
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IOP(cor):		Lens Th.:	
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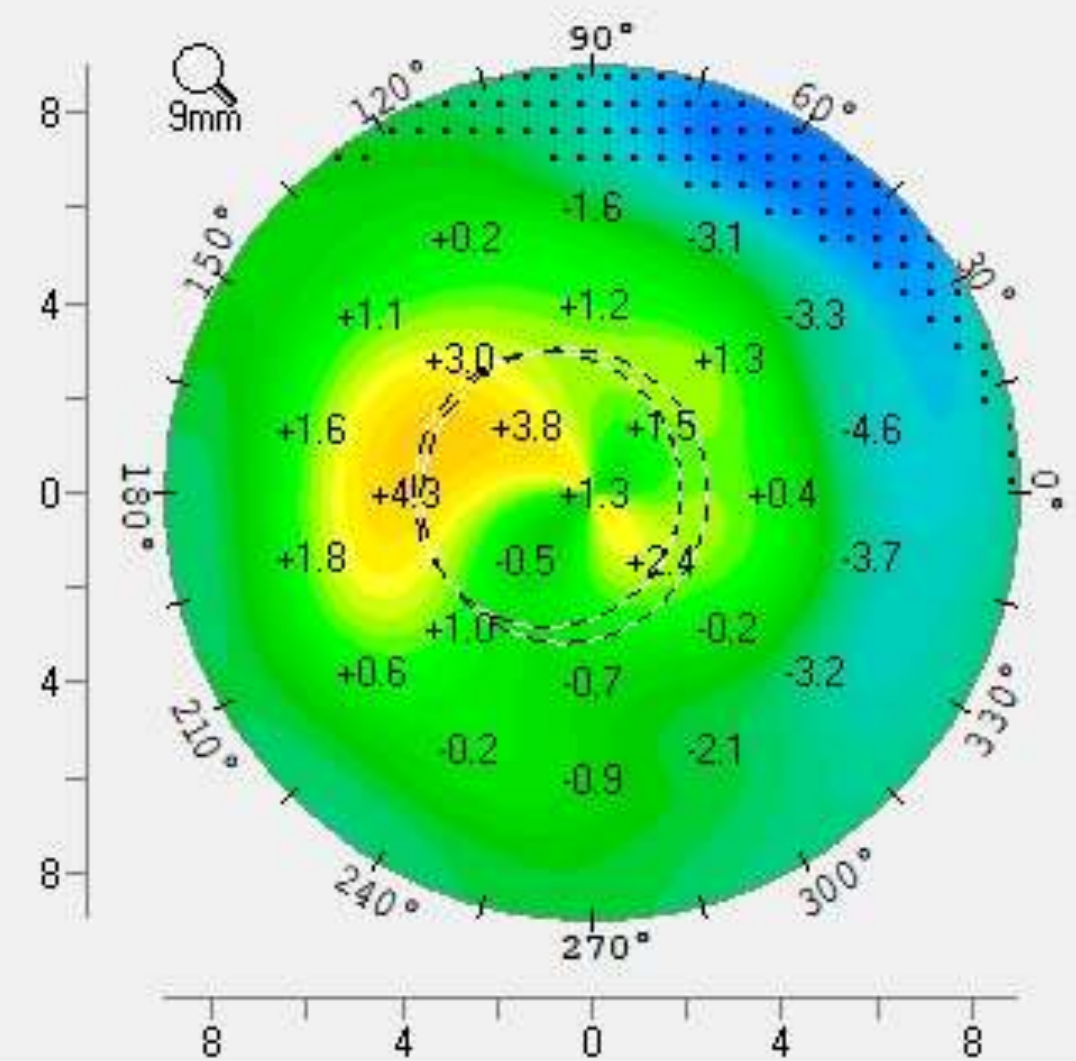
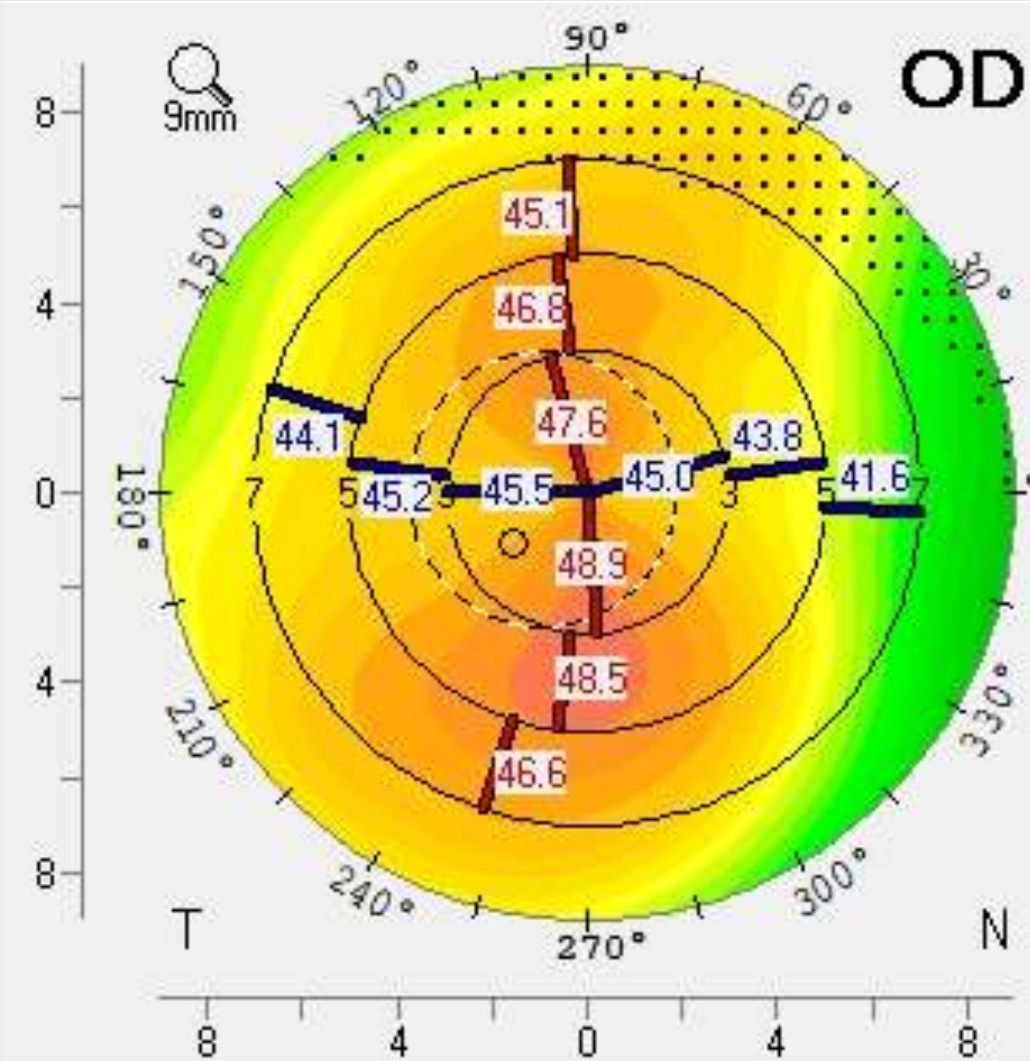
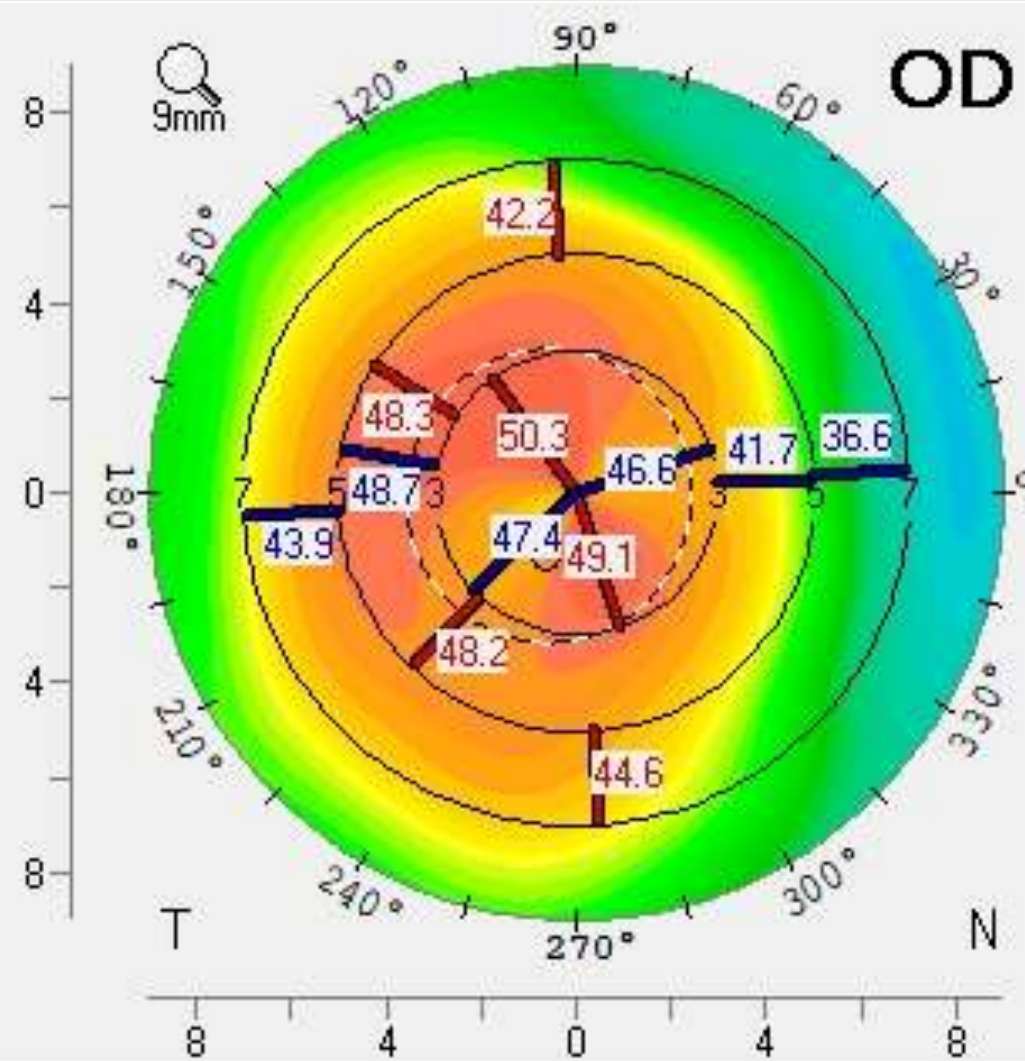
IOP(cor):		Lens Th.:	
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IOP(cor):		Lens Th.:	
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Axial / Sagittal Curvature (Front)

Axial / Sagittal Curvature (Front)

Axial / Sagittal Curvature (Front)



D

Curvature

Abs.

0.50 D

Curvature

Rel.

2025

OCULUS - PENTACAM Compare 2 Exams

1.30:04

Name:

ID:

Date of Birth:

05/23/1975

Exam

A: A: 02/06/2020 02:44:25 Right (25) 3D-Scan

B: B: 10/06/2016 01:56:34 Right (25) 3D-Scan



Difference A - B



Pachy: x[mm] y[mm]
Pupil Center: + 413 μm -0.29 -0.03
Thinnest Locat.: O 403 μm -0.33 -0.66

Pachy: x[mm] y[mm]
Pupil Center: + 508 μm -0.48 +0.03
Thinnest Locat.: O 502 μm -0.78 -0.52

Pachy: x[mm] y[mm]
Pupil Center: + 95 μm +0.19 -0.06
Thinnest Locat.: O 99 μm +0.45 -0.14

Chamber Volume: 107 mm³ Angle: 25.7°

Chamber Volume: 110 mm³ Angle: 27.2°

Chamber Volume: -3 mm³ Angle: -1.5°

A. C. Depth (Int.): 2.58 mm Pupil Dia: 3.05 mm

A. C. Depth (Int.): 2.62 mm Pupil Dia: 2.85 mm

A. C. Depth (Int.): -0.04 mm Pupil Dia: +0.19 mm

IOP(cor): Lens Th.:

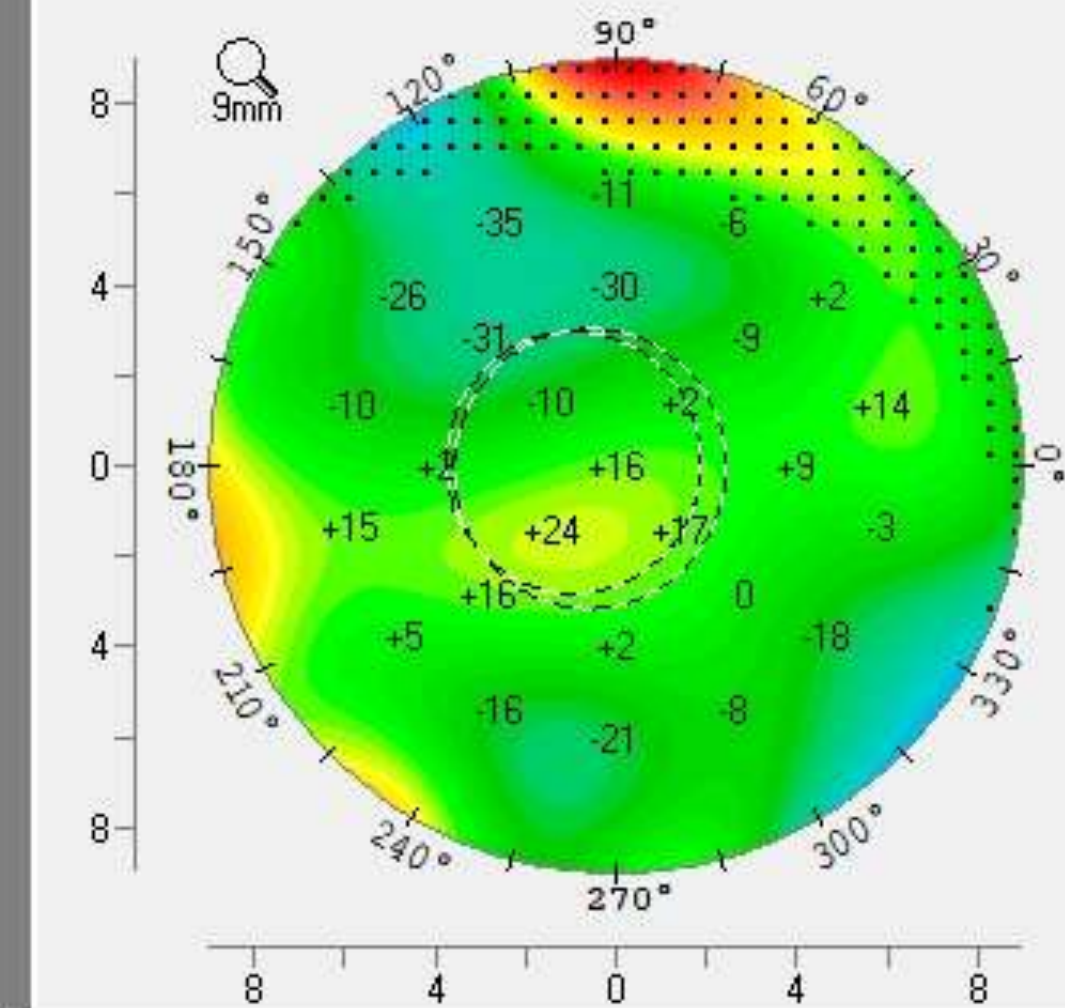
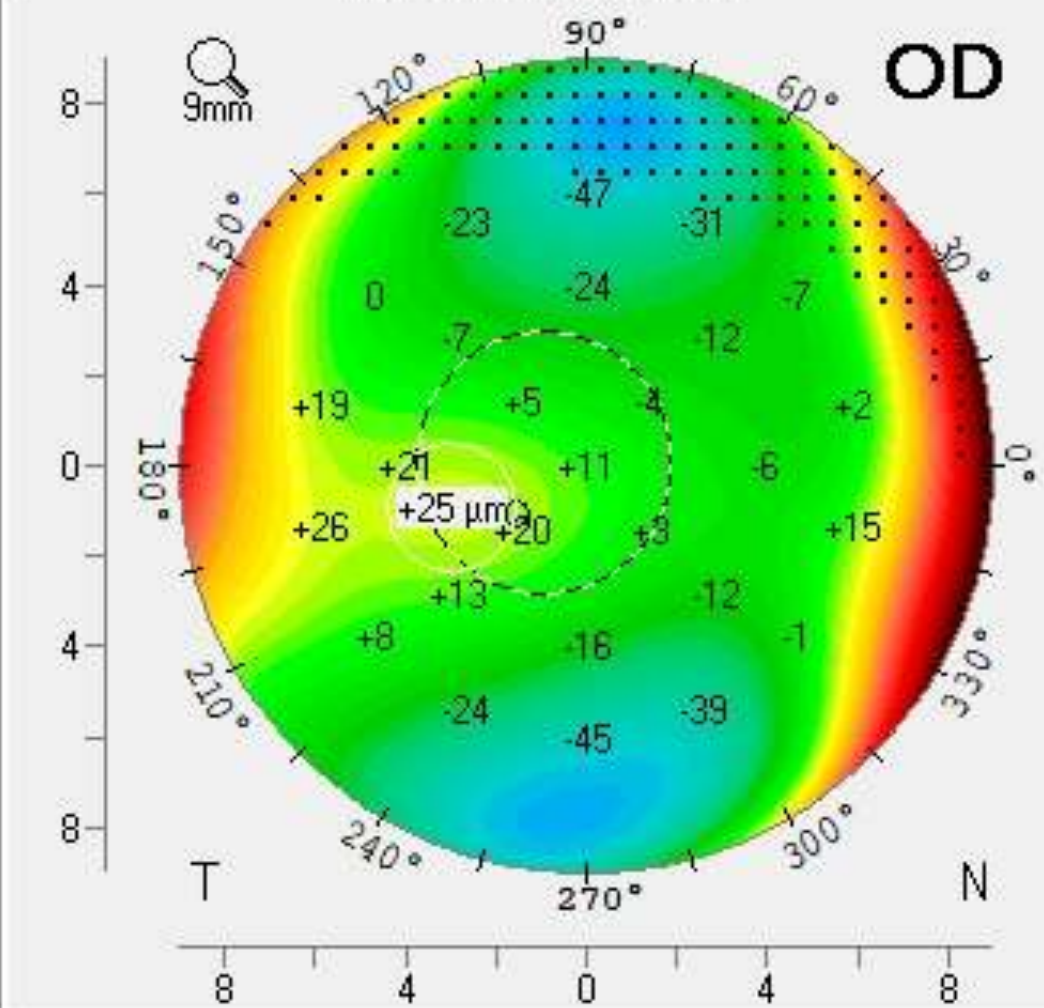
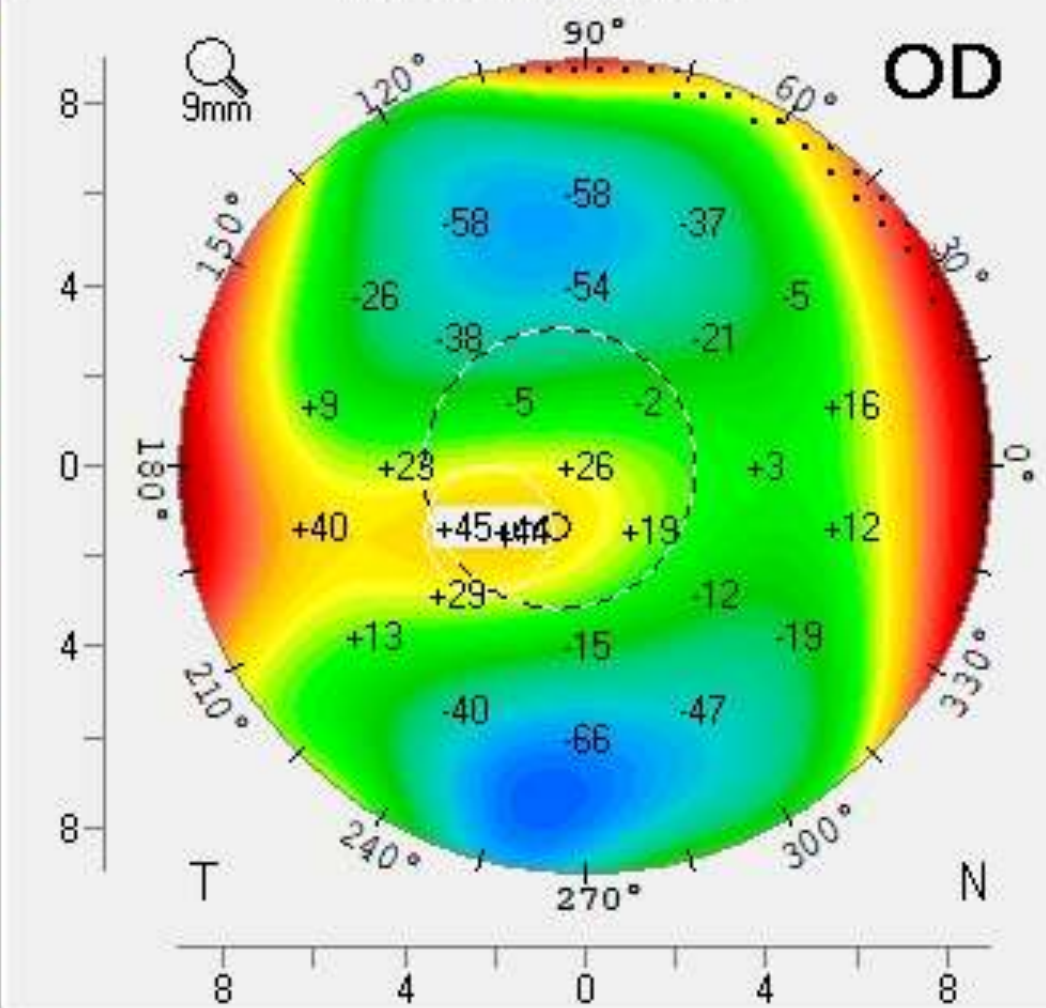
IOP(cor): Lens Th.:

IOP(cor): Lens Th.:

Elevation (Back)
BFS=6.13 Float, Dia=8.00

Elevation (Back)
BFS=6.11 Float, Dia=8.00

Elevation (Back)



5.0 μm

Elevation

Height

5.0 μm

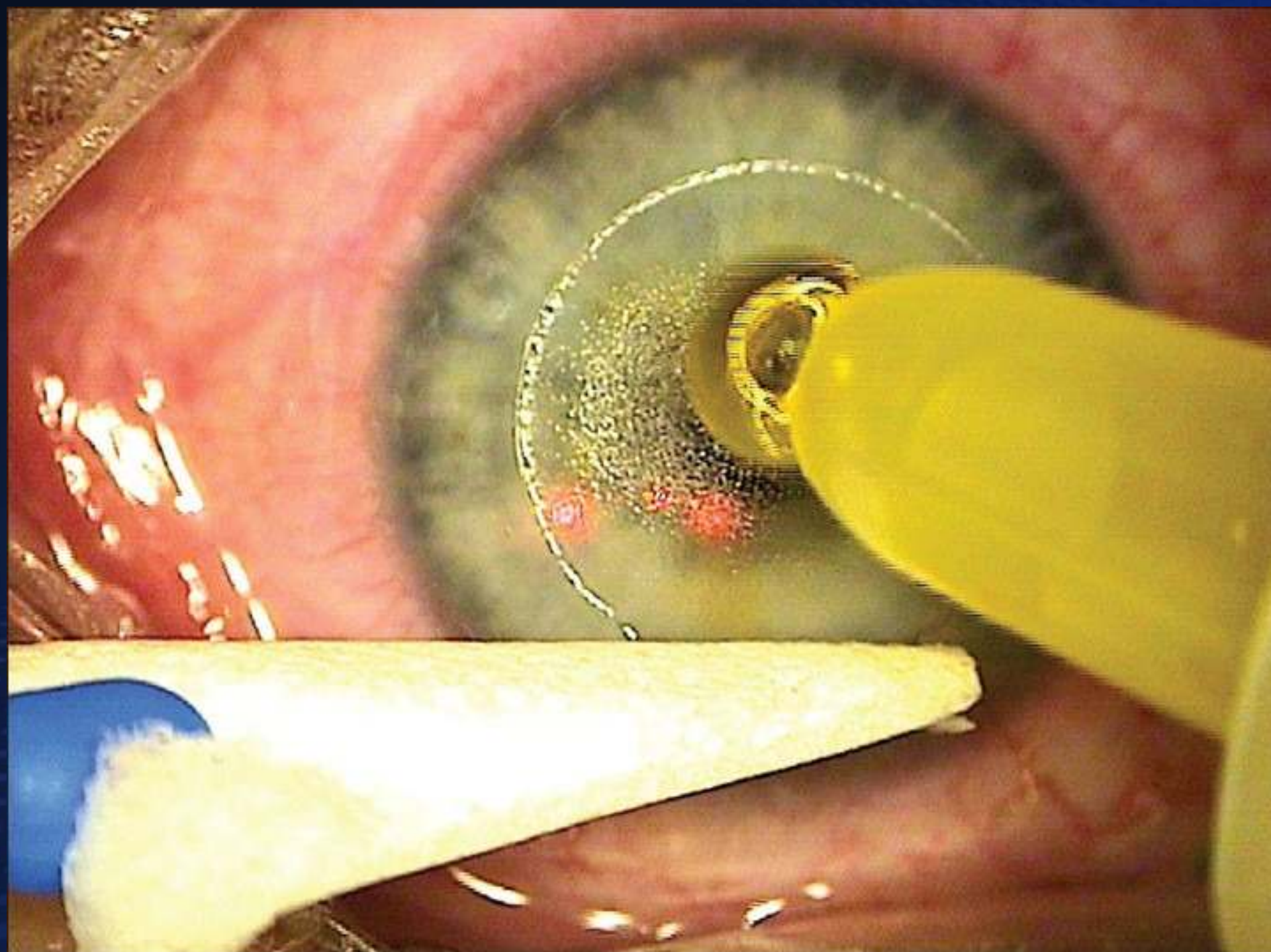
Elevation

Height

LASIK Xtra??

LASIK Xtra

- Creation of LASIK flap followed by laser ablation
- Lifting of the flap and with the flap open, application of 0.22% riboflavin onto the underlying stromal bed and allowed to soak for 45-120s
- Irrigation of the stromal bed to rinse off the riboflavin solution followed by corneal flap repositioning
- UV-A irradiation performed through the corneal flap at 30 mW/cm² for 45-90s (1.4-5.4 J/cm²)



Kanellopoulos AJ, Pamel GJ. Review of current indications for combined very high fluence collagen cross-linking and laser in situ keratomileusis surgery. *Indian J Ophthalmol*. 2013 Aug;61(8):430-2. doi: 10.4103/0301-4738.116074. PMID: 23925331; PMCID: PMC3775081.

Biomechanical Changes After LASIK Flap Creation Combined With Rapid Cross-Linking Measured With Brillouin Microscopy

J. Bradley Randleman, MD, Johnny P. Su, PhD, and Giuliano Scarcelli, PhD

Journal of Refractive Surgery, 2017;33(6):408–414

[Cite this article](#) · Published Online: April 21, 2017 · <https://doi.org/10.3928/1081597X-20170421-01> · Cited by: 20

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Abstract

PURPOSE: To evaluate the biomechanical changes occurring after LASIK flap creation and rapid corneal cross-linking (CXL) measured with Brillouin light microscopy.

METHODS: Porcine eyes ($n = 11$) were evaluated by Brillouin light microscopy sequentially in the following order: virgin state, after LASIK flap creation, and after rapid CXL. Each eye served as its own control. Depth profile of the Brillouin frequency shift was computed to reveal the depth-dependent changes in corneal stiffness.

RESULTS: There was a statistically significant reduction of Brillouin shift (reduced corneal stiffness) after LASIK flap creation compared to virgin corneas across total corneal thickness (-0.035 GHz, $P = .0195$) and within the anterior stromal region (-0.104 GHz, $P = .0039$). Changes in the central (-0.029 GHz, $P = .0391$) and posterior (-0.005 GHz, $P = .99$) stromal regions were not significant. There was a small increase in Brillouin shift after rapid cross-linking that was not statistically or clinically significant across total corneal thickness (0.006 GHz, $P = .4688$ for any specific stromal region; 0.002 to 0.009 GHz, $P > .46$ for all).

CONCLUSIONS: LASIK flap creation significantly reduced Brillouin shift in the anterior third of the stroma in porcine eyes. Rapid corneal cross-linking had no significant effect on Brillouin shift after LASIK flap creation in porcine eyes. With further validation, non-contact, non-perturbative Brillouin microscopy could become a useful monitoring tool to evaluate the biomechanical impact of corneal refractive procedures and corneal cross-linking protocols.

Conclusion: Rapid corneal cross-linking had no significant effect on Brillouin shift after LASIK flap creation in porcine eyes

Ectasia after LASIK Xtra !!!

Corneal Ectasia After LASIK Combined With Prophylactic Corneal Cross-linking

Suphi Taneri, MD; Saskia Kiessler, Dipl-Ing; Anika Rost, MSc; H. Burkhard Dick, MD

ABSTRACT

PURPOSE: To report a case of unilateral corneal ectasia following LASIK surgery combined with prophylactic corneal cross-linking (CXL) in a young patient.

METHODS: Case report.

RESULTS: Preoperative topography was unremarkable in both eyes with a minimum corneal thickness of 554 μm in the right eye and 546 μm in the left eye. Preoperative corrected distance visual acuity (CDVA) was 1.0 (20/20 Snellen) in both eyes with a refraction of +1.25 -2.75 $\times$ 10 in the right eye and +0.50 -2.00 $\times$ 163 in the left eye. LASIK combined with CXL was uneventful. After 12 months, postoperative topography was unremarkable with an uncorrected distance visual acuity (UDVA) of 1.0 in both eyes. Two years after surgery, the patient presented with a loss of vision (UDVA 0.25) and an inferior steepening on topography in the left eye. Standard CXL was performed to arrest further progression.

CONCLUSIONS: This report illustrates that the currently used prophylactic CXL protocol in combination with LASIK may not be effectively preventing corneal ectasia in every case.

[J Refract Surg. 2017;33(1):50-52.]

Keratectasia after LASIK is a rare complication but may potentially lead to a permanent loss of visual quality.¹ Prophylactic corneal cross-linking (CXL) may be added after laser ablation to increase corneal rigidity, thus reducing the risk of ectasia after LASIK.² We report the first case of unilateral corneal ectasia following LASIK combined with prophylactic CXL (LASIK+CXL) in a patient with unremarkable preoperative findings.

From the Center for Refractive Surgery, Eye Department St. Francis Hospital, Muenster, Germany (ST, SK, AR); and Ruhr-University, Eye Clinic, Bochum, Germany (ST, HBD).

Submitted: June 6, 2016; Accepted: October 10, 2016

The authors have no financial or proprietary interest in the materials presented herein.

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doi:10.3928/1081597X-20161019-03

CASE REPORT

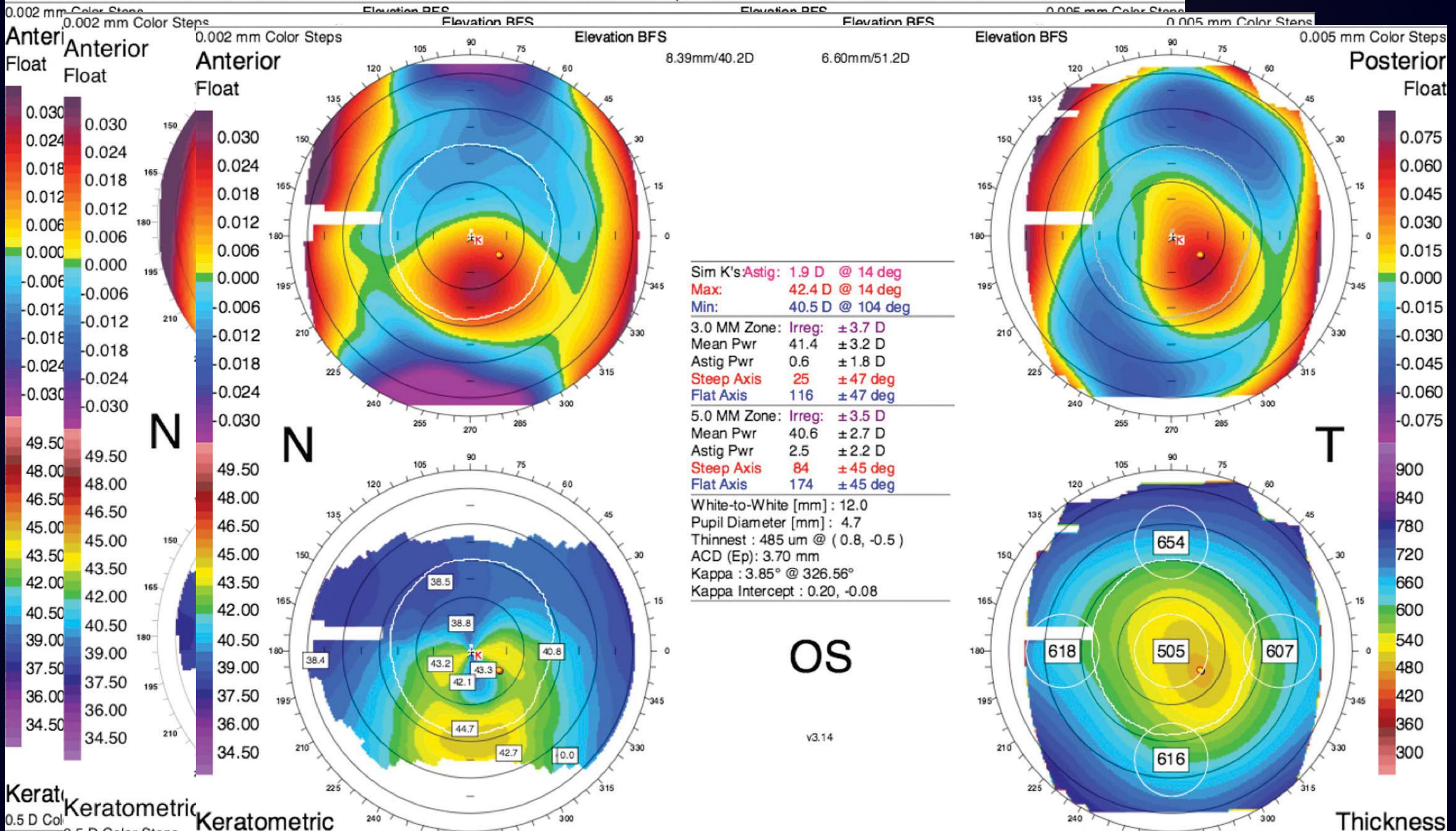
A healthy 18-year-old man was seeking laser vision correction. His preoperative refraction was +1.25 -2.75 $\times$ 10 in the right eye and +0.50 -2.00 $\times$ 163 in the left eye. The corrected distance visual acuity (CDVA) was 1.0 (20/20 Snellen) in both eyes. Orbscan results (Orbscan IIz; Bausch & Lomb, Rochester, NY) demonstrated an asymmetric bow tie pattern in the left eye only but were within normal limits with a maximum keratometry value of 43.20 diopters (D) and corneal astigmatism of 2.60 D in the right eye, and 43.20 D with corneal astigmatism of 1.90 D in the left eye, respectively. Minimum corneal thickness was 554 and 546 μm in the right and left eye, respectively (Figure A, available in the online version of this article). The following preoperative measurements were performed: slit-lamp examination, wavefront analysis, endothelial specular microscopy, tonometry, Orbscan examination, and dilated fundus examination. No risk factors for ectatic disease was found. The patient denied rubbing his eyes and did not use any long-term medication. He did not have floppy eyelids or sleep apnea. The patient's family history was negative; no relative had high astigmatism or was wearing rigid contact lenses.

Microkeratome-assisted LASIK combined with CXL was uneventful (Zyoptix XP microkeratome with Zero Compression head; Bausch & Lomb; suction ring with 9.5-mm inner diameter). A new microkeratome blade was used for each flap cut. Intended flap thickness was 120 μm in both eyes. Achieved flap thickness was 88 μm in the right eye and 115 μm in the left eye as intraoperatively measured using subtraction ultrasound pachymetry: central corneal thickness was recorded three times using the same ultrasound probe (DGH-500 Pachette; DGH Technology, Inc., Exton, PA) immediately before applying the suction ring. After lifting the flap, the pachymeter was again used three times to determine central corneal bed thickness before ablation. The difference between the mean values was considered to be the flap thickness. Flap diameter was 8.9 mm in the right eye and 9.5 mm in the left eye as measured with a measuring tool in the anterior segment optical coherence tomography (OCT) image 3 months postoperatively. Maximum laser ablation was 59 μm in the right eye and 51 μm in the left eye, leaving a residual stromal thickness of 397 μm in the right eye and 390 μm in the left eye (Technolas 217P laser; Bausch & Lomb). Optical zone was 7 mm in both eyes with a blend zone of 12 $\times$ 10.1 mm in the right eye and 11.9 $\times$ 9.6 mm in the left eye.

Intraoperative CXL was performed as follows. Immediately after laser ablation, riboflavin phosphate 0.22% (Vibex Xtra; Avedro Inc., Waltham, MA) was

CONCLUSIONS: This report illustrates that the currently used prophylactic CXL protocol in combination with LASIK may not be effectively preventing corneal ectasia in every case.

[J Refract Surg. 2017;33(1):50-52.]



SMILE Xtra??

SMILE Xtra

- 0.22% or 0.25% riboflavin in the Pocket
- Allow to diffuse for 60 to 180 Sec, followed by irrigation with BSS.
- UV-A irradiation through the cap:
 - 18 mW/cm² for 3 mins (3.2 J/cm²)
 - 45 mW/cm² for 75s (3.4 J/cm²)

Clinical Study

Clinical Outcomes of Small Incision Lenticule Extraction with Accelerated Cross-Linking (ReLex SMILE Xtra) in Patients with Thin Corneas and Borderline Topography

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Received 3 March 2015; Revised 24 May 2015; Accepted 27 May 2015

Academic Editor: Vasilios F. Diakonis

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Purpose. To study the safety and clinical outcomes of ReLex SMILE with accelerated cross-linking in individuals with thinner corneas, borderline topography, and higher refractive errors. **Methods.** Eligible patients first underwent SMILE procedure for correction of myopic refractive error. Following the removal of lenticule, 0.25% riboflavin in saline was injected into the interface and allowed to diffuse for 60 seconds. Finally, eye was exposed to UV-A radiation of 45 mW/cm² for 75 seconds through the cap. Total energy delivered was 3.4 J/cm². **Results.** 40 eyes of 20 patients with mean age of 26.75 ± 5.99 years were treated. Mean follow-up was 12 months ± 28.12 days. Mean spherical equivalent (SE) was -5.02 ± 2.06 D preoperatively and -0.24 ± 0.18 D postoperatively. The mean central corneal thickness (CCT) and keratometry changed from 501 ± 25.90 μm to 415 ± 42.26 μm and 45.40 ± 1.40 D to 41.2 ± 2.75 D, respectively. Mean uncorrected visual acuity (UCVA) was 20/25 or better in all eyes. No eyes lost lines of corrected distant visual acuity (CDVA). There were no complications like haze, keratitis, ectasia, or regression. **Conclusion.** Based on the initial clinical outcome it appears that SMILE Xtra may be a safe and feasible modality to prevent corneal ectasia in susceptible individuals.

1. Introduction

Refractive surgery in high myopia with thinner corneas and borderline topography is a challenging decision, with the most feared complication being regression and postoperative ectasia [1–4]. Collagen cross-linking (CXL) has been proven to be an effective modality to strengthen and stabilize the cornea in keratoconus and ectasia after corneal refractive surgery [5–11].

Another novel application of CXL is the combination of this technique with photo ablative procedures such as LASIK and PRK [12, 13], which has improved safety and better outcomes in subjects that were not suitable for corneal refractive correction due to their corneas being borderline. One such technique is LASIK Xtra which has been suggested as a safe and effective procedure for prophylaxis against postoperative ectasia in susceptible patients [13].

ReLex SMILE is a flapless, all femtosecond laser technique which involves creation of a refractive lenticule with

femtosecond laser and its removal from a small incision. This procedure has significant advantages over LASIK as there are no flap related complications, faster visual recovery, better long-term biomechanical stability, less postoperative dry eye, and fewer induction of aberrations [14]. ReLex SMILE, when combined with collagen cross-linking intraoperatively, may further prevent the risk of future ectasia in susceptible individuals. Hence, this study was undertaken to observe the safety and visual outcomes following this procedure. The efficacy of the procedure in stabilizing the corneal biomechanics has not been studied. However, the one-year follow-up may establish safety.

2. Materials and Methods

The study was approved by Institutional Ethics Committee and adhered to the tenets of declaration of Helsinki. The nature of the procedure was explained and informed consent was obtained from all the patients participating in the study.

May 2015

Research Article

Comparison of Long-Term Outcomes and Refractive Stability following SMILE versus SMILE Combined with Accelerated Cross-Linking (SMILE XTRA)

Sheetal Brar , Skanda Sriganesh, Smith Snehal Sute , and Sri Ganesh

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Received 9 December 2021; Accepted 28 January 2022; Published 28 February 2022

Academic Editor: Alessandro Meduri

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Purpose. To compare the long-term safety, efficacy, predictability, and refractive stability following SMILE versus SMILE combined with accelerated cross-linking (SMILE XTRA), and to specifically study the regression patterns following the two procedures. **Methods.** This retrospective study included 54 eyes of SMILE and 54 eyes of SMILE XTRA treated for normal and borderline cases of myopia/myopic astigmatism, respectively, based on certain predefined topographic features and risk factors. Patients in both the groups were matched for age and refractive error. The mean postoperative follow-up for the SMILE group was 22.18 ± 10.41 months and the SMILE XTRA group was 21.81 ± 10.19 months. **Results.** At the end of follow-up, the mean sphere, cylinder, and SE reduced to -0.03 , -0.09 , and -0.08 D in the SMILE group and -0.06 , -0.15 , and -0.13 D in the SMILE XTRA group. 96% and 93% eyes remained within ± 0.50 D in SMILE and SMILE XTRA groups, respectively, and 94% eyes maintained an UDVA of 20/20 or better in the SMILE as well as SMILE XTRA groups. Safety and efficacy indices for the SMILE group were 1.03 and 1.00. For the SMILE XTRA group, the safety and efficacy indices were 1.00 and 0.99. No eye in either group had postoperative ectasia or enhancement performed for significant residual refractive error. **Conclusion.** Both the SMILE and SMILE XTRA groups exhibited comparable visual outcomes, safety, and efficacy. Contrary to the belief, combination of prophylactic CXL with SMILE did not result in a hyperopic shift in the long term. No eye in either group encountered postoperative ectasia; however, further follow-up is suggested to establish the long-term effects on refractive and corneal stability following SMILE XTRA, as all the eyes treated in this group were borderline.

Ectasia after SMILE Xtra !!!

Bilateral Ectasia After SMILE Combined With Accelerated Corneal Cross-linking (SMILE-Xtra)

Luca Pagano, MD, FEBO; Paolo Vinciguerra, MD; Marco Fantozzi, MD;
Anna Maria Catanese, MD; Riccardo Vinciguerra, MD

DEC 2024

ABSTRACT

PURPOSE: To present the first reported case of bilateral ectasia following small incision lenticule extraction (SMILE) associated with corneal cross-linking (CXL).

METHODS: A 20-year-old woman was referred for bilateral corneal ectasia 2 years after uneventful bilateral SMILE combined with accelerated CXL (SMILE-Xtra) for myopic correction. The preoperative refraction was $-3.00 -0.75 \times 10^\circ$ in the right eye and $-2.50 -0.50 \times 165^\circ$ in the left eye. The preoperative corneal topography showed a minimum corneal thickness of $488 \mu\text{m}$ in the right eye and $498 \mu\text{m}$ in the left eye.

RESULTS: Initial follow-up results showed stable visual acuity, but she presented 24 months later with reduced vision in the left eye, revealing bilateral ectasia. Scheimpflug examination confirmed central ectasia in the left eye and subtle ini-

tial ectasia in the right eye. Biomechanical analysis demonstrated altered parameters and epithelial mapping revealed epithelial thinning.

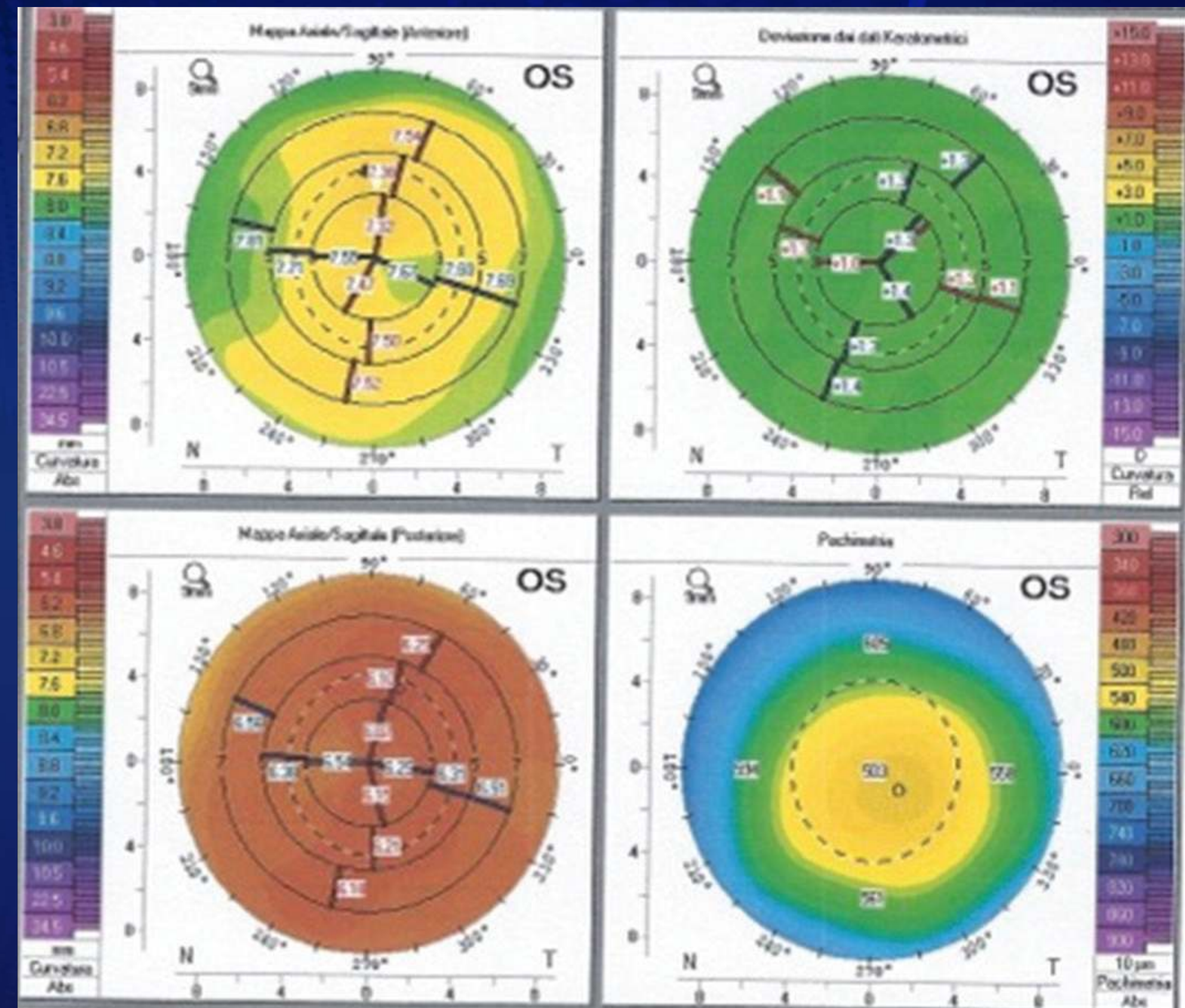
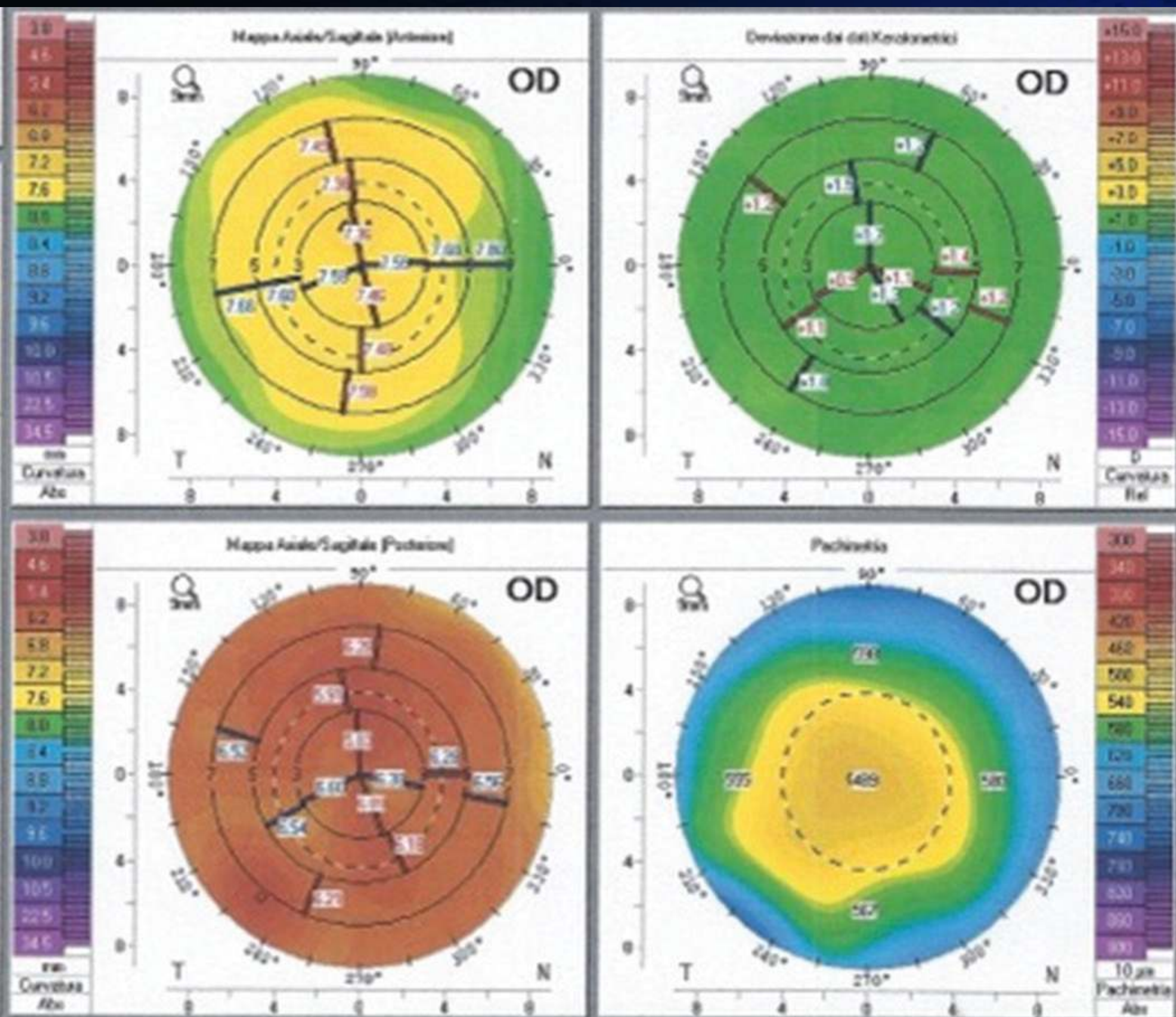
CONCLUSIONS: This study challenges previous assertions about the efficacy of SMILE-Xtra in preventing ectasia, because it presents the first documented case of this complication. The findings emphasize the importance of exercising caution in treating corneas at risk, regardless of the association of CXL, especially when the cornea is considered suspicious. This highlights a broader concern that all refractive surgeries may carry a risk of inducing ectasia, underscoring the necessity for careful patient selection and continuous refinement of surgical protocols for optimal safety outcomes.

[*Journal of Refractive Surgery Case Reports*. 2024;4(4):e40-e45.]

Small incision lenticule extraction (SMILE) is a safe and effective refractive procedure designed to address myopia and myopic astigmatism.¹ As the third-generation refractive laser vision correction method, it follows the first-generation photorefractive keratectomy (PRK) procedure and the second-generation laser in situ keratomileusis (LASIK) procedure.² Unlike LASIK, SMILE is a flapless procedure, eliminating flap-related complications and providing sufficient biomechanical stability.³ However, ectasia cases have been observed even

after SMILE, particularly in those with borderline or abnormal preoperative topography.³⁻⁵ Consequently, significant attention has been given to preoperative evaluation for corneal refractive surgery, leading to the development of various risk scoring systems, tomographic indices, and biomechanically informed screening tools.⁶⁻⁹

In recent years, a new approach to enhance postoperative corneal biomechanical stability and mitigate the risk of future keratectasia has emerged. This involves combining corneal cross-linking (CXL)



A 20-year-old F
 Kmax 46.10 D OD / 46.10 D OS
 CT 488 μ m OD / 498 μ m OS
 Preop MR was -3.00 -0.75 $\times$ 10° OD / -2.50 -0.50 $\times$ 165° OS

Operazione corneale – ReLEx SMILE

OD | OS

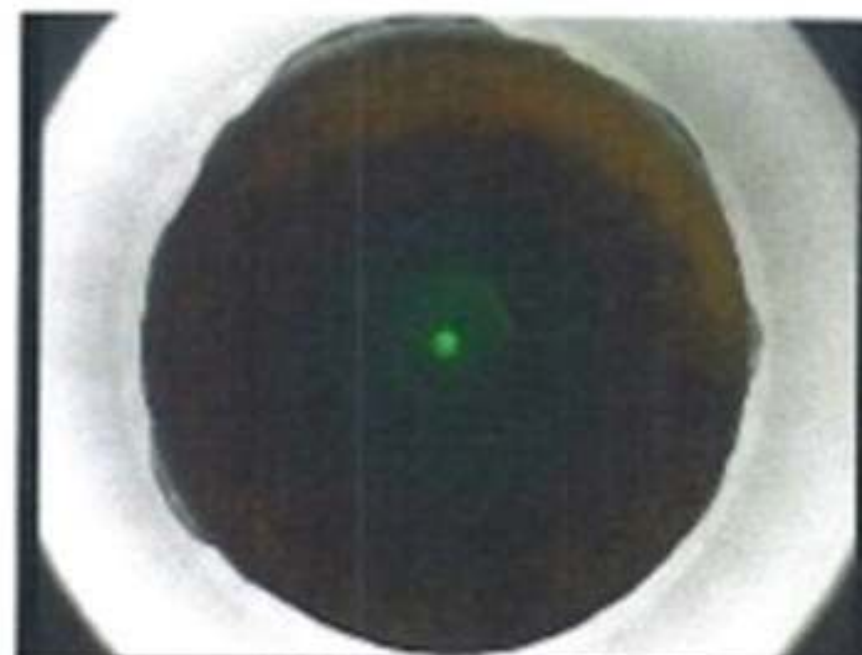
Dati diagnostici

Distanza del vertice corneale [mm]: 12,00

Manifesta

Sfera [D]: -3,75
Cilindro [D]: -1,00
Asse [°]: 10

Raggio corneale [mm]: 7,49
Valore K medio [D]: 45,05
Pachimetria [μm]: 488



Dati di trattamento

Misura del Treatment Pack: S
Tempo di suzione [hh:mm:ss]: 00:00:33

Informazioni nomogramma
Refraction, Versione 3.0

Dati lenticolari

Zona ottica [mm]: 7,00
Zona di passaggio [mm]: 0,10
Spessore [μm]: Min.: 15 Max: 107
Angolo di taglio del bordo [°]: 90
Correzione refrattiva
Sfera [D]: -3,75
Cilindro [D]: -1,00
Asse [°]: 10

Dati del cap

Diametro [mm]: 7,80
Spessore [μm]: 130
Angolo di taglio del bordo [°]: 90
Posizione incisione [°]: 135
Angolo incisione [°]: 29
Incisione larga [mm]: 2,00

Operazione corneale – ReLEx SMILE

OD | OS

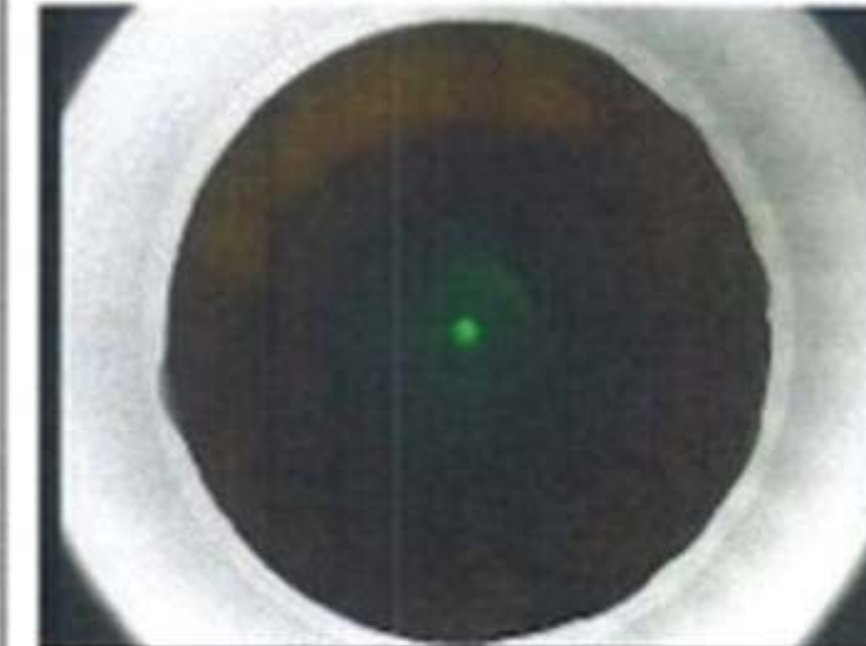
Dati diagnostici

Distanza del vertice corneale [mm]: 12,00

Manifesta

Sfera [D]: -3,25
Cilindro [D]: -0,75
Asse [°]: 165

Raggio corneale [mm]: 7,52
Valore K medio [D]: 44,90
Pachimetria [μm]: 498



Dati di trattamento

Misura del Treatment Pack: S
Tempo di suzione [hh:mm:ss]: 00:00:33

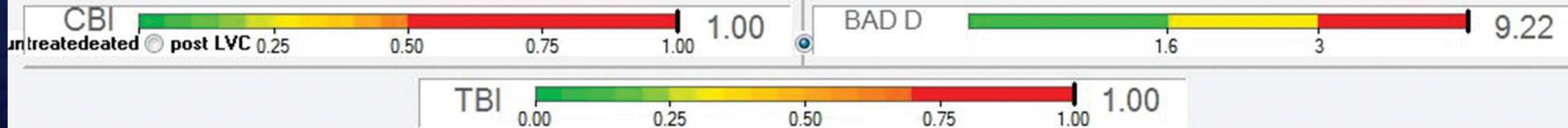
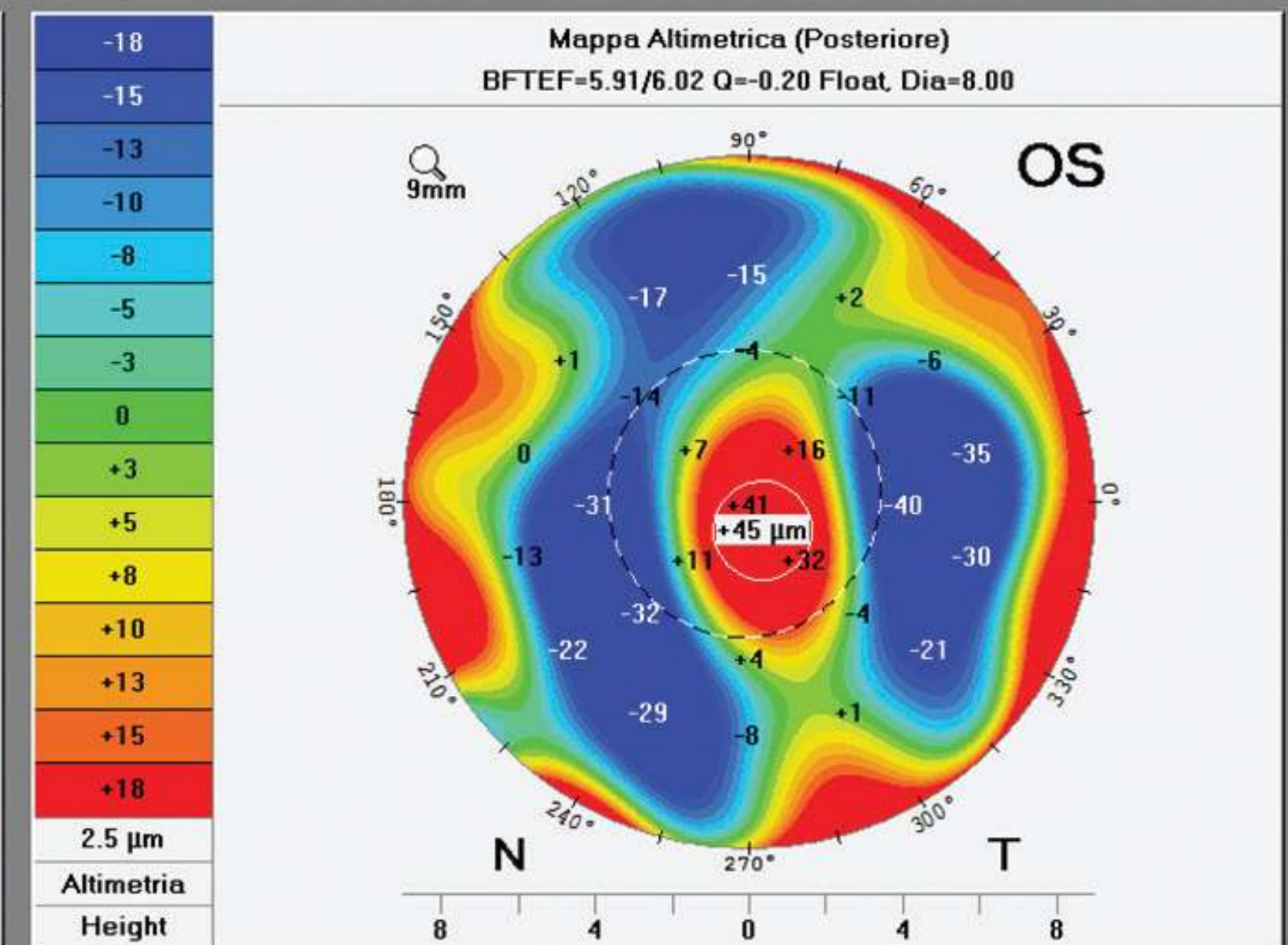
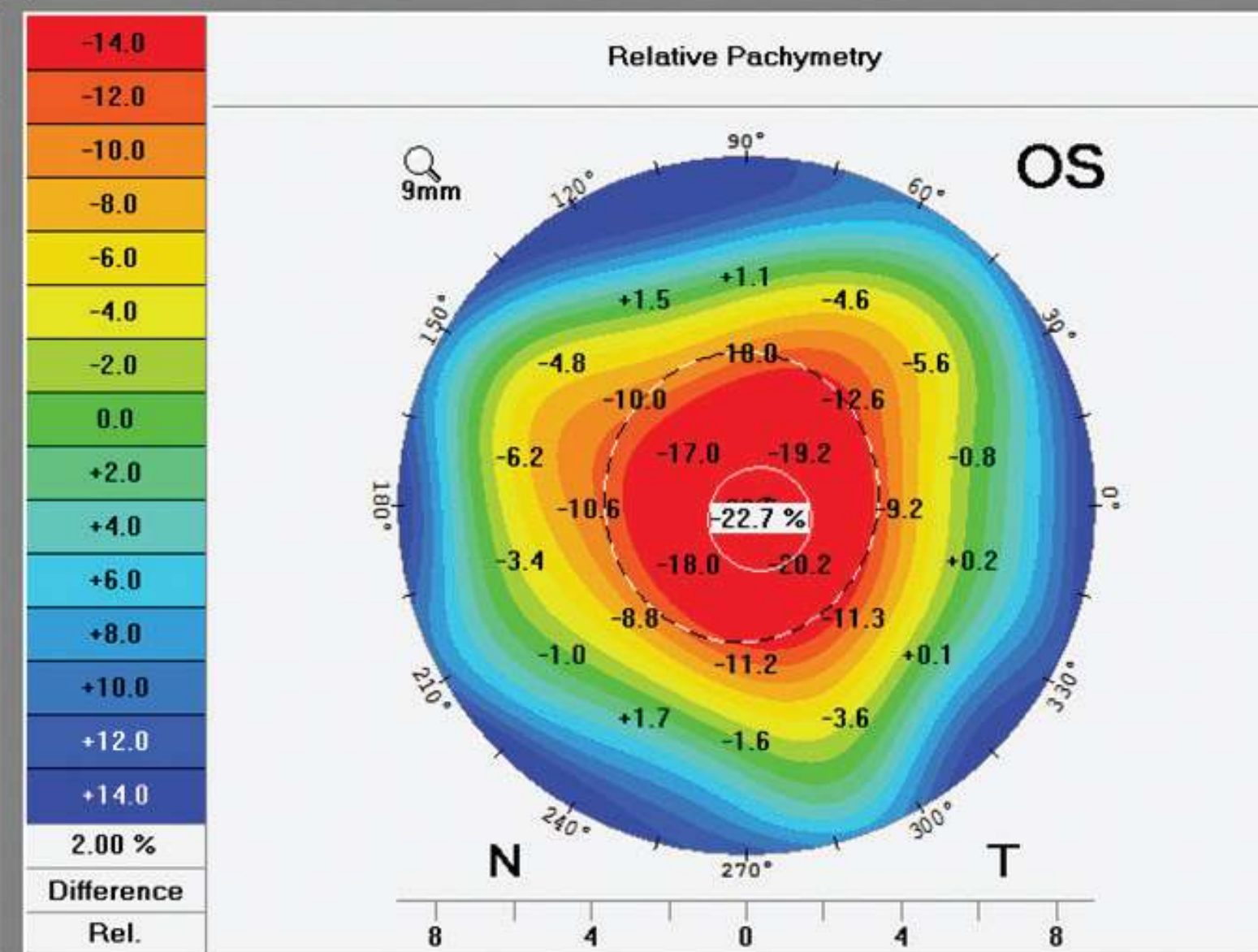
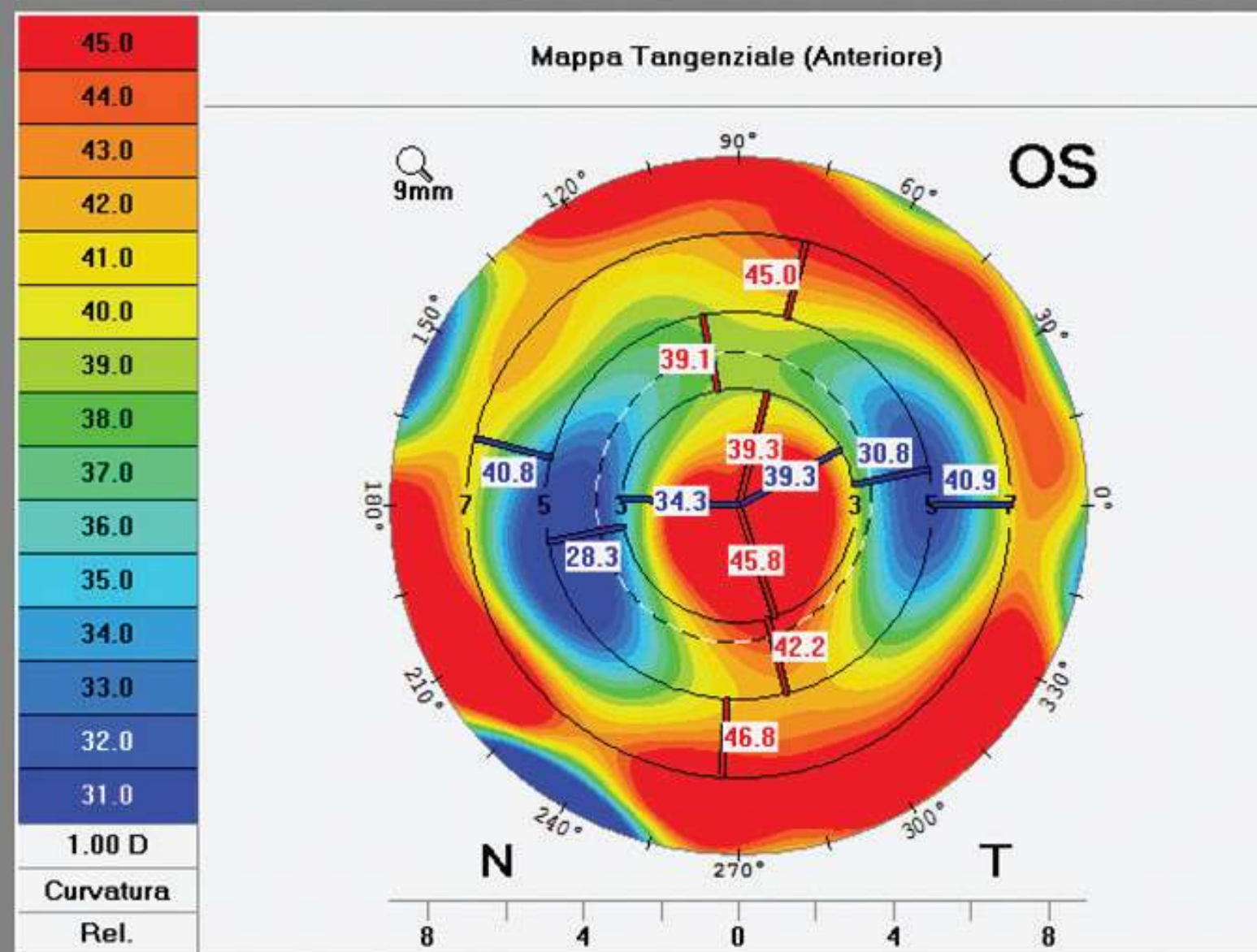
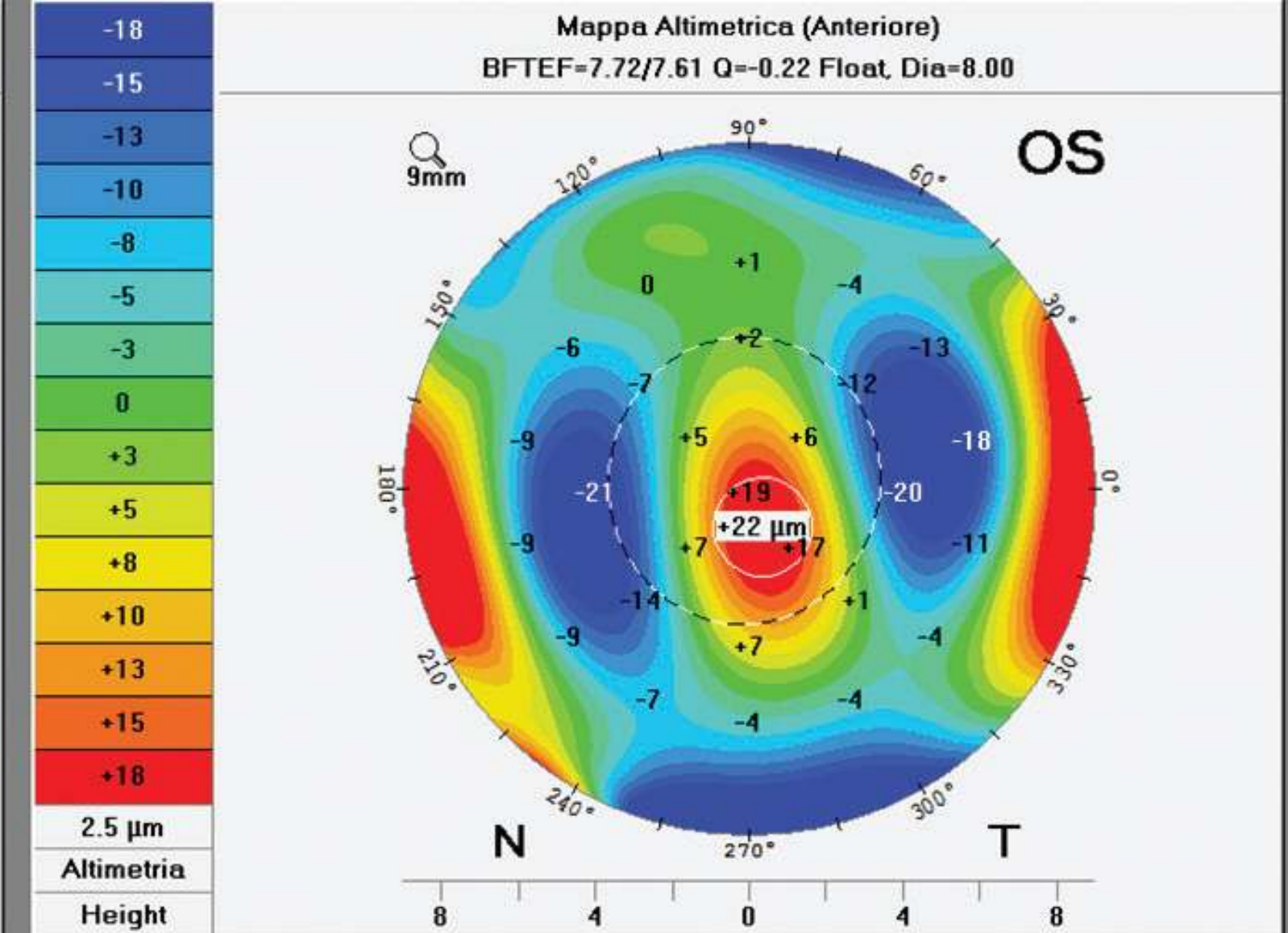
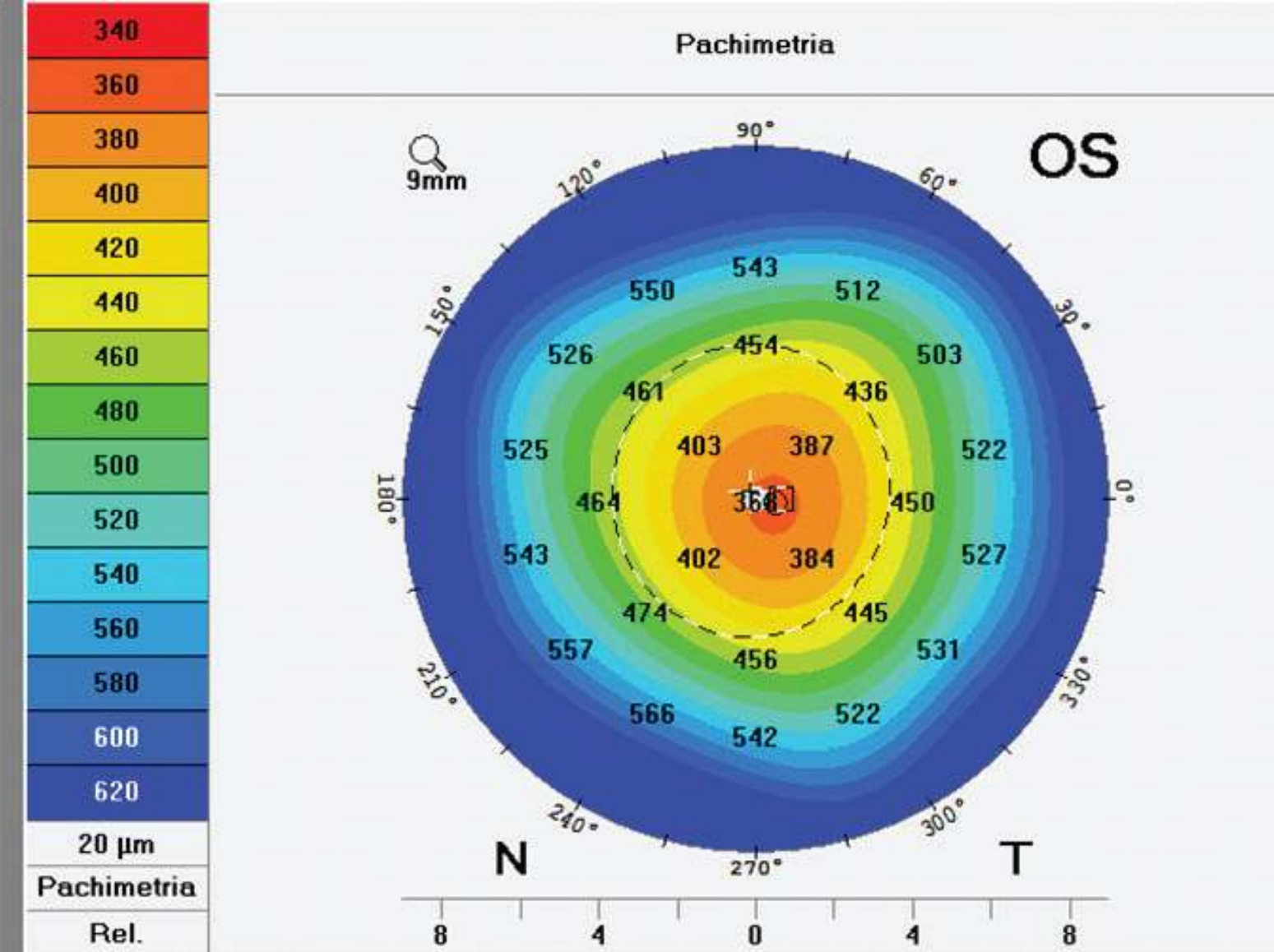
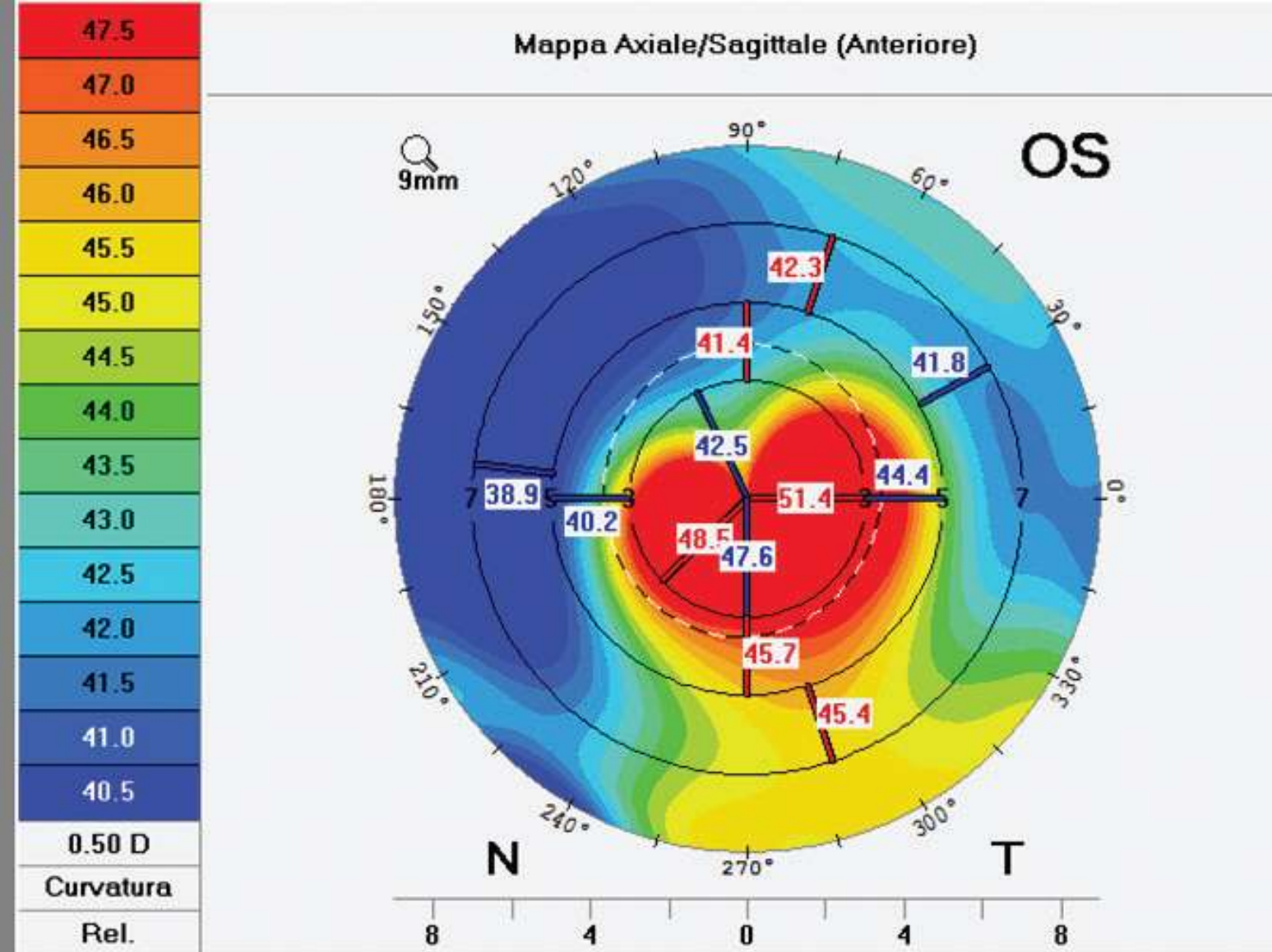
Informazioni nomogramma
Refraction, Versione 3.0

Dati lenticolari

Zona ottica [mm]: 7,00
Zona di passaggio [mm]: 0,10
Spessore [μm]: Min.: 15 Max: 93
Angolo di taglio del bordo [°]: 90
Correzione refrattiva
Sfera [D]: -3,25
Cilindro [D]: -0,75
Asse [°]: 165

Dati del cap

Diametro [mm]: 7,80
Spessore [μm]: 140
Angolo di taglio del bordo [°]: 90
Posizione incisione [°]: 135
Angolo incisione [°]: 29
Incisione larga [mm]: 2,00



Conclusion

- Xtra procedures are generally safe with few reported complications
- Efficacy of the procedure ??
 - Small sample sizes
 - Lack of long-term data
 - Variable total UV-A energy exposure Protocols
- More randomized studies with longer follow-ups It's crucial to weigh the long-term risks and benefits since this approach isn't yet recognized as standard care.

Take home message

Xtra Procedures might delay ectasia development or it
may not be effective at all!

Currently Xtras should be done only with great caution

Thank you