Excellence Eye Research Centre
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University "G. d'Annunzio" Chieti-Pescara
Head. Prof. Leonardo Mastropasqua

Centro Nazionale di Alta Tecnologia in Oftalmologia

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La chirurgia refrattiva, oggi

SOSi Società Oftalmologica Siciliana

XLIX CONGRESSO REGIONALE

PRESIDENTE: PROF. PASQUALE ARAGONA

10-12 APRILE 2025
UNAHOTELS - NAXOS BEACH SICILIA (ME)

Prof. Leonardo Mastropasqua

Table 1-1 Overview of Keratorefractive Procedures

Location	Type of Procedure	Specific Procedures	Common Abbreviations	Refractive Error Treated
Cornea	Incisional	Radial keratotomy	RK	Myopia (historical)
		Astigmatic keratotomy	AK	Astigmatism
		Arcuate keratotomy		
		Femtosecond laser–assisted arcuate keratotomy	FLAAK	Astigmatism
		Limbal relaxing incisions	LRI	Astigmatism
	Excimer laser	Photorefractive keratectomy	PRK	Myopia, hyperopia, astigmatism
		Laser in situ keratomileusis	LASIK	Myopia, hyperopia, astigmatism
		Laser subepithelial keratomileusis	LASEK	Myopia, hyperopia, astigmatism
		Epipolis laser in situ keratomileusis	Epi-LASIK	Myopia, hyperopia, astigmatism
	Excimer and femtosecond lasers	Femtosecond laser–assisted laser in situ keratomileusis	Femto-LASIK	Myopia, hyperopia, astigmatism
	Femtosecond laser	Refractive lenticule extraction	ReLEx, FLEx, SMILE	Myopia, astigmatism
		Refractive indexing		Investigational
	Inlays/onlays	Corneal inlays/onlays		Presbyopia
	Nonlaser lamellar	Epikeratophakia, epikeratoplasty		Myopia, hyperopia, astigmatism (historical)
		Intrastromal corneal ring segments	ICRS	Myopia, keratoconus
	Collagen shrinkage	Laser thermokeratoplasty	LTK	Hyperopia, astigmatism (historical)
		Conductive keratoplasty	CK	Hyperopia, astigmatism
	Corneal crosslinking		CXL	Keratoconus, myopia (investigational)

Table 1-2 Overview of Scleral and Intraocular Refractive Procedures

Location	Type of Procedure	Specific Procedures	Refractive Error Treated
Scleral		Scleral laser anterior ciliary excision	Presbyopia (investigational)
		PMMA microinserts placed in scleral tunnels	Presbyopia (investigational)
Intraocular	Phakic	Anterior chamber (angle-supported) phakic IOL implantation	Myopia (investigational)
		Iris-fixated phakic IOL implantation	Myopia, astigmatism
		Posterior chamber phakic IOL implantation	Myopia, astigmatism
	Pseudophakic	Refractive lens exchange (multifocal/ accommodating/ extended depth of focus IOLs)	Myopia, hyperopia, presbyopia, astigmatism

IOL = intraocular lens; PMMA = polymethyl methacrylate.

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BCSC
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Refractive Surgery

Overall (estimated) number of refractive procedures worldwide

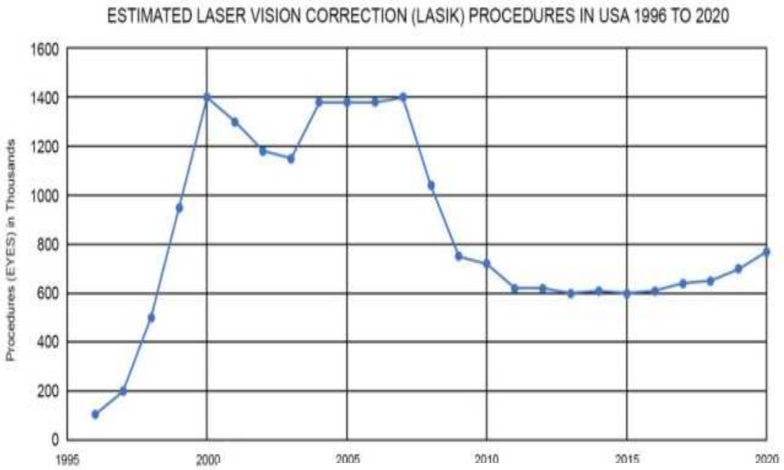
Laser Vision Correction

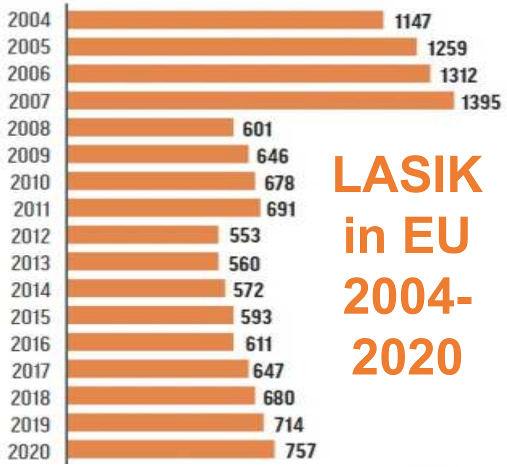
>60 millions (2024)

LASIK ≈ 35 millions

PRK ≈ 15 millions

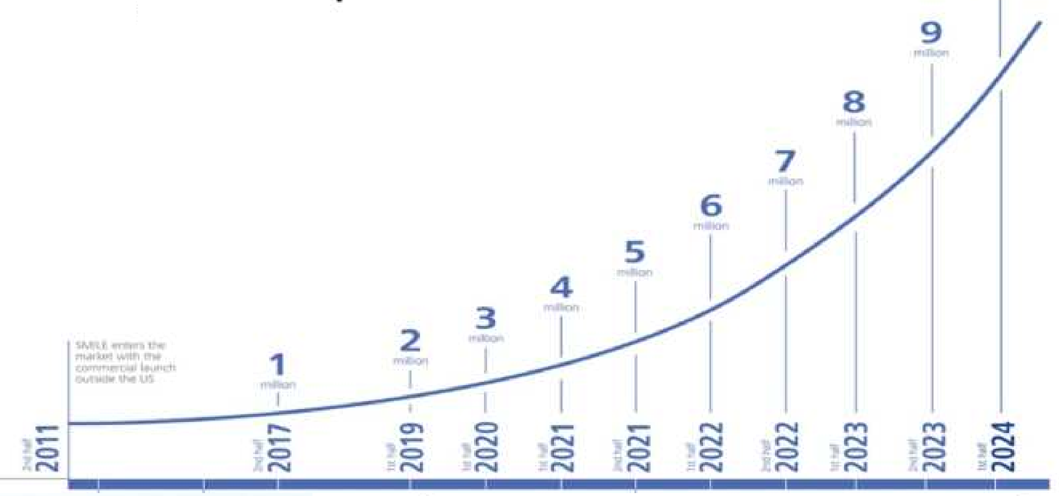
SMILE ≈ 10 millions

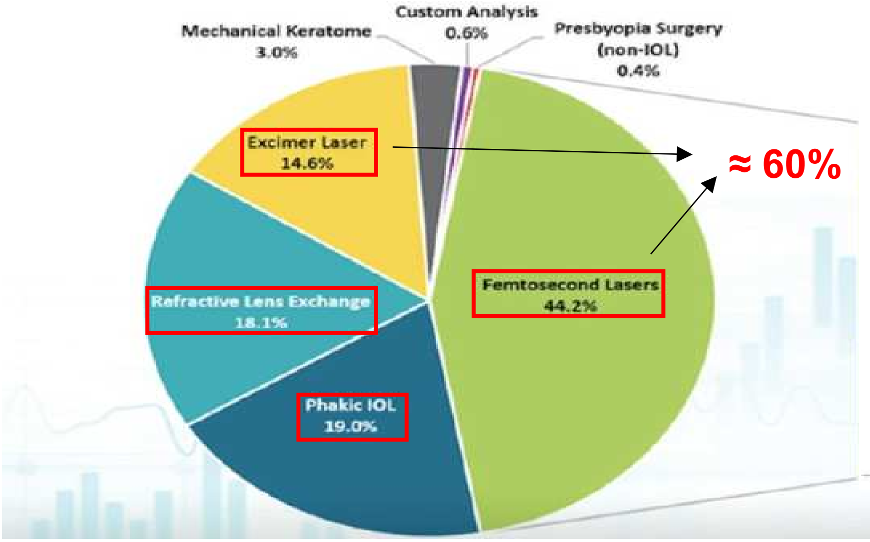




LASIK in EU 2004-2020

10 million eyes treated with SMILE & SMILE pro





Reimagining, Rethinking, and Reinventing Refractive Surgery

Charles H. Williamson, MD, FACS, and Blake K. Williamson, MD, MPH, MS

CRST Cataract & Refractive Surgery Today

Phakic IOLs

Overall (estimated) number of refractive publications worldwide

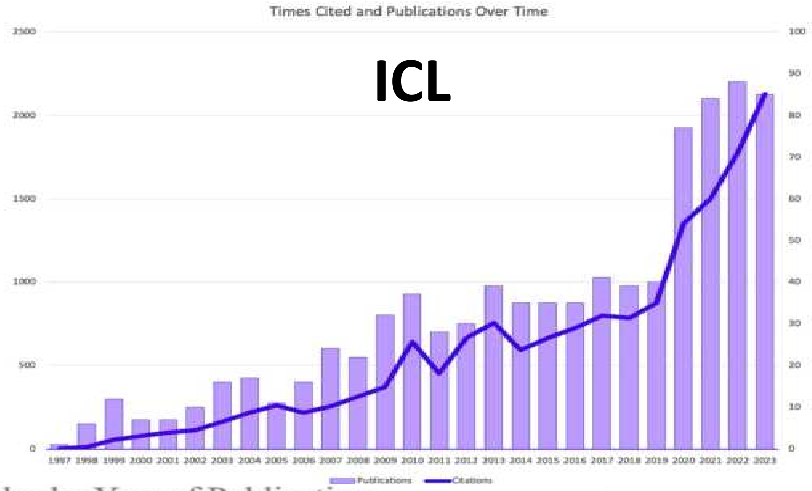
PubMed®

ALL TIME

LVC ≈ 14000

- LASIK: ≈ 8000
- PRK: ≈ 5000
- SMILE: ≈ 1000

PIOL/ ICL ≈ 4000



LAST 5 YRS

LVC ≈ 2500

- LASIK: ≈ 1300
- PRK: ≈ 600
- SMILE: ≈ 600

PIOL/ ICL ≈ 2000

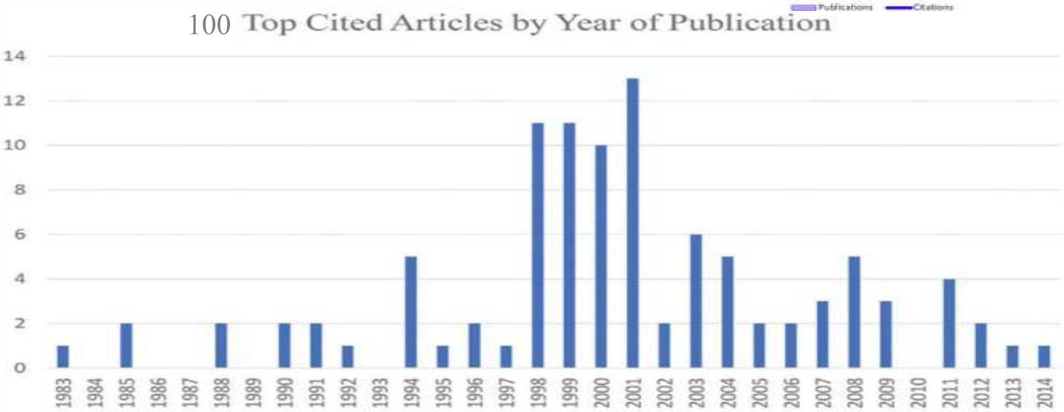
Outcomes substantially equivalen

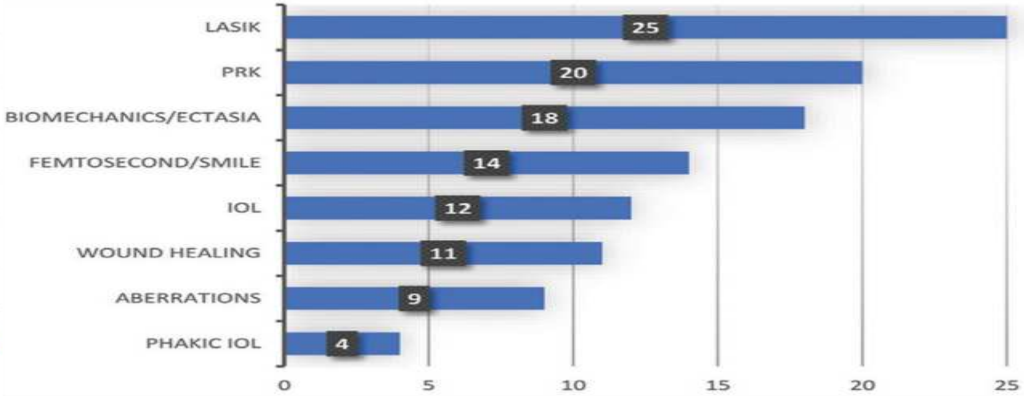
REVIEW

Open Access

The Most Cited Articles and Authors in Refractive Surgery

J. Bradley Randleman, MD; Lara Asroui, MD; Imane Tarib, MD; Giuliano Scarcelli, PhD

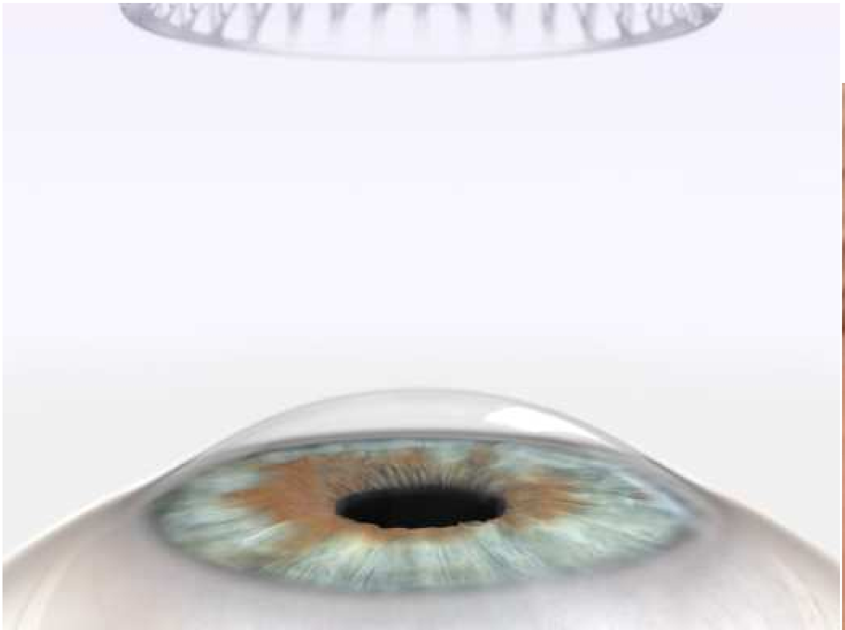


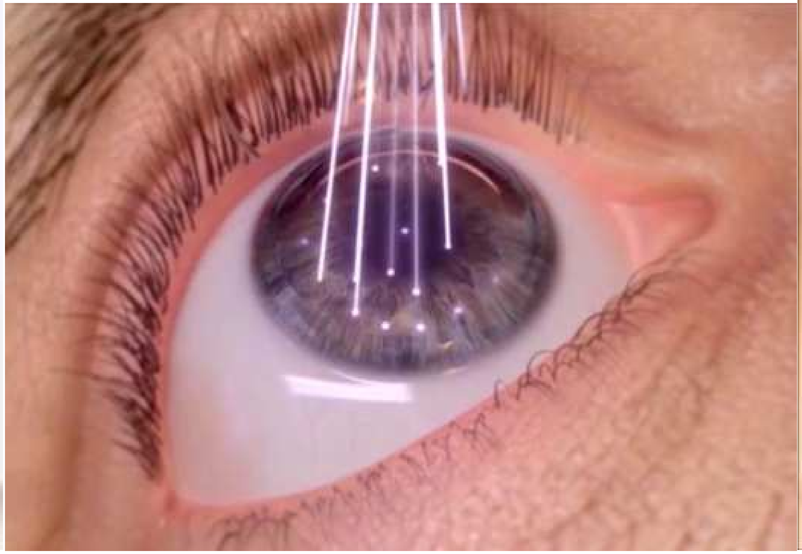


Journal of Refractive Surgery

2023;39(2):78–88

Laser or Lens?





- ➢ Definitive vs reversible technique?
- ➢ Closed vs open eye technique?
- ➢ Low vs high refractive error?
- ➢ Gold standard technique or likewise effective?
- ➢ Cheaper or more expensive?

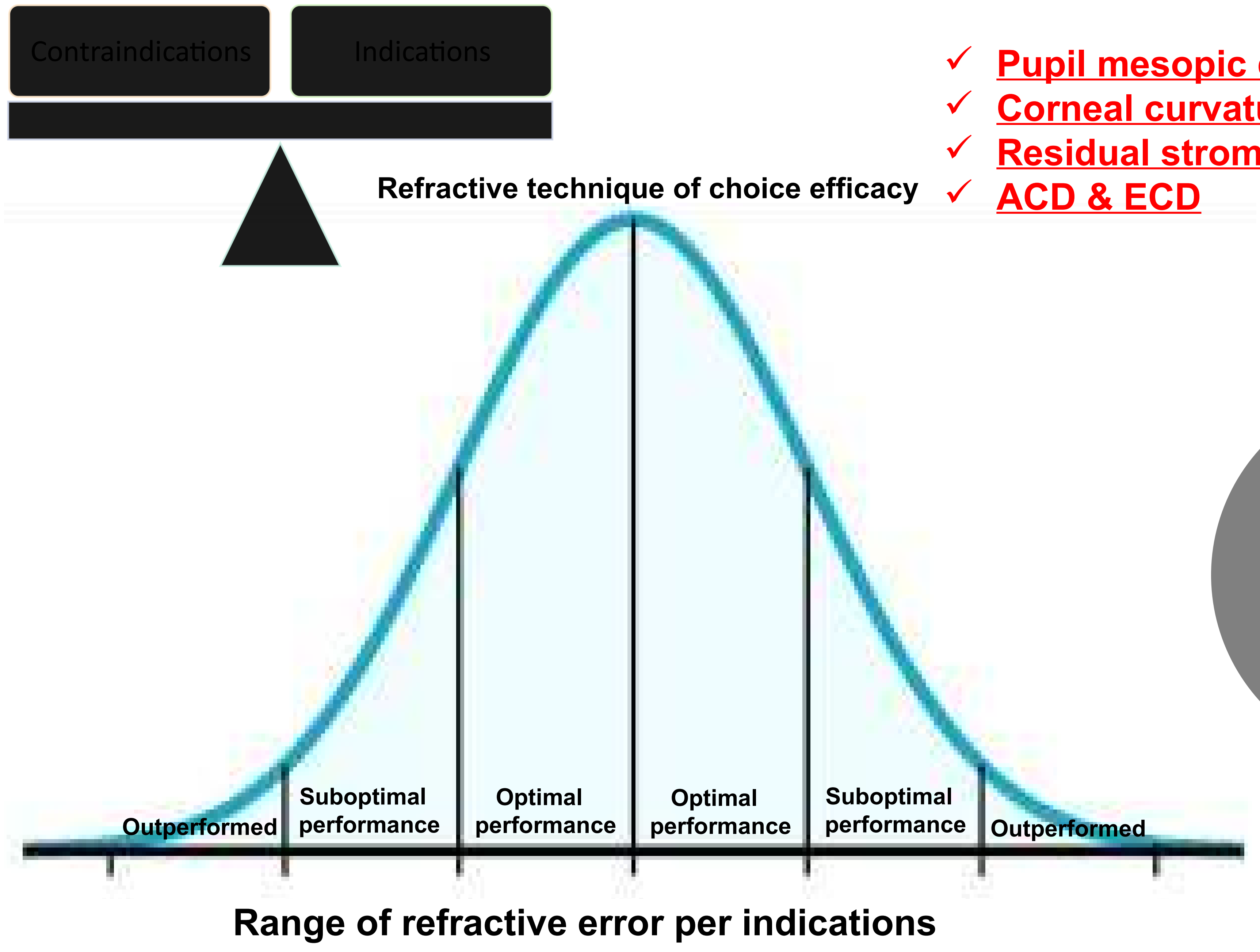
In conclusion, up to date several studies investigated one technique superiorities to the other technique. However, as mentioned in this article, **LASIK, SMILE, and phakic IOLs have their own utilization, advantages, disadvantages, and complications**. Therefore, a **proper presurgical evaluation is necessary to determine the best refractive surgery technique for each patient individually**.

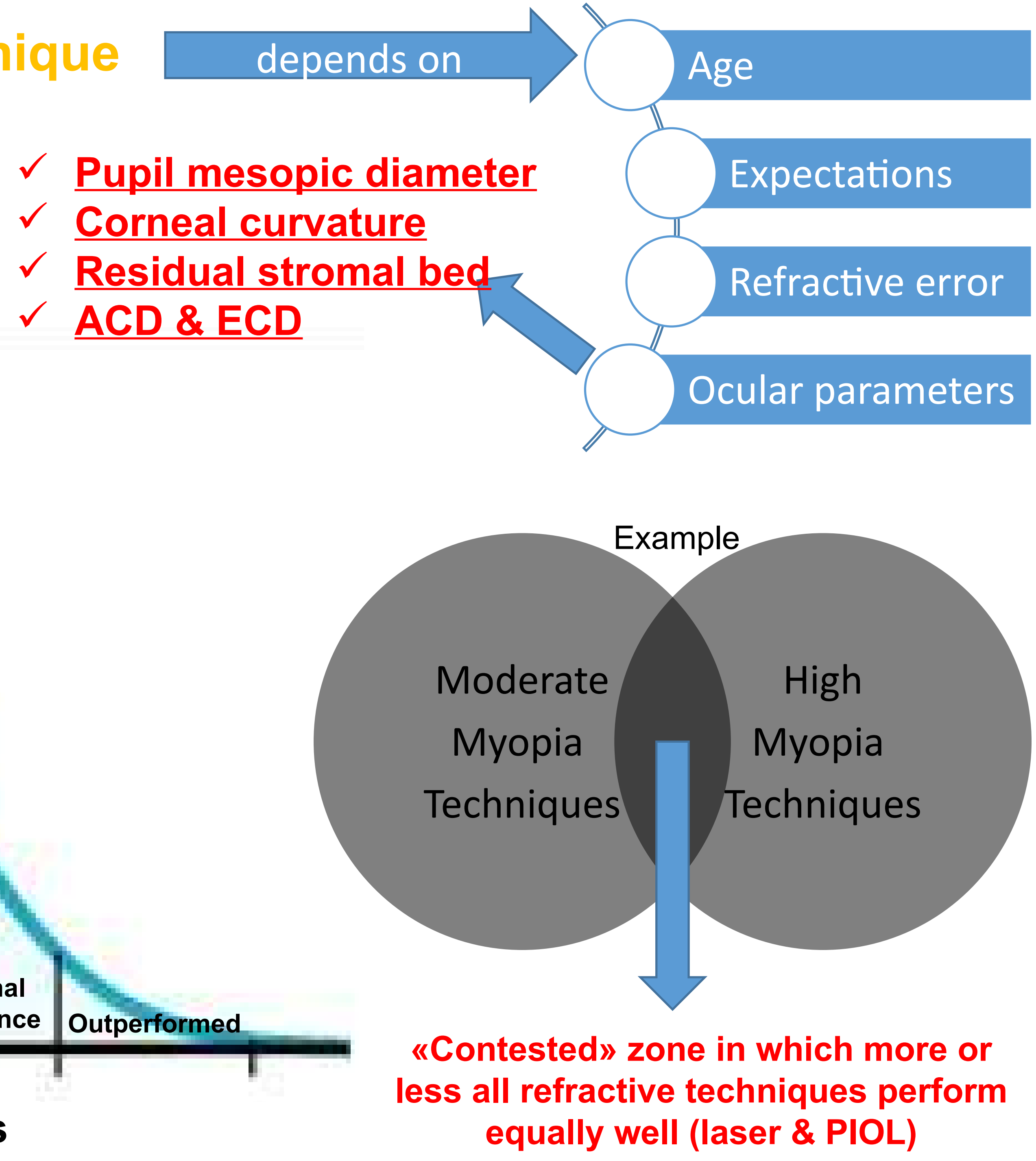
INTERNATIONAL OPHTHALMOLOGY CLINICS
Volume 56, Number 3, 137–147

Nilufer Yesilirmak, MD
Zachary Davis, BS
Sonia H. Yoo, MD

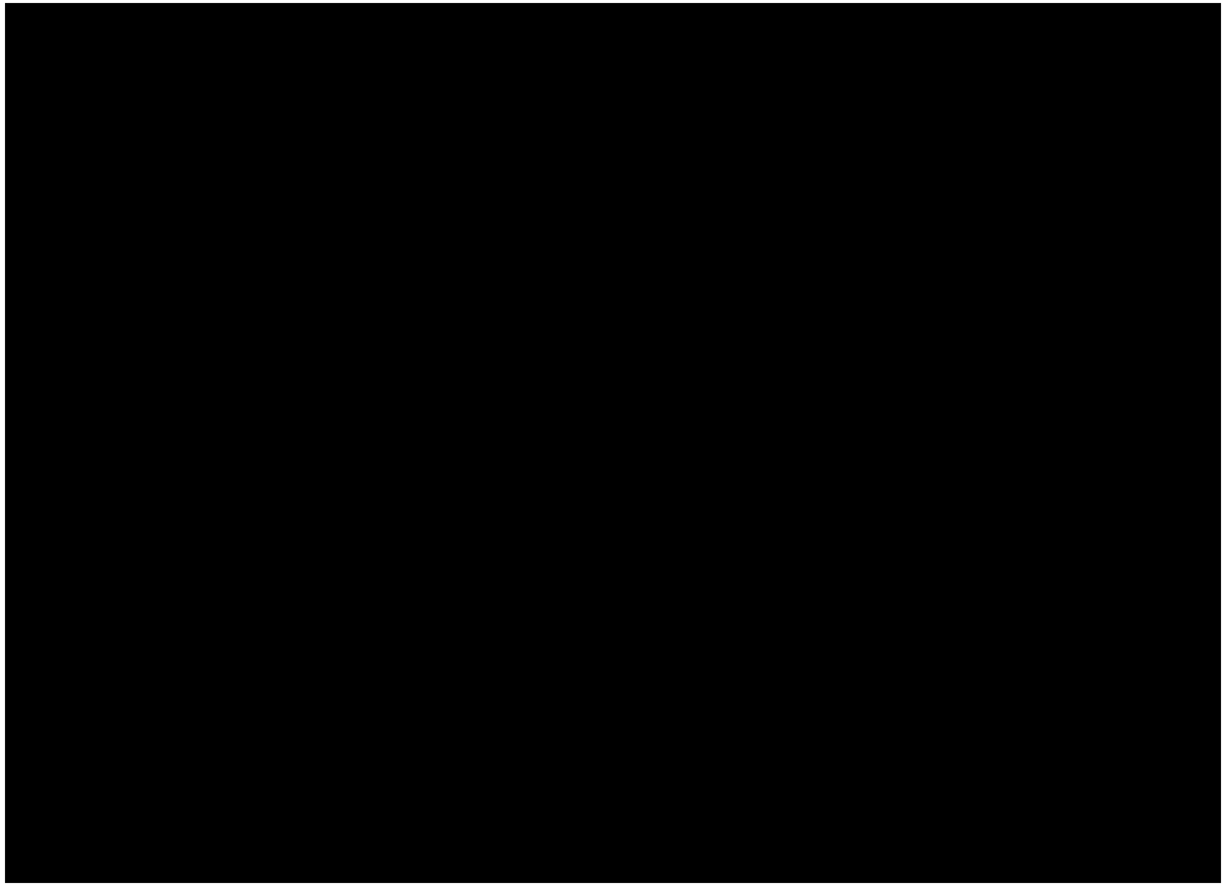
Refractive Surgery (SMILE vs. LASIK vs. Phakic IOL)

Efficacy range for each refractive technique





Photorefractive Keratectomy (PRK) and surface ablation techniques



PRK Complications

Undercorrection, overcorrection, or regression
Dry eye
Corneal haze
Visual acuity loss
Irregular astigmatism
Infection, inflammation

The customary accepted values are in parentheses; the extreme values are in brackets.

	Surface Ablation*
Age (years)	[14 (18–55) 75]
Refraction sphere (diopters)	[–13.00 (–12.0 to +4.0) +7.00]
Refraction cylinder (diopters)	[(6.00) 7.00]‡
Pachymetry (μm)	Minimal residual stromal thickness [>240 (250)]
Minimal residual stromal thickness (μm)	[>240 (250)]
Topographic regularity (regular, borderline, or irregular)¶	[Irregular (regular)]
Interocular topographic and pachymetric differences (similar, borderline, different)	[Different (similar)]
Corneal apex location (centered, borderline, or decentered)	[Decentered (centered)]
Average keratometry (diopters)	Postoperative [34 (38–48) 50] Calculate preoperatively††
Pupil size (mm)	[(<8.0)]
Lens opacity (grade 0–4)	[(0–1) 2]

- Correction of myopia up to -6,00 sph
- Correction of hyperopia up to +3,00 sph
- Correction of astigmatism up to ±3,00 D

in relation to corneal parameters, pupil parameters, RSB (400 μm) and age

Preferred practice patterns for photorefractive keratectomy surgery

Rajesh Fogla, Gaurav Luthra[1], Aishwarya Chhabra[2], Krati Gupta[3], Ritika Dalal[4], Pooja Khamar[2]

© 2020 Indian Journal of Ophthalmology

(Femto)Laser In situ Keratomileusis (F-LASIK)

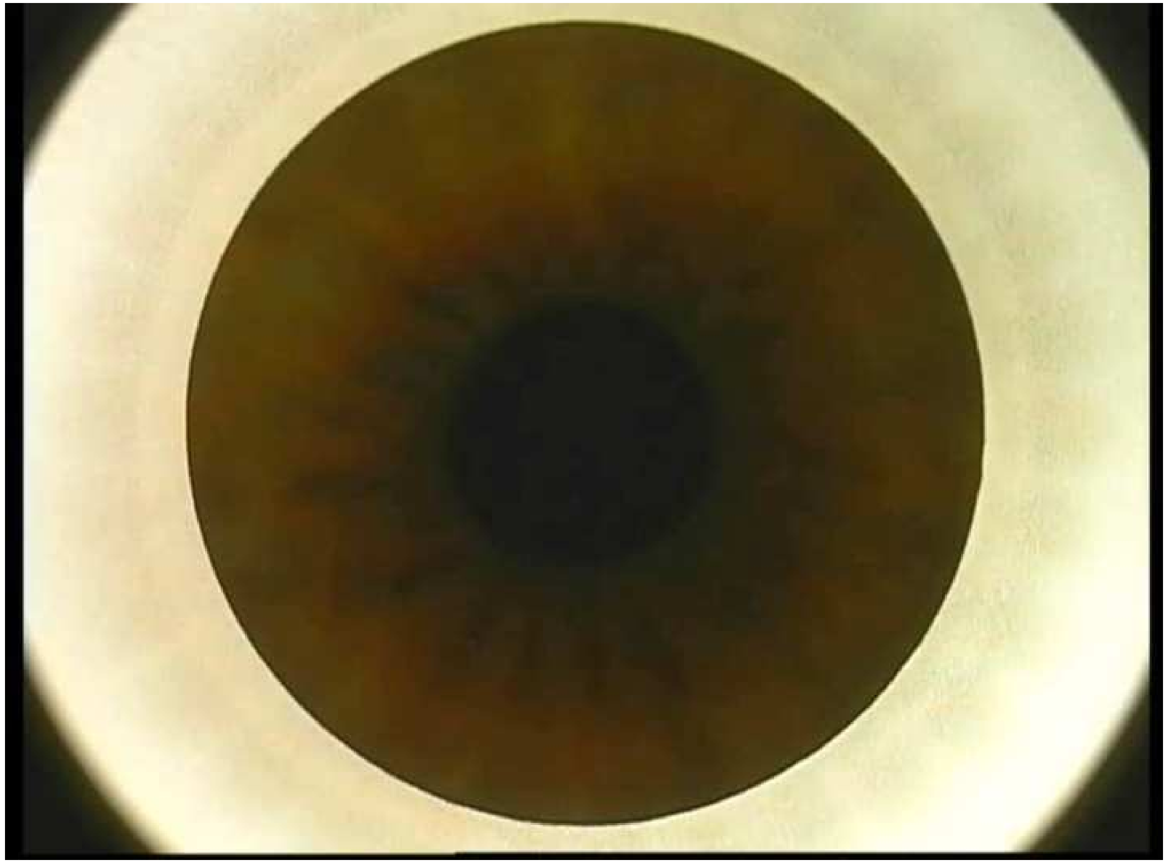


Table 1. Complications of LASIK surgery

- I. Flap complications
  - a. Incomplete flap
  - b. Free cap
  - c. Thin flaps and buttonholes
  - d. Dislocated flaps
  - e. Corneal perforation
  - f. Corneal epithelial defect
- II. Flap striae
- III. Epithelial ingrowth
- IV. Diffuse lamellar keratitis
- V. Dry eyes
- VI. Corneal ectasia
- VII. Ablation problems
- VIII. Undercorrection and overcorrection
- IX. Microbial keratitis

	Thin-Flap LASIK*
Age (years)	[14 (18–55) 75]
Refraction sphere (diopters)	[−13.00 (−10.0 to +4.0) +7.00]
Refraction cylinder (diopters)	[(6.00) 7.00]‡
Pachymetry (µm)	[475 (500–620) 650]
Minimal residual stromal thickness (µm)	[>240 (250)]
Topographic regularity (regular, borderline, or irregular)¶	[Borderline (regular)]
Interocular topographic and pachymetric differences (similar, borderline, different)	Borderline (similar)]
Corneal apex location (centered, borderline, or decentered)	[Borderline (centered)]
Average keratometry (diopters)	Postoperative [34 (38–48) 50] Calculate preoperatively††
Pupil size (mm)	[(<8.0)]
Lens opacity (grade 0–4)	[(0–1) 2]

The customary accepted values are in parentheses; the extreme values are in brackets.

- **Correction of myopia up to -8,00 sph**
- **Correction of hyperopia up to +4,00 sph**
- **Correction of astigmatism up to ±4,00 D**

in relation to corneal parameters, pupil parameters, RSB (270-300 µm) and age

Refractive Surgery Preferred Practice Pattern® 2022

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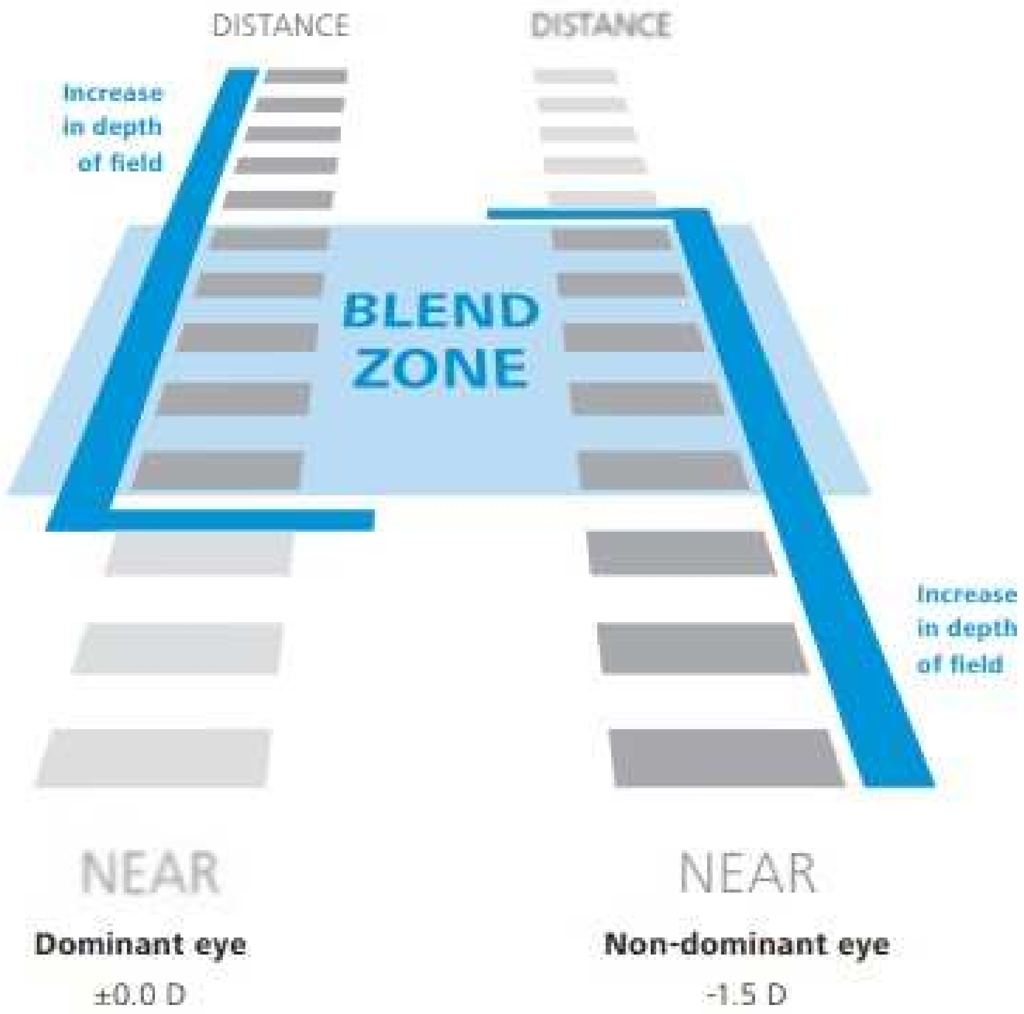
Laser correction of presbyopia: Presbyond

HOA



Similar to conventional monovision, the dominant eye is corrected for distance vision to almost plano, whereas the non-dominant eye is corrected to be slightly myopic for near vision to −1.5 D. This micro-anisometropia strategy is further enhanced by a decisive difference: an increase in the depth of field of each eye using a wavefront-optimized ablation profile to create a continuous refractive power gradient for the whole optical zone of the cornea.

Essentially, the Blend Zone makes it easier for the brain to merge the images of both eyes, thereby achieving true binocular vision.

The best candidates for monovision using these approaches are patients over 40 years old who place a high premium on maximizing their freedom from optical aids and are willing to sacrifice uncorrected distance stereoacuity to achieve this goal. Larger degrees of anisometropia produce better visual function at near, but smaller degrees of anisometropia may be better tolerated and are a viable option for some patients willing to accept a compromise.[354, 355]

Small Incision Lenticule Extraction (SMILE)

History and Results; Indications and Contraindications of SMILE Compared With LASIK

Rupal Shah, MS (Ophthalmology) (*Asia Pac J Ophthalmol (Phila)* 2019;8:371–376)

TABLE 2. Indications for SMILE

Refractive error **HYPEROPIA NOW AVAILABLE**	Within −0.5D to −10D spherical equivalent, with upto −5D of astigmatism
Age	>18 y
Mesopic pupil size	<7 mm
Residual stromal bed	>250 μm/275 μm
Central corneal thickness	>475 μm
Stability of refraction	>1 y
Keratometry	Expected keratometry after procedure >35D and <47D

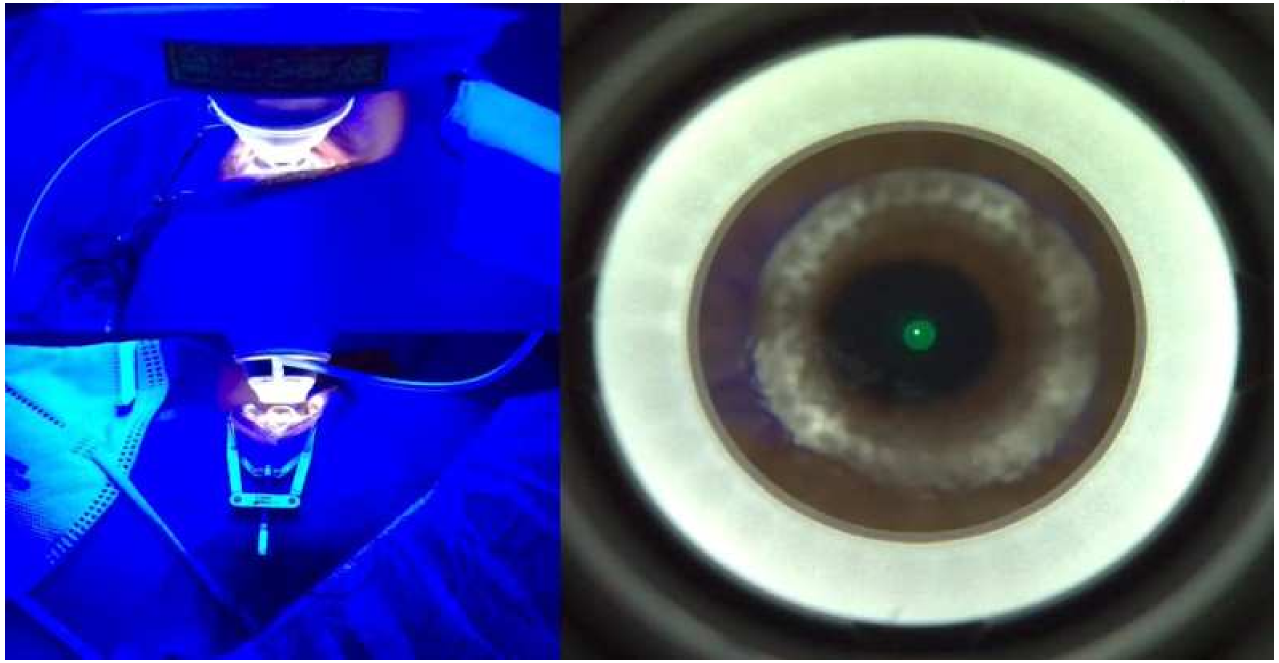


TABLE 181.1 Complications in Small-Incision Lenticule Extraction

Intraoperative Complications

- Lenticule creation related
  - Opaque bubble layer
  - Black spots
  - Suction loss
- Lenticule dissection or extraction related
  - Cap-lenticule adhesion
  - Lenticule extraction difficulties or not possible
  - Abrasions or tears at incision
  - Cap perforation
  - Lenticule tear
  - Lenticule remnant

Postoperative Complications

- Dry eye
- Diffuse lamellar keratitis
- Corneal haze
- Ectasia
- Infectious keratitis
- Epithelial ingrowth
- Irregular astigmatism

MAIN ADVANTAGES OF INTRASTROMAL SMILE SURGERY

- PRESERVE THE CORNEA TENSILE STRENGTH:
  - Reduced risk of ectasia
  - Better stability over time – **no regression**
  - Resistance to trauma
  - Wider range of thickness (low thickness)
  - All range of myopia
- AVOID FLAP COMPLICATIONS
- PRESERVE THE CORNEAL SUPERFICIAL NERVE PLEXUS:
  - Reduced risk of severe Dry-Eye
- DECREASED HOA VS LASIK
  - Better quality of vision
- LONG TERM STABILITY

SMILE EVOLUTION: SMILE Pro

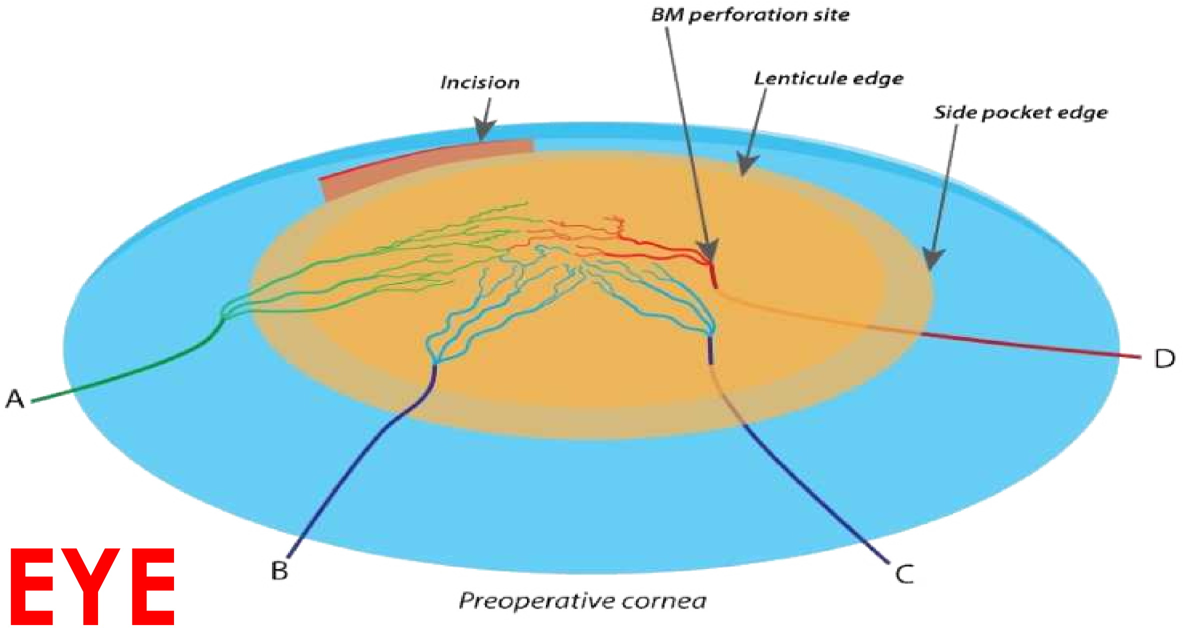
- Reduced intraoperative complications (suction loss)
- Faster procedure (10 sec)

PRESERVING CORNEAL NEURAL ARCHITECTURE WITH A FLAPLESS TECHNIQUE

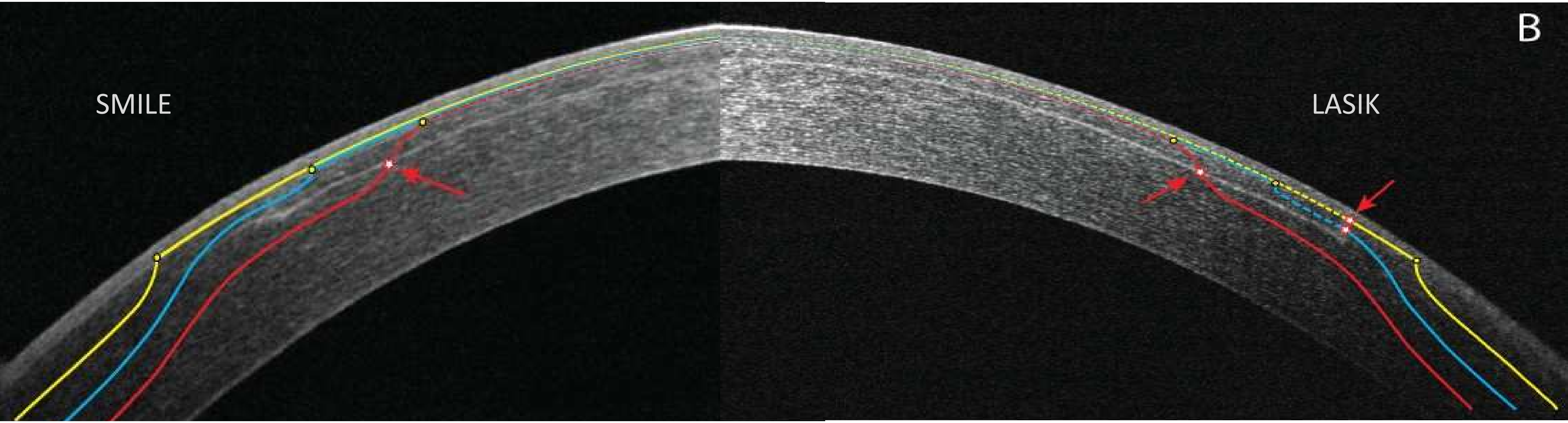
Fewer nerves are severed in ReLEx SMILE than in LASIK.

BY LEONARDO MASTROPASQUA, MD; MARIO NUBILE, MD; NICCOLÒ SALGARI, MD; AND ROBERTA CALIENNO, MD

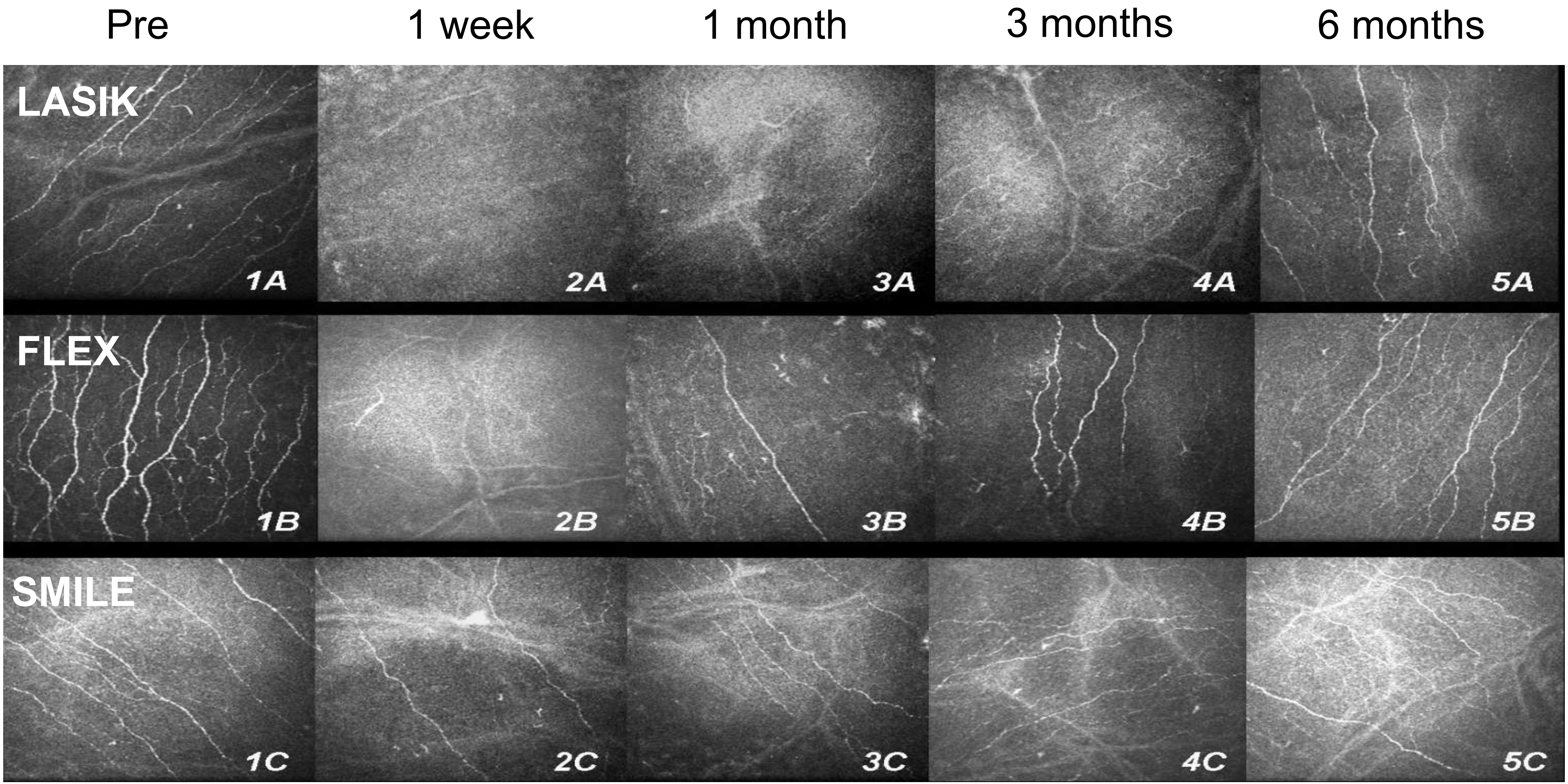
REFRACTIVE SURGERY



LESS DRY EYE



Central corneal sub-basal nerve density



Dry eye in refractive surgery: what evidences?

Table 1: Clinical manifestations after corneal laser refractive surgery and their salient characteristics

Clinical Manifestations	Salient Characteristics
Vital staining of cornea	Positive vital staining at 1 week; predominantly involving the flap in LASIK, less severe in SMILE Symptoms less severe due to reduced sensitivity Resolves by 6-12 months after LASIK[7] Resolves by about 1-3 months after SMILE[16] Resolves by about 3 months after PRK[9]
Tear breakup time	Reduced; most severe at 1 week Normalizes by about 6-12 months post-LASIK[16,27,70] Normalizes by about 3-6 months after SMILE[42,70] Normalizes by about 3 months after PRK[9]
Schirmer test	Reduced after surgery; maximally during first month Normalizes by 6-9 months after LASIK[7,59] Normalizes by about 3 months after SMILE[42] Normalizes by about 3-6 months after PRK[9,33]
Corneal sensitivity	Greater reduction after LASIK; decreased maximally at 1-2 weeks Recovers by about 12 months after LASIK[7] Recovers faster, by 3-6 months after SMILE[16,71,72] Recovers in 3-12 months after PRK[51,73,74]
Lipid layer thickness	Reduced after SMILE by 1 week, recovers by 3 months[16,42] No significant change reported by one study after LASIK[76]
Tear osmolarity	Increased; more after LASIK than PRK and SMILE Levels raised for up to 3-6 months after LASIK and SMILE[25] Levels raised for up to 4 months after PRK[75]
Nerve morphology on confocal scanning	Sub-basal nerve density, stromal nerve cells reduced after surgery; other features include nerve beading, irregular branching, microneuromas and increased dendritic cells. Microneuroma in post-LASIK neuropathic corneal pain.[64] Recovery may take up to 24-60 months after LASIK[74] Recovery by about 12 months after SMILE[25,51] Recovery by about 24 months after PRK[51]

LASIK-laser-assisted in situ keratomileusis; SMILE- small-incision lenticule extraction; PRK-photorefractive keratectomy

Review Article - Clinical Refractive surgery and dry eye - An update

Sridevi Nair, Manpreet Kaur, Namrata Sharma, Jeewan S Titiyal 2023 Indian Journal of Ophthalmology

Five-year results of Small Incision Lenticule Extraction (ReLEx SMILE)

Marcus Blum,[1] Kathrin Täubig,[1] Christin Gruhn,[1] Walter Sekundo,[2] Kathleen S Kunert[1] BJO 2016

Results 5 years postoperatively, no significant change to the 6-month data was found. Spherical equivalent was −0.375 D and therefore close to target refraction (emmetropia).

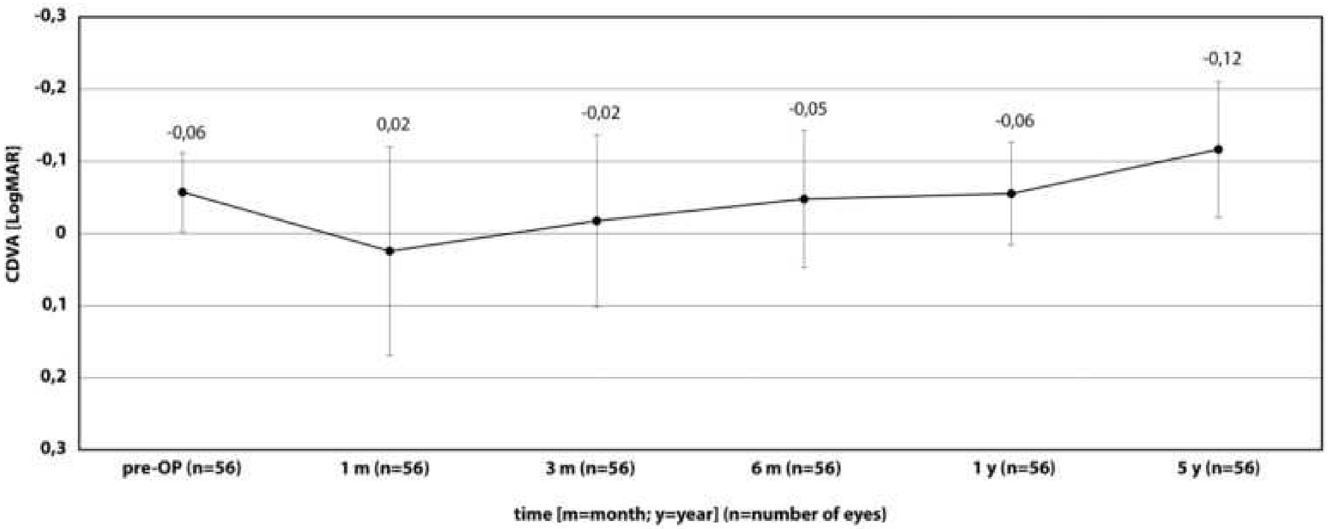


Figure 1 Corrected distance visual acuity (CDVA) 5 years after Small Incision Lenticule Extraction (SMILE) technique for myopia. Visual acuity is presented inlogMAR (transverse axis). Examinations took place at 1 month, 3 months, 6 months and 1 year and 5 years after surgery (longitudinal axis).

Regression might have been the result of long- term growth of the axial length (AL)

The long-term visual outcome remained stable after SMILE, but with an average regression of -0.34 D over 7 years. A minor group with high myopic correction exhibited considerable refractive regression years after SMILE. Damgard IB et al[***J Refract Surg*. 2021;37(10):654-661.**].

> J Refract Surg. 2019 Oct 1;35(10):618-623. doi: 10.3928/1081597X-20190826-02.

10-Year Results of Small Incision Lenticule Extraction

Marcus Blum, Anna S Lauer, Kathleen S Kunert, Walter Sekundo

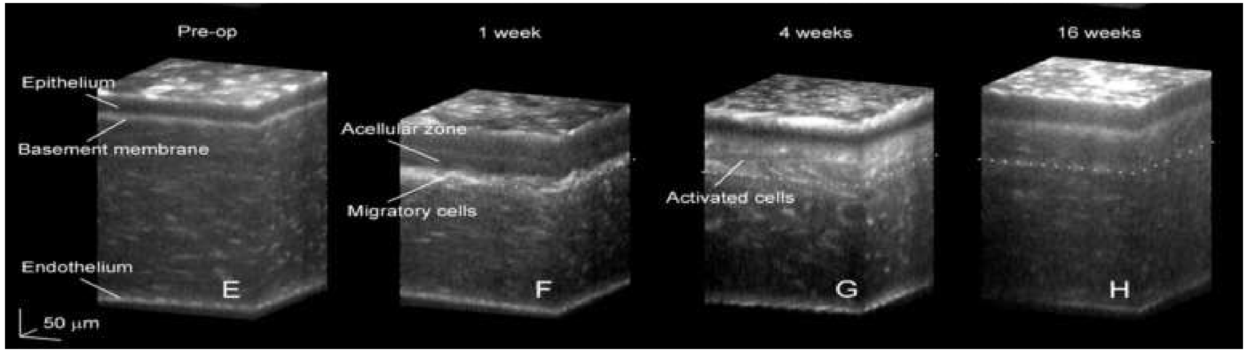
PMID: 31610002 DOI: 10.3928/1081597X-20190826-02

Results: At 10 years postoperatively, there was no significant change from the 6-month results. Spherical equivalent was -0.35 ± 0.66 diopters and therefore close to target refraction. Sixteen of the 56 eyes (29%) had gained one to two Snellen lines. There was no loss of two or more lines in the long term. Regression was -0.35 ± 0.66 diopters over the 10-year period.

Conclusions: This 10-year long-term study demonstrates SMILE to be an effective, stable, and safe procedure for the treatment of myopia and myopic astigmatism. [J Refract Surg. 2019;35(10):618-623.].

LONG TERM STABILITY

Excimer vs FS Laser stromal wound healing

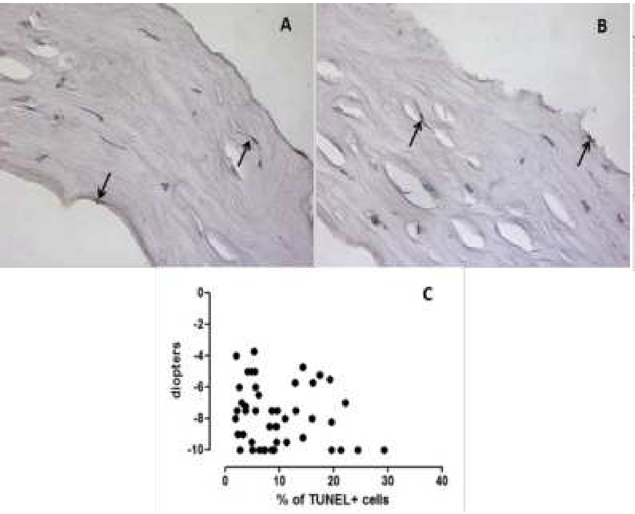


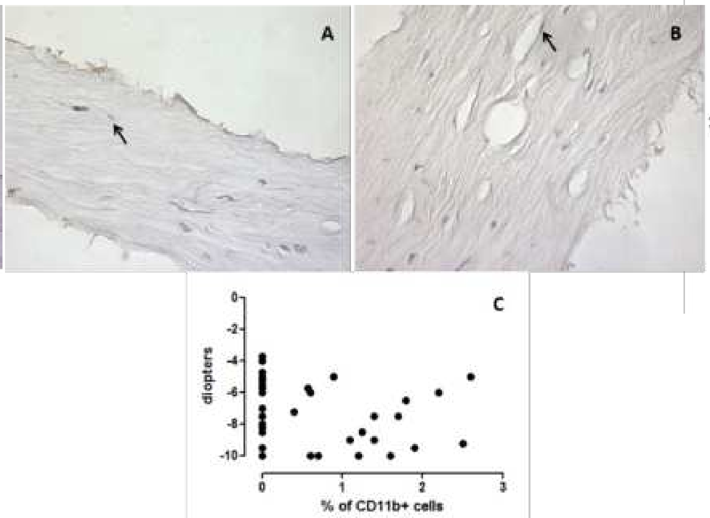
Role of Keratocyte Loss on Corneal Wound Repair after LASIK

IOVS 2004

Anders Ivarsen, Tinne Laurberg, and Torben Møller-Pedersen

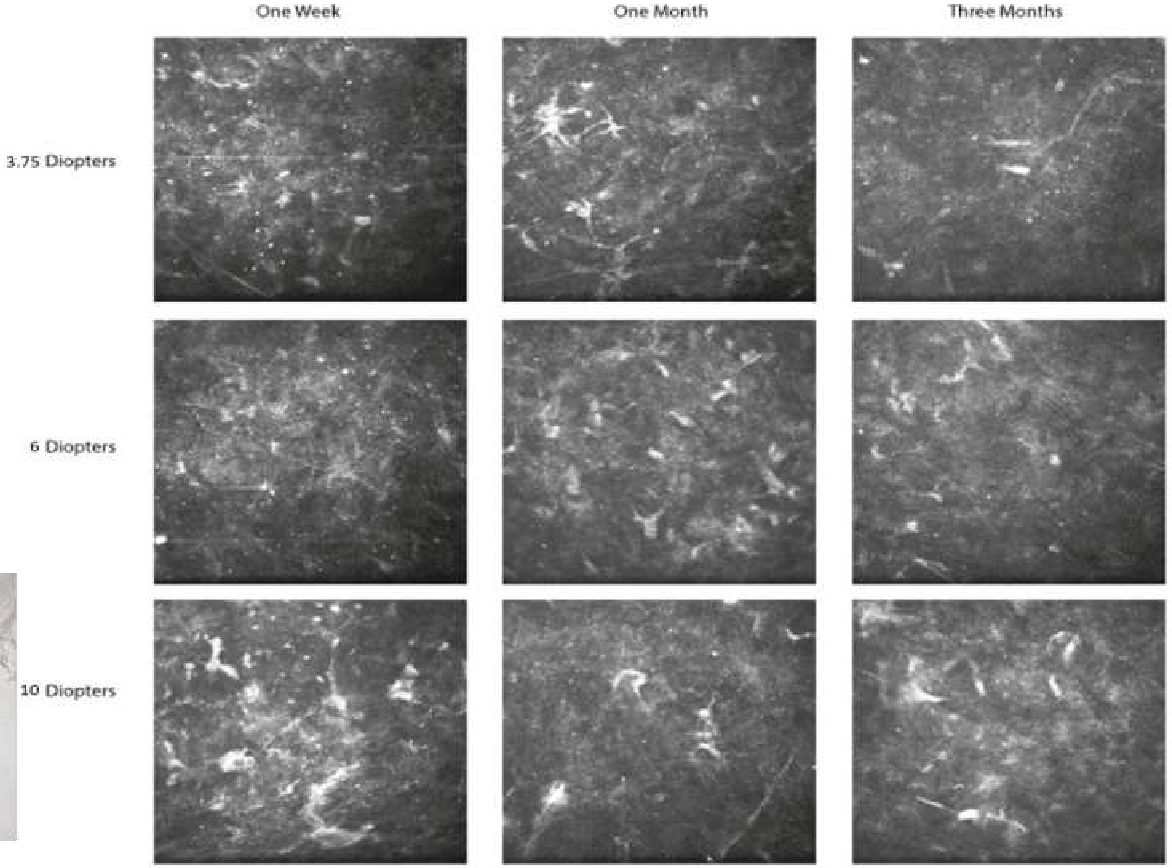
The cellular wound healing response after high myopia treatment are likely determinants of the clinical differences in refractive outcome and regression Mohan RR, et al. Exp Eye Res. 2003





LESS REGRESSION

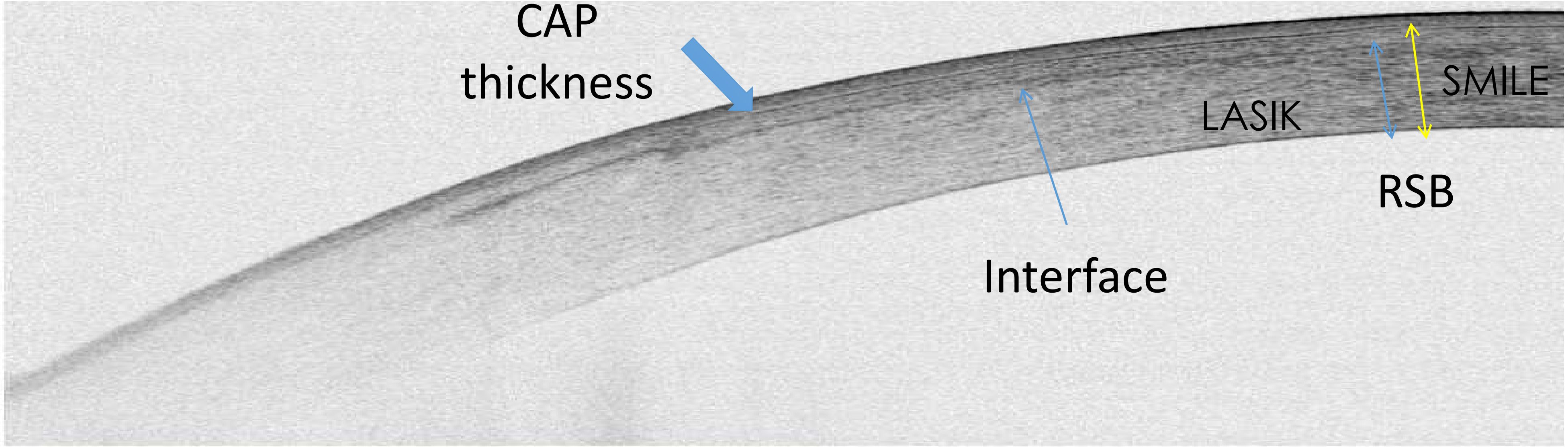
In vivo and ex vivo evaluation of corneal inflammatory response and apoptosis induced after SMILE procedures for different refractive error range.

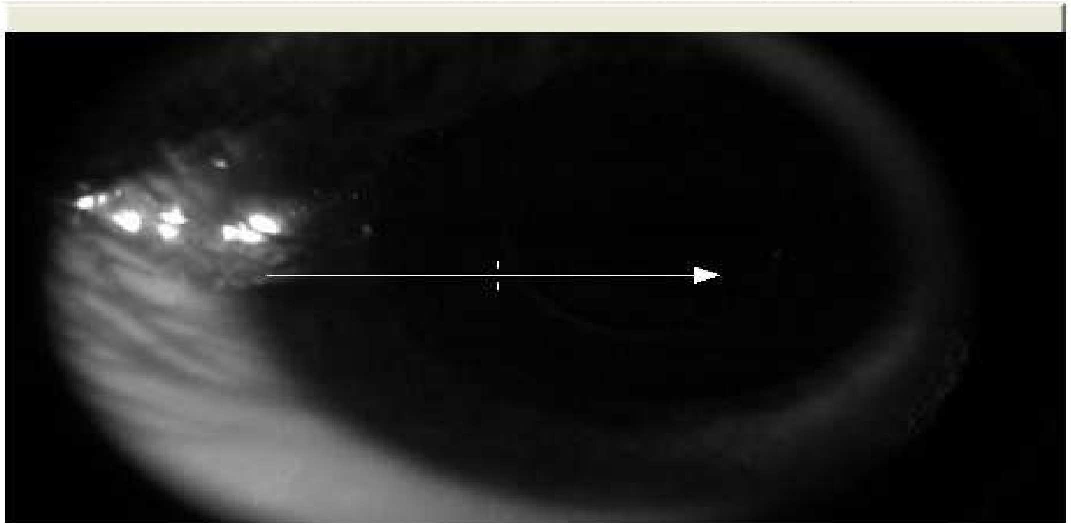


Induced inflammation and apoptosis is indipendent from refractive correction

Mastropasqua L, Nubile M et al. 2016 Exp Eye Res

SMILE morphometrical outcomes explain the BETTER BIOMECHANICS in high myopia





Residual stromal bed in SMILE starts from the Bowman's (Similar to PRK)

Differently than LASIK

Mastropasqua L, Nubile M, Lanzini M, 2015

Influence of Preoperative Parameters on the Ratio of Keratometric Change per Diopter of Attempted Spherical Equivalent (ΔK/ΔSEQ) for Myopic Correction Within LASIK, PRK, and SMILE

Clinical Ophthalmology 2023:17 2563–2573

Majid Moshirfar[1–3], Joshua S Theis[4], David S Cha[5], Kaiden B Porter[4], Carter J Payne[1,6], Phillip C Hoopes[1]

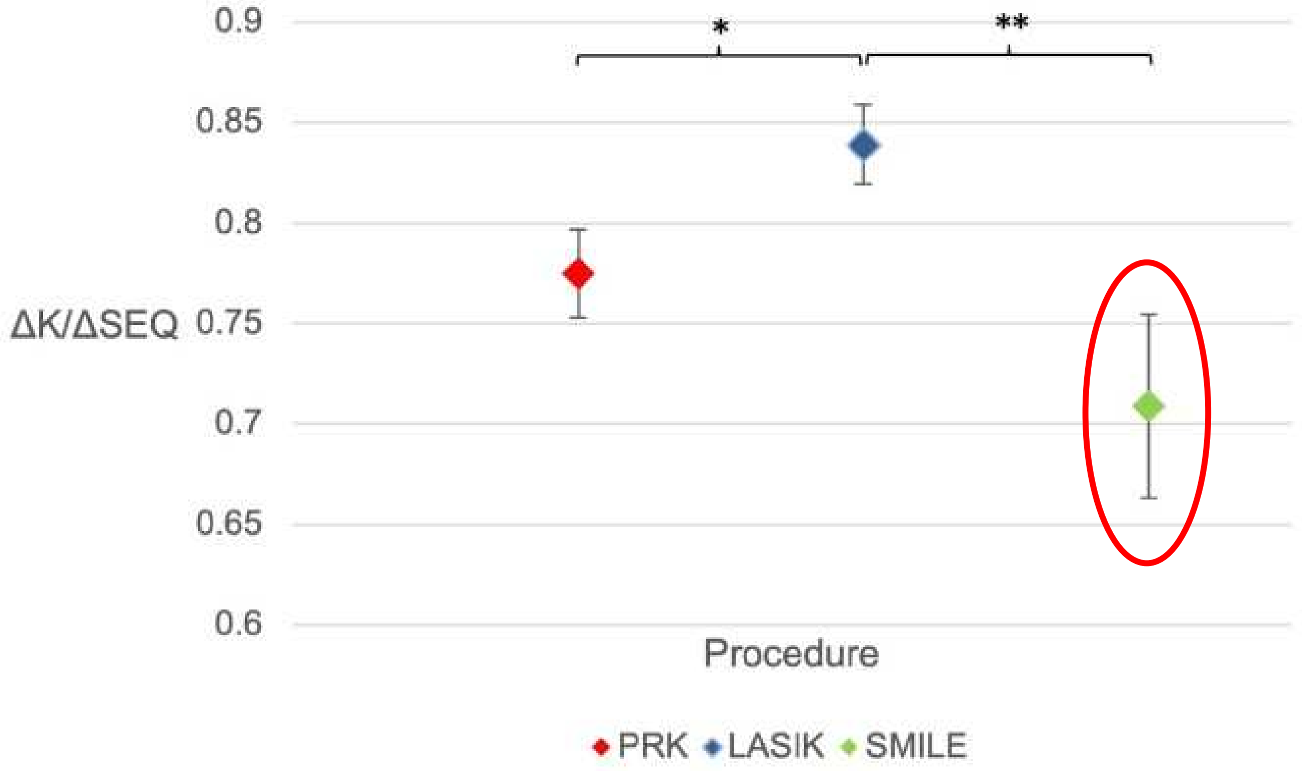


Figure 1 Comparison of ΔK/ΔSEQ by procedure: PRK was found to have a ratio of 0.775 ± 0.022, LASIK had a ratio of 0.839 ± 0.020, and SMILE had a ratio of 0.709 ± 0.046. PRK and LASIK were significantly different from one another, as were LASIK and SMILE.
Notes: *Significance at p = 0.031, **Significance at p = 0.009.
Abbreviations: ΔSEQ, change in spherical equivalent; ΔK, change in keratometry.

K1 & K2 post op 35 – 48

Excimer Ablation Simulator 90	
Prof. Leonardo Mastropasqua	
Cognome Paziente	x
Nome Paziente	x
OD/OS	OD
PRK/LASIK	LASIK
Zona Ottica (mm)	7,00
Sfera (D)	-6,50
Cilindro (D)	0,00
Pachimetria Pre-Op (µm)	530
Spessore Flap (µm)	120
Stroma Residuo Post-Op (µm)	NON DISP
Ablazione (µm)	118

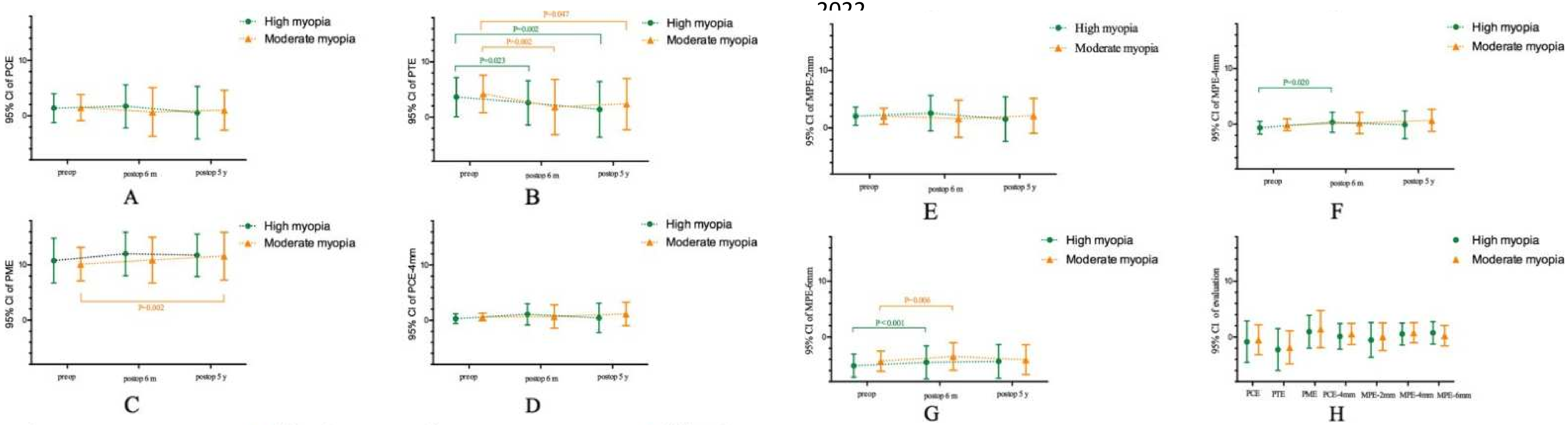
Excimer Ablation Simulator 90	
Prof. Leonardo Mastropasqua	
Cognome Paziente	x
Nome Paziente	x
OD/OS	OD
PRK/LASIK	PRK
Zona Ottica (mm)	7,00
Sfera (D)	-6,50
Cilindro (D)	0,00
Pachimetria Pre-Op (µm)	530
Spessore Flap (µm)	
Stroma Residuo Post-Op (µm)	426
Ablazione (µm)	104

Smile Lenticule Simulator	
Prof. Leonardo Mastropasqua	
Cognome Paziente	x
Nome Paziente	x
OD/OS	OD
Zona Ottica (mm)	7,00
Sfera (D)	-6,50
Cilindro (D)	0,00
Pachimetria Pre-Op (µm)	530
Spessore Cap (µm)	
Stroma Residuo Post-Op (µm)	394
Spessore Lenticolo (µm)	136

SMILE: Posterior Elevation at 5 years

- MODERATE MYOPIA: -300 to -6.00 D (n=40)
- HIGH MYOPIA: -6.00 to -9.00 D (n=40)

Zhao Y, Lin X, Chen Z, Zhou X. Five-year stability of posterior corneal surface after small incision lenticule extraction for high myopia. BMC Ophthalmol. 2022

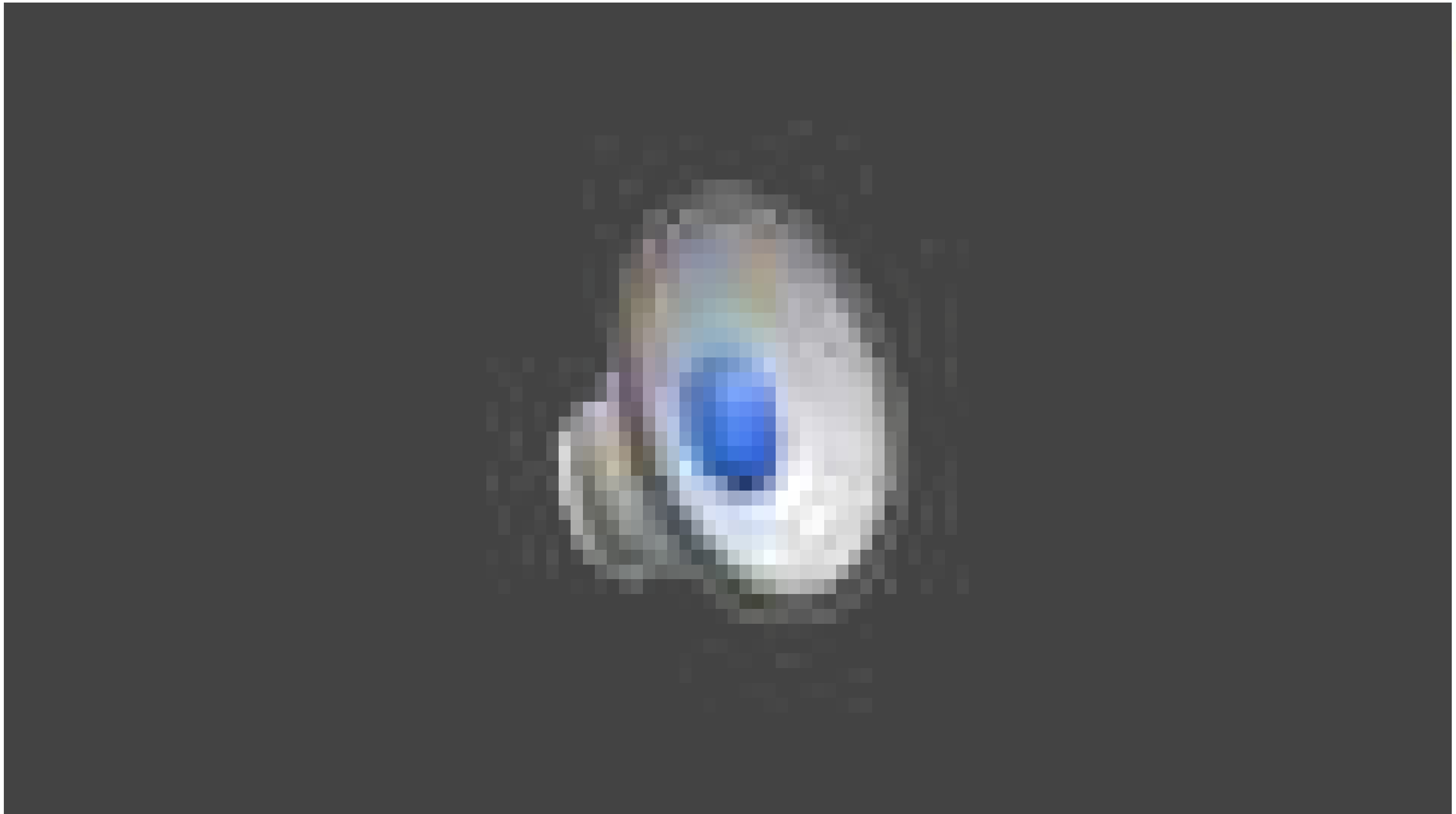


SMILE causes **NO PROTRUSION** in posterior corneal surface for correction of high myopia at the follow-up visit of 5 years.

SMILE in low myopia: myth or reality?

Weighted average of the above studies			294	3–12 months		SE −2.69 D; sphere −2.49 D; cylinder −0.4 D	SE −0.07D; sphere 0.25 D; cylinder −0.34 D	88.7	99.3	100	91.45	99.55	0.94	3.7	0	1.02
Present SMILE study	Correction of low myopia with SMILE	VisuMax 500-kHz femtosecond laser	50 (50 patients)	3 months	Attempted SE ≤ −3.5 D; cylinder ≤ −1.5 D; CDVA ≥ 20/20	SE −2.75 ± 0.63 D (range −1.25 to −3.5 D); sphere −2.47 ± 0.64 D (range −1 to −3.25 D); cylinder −0.56 ± 0.42 D (range: 0 to −1.5 D)	SE 0.02 ± 0.28 D; sphere 0.14 ± 0.30 D; cylinder −0.24 ± 0.21 D	96	100	100	88	98	0.96	2	2	1.05

SMILE: small incision lenticule extraction; PRK: photorefractive Keratectomy; UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; SE: spherical equivalent; D: diopter; n/r: not reported.



Clinical outcomes of small incision lenticule extraction versus advanced surface ablation in low myopia

Suphi Taneri[1,2], Saskia Kießler[1], Anika Rost[1], Tim Schultz[2] and H Burkhard Dick[2]

EJO European Journal of Ophthalmology
European Journal of Ophthalmology 1–9

SMILE for low myopia was found to be **safe and effective** with **outcomes similar to** those obtained with **ASA** while offering a **quicker visual recovery**.

Hyperopic SMILE: what do we know?

TABLE F
Literature Review of Hyperopic LASIK Studies

First Author	Year	N [Eyes]	Technique	Preop SEQ [D]	Age [Years]	Timepoint	Accuracy: Mean ± SD [Range]	Accuracy: ± 0.50D	Accuracy: ± 1.00D	CDVA Preop: ≤20/20	UDVA: ≤20/20	UDVA: ≤20/40	Safety: 1 line	Safety: ≥2 lines
Sekundo[1]	2018	39	FLEx	+1.96 ± 1.04 [+0.63 to +4.50]	49 [27 to 56]	9 months	-0.40 ± 0.61 [-1.50 to +0.75]	70	89	50	6	88	10	0.0
Pradhan[2]	2019	93	SMILE	+5.61 ± 1.21 [+1.00 to +6.90]	27 ± 6 [21 to 50]	12 months	-0.22 ± 0.88 [-2.20 to +3.00]	53	76	24	27	95	16	0.0
Current Study	2022	374	SMILE	+3.49 ± 1.38 [0.75 to +6.50]	39 ± 12 [18 to 69]	12 months	+0.12 ± 0.56 [-1.75 to +3.00]	81	93	85	68	100	11	1.2
Reinstein[3]	2009	258	MEL 80 Hansatome zero compression	+2.54 ± 1.16 [+0.25 to +5.75]	56 [44 to 66]	12 months	+0.09 ± 0.48	79	95	94	81	98	14	0.5
FDA[4]	2016	160	MEL 80	2.70 ± 1.07 [+0.88 to +6.38]	47 ± 9 [22 to 69]	12 months	-0.023 ± 0.541	78	92	-	67	97	-	0.3
Reinstein[5]	2013	30	MEL 80 Hansatome zero compression Small angle kappa	+4.15 ± 1.10 [+2.50 to +5.88]	51 ± 9 [22 to 60]	12 months	+0.40 ± 0.78 [-1.38 to +2.29]	53	77	93	80	100	20	0.0
Reinstein[5]	2013	30	MEL 80 Hansatome zero compression Large angle kappa	+4.33 ± 0.89 [+2.75 to +5.75]	43 ± 12 [18 to 60]	12 months	+0.45 ± 0.74 [-1.13 to +1.87]	47	70	93	77	100	20	0.0
Alio[6]	2013	27	Intralase & 500kHz Amaris excimer OZ 6.2-6.9mm	+6.33 ± 0.83 [+5.00 to +8.50]	Not reported	6 months	+0.55 ± 1.09 [-0.50 to +3.38]	-	70	57	44	92	8	0.0
Leccisotti[7]	2014	800	Ziemer LDV Z2 Technolas 217P	+3.41 ± 1.16 [+1.00 to +6.50]	41 ± 9	9 months	-0.06 ± 0.26	74	88	-	-	95	7.3	0.3
Plaza-Puche[8]	2015	86	Intralase & 500kHz Amaris excimer OZ 6.3-7.0mm	+2.66 ± 1.68 [-1.38 to +5.75]	40 ± 10 [23 to 64]	36 months	+0.40 ± 0.65 [-1.63 to +2.00]	70	85	77	76	99	6.2	1.2
Amigo[9]	2015	24	Wavelight Allegretto 400 Hz & Hansatome Wavefront Optimized	+3.66 ± 0.61 [+2.75 to +5.00]	39 ± 9 [20 to 49]	6 months	+0.08 ± 0.56 [-0.75 to +1.25]	57	96	79	67	92	21	4
Amigo[9]	2015	16	Wavelight Allegretto 400 Hz & Hansatome Aspheric Customized Profile	+4.05 ± 0.59 [+2.75 to +5.13]	39 ± 9 [20 to 49]	6 months	+0.21 ± 0.44 [-0.50 to +1.00]	87	100	81	81	100	12	0.0
Antonios[10]	2015	53	Amaris M2	+2.25 ± 1.06 [+0.75 to +5.00]	45 ± 12 [19 to 61]	6 months	+0.22 ± 0.75 [-1.25 to +1.75]	43	72	90	85	92	0.0	0.0
Antonios[10]	2015	72	Amaris LDV femto	+2.24 ± 0.95 [+0.50 to +4.75]	46 ± 10 [18 to 66]	6 months	-0.32 ± 0.76 [-2.13 to +1.50]	65	90	96	87	100	0.0	0.0
de Ortueta[11]	2017	38	Amaris Carriazo-Pendular	+4.07 ± 0.90 [+2.38 to +5.75]	40 ± 10 [18 to 57]	6 months	+0.28 ± 0.58	61	96	33	18	84	8	8
Plaza-Puche[12]	2016	51	Intralase & Amaris OZ 6.2-6.9mm	+6.33 ± 0.83 [+5.00 to +8.50]	33 ± 9 [21 to 54]	6 months	+0.50 ± 1.06 [-0.50 to +3.38]	-	71	92	53	98	11	6.5
Arba-Mosquera[13]	2016	46	AMARIS 750S Carriazo-Pendular	+3.64 ± 1.42 [+1.27 to +6.18]	45 ± 11 [18 to 62]	6 months	+0.19 ± 0.61	61	93	52	30	85	13	6.5
Reinstein[14]	2017	785	MEL80 VisuMax or Hansatome zero compression	+4.52 ± 0.84 [+2.00 to +6.96]	50 ± 12 [18 to 70]	24 months	+0.30 ± 0.85 [-3.63 to +4.25]	50	77	100	62	96	22	0.5
El-Naggar[15]	2017	20	Wavelight FS200 Wavelight EX500	+2.55 ± 1.17 [+1.00 to +6.00]	47 ± 4 [42 to 56]	12 months	+0.10	95	100	85	90	100	0.0	0.0
Garcia-Gonzalez[16]	2018	76	Esiris Intralase 60kHz With mitomycin-C	+2.71 ± 1.30 [+2.00 to +6.25]	45 ± 1 [41 to 55]	6 months	+0.18	87	97	-	71	100	6.6	2.6
Garcia-Gonzalez[16]	2018	76	Esiris Intralase 60kHz No mitomycin-C	+2.90 ± 1.10 [+2.00 to +6.25]	44 ± 1 [41 to 55]	6 months	+0.42	75	91	-	54	100	9.2	6.6
Reinstein[17]	2018	1,350	MEL 90 VisuMax	+2.77 ± 1.34 [+0.13 to +6.50]	54 ± 11 [21 to 75]	12 months	-0.11 ± 0.55 [-2.13 to +2.50]	73	93	93	75	99	17	0.6
Gauthier-Fournet[18]	2019	146	Amaris 750S Moria	+6.64 ± 1.01 [+5.25 to +9.50]	-	6 months	-0.06 ± 0.83	66	87	86	60	97	10	0.0
Moshirfar[19]	2021	189	EX500 Intralase 150kHz	+1.79 ± 0.90 [+0.13 to +4.38]	46 ± 11 [18 to 72]	12 months	-0.46 ± 0.79 [-2.13 to +1.25]	78	96	90	69	97	4.8	1.1
Tăbăcaru[20]	2021	593	MEL 80 VisuMax	+4.08 ± 1.57 [+1.50 to +6.00]	33 ± 8 [22 to 49]	12 months	+0.50 ± 0.83	49	74	56	59	96	1.0	0.0

FLEx = femtosecond lenticule extraction; LASIK = laser in situ keratomileusis; SMILE = small incision lenticule extraction

- **Only 2 studies** (1 FLEx & 1 SMILE)
- **Comparable accuracy** vs LASIK
- **Comparable refractive target post surgery** vs LASIK
- **Comparable safety** vs LASIK

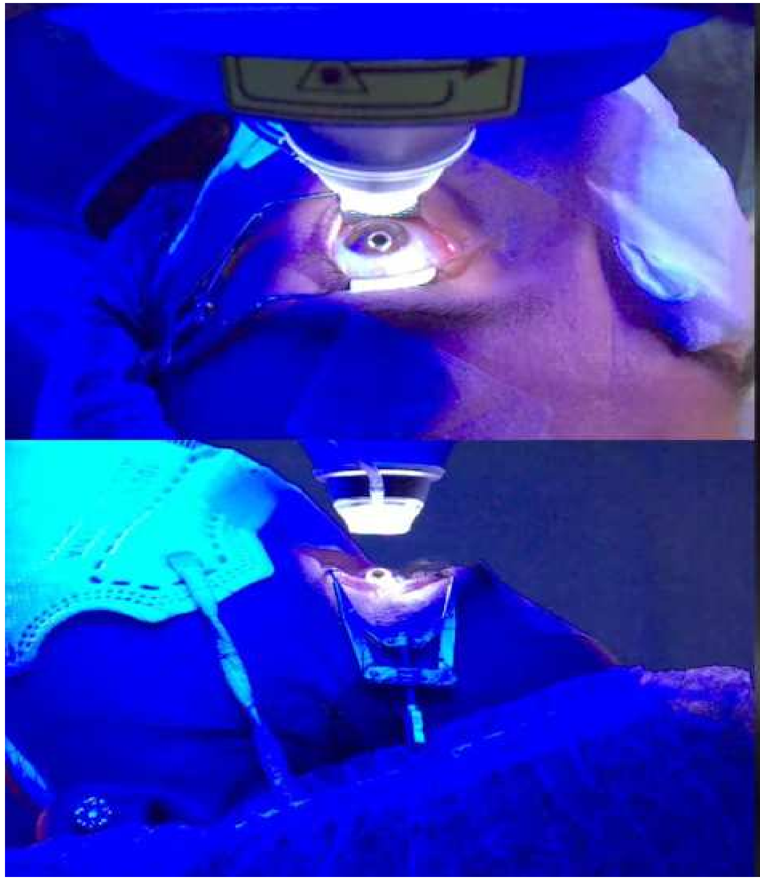
Challenge of Hyperopic SMILE

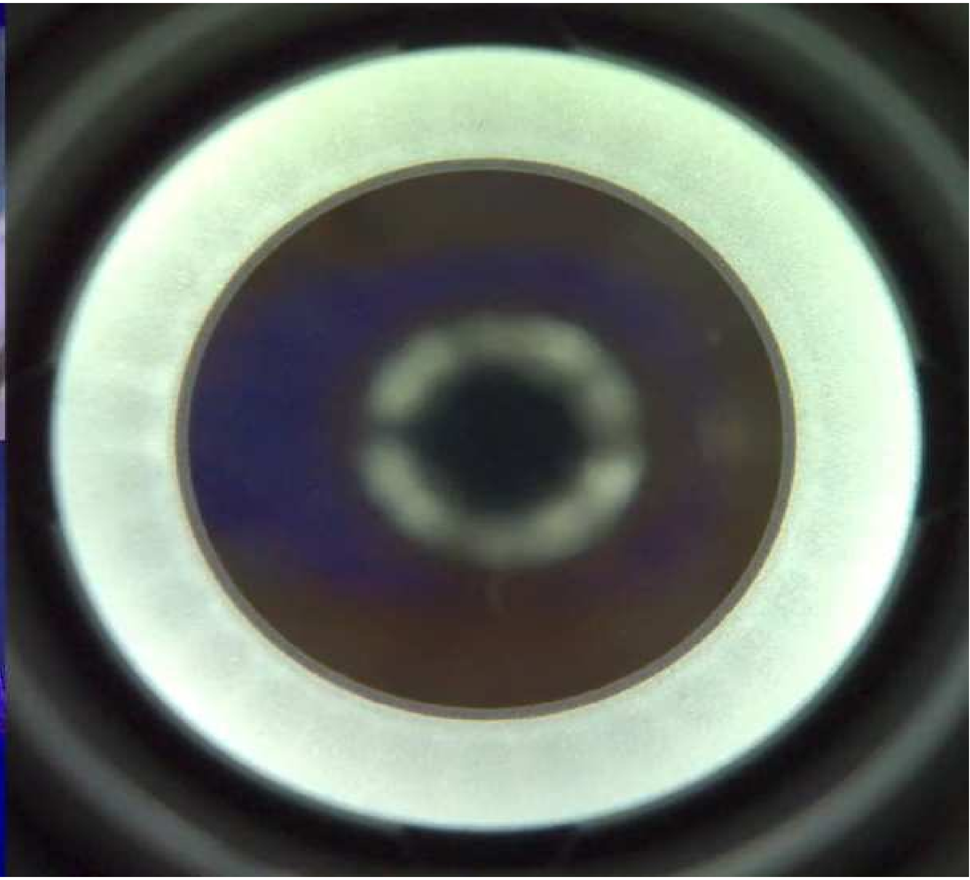
- **Centration is crucial**
- **Large Optical Zone required**
- **Larger volume of tissue removed** (vs. myopia)
- **Hyperopic astigmatism even more challenging (cyclotorsion compensation)**

New Technologies in SMILE surgery: SMILE Pro

Latest innovation in Femtolaser surgery:
Visumax 800 ® (Carl Zeiss, Germany)

Laser type	Femtosecond laser
Available treatment options	Flap, SMILE® pro, CIRCLE, ICR, Keratoplasty[1]
Digital assistant systems	Centration aid CentraLign® Cyclotorsion adjustment OcuLign® import of VISULYZE® user nomograms
Optical data	
Maximum laser repetition frequency	2 MHz
Wavelength	1043 nm
Pulse duration	220–580 fs





Extremely reduced laser sculpting times (<u>only 10 seconds to carve a SMILE lenticule</u>) thanks to a 2 MHz laser impulse repetition rate = reduction of intraoperative suction

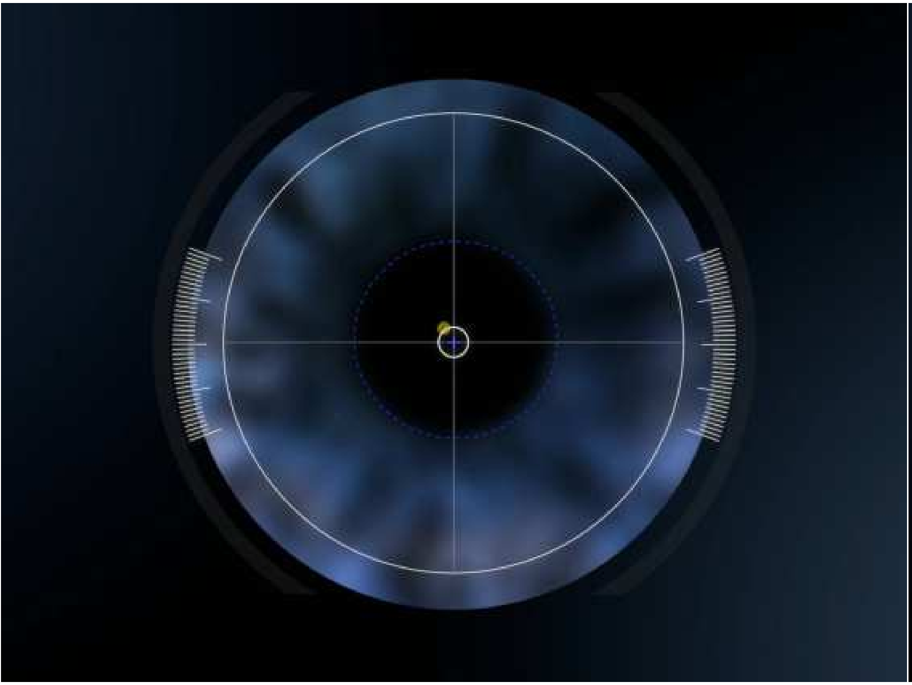
Refractive outcomes of small lenticule extraction (SMILE) Pro® with a 2 MHz femtosecond laser

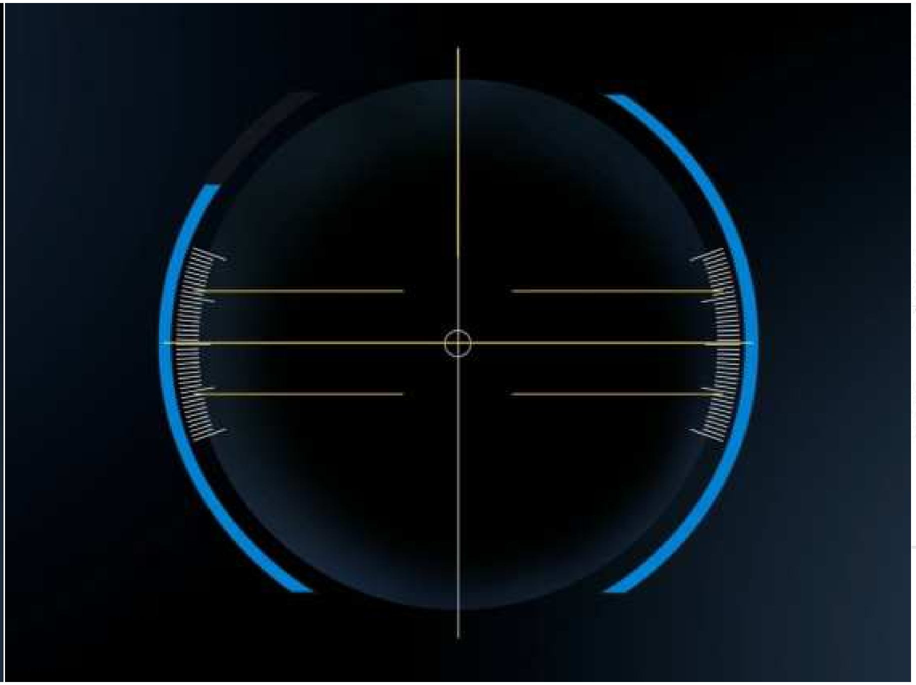
Amr Saad · Karsten Klabe · Mücella Kirca · Florian A. T. Kretz · Gerd Auffarth · Detlev R. H. Breyer Int Ophthalmol (2024) 44:52

Conclusion The SMILE Pro® is a safe, efficient, and predictable procedure for the treatment of myopia and myopic astigmatism, with comparable results of conventional SMILE surgery. High myopic eyes achieve better results than low and moderate myopia. No complications were recorded in our patients.

New Technologies in SMILE surgery: SMILE Pro

Improved control systems for ciclotorsion and centration

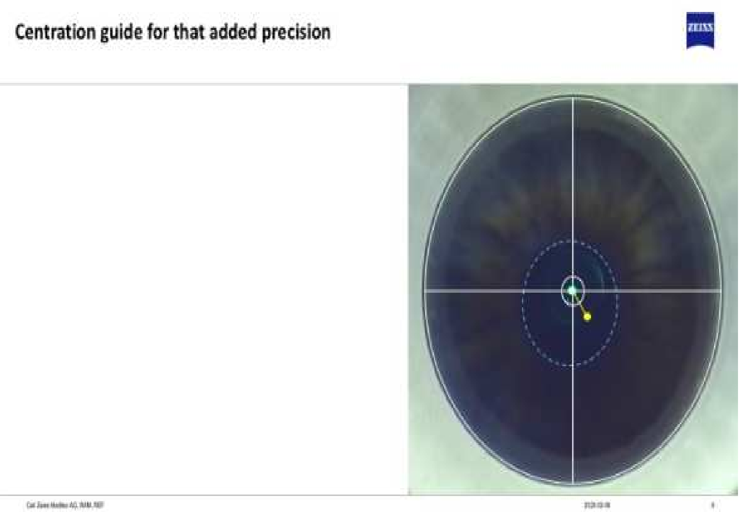




However, there is the potential for workflow improvement and greater consistency between surgeons by incorporating automated centration and cyclotorsion control tools into the software. The VISUMAX 800 CentraLign system allows the (x,y) location of the corneal vertex to be manually entered into the software, and the surgeon is guided by visual overlays on the treatment monitor to align the eye.

Refractive and Visual Outcomes of SMILE for Compound Myopic Astigmatism With the VISUMAX 800 [*J Refract Surg*. 2023;39(5):294-301.]

Dan Z. Reinstein, MD, MA(Cantab), FRCOphth; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab), PhD; Joseph G. Potter, BMedSc; Ruchi Gupta, MOptom; Rainer Wiltfang, MD

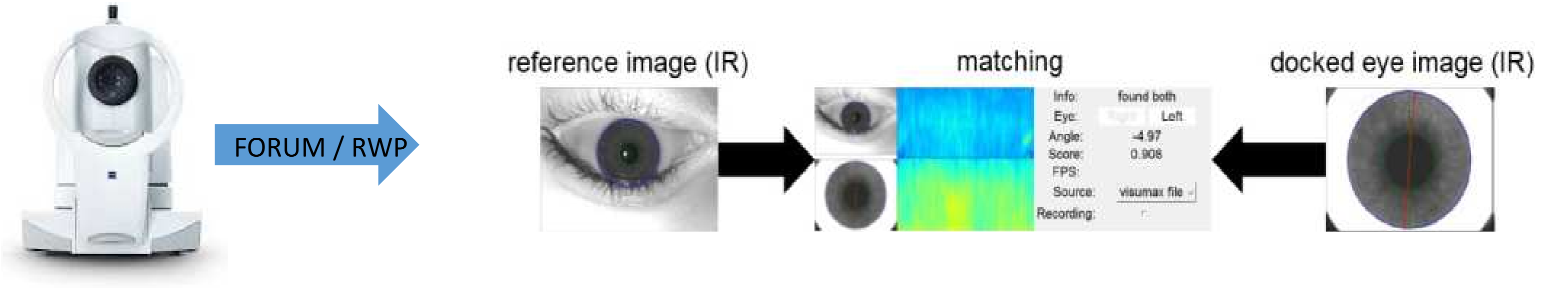


CentraLign ® centration aid

- Easy vertex centration
- Vertex position entered in treatment planning
- Centration before docking

OcuLign ® cyclotorsion adjustment

- Using IOLMaster 700 iris image
- Electronic alignment of the treatment pattern

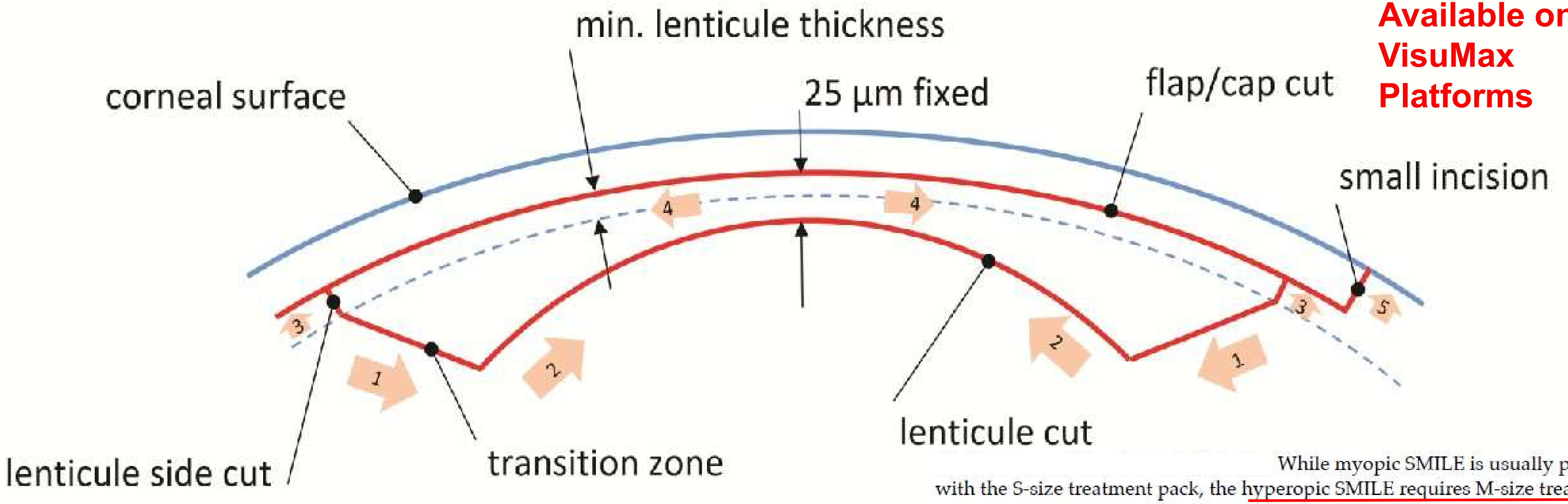


- Pupil edge (dotted blue circle)
- Pupil center (blue dot)
- Centration target (yellow dot)
- Centration guide (yellow line)

Hyperopic SMILE: the future is now!

CE Mark 2024

Available on both VisuMax Platforms



Lenticule diameter 6,3 mm + transition zone 2 mm

While myopic SMILE is usually performed with the S-size treatment pack, the hyperopic SMILE requires M-size treatment pack due to the large size of the lenticule (usually 8.3 mm). The combination bares an increasing risk of conjunctival aspiration and suction loss. Furthermore, this risk is increased by the longer laser time, which is approximately 35 seconds with the 500 Hz FS laser.

The solution for hyperopic lenticule extraction procedure with SMILE is the 2 MHz VisuMax 800 (Figure 2), which is 3x faster, which means that a hyperopic lenticule extraction takes 12 seconds with this laser platform. In addition, the new laser comes with centration and cyclotorsion assisting tools, which are of imperative significance for hyperopic treatments.

SMILE for Hyperopia With and Without Astigmatism: Results of a Prospective Multicenter 12-Month Study

Dan Z. Reinstein, MD, MA(Cantab), FRCOphth; Walter Sekundo, MD, PhD; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab), PhD; Pavel Stodulka, MD; Sri Ganesh, MD; Beatrice Cochener, MD, PhD; Marcus Blum, MD, PhD; Yan Wang, MD, PhD; Xingtao Zhou, MD, PhD

[*J Refract Surg*. 2022;38(12):760-769.]

Open Access

SMILE for Hyperopia With and Without Astigmatism: Results of a Prospective Multicenter 12-Month Study

JRS 2022

Dan Z. Reinstein, MD, MA(Cantab), FRCOphth; Walter Sekundo, MD, PhD; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab), PhD; Pavel Stodulka, MD; Sri Ganesh, MD; Beatrice Cochener, MD, PhD; Marcus Blum, MD, PhD; Yan Wang, MD, PhD; Xingtao Zhou, MD, PhD

- 374 eyes of 199 patients

- Mean +3.20 ± 1.48 D (range: +0.25 to +6.50 D): **81% of eyes treated were within ±0.50 D and 93% of eyes were within ±1.00**

- safety index of 1.005 at 12 months

- no statistically significant changes in contrast sensitivity.

- High level of **efficacy, predictability, safety, and stability.**

Main issues: **learning curve, interface, centration**

INCLUSION CRITERIA

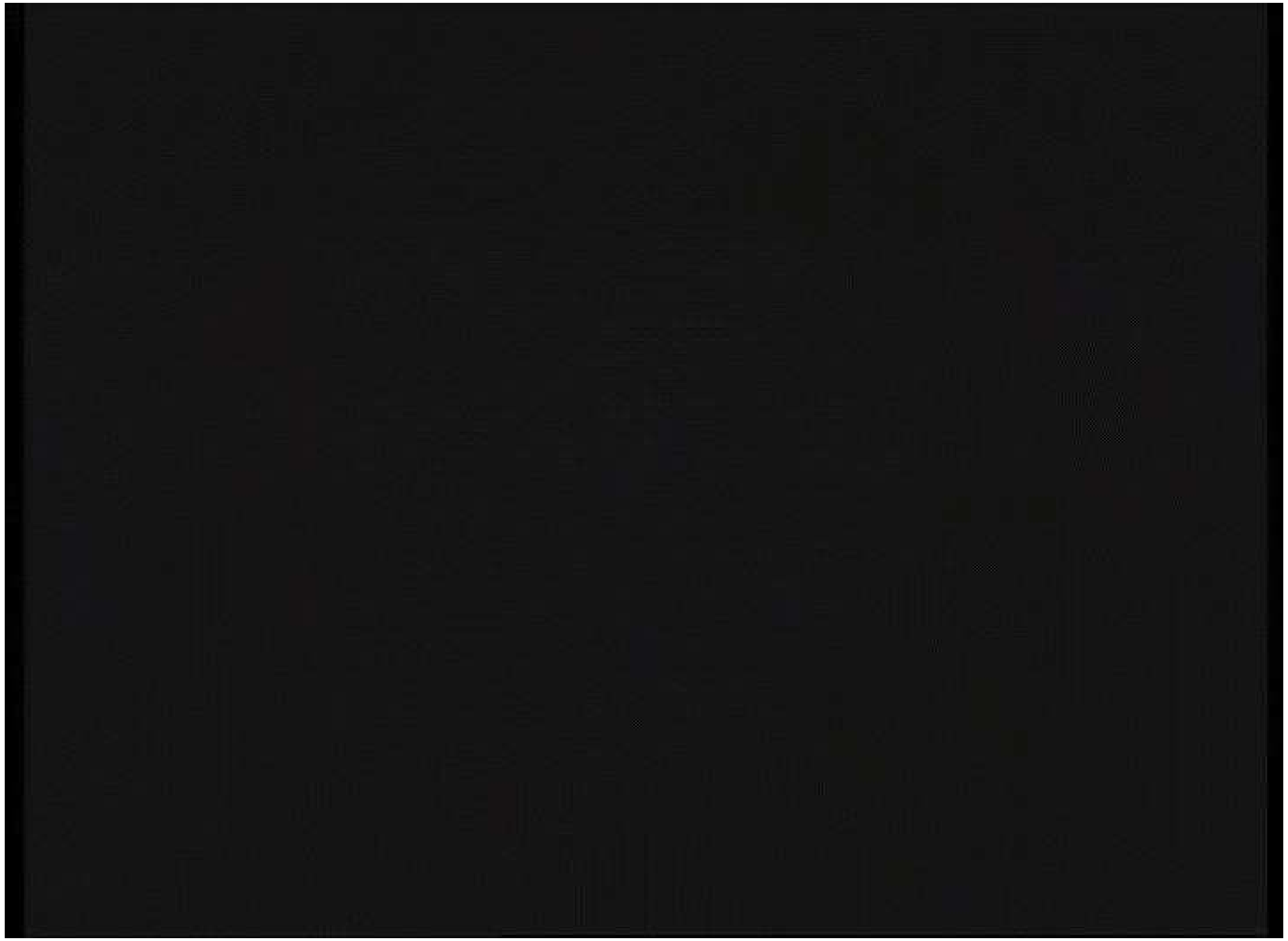
- Hyperopia and/or hyperopic astigmatism
- With no previous corneal surgery
- Hyperopic sphere **≤ 6D**, cylinder **≤ 5D**
- Correction **up to 7D** (on the most hyperopic meridian) with postop Kmax. **51D maximum**
- Preop. BCVA **≥ 0,8**

At this stage, key advantages over LASIK:

- **Better quality of vision** (decentration tolerance and larger OZ
- **Faster recovery**
- **One incision vs. one flap** (hemorrhage, easier interface management

Surgical Challenge

- **Large docking on small eye**
  - Risk of suction loss
  - Chemosis on incision
- **Incision placing and creation**
  - Temporal (+ 2° for security)
  - Narrow margin of dissection between 2 plans (0.2 mm)
- **Large lenticule thinner at center**
  - Delicate dissection: from periphery to center
  - Forceps to maintain the eye recommended
  - Instrument longer and angulated

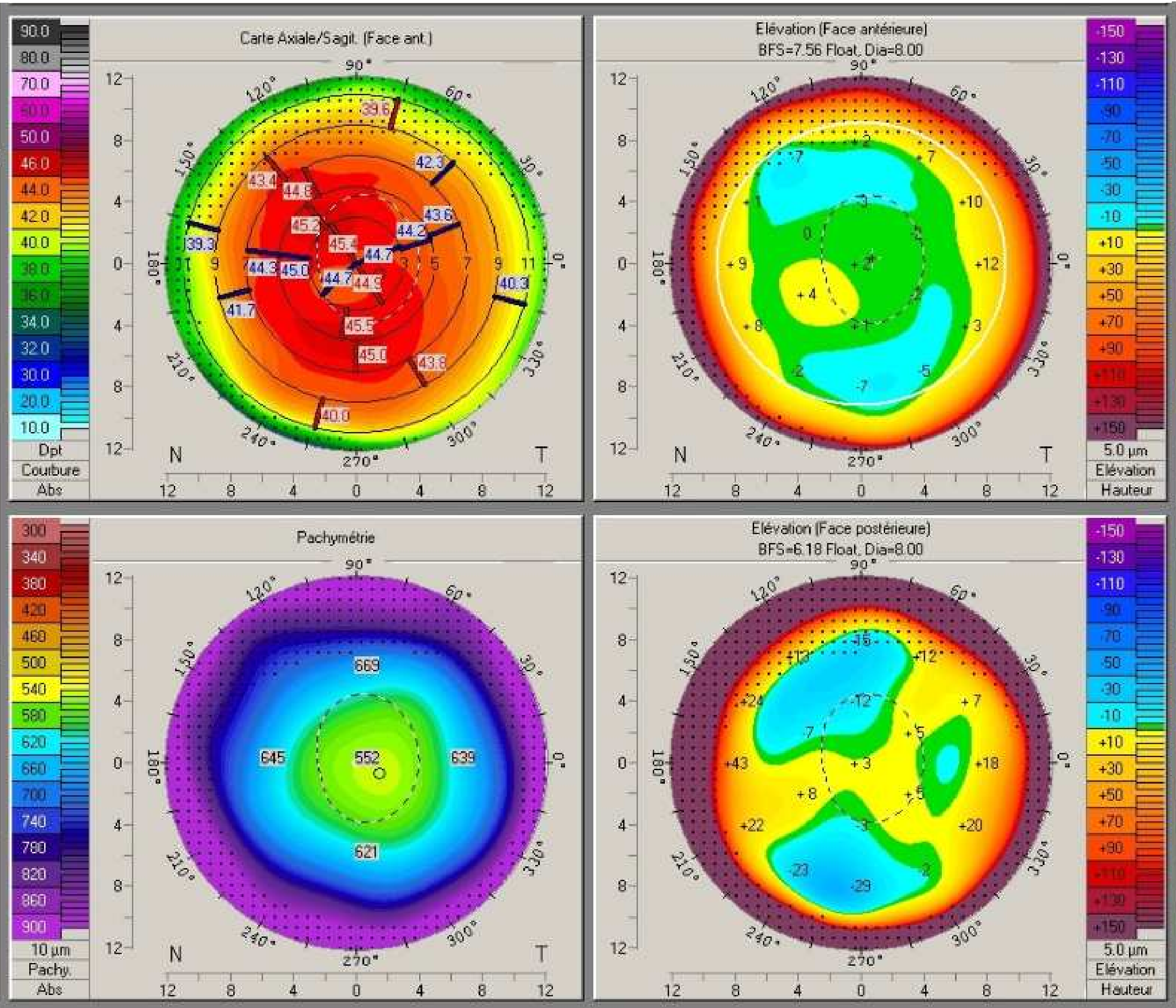


Courtesy of Béatrice COCHENER – LAMARD

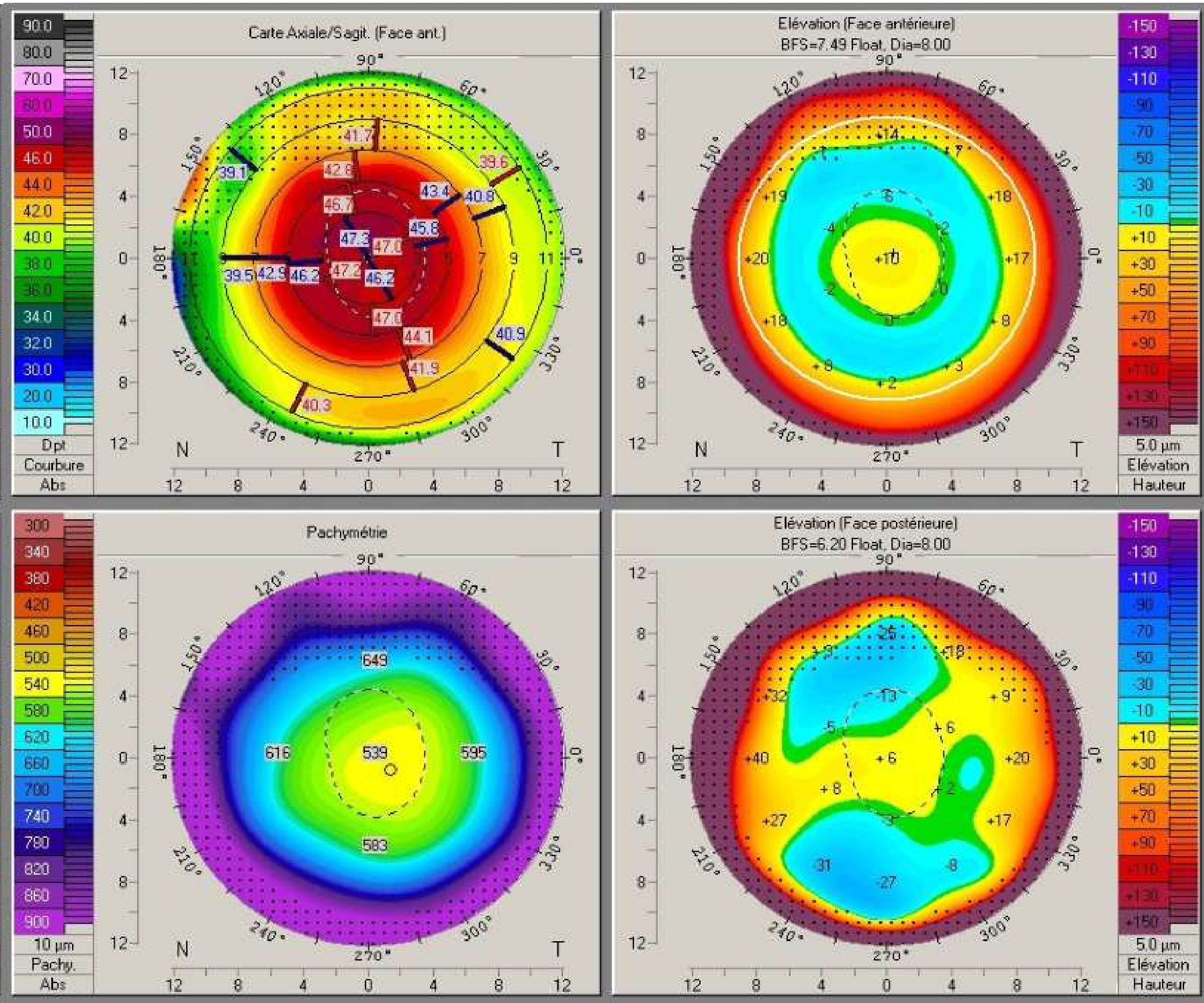
UBO Université de Bretagne Occidentale | Faculté de Médecine & Sciences de la Santé BREST | CHU BREST

Courtesy of Béatrice COCHENER – LAMARD

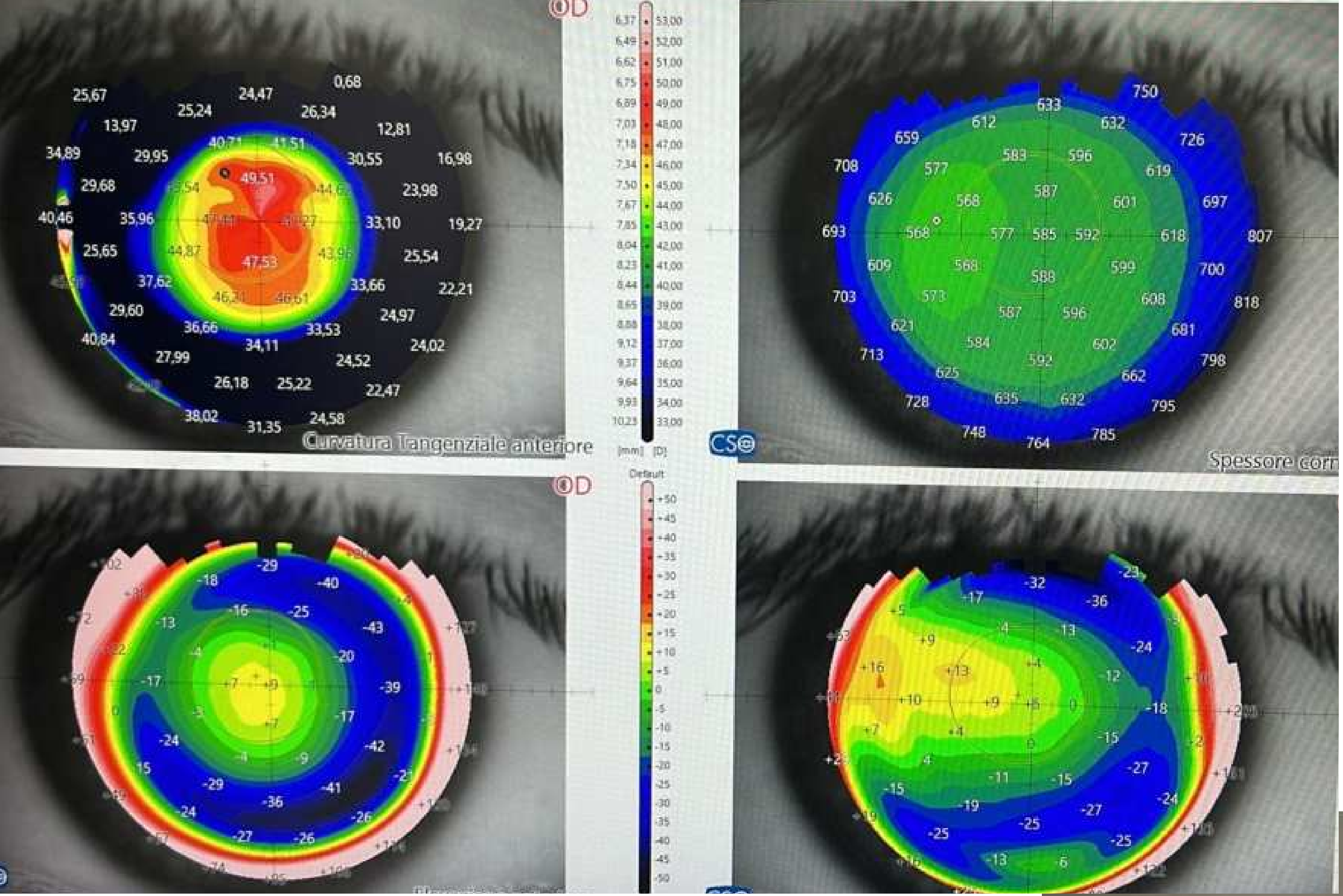
Pentacam OS
Pre



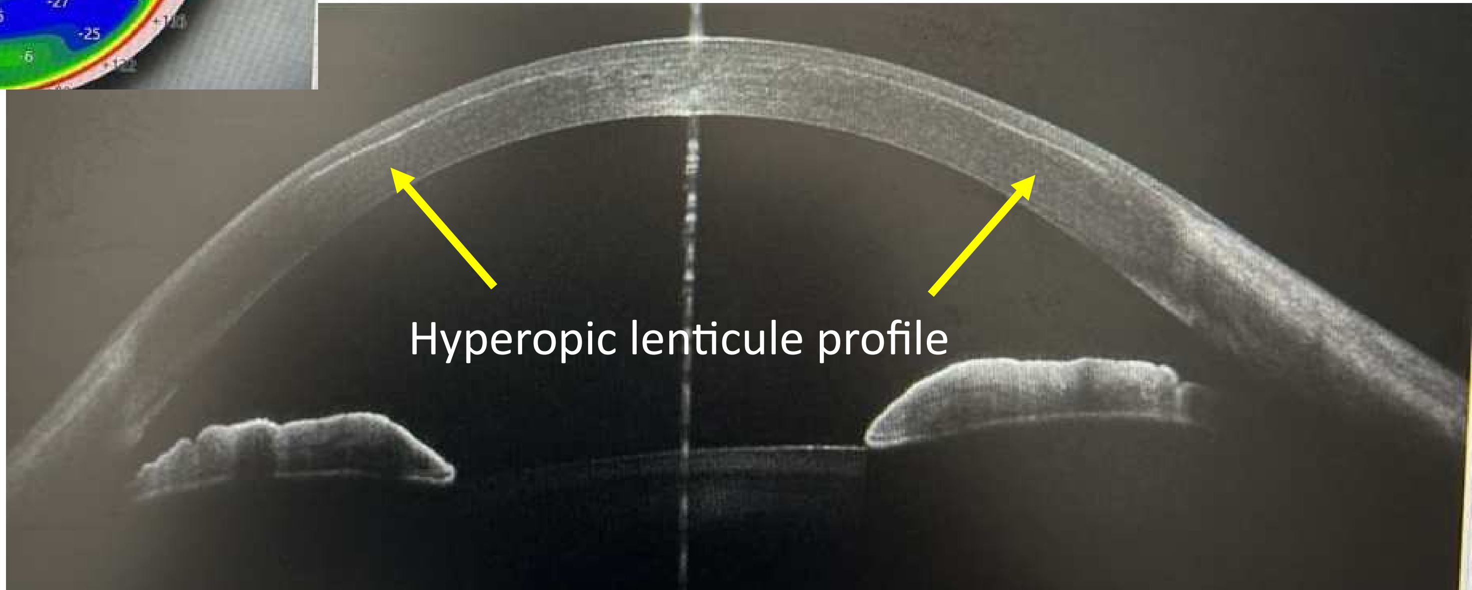
Pentacam OS
1 Month

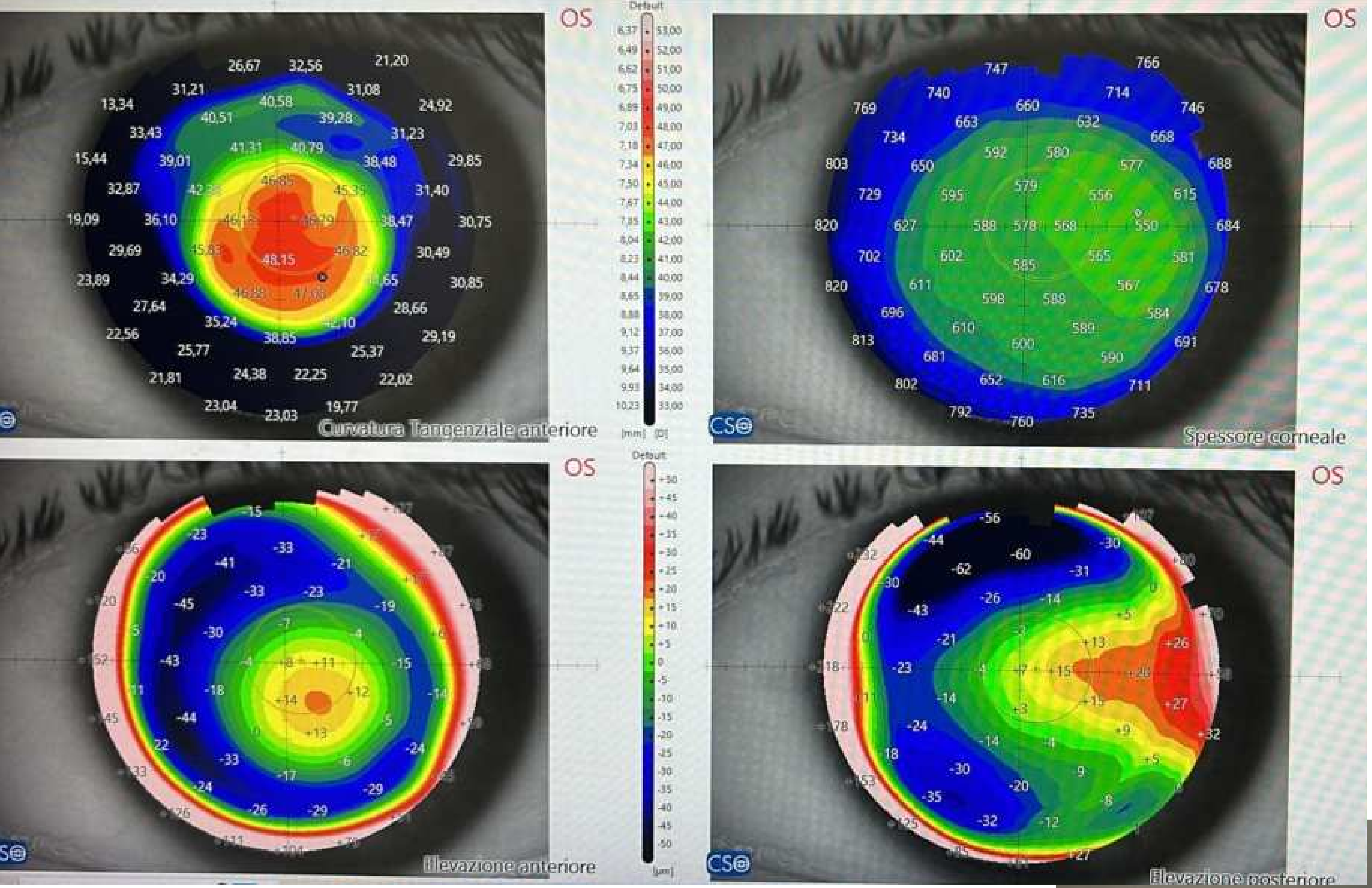


Tomography and ASOCT 1 day after Hyperopic SMILE



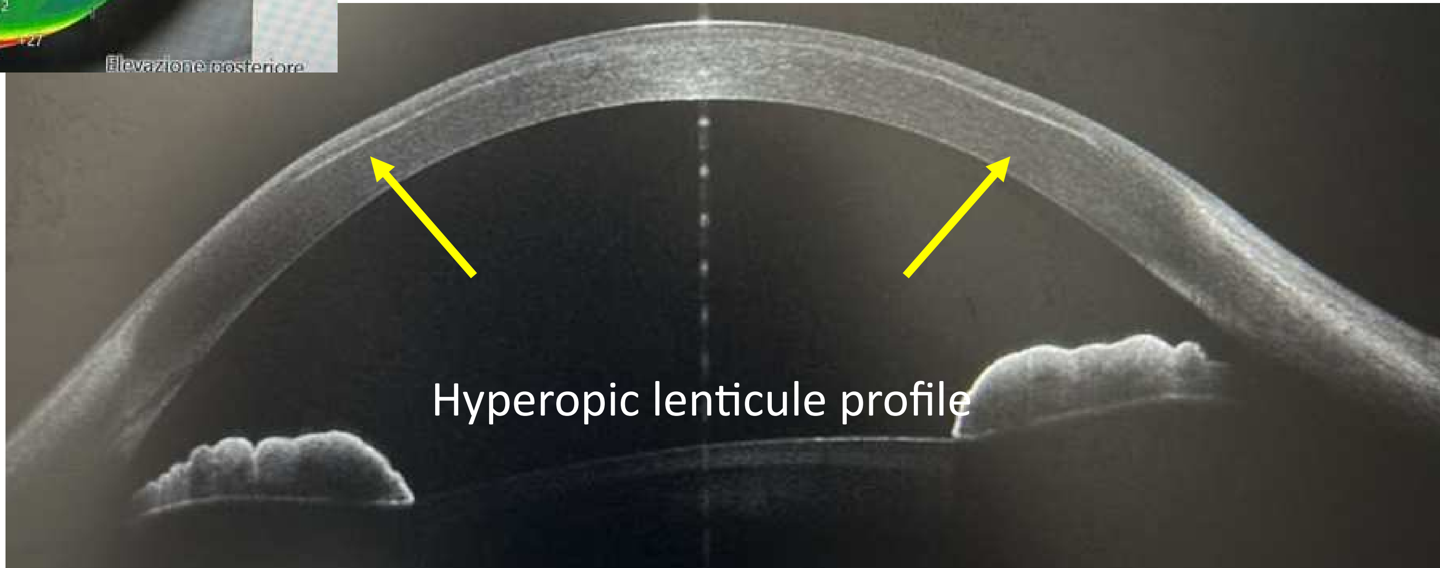
HYPEROPIC SMILE +4.25 + 1 Ax 20





Tomography and ASOCT 1 day after Hyperopic SMILE

HYPEROPIC SMILE +4.50 + 0.50 Ax 140



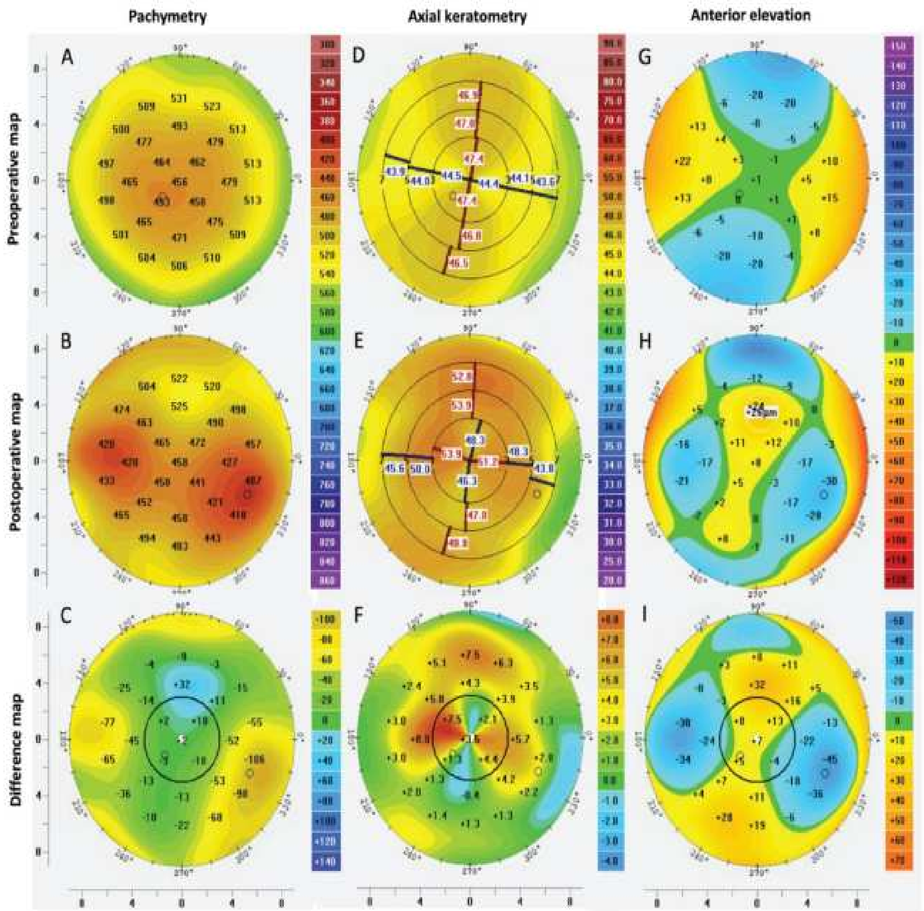
Lenticule manipulation: ASTIGMATISM

Intrastromal Lenticule Rotation for Treatment of Astigmatism Up to 10.00 Diopters Ex Vivo in Human Corneas

Iben Bach Damgaard, MD, Anders Ivarsen, MD, PhD, and Jesper Hjortdal, MD, DMSci

Journal of Refractive Surgery 2019

5.00 D cylinder intrastromal lenticule rotation



Intrastromal Lenticule Rotation for the Treatment of High Astigmatism

Pavel Stodulka, MD, PhD, Jesper Hjortdal, MD, DMSci, and Martin Slovak, ME, PhD

Journal of Refractive Surgery 2020

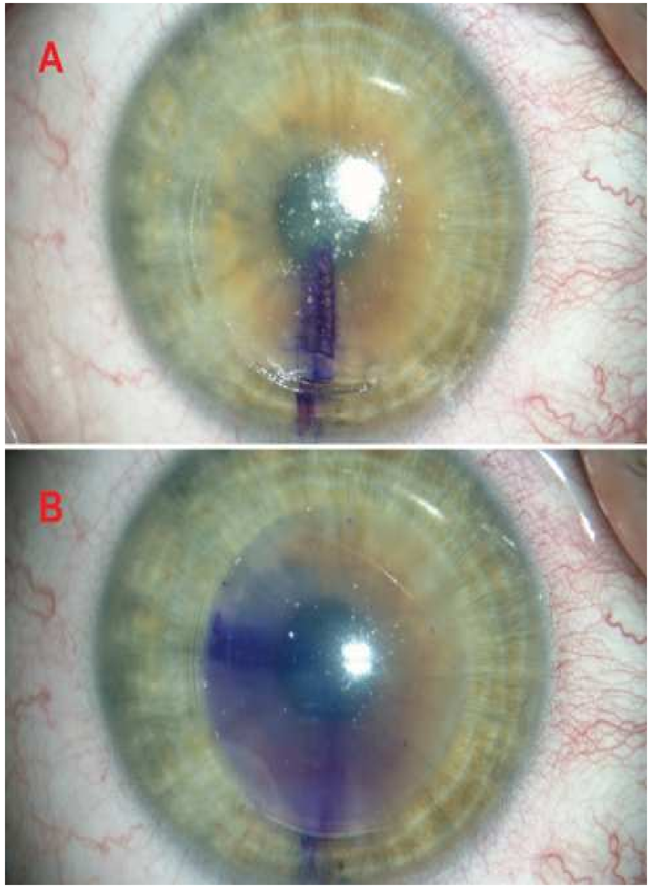
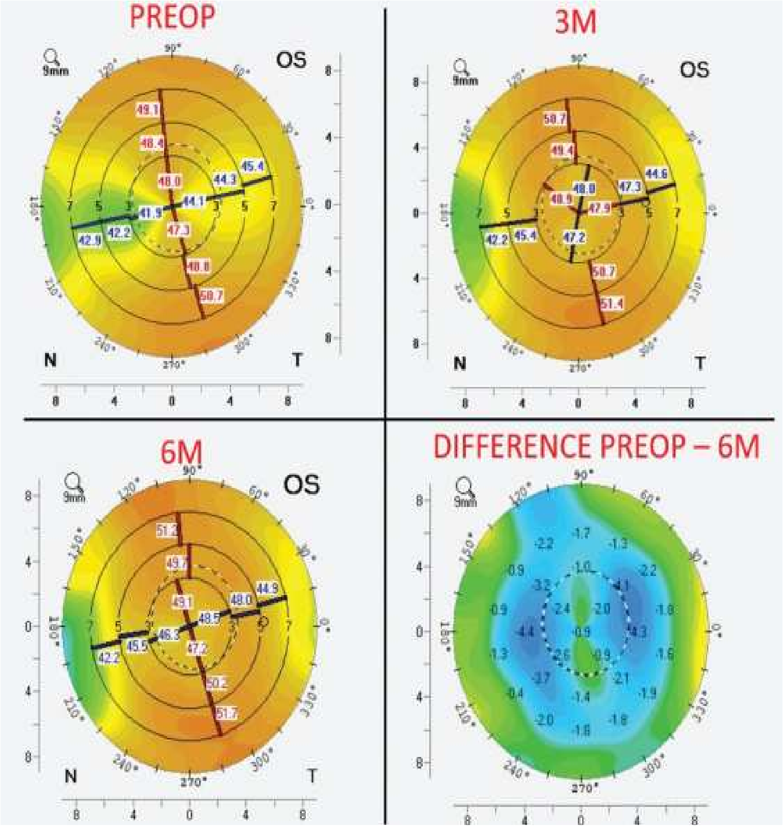


Figure 1. (A) An initial radial mark at both the lenticule and the cap. (B) The lenticule mark perpendicular to the initial cap mark after the 90° lenticule rotation.



KLEx complications overview

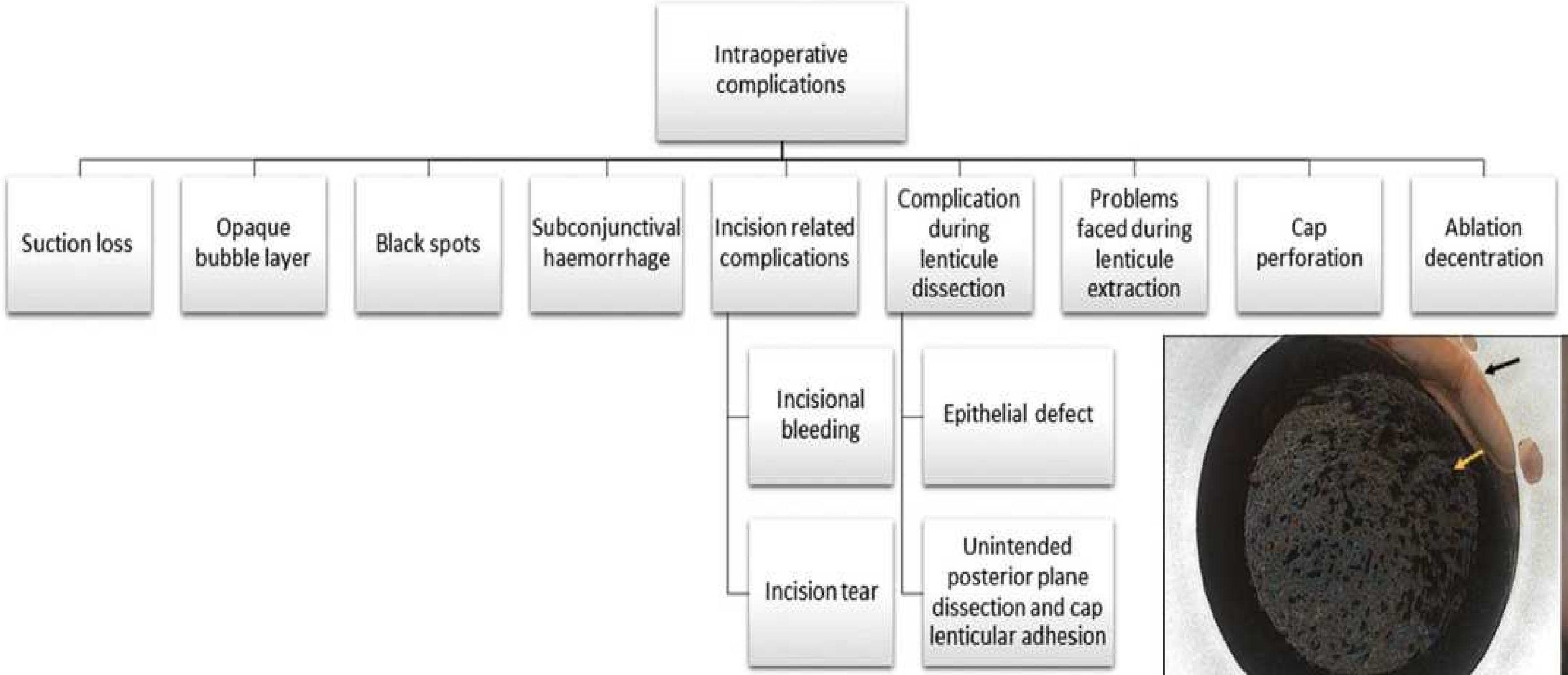


Figure 1: Flowchart of intraoperative complications of SMILE

Review Article

Complications of small incision lenticule extraction

Mohamed Ibrahime Asif[#], Rahul Kumar Bafna[‡], Jodhbir Singh Mehta[1], Jagadesh Reddy[2], Jeewan Singh Titiyal, Prafulla K Maharana, Namrata Sharma

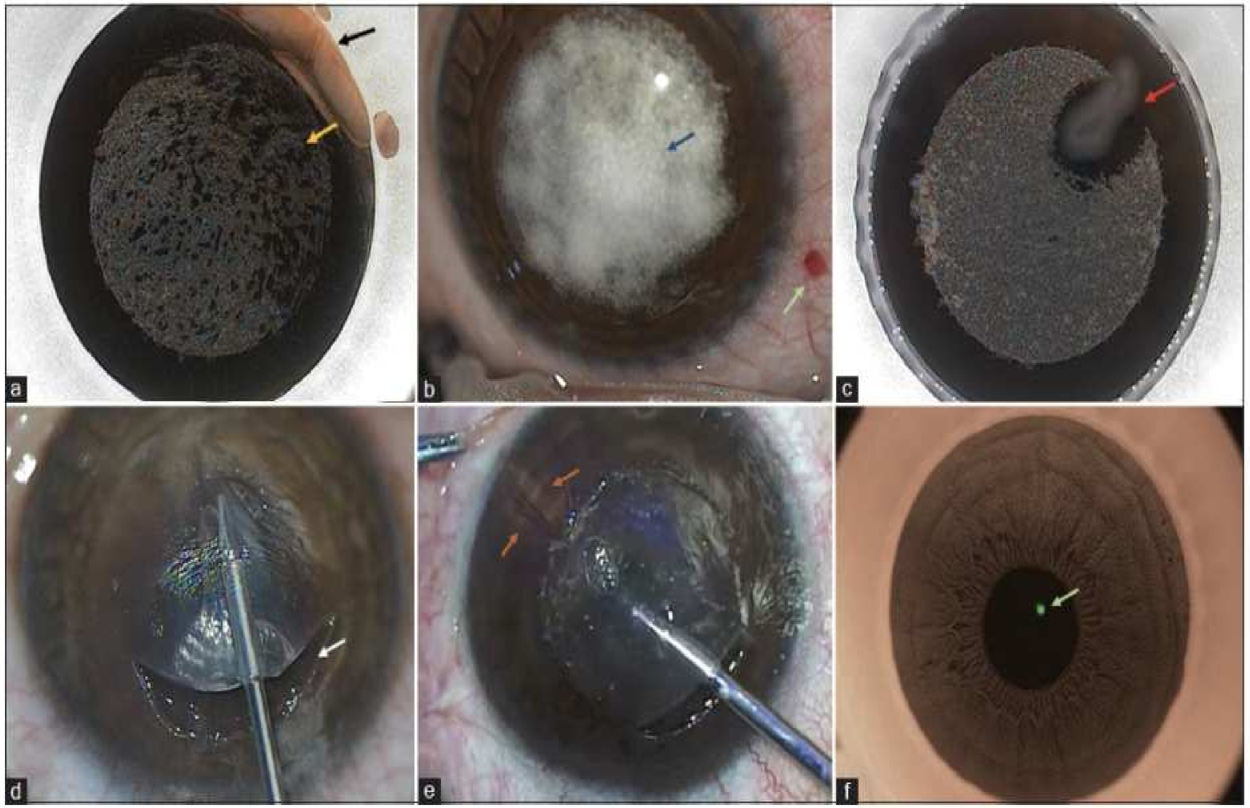
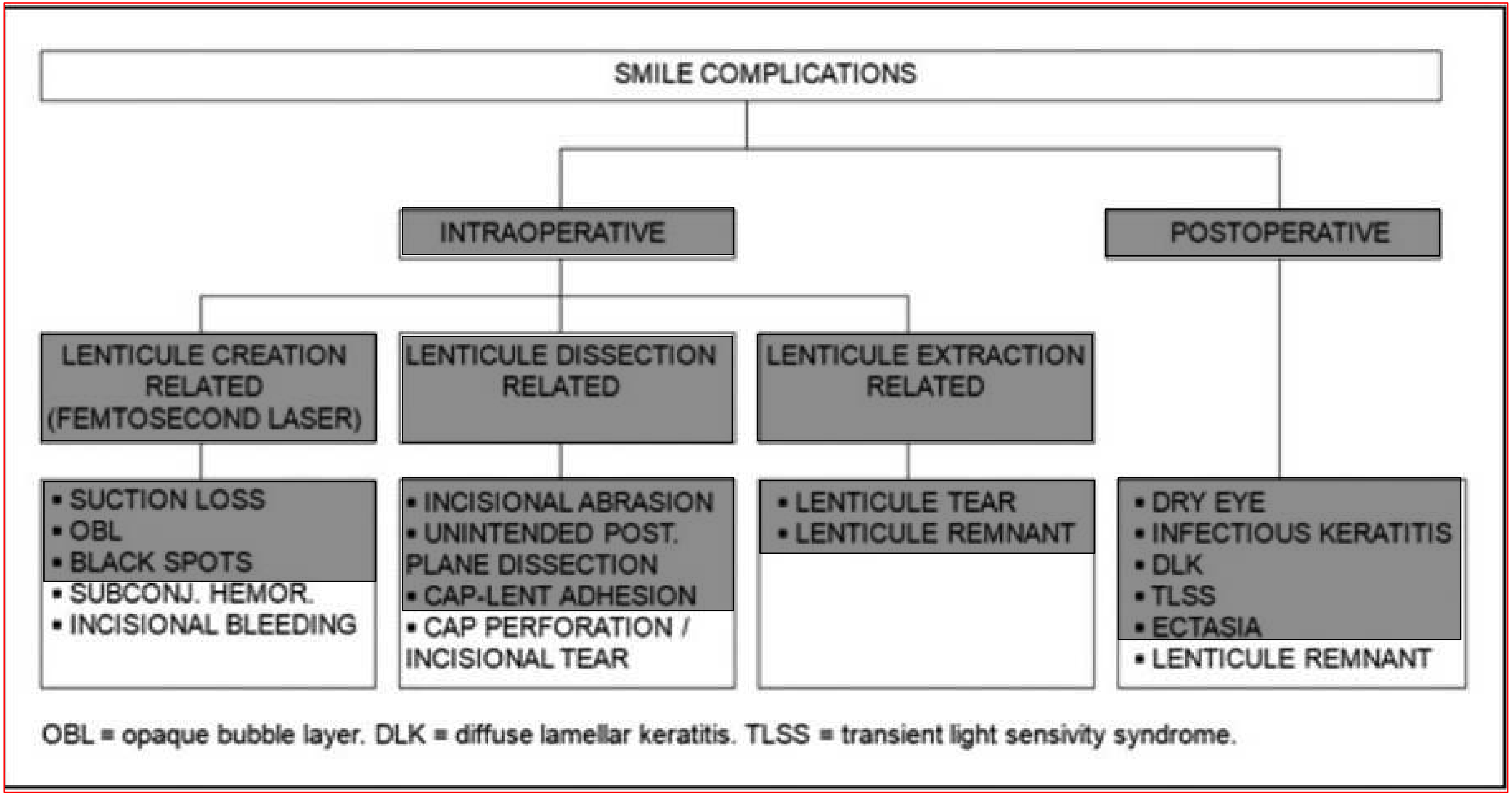


Figure 2: (a) Black spots (yellow arrow) with pseudo suction due to conjunctiva entrapment (black arrow) between the suction cup and cornea (b) OBL (blue arrow) and subconjunctival hemorrhage (green arrow) (c) Black island (red arrow) with cotton fiber between cornea and suction cup (d) Incisional tear (white arrow) (e) Tractional striae (orange arrow) formed in the attempt of pulling adherent lenticule during extraction (f) Decentered coaxial light reflex imaged in infrared mode (green arrow)

Categorical Chart



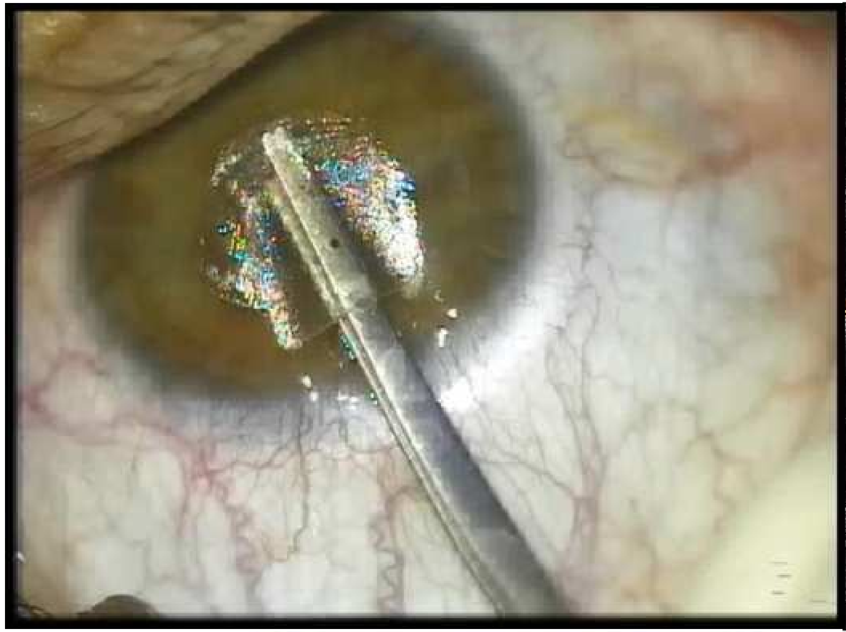
A review of small incision lenticule extraction complications. R.R. Krueger and C.S. Meister. Curr Opin Ophthalmol. 2018.

LENTICULE DIFFICULT EXTRACTION

Incidence: 1.9% [1]- 2.7%[2].

Difficult lenticule extraction in most cases is related to wrong indentification of the first (ANTERIOR) cleavage plane.

It can led to excessive manipulation and eventually remnants after lenticule extraction and resultant irregular astigmatism.



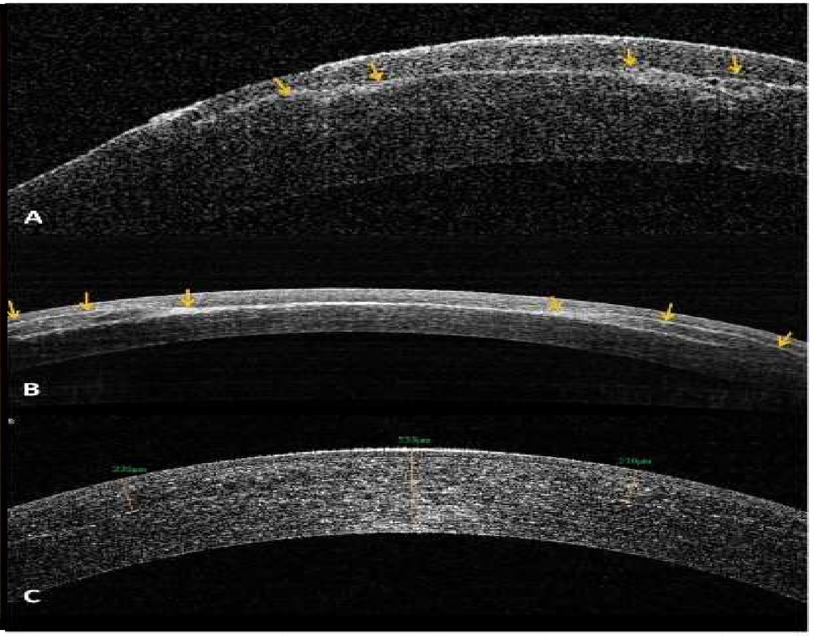


FIGURE 3. A, Posterior stromal damage due to excessive surgical manipulation in a case with difficult lenticule dissection (arrows: posterior stromal damage). B, Partially retained lenticule fragments in a case of SMILE with forceful lenticule extraction (arrows: partially retained lenticule fragments). C, Completely retained intrastromal lenticule in a case of SMILE.

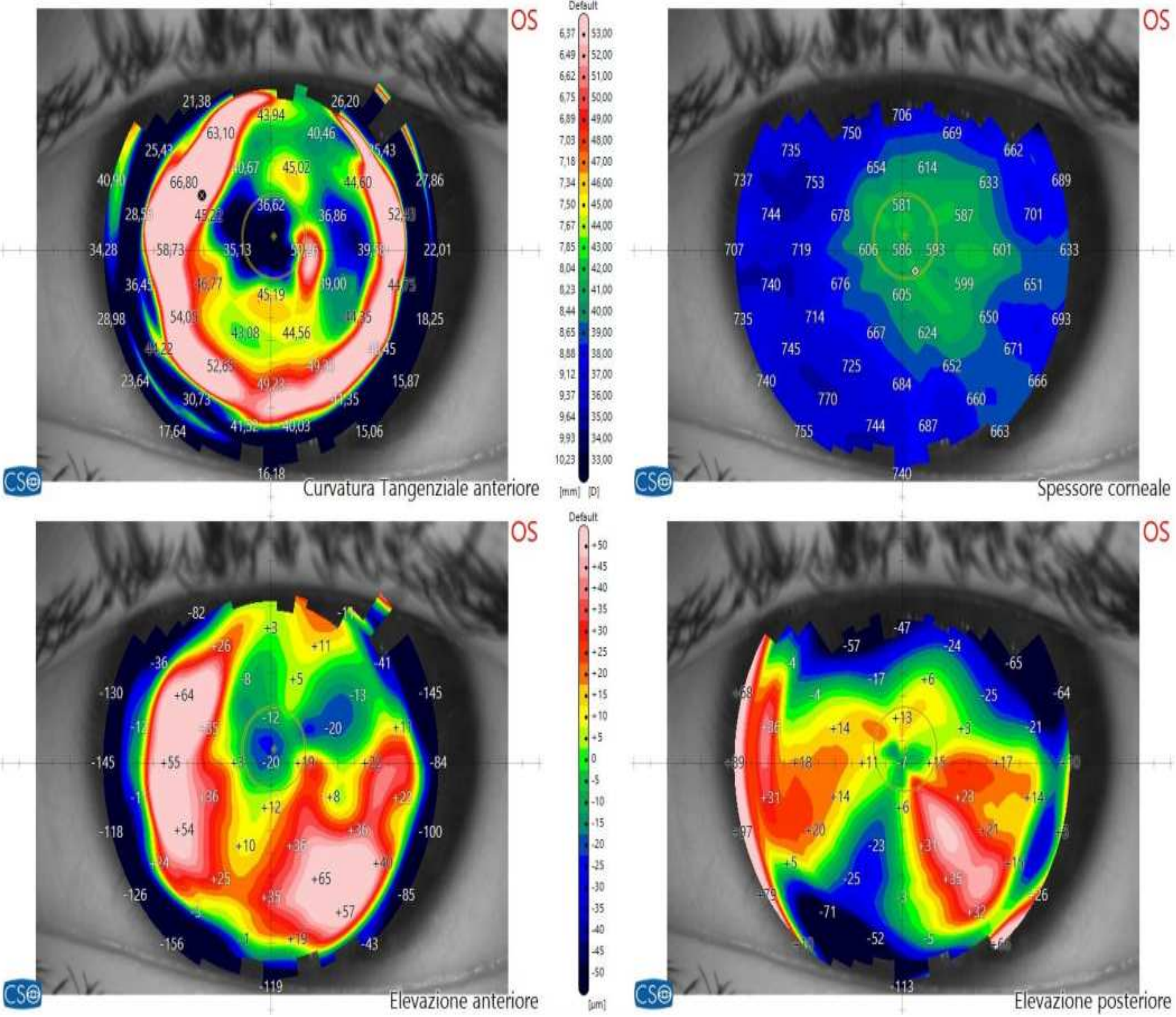
A. Posterior stromal damage
B. Partially retained lenticule fragments
C. Completely retained intrastromal lenticule[1]

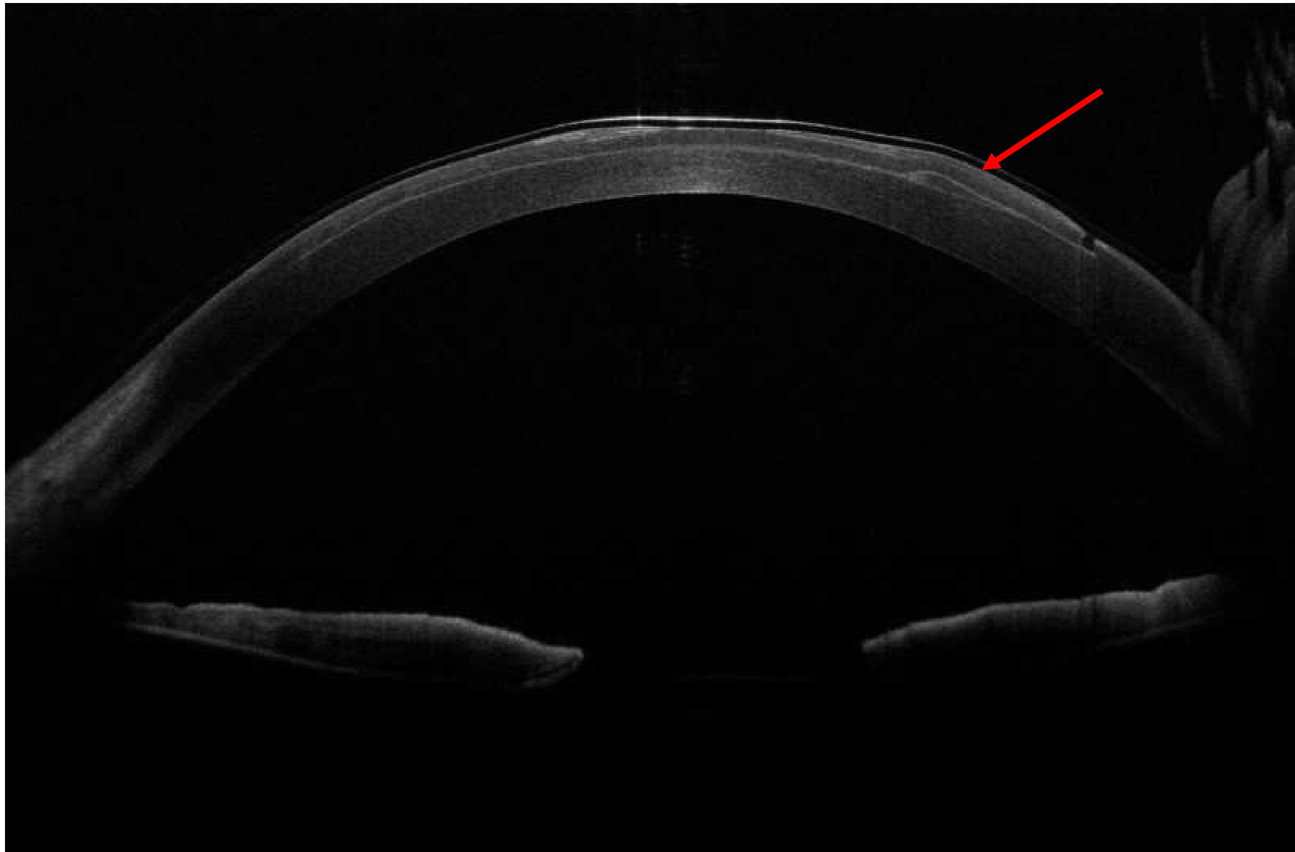
WHAT TO DO?

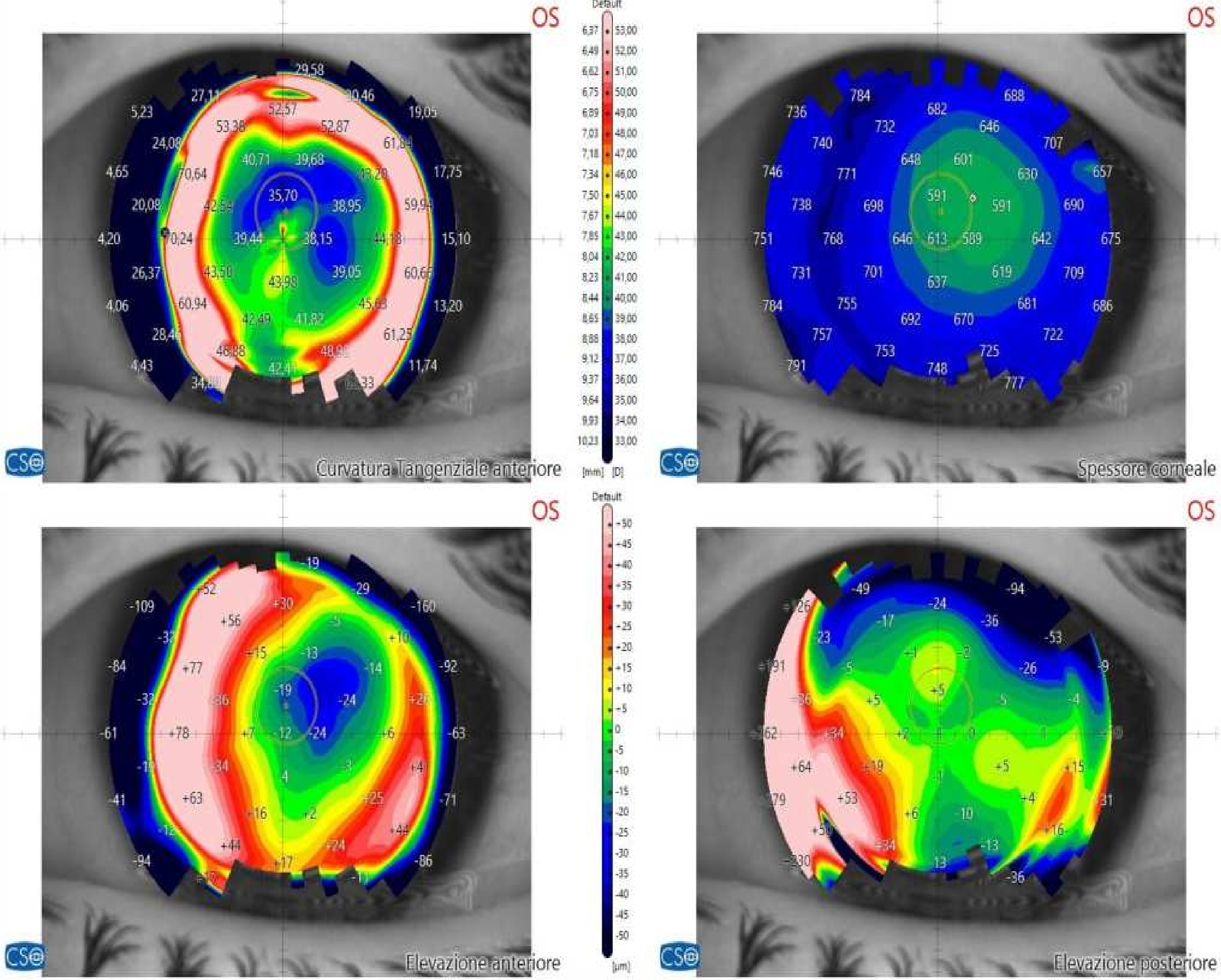
Topography-guided custom ablation may be an effective treatment modality in such cases; however, post- operative haze may be a problem[1]

Lenticule remnant after extraction[3]

1. Learning Curve of Small Incision Lenticule Extraction: Challenges and Complications. Jeewan S. Titiyal; Manpreet Kaur; Anubha Rathi; Ruchita Falera; Manthan Chaniyara; Namrata Sharma. Cornea 2017
2. A review of small incision lenticule extraction complications. Ronald R. Krueger and Caio S. Meister. Curr Opin Ophthalmol. 2018.
3. Secondary lenticule remnant removal after SMILE. Alex LK, Kwok PSK, Chan TCY. J Cataract Refract Surg 2017


OS
Curvatura Tangenziale anteriore
Spessore corneale
Elevazione anteriore
Elevazione posteriore
Default
[mm] [D]
[µm]

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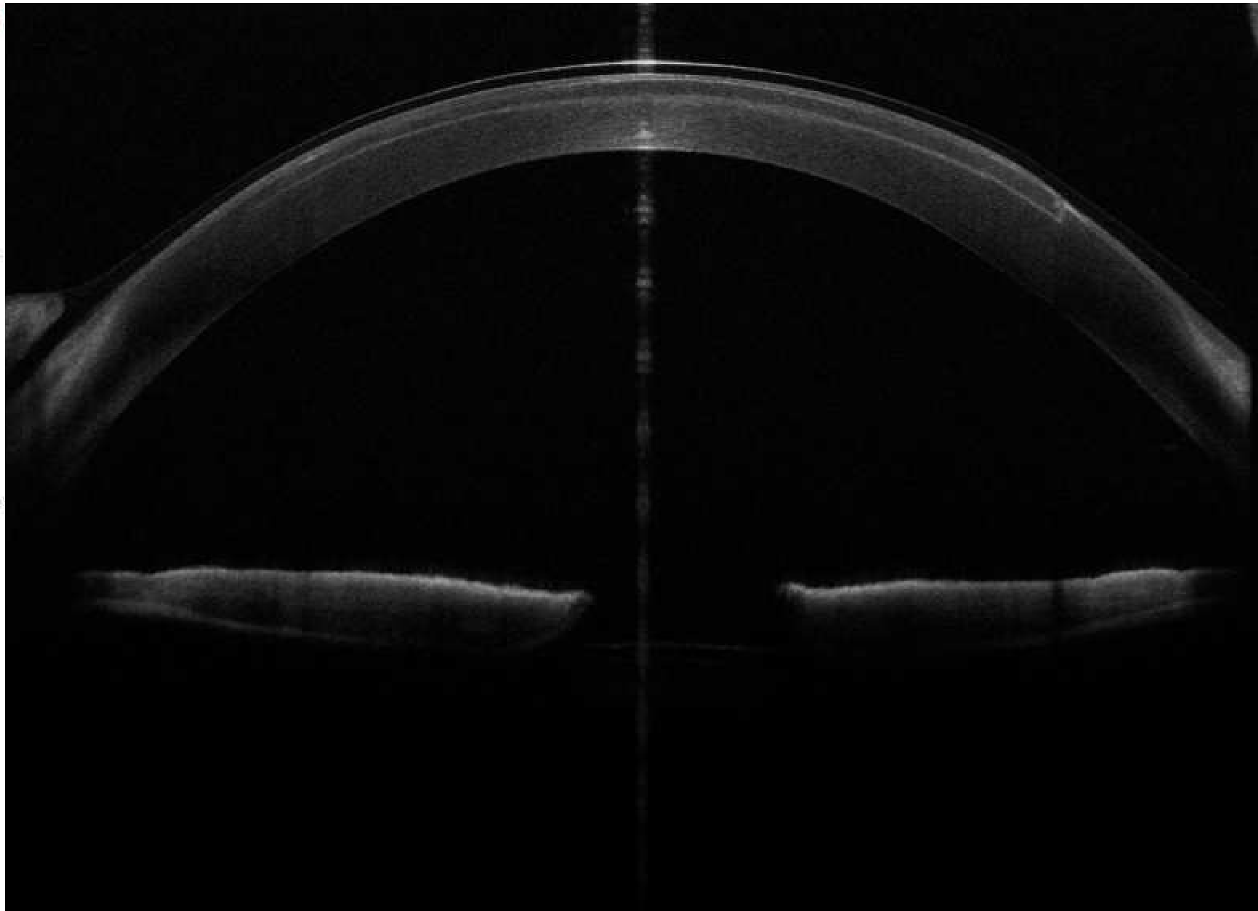
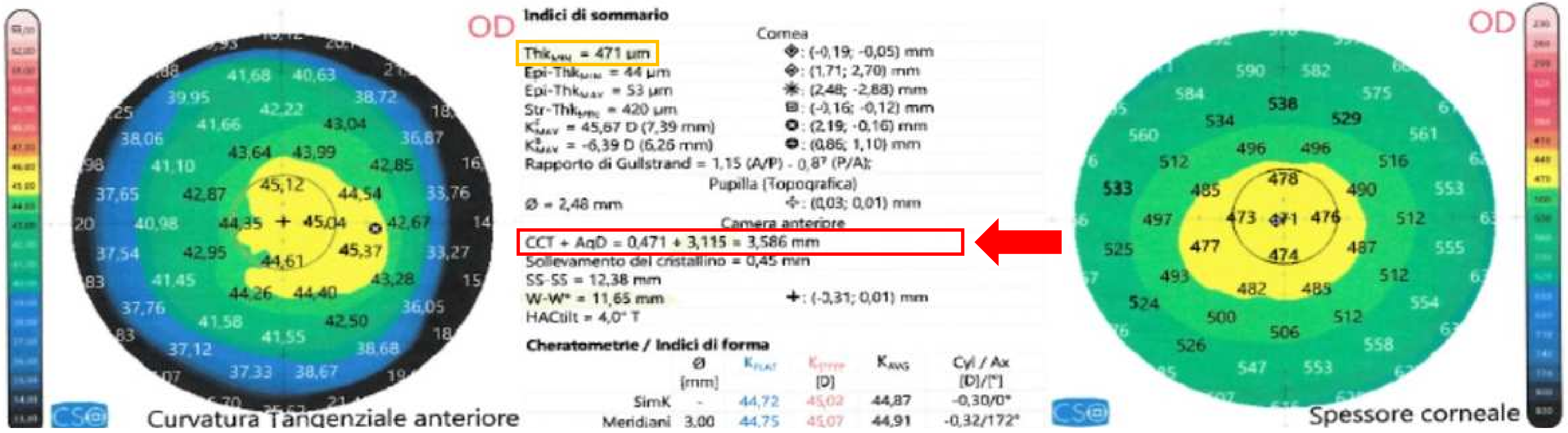
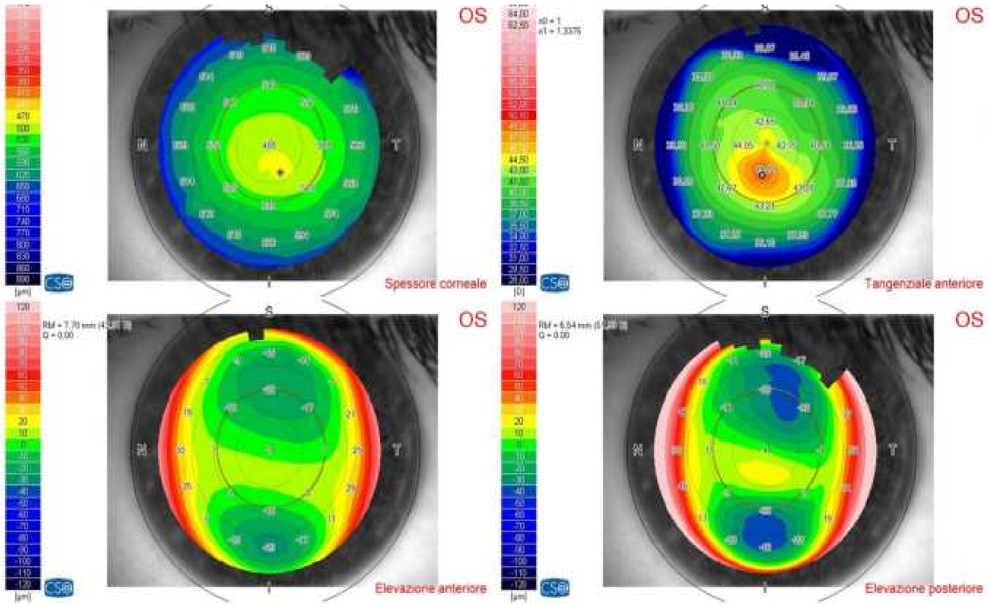


Is corneal refractive surgery the only possibility?

NO!



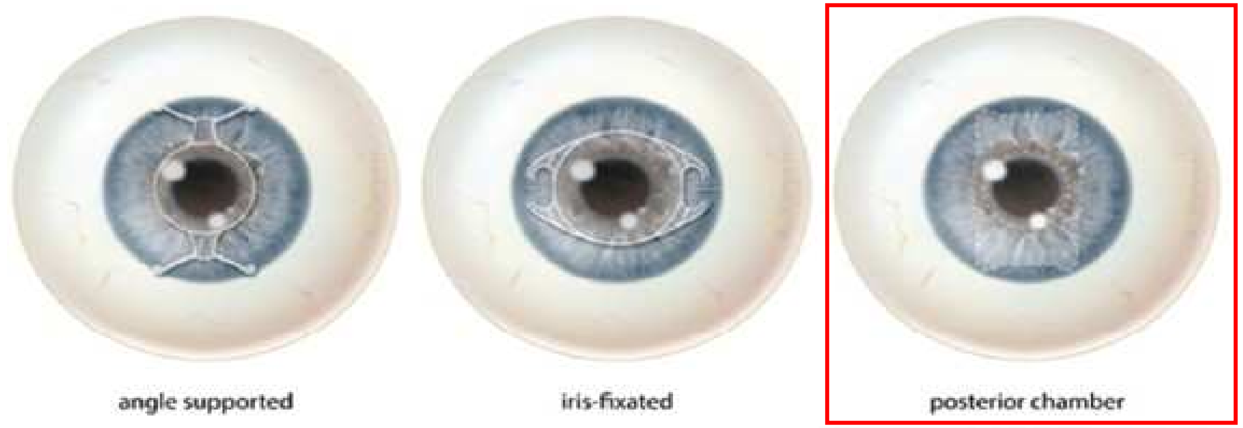
- Corneal abnormalities, tear film

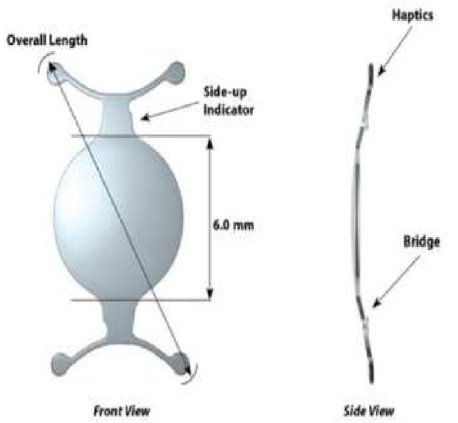


- Normal cornea but inadequate for specific refractive error
- Refractive error inadequate for corneal surgery

- Aberrometry and quality of vision

Phakic intraocular lens (PIOL) and Implantable Collamer Lens (ICL)





- Correction of **myopia up to -18,00 sph**
- Correction of **hyperopia up to +12,00 sph**
- Correction of **astigmatism up to ±6,00 D**

Beyond corneal laser refractive surgery

Phakic Intraocular Lenses and their Special Indications

J Ophthalmic Vis Res 2016; 11 (4): 422–428.

Roberto Pineda II, MD; Tulika Chauhan, MD

Phakic IOL Complications

Retreatments
Cataract
Endothelial cell loss
Glaucoma
Retinal detachment
Iritis
Decentration
Hyphema

Box 3.7.1 General Criteria for Implanting Phakic Intraocular Lenses

- Age > 21 years Up to 55-60 in myopia, 45 in hyperopia
- Stable refraction (<0.50-D change) for 1 year
- Clear crystalline lens
- Ametropia not suitable/appropriate for excimer laser surgery
- Unsatisfactory vision with/intolerance of contact lenses or spectacles
- Functional and occupational requirements
- ACD (measured from endothelium)
  - Artisan–Verisyse / Artiflex–Veriflex: ≥2.7 mm
  - ICL: ≥2.8 mm for myopia, ≥3.0 mm for hyperopia
- A minimum endothelial cell density of:
  - ≥3000 cells/mm² at 21 years of age
  - ≥2600 cells/mm² at 31 years of age
  - ≥2200 cells/mm² at 41 years of age
  - ≥2000 cells/mm² at ≥45 years of age
- No ocular pathology (corneal disorders, iris or pupil anomaly, glaucoma, uveitis, maculopathy, etc.)
- WTW: 10.8-13.0 mm (11.2-12.4 mm)

New generation ICL offers high quality of vision with low complcations vs old generation

Clinical Ophthalmology · Dovepress
CLINICAL TRIAL REPORT

The EVO ICL for Moderate Myopia: Results from the US FDA Clinical Trial

Mark Packer

Packer Research Associates, Boulder, CO, USA

Correspondence: Mark Packer, Packer Research Associates, 1400 Bluebell Ave, Boulder, CO, 80302, USA, Tel +1 541 915 – 0291, Email mark@markpackerconsulting.com

Purpose: To evaluate the safety and effectiveness of collamer posterior chamber phakic refractive lenses with a central port design (EVO and EVO+ Sphere and Toric implantable collamer lenses [ICLs]) for correction of moderate myopia with or without astigmatism.
Patients and Methods: Six-month results of a multicenter clinical trial were performed under United States FDA Investigational ... to −6.00 ... corrected ... were

Clinical Ophthalmology · Dovepress
ORIGINAL RESEARCH

Visual Acuity Improvement in Low, Moderate and High Myopia After Posterior-Chamber Phakic Implantable Collamer Lens Surgery in a Large Patient Cohort

Roger Zaldivar, Roberto Zaldivar, Carlos H Gordillo, Pablo Adamek

Surgery Department, Instituto Zaldivar, Mendoza, Argentina

Correspondence: Roger Zaldivar, Instituto Zaldivar, Av. Emilio Civit 701, Mendoza, Argentina, Email zaldivarroger@gmail.com

Purpose: To compare best-corrected visual acuity (BCVA) before and after implantable collamer lens (ICL) surgery in patients with low, moderate and high myopia.
Methods: A single-centre, prospective, registry-based study involving patients with myopia who received ICLs between

A Nationwide Multicenter Study on 1-Year Outcomes of Posterior Chamber Phakic Intraocular Lens Implantation for Low Myopia

Kazutaka Kamiya[1], Kimiya Shimizu[2], Akihito Igarashi[2], Yoshihiro Kitazawa[3], Takashi Kojima[4], Tomoaki Nakamura[5], Kazuo Ichikawa[6], Sachiko Fukuoka[7], Kahoko Fujimoto[8] and the Japan ICL Study Group*

[1] Visual Physiology, School of Allied Health Sciences, Kitasato University, Tokyo, Japan, [2] Department of Ophthalmology, Sanno Hospital, Tokyo, Japan, [3] Department of Ophthalmology, Sapia Tower Eye Clinic Tokyo, Tokyo, Japan, [4] Department of Ophthalmology, Keio University, Tokyo, Japan, [5] Department of Ophthalmology, Nagoya Eye Clinic, Aichi, Japan, [6] Department of Ophthalmology, Chukyo Eye Clinic, Aichi, Japan, [7] Department of Ophthalmology, Tane Memorial Eye Hospital, Osaka, Japan, [8] Department of Ophthalmology, Fujimoto Eye Clinic, Osaka, Japan

Purpose: To assess the nationwide multicenter outcomes of posterior chamber phakic intraocular lens implantation with a central hole (EVO-ICL, STAAR Surgical) for patients with low myopia.

Methods: This multicenter study comprised 172 eyes of 111 consecutive patients undergoing hole ICL implantation to correct low myopia and myopic astigmatism [manifest spherical equivalent (MSE);−3 diopters (D) or less] at seven nationwide major surgical facilities. We retrospectively determined safety, efficacy, predictability, stability, and adverse events at 1 week, 1, 3, 6, and 12 months postoperatively, and at the final visit.

Results: The mean follow-up period was 1.4 ± 1.0 years. Uncorrected and corrected visual acuities at 1 year postoperatively were −0.17 ± 0.12 and −0.24 ± 0.07 logarithm of the minimal angle of resolution (logMAR), respectively. At 1 year postoperatively, 91% and 100% of eyes were within 0.5 and 1.0 D of the target correction, respectively. No significant manifest refraction changes of −0.07 ± 0.26 D occurred from 1 week to 1 year. No vision-threatening complications occurred at any time in this series.

Conclusions: According to our experience, the EVO-ICL performed well without significant complications throughout the 1-year observation period, even for the correction of low myopia. It is suggested that current ICL implantation is one of the viable surgical options for correcting low myopia.

Clinical Ophthalmology · Dovepress
open access to scientific and medical research
Open Access Full Text Article
ORIGINAL RESEARCH

Low Diopter Phakic Implantable Collamer Lens: Refractive and Visual Outcomes in Low Myopia and Myopic Astigmatism

Ernesto Alonso-Juárez[1], Daniel Velázquez-Villoria[2]

[1]INSADOF Clinic, Salamanca, Spain; [2]Villoria Clinic, Vigo & Pontevedra, Spain

Correspondence: Ernesto Alonso-Juárez, INSADOF, Calle Doctrinos, 4, 1, Salamanca, 37002, Spain, Email info@insadof.com

Purpose: Nowadays the Implantable Collamer Lens (ICL – STAAR Surgical. Monrovia. CA) is a refractive surgical technique offered not only when laser corneal correction is not possible but also when the patient requires premium quality indexes and when dry eye is a concern. The use of ICL phakic lenses in low myopic patients is an emanate factor to study and analyze in order to determine treatment predictability and stability in such patients. In this paper, we conducted a 1-year follow-up study on patients with myopia below −3.5D implanted with ICL lenses.
Methods: This was a retrospective analytical study that includes patients with phakic ICL implantation from 2 independent clinics with a minimum follow-up of 12 months. Visual acuity, refractive outcomes, vault, and intraocular pressure (IOP) were assessed at 1, 6 and 12 months.
Results: Eighty-two eyes from 82 patients were included in this analysis. Mean spherical equivalent was −2.34 ± 0.82 (Range −5.50 to −1.00 D). Mean spherical implanted ICL power was −3.04 ± 0.78 D. In 25 eyes (30.5%) a Toric-ICL (TICL) was implanted with a mean TICL cylinder power of +1.64±0.64. Efficacy and security index remained stable for 12 months at 1.07 and 1.09, respectively. Mean vault at 12 months was 513.78 ± 262.87 μm and IOP was 15.63 ± 2.17 mmHg.
Conclusion: Phakic Implantable Collamer Lens implantation in very low myopia is a predictable, stable, safe, and effective technique with high efficacy and security indexes. Low diopter Toric ICL is also an excellent option for refractive surgery in cases of low diopter astigmatism.
Keywords: low myopia, phakic intraocular low power lens, refractive surgery

EVO/EVO+ Visian Implantable Collamer Lenses for the correction of myopia and myopia with astigmatism

Elena Martínez-Plaza, Alberto López-de la Rosa, Alberto López-Miguel, Alfredo Holgueras & Miguel J. Maldonado

Pages 75-83 | Received 12 Oct 2022, Accepted 26 Jan 2023, Published online: 10 Feb 2023

EVO vs EVO+: 5,0 vs 6,1 mm optic diameter

	EVO	LASIK	PRK
Safety Features			
Reversible lens implant	✓	✗	✗
Flexibility for future procedures	✓	✗	✗
Treats eyes with thin corneas[9]	✓	✗	✗
UV Protection	✓	✗	✗
Long term history	✓	✓	✓
Vision Quality			
Sharp and Clear Vision[2,3]	✓	✓	✓
Patient Experience			
20-30 Minute Outpatient Procedure	✓	✓	✓
No Corneal Tissue Removed	✓	✗	✗
Does Not Cause Dry eye Syndrome[5,6]	✓	✗	✗

- EVO and EVO+ Visian Implantable Collamer Lenses (ICL) incorporate a central hole to allow aqueous humor circulation avoiding laser iridotomy and reducing the prevalence of related complications.
- The implantation of EVO and EVO+ ICL is a safe, effective, and predictable procedure widely used for the correction of myopia and myopia with astigmatism.
- Dysphotopic phenomena could be perceived after ICL implantation although it is expected to progressively disappear during the medium postoperative period.
- The ocular structures and lens integrity should be monitored in order to guarantee long-term safety on a yearly basis eye examination.

Excimer Laser Versus Phakic Intraocular Lenses for Myopia and Astigmatism: A Meta-Analysis of Randomized Controlled Trials

REVIEW ARTICLE — *Eye & Contact Lens* 2016

Haiting Chen, M.Med., Yu Liu, M.Med., Guangzeng Niu, M.Med., and Ma Jingxue, D.Med.

PIOL more accurate than excimer laser surgery for refractive errors, better visual quality, comparable complications (follow up: 12 months)

Comparison of Visual Outcomes and Optical Quality of Femtosecond Laser-Assisted SMILE and Visian Implantable Collamer Lens (ICL V4c) Implantation for Moderate to High Myopia: A Meta-analysis

Di Chen, Xinyu Zhao, Yuyu Chou, Yan Luo Review J Refract Surg. 2022 Jun;38(6):332-338.

PIOL and SMILE both equally efficient in moderate/high myopia, PIOL probably offer better quality of vision vs SMILE (aberrations higher in SMILE)

A meta-analysis of visual outcomes and optical quality after small incision lenticule extraction versus implantable collamer lens for myopia

Yu Di [1], Ge Cui [1], Ying Li [1], Yan Luo [1] Meta-Analysis Eur J Ophthalmol. 2023 Jan;33(1):136-144.

PIOL comparable to SMILE in efficacy, safety and predictability in short term

Four-year visual outcomes and optical quality of SMILE and implantable collamer lens V4c (EVO-ICL) implantation for high myopia: a retrospective study

BMC (2023) 23:341

Wuqiang Luo[1†], Aruma Aruma[2†], Meiyan Li[2], Jing Wang[3], Jing Xie[4], Xin Xiao[1], Yang Shen[2], Lingling Niu[2], Xiaoying Wang[2] and Xingtao Zhou[2,5*]

PIOL comparable to SMILE in efficacy, safety and predictability, probably SMILE has better predictability at long term (4 years)

SMILE = PIOL

But no long term comparisons

Hi-Tech & AI for ICL surgery

Clinical Ophthalmology

Dovepress
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ORIGINAL RESEARCH

Descriptive Analysis of Footplate Position After Myopic Implantable Collamer Lens Implantation Using a Very High-Frequency Ultrasound Robotic Scanner

Roger Zaldivar[1], Roberto Zaldivar[1], Pablo Adamek[1], Gabriel Quintero[1], Alejandro Cerviño[2]

[1]Instituto Zaldivar, Mendoza, Argentina; [2]Department of Optics & Optometry & Vision Sciences, University of Valencia, Valencia, Spain

Correspondence: Alejandro Cerviño, Department of Optics & Optometry & Vision Science, University of Valencia, C / Dr. Moliner, 50. Burjassot, Valencia, 46100, Spain, Tel +34 963 544 852, Email alejandro.cervino@uv.es

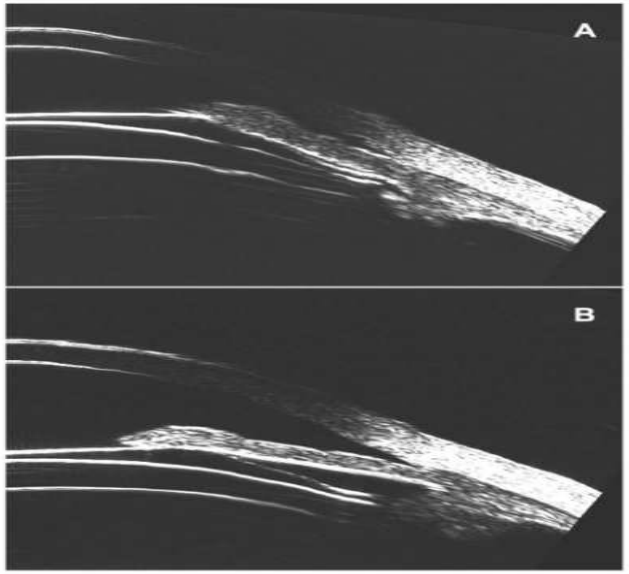
Purpose: To assess the position of the haptics of the implantable collamer lens (ICL) in myopic eyes using a high-frequency ultrasound robotic scanner.

Methods: This was a prospective, single-arm, observational study carried out at the Instituto Zaldivar SA (Mendoza, Argentina) in a sample of 52 eyes who have been submitted to successful ICL implantation prior to enrollment. Images of the eyes were obtained using a very-high frequency digital ultrasound robotic scanner (VHFDU) to establish the position of the ICL in the posterior chamber and its relation to the ciliary sulcus. New parameters for lens position analysis were also described.

Results: In 81% of cases (42 eyes), the ICL rests on the ciliary body (CB) in both temporal and nasal sides, being slightly lower than 6% (3 eyes) those that rest on the sulcus in both sides, with significant correlations between ICL position and vault values ($p<0.05$). Cases in which the ICL position was CB-CB yielded central vault values across the whole range determined within the sample, but most of the eyes where the ICL rests on both the sulcus in one side and the CB in the other side yield greater central vault values. Correlation was significant between ICL position and retroposition distance on the temporal side (Spearman's rho −0.487, $p<0.001$). A significant but weaker correlation was also found between ICL position and retroiridian space ($p<0.05$).

Conclusion: ICL for myopia footplates tend to locate outside of the sulcus in a significant percentage of patients after successful implantation. VHFDU assessment in eyes implanted with an ICL to properly study the lens footplate position and posterior anatomical relations provides important additional information besides post-surgery vault.

Keywords: myopia, implantable collamer lens, ultrasound biometry, high-frequency, ciliary sulcus



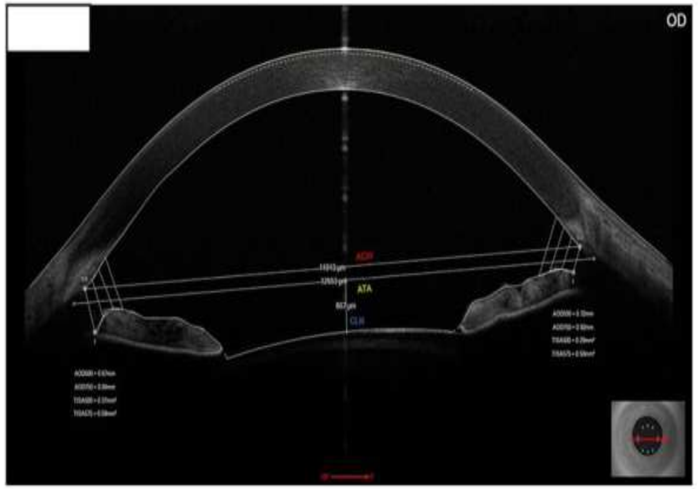
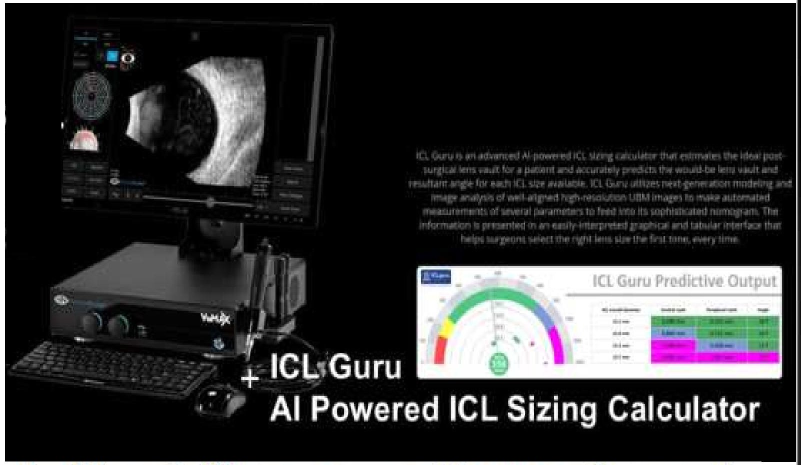
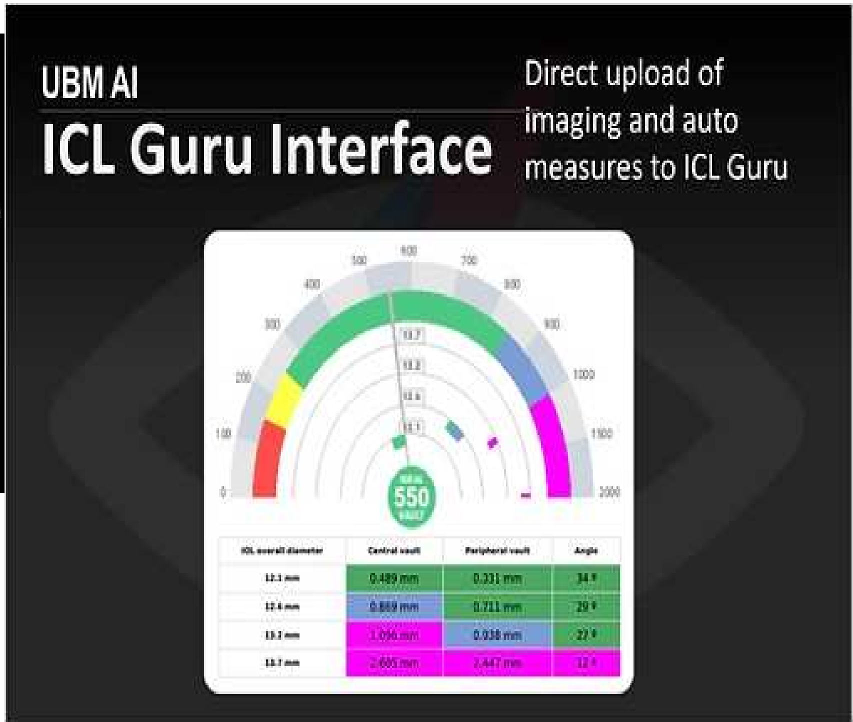


Figure 6 Angle-to-angle (ATA) diameter measurement with optical coherence tomography (OCT). The distance from the anterior surface of the crystalline lens to the ATA line is the crystalline lens rise (CLR). The anterior chamber width (ACW) from scleral spur to scleral spur is also marked. Courtesy of Arthur Cummings.

A promising new UBM-based planning methodology tool, "ICLguru", was first presented in the Zaldivar Institute International Course in Mendoza, Argentina in November, 2023. It predicts central and peripheral vault and postoperative iridocorneal angles, with >97% of eyes being within 250 μm of the predicted vault. Published data on this methodology is anticipated in the near future.





In summary, innovations in ICL design have significantly improved safety and efficacy across a wide range of measured vaults. All currently employed methods, including those based on WTW, STS, and ATA for predicting vault and selecting EVO ICL sizing produce acceptable results. Therefore, experienced surgeons should investigate the best method for their own personal use, based on the available measurement technology and their analytical optimization tools.

Presbyopia

FUTURE ADVANCES IN ICL

EVO VIVA ™
Sphere &

Binocular uncorrected visual acuity

Binocular	6 months postoperative (logMAR (Snellen))	Change in lines from baseline (lines)
Mean UNVA	-0.01 ± 0.05 (20/20)	6.1 ± 4.0
Mean UIVA	-0.02 ± 0.08 (20/19)	7.8 ± 3.6
Mean UDVA	0.07 ± 0.10 (20/23)	10.0 ± 2.8

97% of patients achieved binocular **UNVA** of 20/25 (J1) or better[1]

100% of patients achieved binocular **UIVA** of 20/32 (J2) or better[1]

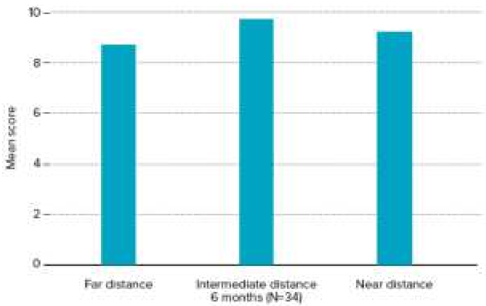
Data from multicenter clinical trial.

J1: Jaeger eye chart paragraph 1; **J2:** Jaeger eye chart paragraph 2; **UIVA:** uncorrected intermediate visual acuity; **UNVA:** uncorrected near visual acuity; **UDVA:** uncorrected distance visual acuity.

EVO Viva

Excellent task performance without glasses or contacts at all distances*,[1]

Postoperative mean task assessment questionnaire scores without glasses or contact lenses*



Data from multicenter clinical trial.

*Patients were asked to evaluate their ability to perform a series of everyday tasks at far, intermediate, and near distances without their contact lenses or glasses. For each distance, the range of possible outcomes was 0 (worst) to 10 (best).

Patients saw improvements in quality of life with EVO *Viva* ICL

In the NEI-RQL-42 quality of life questionnaire, patients reported significant improvement in:[1]

- Near vision (*p* <0.0001)
- Dependence on correction (*p* <0.0001)
- Activity limitations (*p* <0.0001)
- Appearance (*p* <0.0001)
- Satisfaction with correction (*p*=0.0017)

NEI-RQL: National Eye Institute Refractive Error Quality of Life Instrument.

EVO Viva

Performance and Safety of the Extended Depth of Focus Implantable Collamer® Lens (EDOF ICL) in Phakic Subjects with Presbyopia

Mark Packer[1]
Jose F Alfonso[2]
Jaime Aramberri[3]
Daniel Elies[4]
Joaquin Fernandez[5]
Erik Mertens[6]

Clinical Ophthalmology
2020

Clinical and Aberrometric Outcomes of a New Implantable Collamer Lens for Myopia and Presbyopia Correction in Phakic Patients

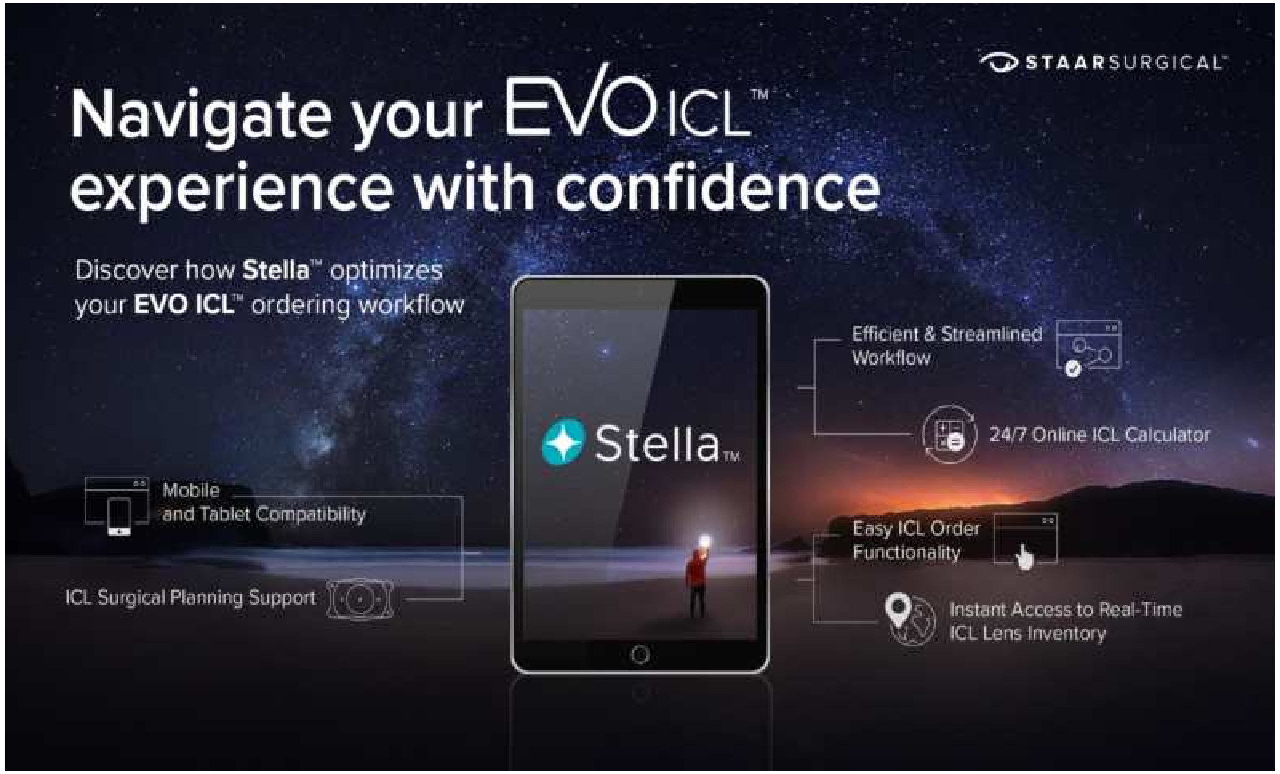
José F Alfonso, Luis Fernández-Vega-Cueto, Carlos Lisa, Belén Alfonso-Bartolozzi, Ana Palacios, David Madrid-Costa

J Refract Surg. 2023 Sep;39(9):589-596

INDICATIONS

- EVO ***Viva*** is indicated for use in phakic eye treatment in patients 21-60 years of age and pseudophakic eye treatment in patients with monofocal IOLs with and without cylinder correction 21 years of age and older for:
- The correction/reduction of myopia in patients ranging from -0.5 D to -20.0 D at the spectacle plane.
- The correction/reduction of myopia with presbyopia in patients ranging from -0.5 D to -20.0 D at the spectacle plane.
  - For extended depth of focus and improved near visual acuity.
- With an anterior chamber depth (ACD) equal to or greater than 2.8 mm as measured from the corneal endothelium to the anterior lens capsule.

FUTURE ADVANCES IN ICL



Injector

- **Is Future lens based?**

Ordering System

- Intermediate Sizes?

↓

- Vault prediction/sizing

- **Costs?**
- **Learning curve?**

Preloaded?

Stella™

- **Immediate Sequential Bilateral Surgery?**

Corneal vs intraocular refractive surgery: when to **avoid** each technique

Corneal refractive surgery Contraindications

- Abnormalities of the cornea (e.g., keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
- Insufficient corneal thickness for the proposed ablation depth
- Visually significant cataract
- Uncontrolled glaucoma
- Uncontrolled external disease (e.g., blepharitis, dry eye syndrome, atopy/allergy)
- Uncontrolled autoimmune or other immune-mediated disease
- Excessively steep or flat corneas

Intraocular refractive surgery Contraindications

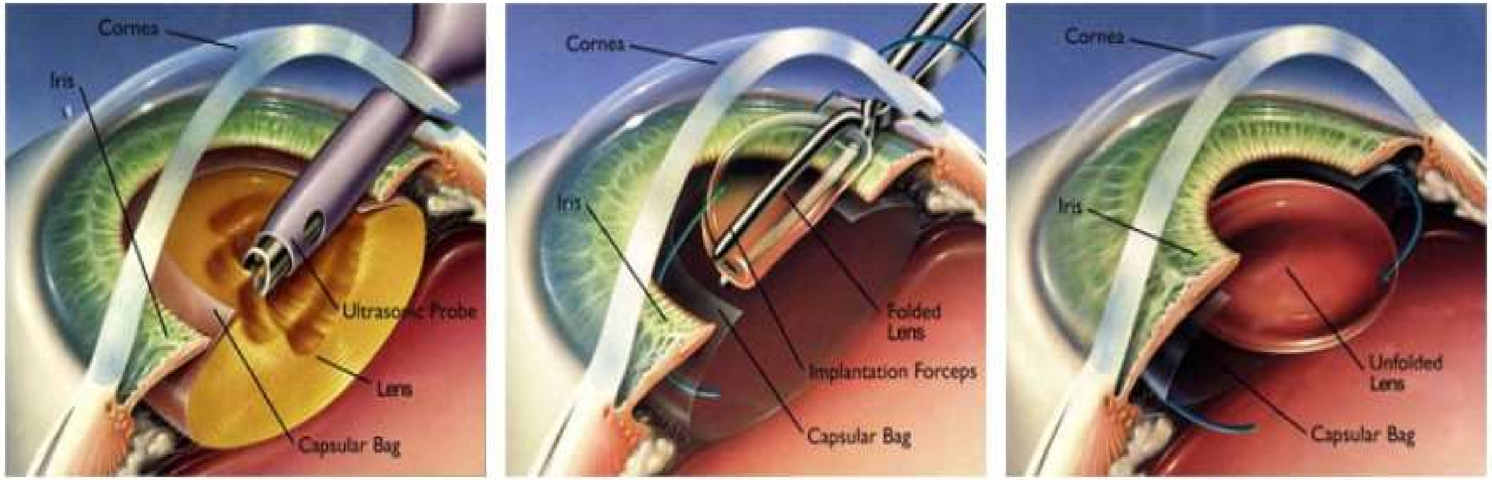
- Shallow anterior chamber
- Corneal endothelial disease, low ECD
- Glaucoma
- Visually significant cataract
- Active or recently active uveitis, or uveitis that requires ongoing treatment or is recurrent in nature
- Uncontrolled autoimmune or other immune-mediated disease
- Excessively large pupil size for lens optical zone (7 mm)

Refractive Surgery Preferred Practice Pattern®

AMERICAN ACADEMY OF OPHTHALMOLOGY®

	EVO	LASIK	PRK
Safety Features			
Reversible lens implant	✓	✗	✗
Flexibility for future procedures	✓	✗	✗
Treats eyes with thin corneas[9]	✓	✗	✗
UV Protection	✓	✗	✗
Long term history	✓	✓	✓
Vision Quality			
Sharp and Clear Vision[2,3]	✓	✓	✓
Patient Experience			
20-30 Minute Outpatient Procedure	✓	✓	✓
No Corneal Tissue Removed	✓	✗	✗
Does Not Cause Dry eye Syndrome[5,6]	✓	✗	✗

Refractive lens exchange (RLE)



- **Hyperopes** with **< 2.5 mm ACD** and **> 45 years**
- **High/very high myopes > 55 years** (with normal fundus)

Accuracy of Intraocular Lens Calculation Formulas

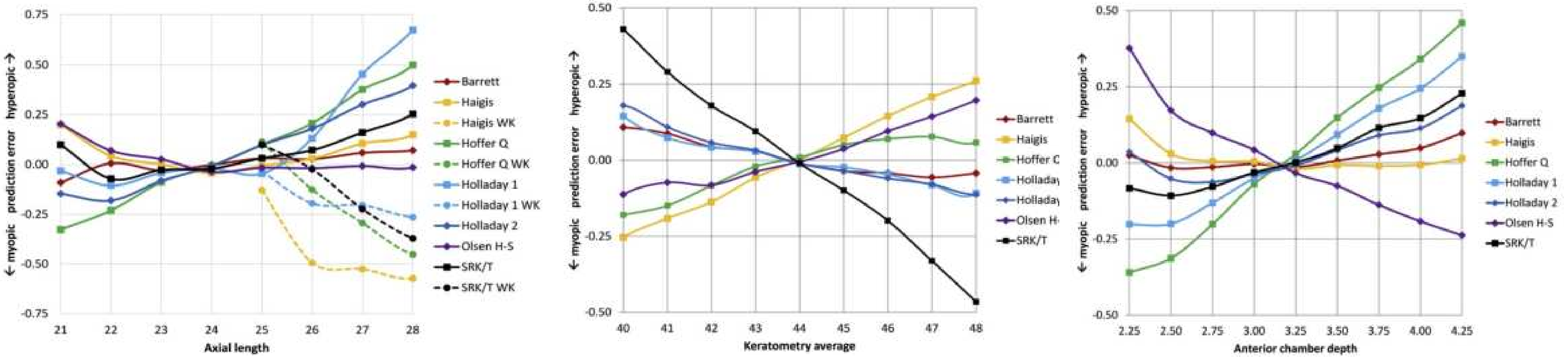
Ophthalmology

Volume 125, Issue 2, February 2018, Pages 169-178

Ronald B. Melles MD[1], Jack T. Holladay MD, MSEE[2], William J. Chang MD[1]

Critical Steps in RLE

IOL power calculations



high myopia & high hyperopia

= increased intra- & post-op complications

IOL selection

Premium IOLs («young» and demanding patient!)

- Multifocal IOLs
- EDOF IOLs
- Toric IOLs

Femtosecond laser assisted cataract surgery

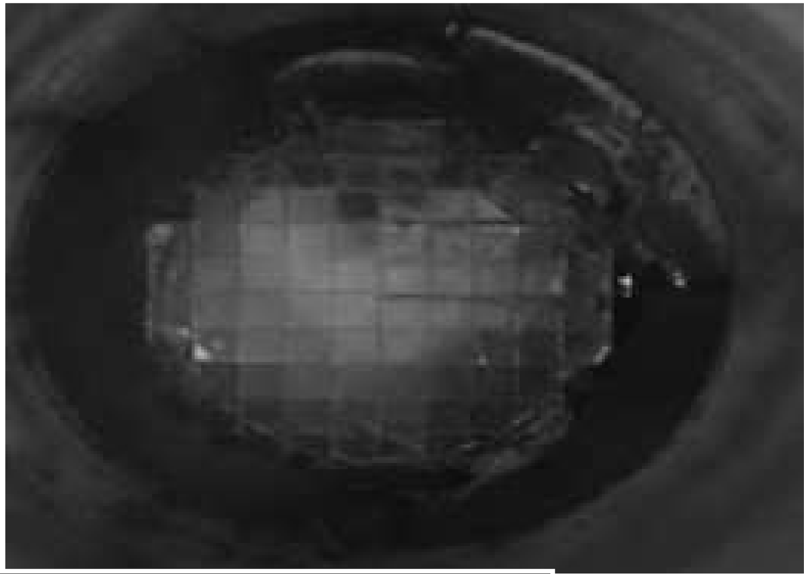
Review of current status of refractive lens exchange and role of dysfunctional lens index as its new indication

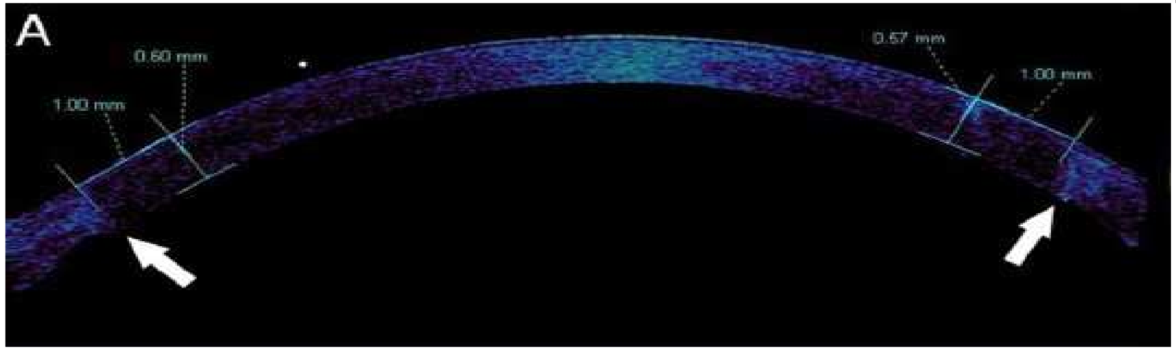
Luci Kaweri, Chandrashekhar Wavikar[1], Edwin James[2], Payal Pandit, Namrata Bhuta

FEMTO-CATARACT

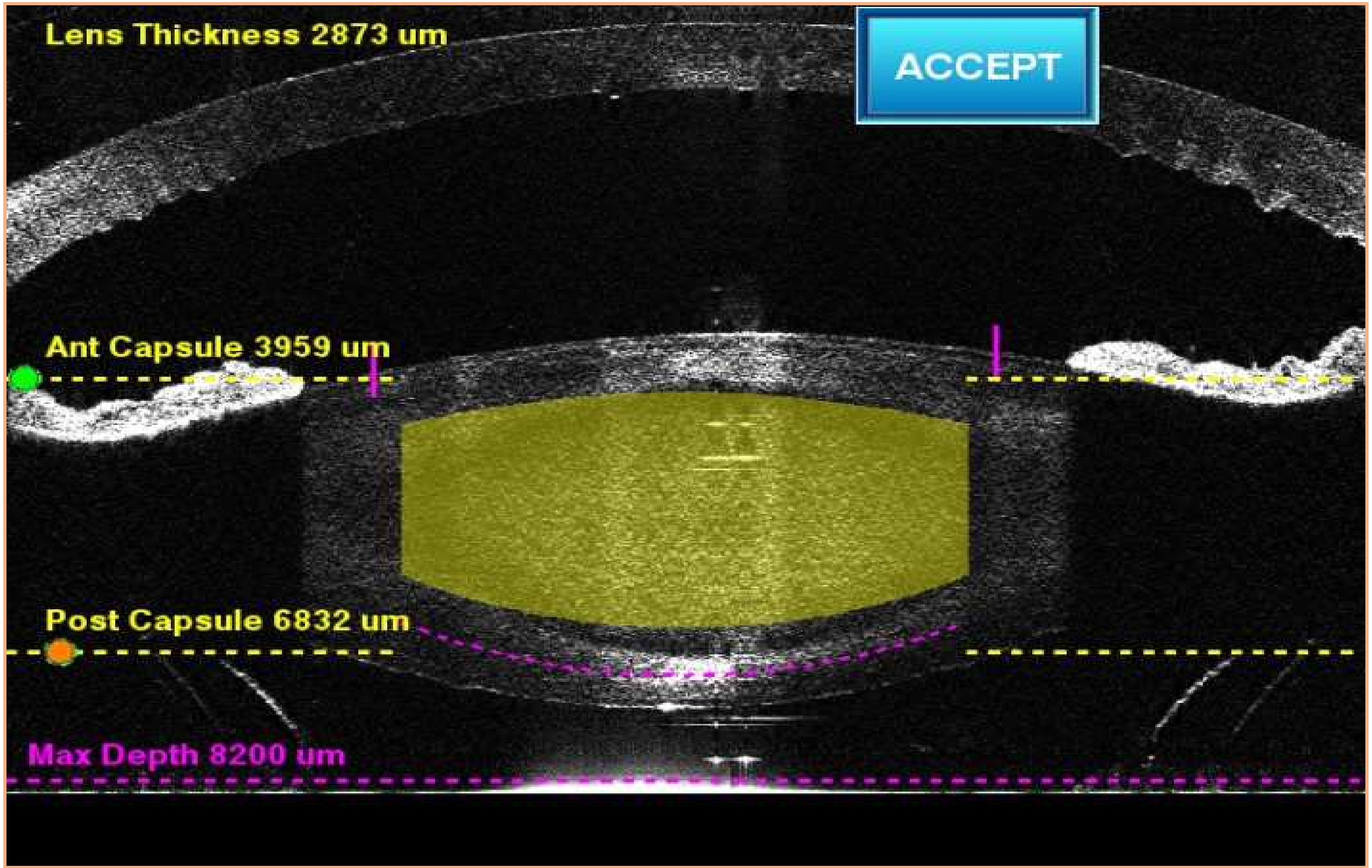
Four types of incisions:

- Corneal Incisions (CCI)
- Capsulotomy
- Lens fragmentation
- Astigmatic corneal incisions





OCT visualization system: robotic



FLACS and capsulotomy

LABORATORY SCIENCE

Scanning electron microscopy evaluation of capsulorhexis in femtosecond laser–assisted cataract surgery

Leonardo Mastropasqua, MD, Lisa Toto, MD, PhD, Roberta Calienno, MD, Peter A. Mattei, MD, PhD, Alessandra Mastropasqua, MD, Luca Vecchiarino, MD, Donato Di Iorio, PhD

ORIGINAL ARTICLE

Induced Inflammation and Apoptosis in Femtosecond Laser-Assisted Capsulotomies and Manual Capsulorhexes: An Immunohistochemical Study

Lisa Toto, PhD; Roberta Calienno, PhD; Claudia Curcio, PhD; Peter A. Mattei, MD; Alessandra Mastropasqua, MD; Manuela Lanzini, PhD; Leonardo Mastropasqua, MD

ORIGINAL ARTICLE

Postoperative IOL Axial Movements and Refractive Changes After Femtosecond Laser-assisted Cataract Surgery Versus Conventional Phacoemulsification

Lisa Toto, MD, PhD; Rodolfo Mastropasqua, MD; Peter A. Mattei, MD, PhD; Luca Agnifili, MD, PhD; Alessandra Mastropasqua, MD; Gennaro Falconio, MD; Marta Di Nicola, PhD; Leonardo Mastropasqua, MD

ARTICLE

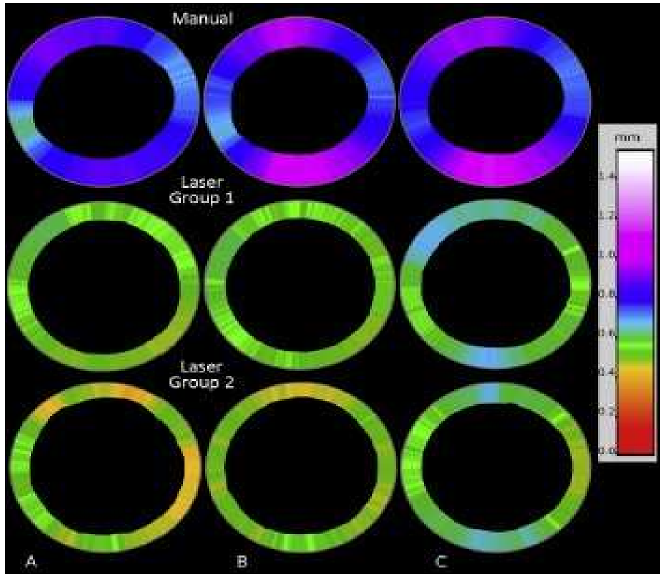
Optical coherence tomography and 3-dimensional confocal structured imaging system–guided femtosecond laser capsulotomy versus manual continuous curvilinear capsulorhexis

Leonardo Mastropasqua, MD, Lisa Toto, MD, PhD, Peter A. Mattei, MD, PhD, Luca Vecchiarino, MD, Alessandra Mastropasqua, MD, Riccardo Navarra, PhD, Marta Di Nicola, PhD, Mario Nubile, MD, PhD

Better circularity, good centration and sizing of capsulotomy = No capsular shrinkage and good IOL

Ocular, Corneal, and Internal Aberrometry Parameters 6 Months After Surgery in Eyes That Underwent Continuous Curvilinear Capsulorrhexis or Femtosecond Laser Capsulotomy

Parameter	Mean±Standard Deviation: CCC Group (n=51)	Mean±Standard Deviation: FS Group (n=48)	*P* Value*
Ocular			
Vertical tilt	0.09±0.44	−0.08±0.35	>.05
Horizontal tilt	0.10±0.49	0.16±0.39	>.05
Vertical coma	0.04±0.19	−0.02±0.16	>.05
Horizontal coma	−0.01±0.16	0.02±0.14	>.05
Corneal			
Vertical tilt	−0.11±0.49	−0.06±0.38	>.05
Horizontal tilt	−0.05±0.41	−0.04±0.32	>.05
Vertical coma	−0.04±0.17	−0.04±0.11	>.05
Horizontal coma	−0.03±0.11	−0.02±0.12	>.05
Internal			
Vertical tilt	0.27±0.57	−0.05±0.36	.006
Horizontal tilt	0.15±0.59	0.16±0.63	>.05
Vertical coma	0.10±0.15	0.003±0.11	.006
Horizontal coma	0.03±0.18	0.06±0.11	>.05

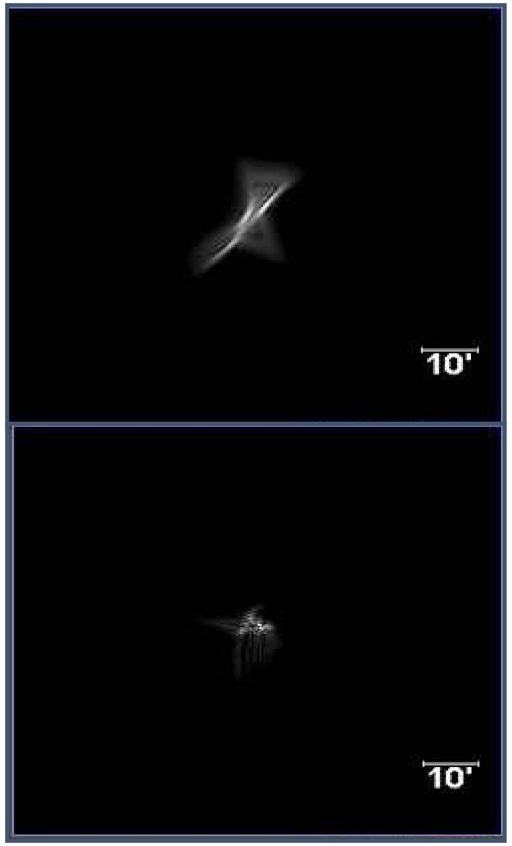


FLACS and HOA

[J Refract Surg. 2011;27(10):711-716.]

Internal Aberrations and Optical Quality After Femtosecond Laser Anterior Capsulotomy in Cataract Surgery

Kata Miháltz, MD; Michael C. Knorz, MD; Jorge L. Alió, MD, PhD; Ágnes I. Takács, MD; Kinga Kránitz, MD; Illés Kovács, MD, PhD; Zoltán Z. Nagy, MD, DSc



Lower high order aberrations in femto vs manual due to better IOL positioning

FLACS

RECOMMENDATION:

To facilitate surgical steps in difficult cases

CURRENT OPINION

Femtosecond laser cataract surgery: challenging cases

Aifric I. Martin[a,b,c], Christopher Hodge[b], Michael Lawless[b,d], Tim Roberts[b,e], Paul Hughes[f], and Gerard Sutton[b,g]

Post trauma/ White cataracts

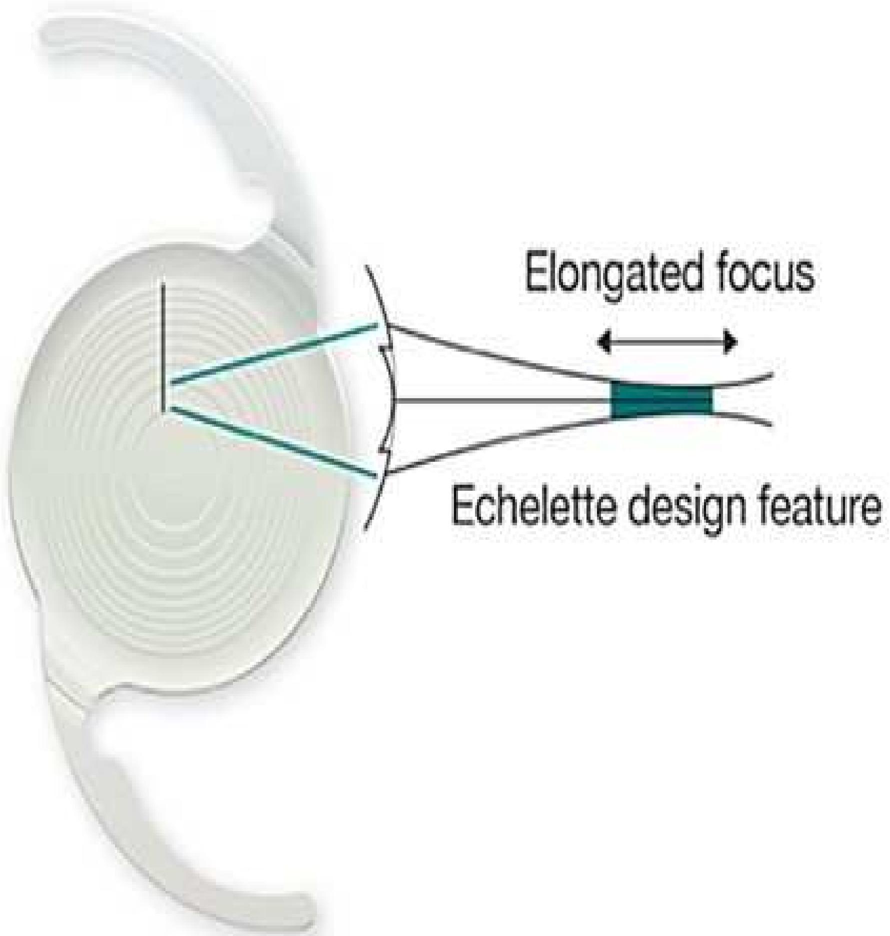
Polar cataract

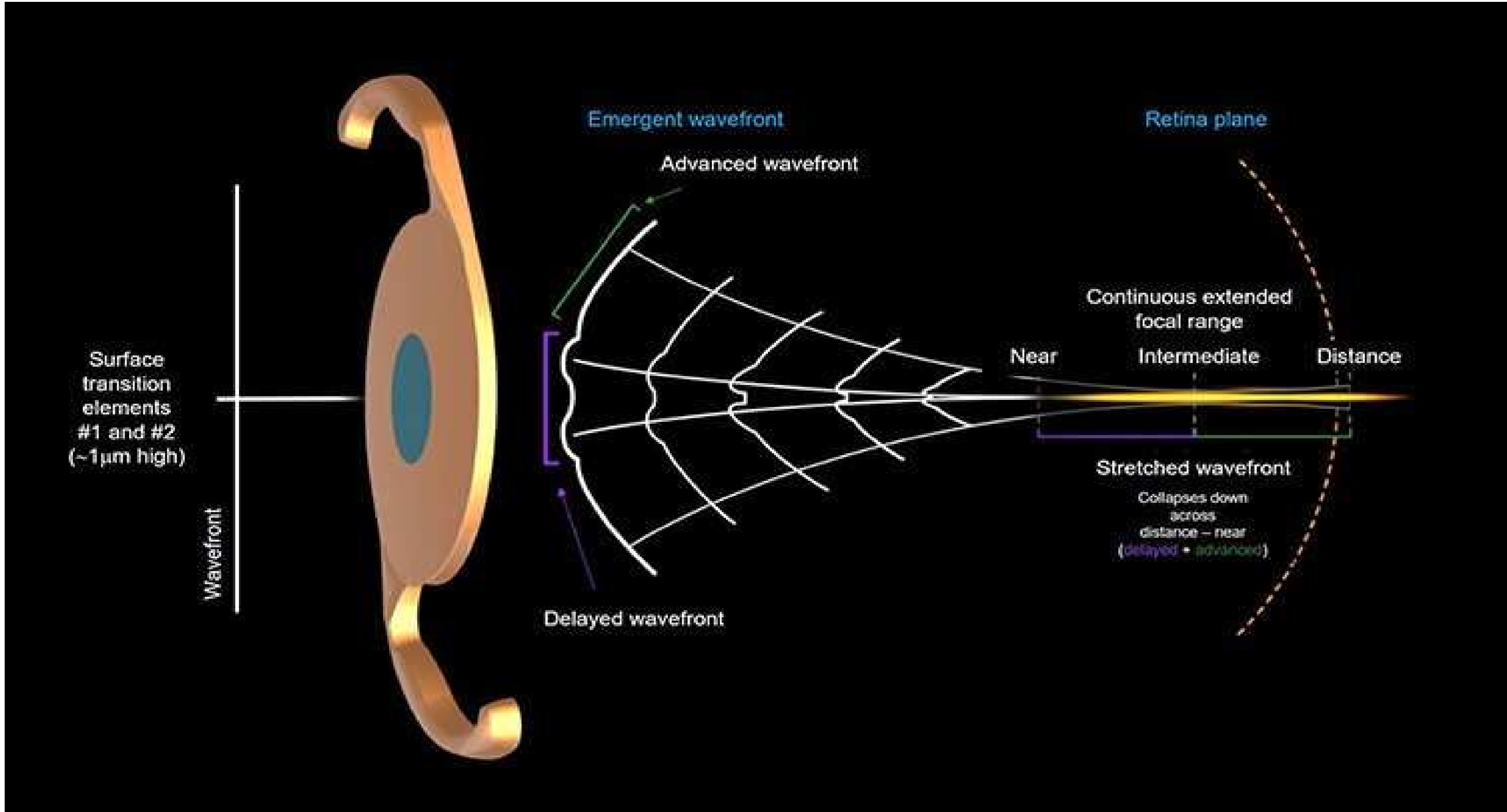
Fuchs endothelial distrophy

Subluxated cataract

Vitrectomized eyes

IOL EDoF: spectacle independence





Spectacle Independence for Pseudophakic Patients – Experience with a Trifocal Supplementary Add-on Intraocular Lens

Clinical Ophthalmology 2020

Carlos Palomino-Bautista[1,2]
Rubén Sánchez-Jean[1]
David Carmona Gonzalez[1]
Marta Romero Domínguez[1,2]
Alfredo Castillo Gómez[1,2]

Purpose: To evaluate the refractive and functional outcomes of the trifocal 1stQ AddOn® (Medicontur) supplementary intraocular lenses (IOLs) designed for implantation into the ciliary sulcus.

Conclusion: The supplementary trifocal add-on IOL seems to be a safe, efficient and stable solution for achieving spectacle independence in pseudophakic patients with monofocal primary IOLs.

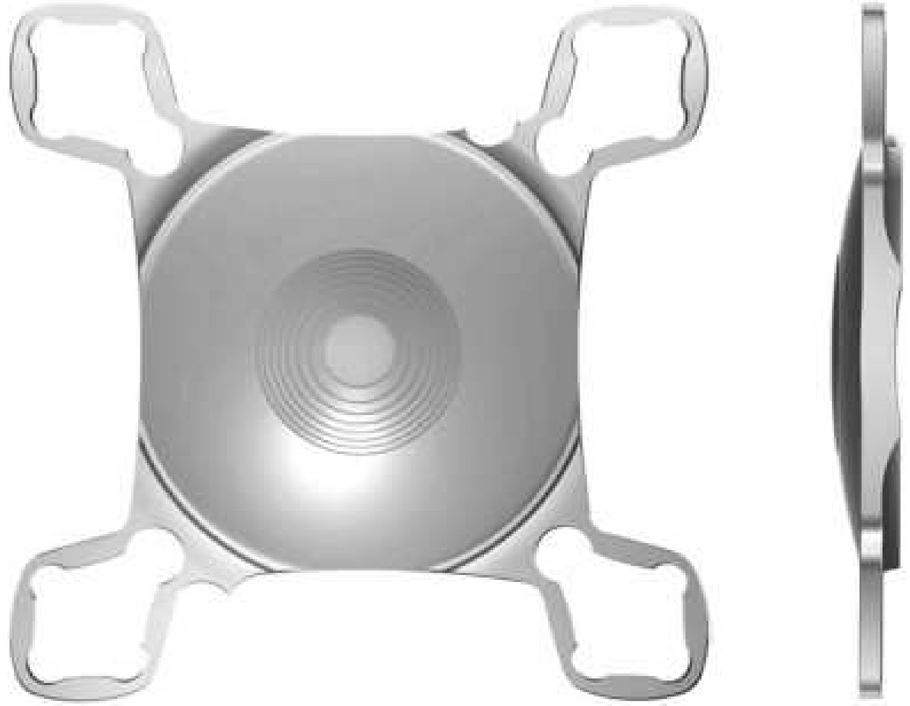
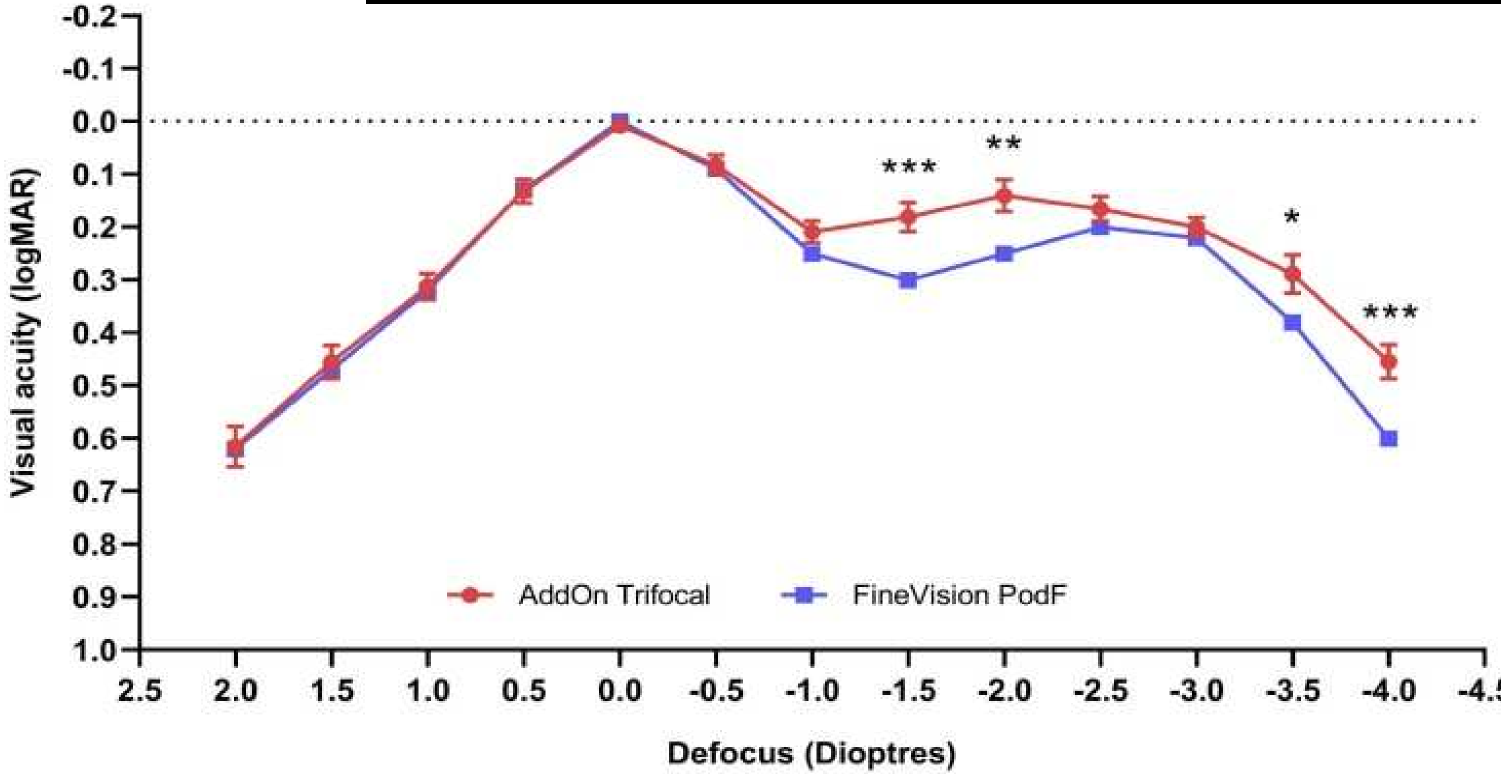


Figure 1 The design of the trifocal supplementary add-on IOL is optimized for implantation into the ciliary sulcus.
Notes: Four flexible haptics position the lens in the ciliary sulcus; Six diffractive rings, and +1.75 D and +3.0 D additions ensure trifocal performance.



IOL POWER ADJUSTMENT BY FEMTOSECOND LASER

This technology can potentially be used with any commercially available IOL.

Figure 2. Light photomicrograph of an IOL explanted from a rabbit eye after in vivo power adjustment by a femtosecond laser. The laser-treated areas can be seen in the darker yellow color.

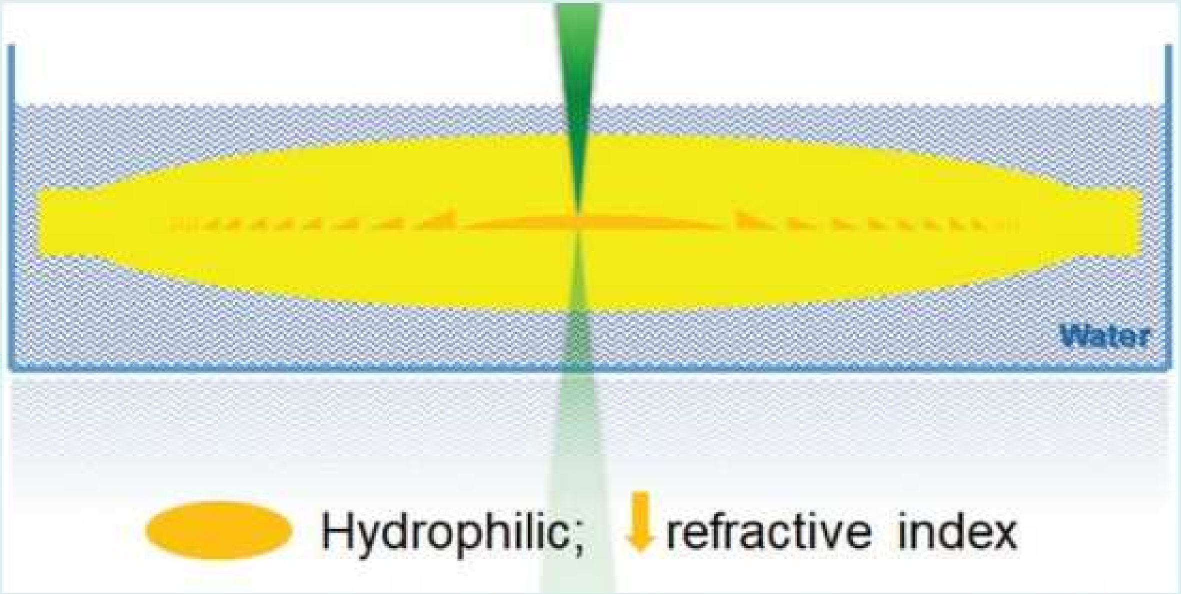


Figure 1. Schematic drawing shows femtosecond laser treatment within the IOL substance for power adjustment.

Adjustable intraocular lens power technology

Joshua Ford, MD, Liliana Werner, MD, PhD, Nick Mamalis, MD

J Cataract Refract Surg 2014;

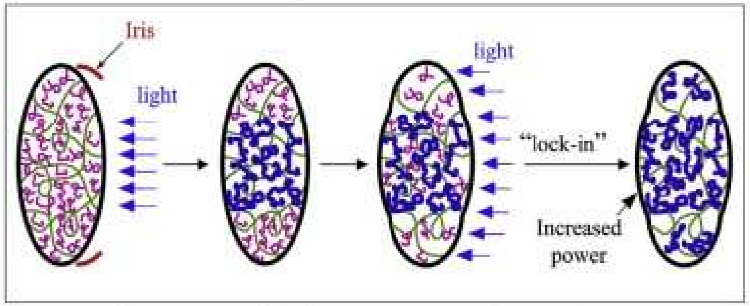
Refractive Index Shaping (RIS)

Femtosecond laser creation of a «lens in a lens» to adjust IOL power (by **modifying refractive index**) and to **transform a monofocal IOL into a multifocal IOL**

Unlike **LAL (light adjustable lens)** that require:

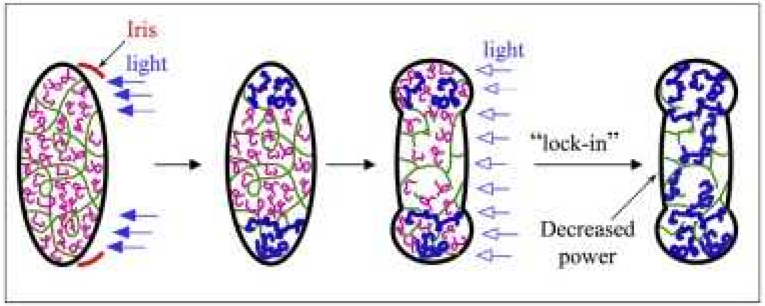
- **Specific three-piece silicone lens** manufactured **with a unpolymerized macromers** within the optic
- After appropriate power adjustment, **the power of this lens has to be locked in by irradiating** the entire lens (2 sessions)
- **The power of the lens can no longer be changed after irradiation**
- **Patient must wear special UV-protective eyeglasses** because **exposure to sunlight can unwanted refractive changes**

Adding Power to the LAL



=> change in radii of curvature => change in power
(*total time for macromer diffusion: 12-18 hours*)

Subtracting Power from the LAL



=> change in radii of curvature => change in power

IOL POWER ADJUSTMENT BY FEMTOSECOND LASER

This technology can potentially be used with any commercially available IOL.

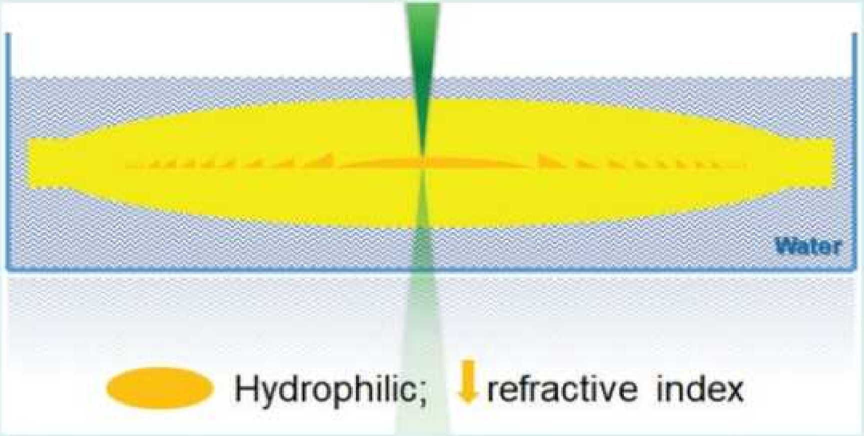
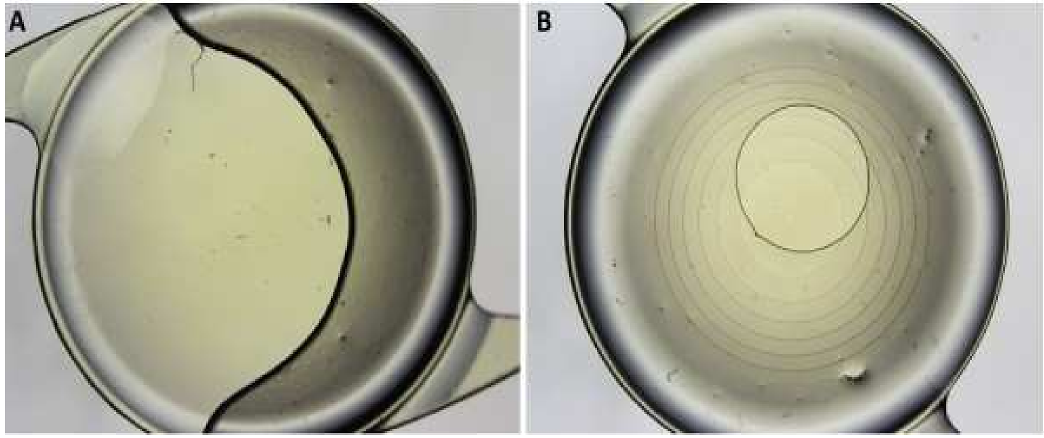


Figure 1. Schematic drawing shows femtosecond laser treatment within the IOL substance for power adjustment.

First human treatments (6 cases) presented at ESCRS 2024 by P. Stodulka (in vivo study soon)



Intraocular lens power adjustment by a femtosecond laser

In vitro evaluation of power change, modulation transfer function, light transmission, and light scattering in a blue light–filtering lens

Jason Nguyen, MD, Liliana Werner, MD, PhD, Jason Ludlow, MD, Joah Aliancy, MD, Larry Ha, BS, Bryan Masino, BS, Sean Enright, BS, Ray K. Alley, BS, Ruth Sahler, MSc

J Cataract Refract Surg 2018; In vitro

WHAT WAS KNOWN

- The refractive properties of a commercially available hydrophobic or hydrophilic acrylic IOL can be customized after implantation using a femtosecond laser through construction of a refractive-index-shaping lens within the implanted IOL with micrometer precision.

WHAT THIS PAPER ADDS

- Evaluation of IOL power, MTF, light transmission, and light scattering of commercially available blue light–filtering IOLs before and after power adjustment of −2.0 D by a femtosecond laser showed accurate changes in dioptric power while not significantly affecting the quality of the IOL optic.

Biocompatibility of intraocular lens power adjustment using a femtosecond laser in a rabbit model *J Cataract Refract Surg 2017;*

Liliana Werner, MD, PhD, Jason Ludlow, MD, Jason Nguyen, MD, Joah Aliancy, MD, Larry Ha, BS, Bryan Masino, BS, Sean Enright, BS, Ray K. Alley, BS, Ruth Sahler, MSc, Nick Mamalis, MD

Animal

Table 1. Power of the IOLs implanted in the rabbit eyes, measured with a PMTF device after explantation of the lenses 4 weeks postoperatively after full hydration.

	IOL Power (D)		
Rabbit	Treated	Contralateral Untreated	Change
1	+26.5	+23.2	+3.3
2	+26.9	+23.2	+3.7
3	+27.0	+23.7	+3.3
4	+26.7	+23.1	+3.6
5	+27.0	+23.0	+4.0
6	+26.8	+23.2	+3.6

WHAT WAS KNOWN

- Refractive properties of commercially available hydrophobic or hydrophilic acrylic IOLs can be customized after implantation using a femtosecond laser through construction of a refractive-index shaping lens within the implanted IOL with micrometer precision.

WHAT THIS PAPER ADDS

- Evaluation of the refractive-index shaping lens using the femtosecond laser in vivo in the rabbit model resulted in similar uveal and capsule biocompatibility outcomes in treated eyes and untreated eyes as well as in the power change to the treated lenses with no damage to their optics.

Take home messages: which technique to use?

L. Mastropasqua, 2025

MYOPIA

Low myopia (-1,00 sph -> -3,00 sph)	Moderate myopia (-3,00 sph -> -6,00 sph)	High myopia (-6,00 sph -> -10,00 sph)	Very high myopia (> -10,00 sph)
PRK LASIK SMILE ICL RLE (age)	LASIK SMILE ICL RLE (age)	SMILE ICL RLE (age)	ICL RLE (age)
- Age - History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit	- Age - History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit	- Age - History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit	Evaluate history, age, ACD & ECD, fundus oculi

Take home messages: which technique to use?

L. Mastropasqua, 2025

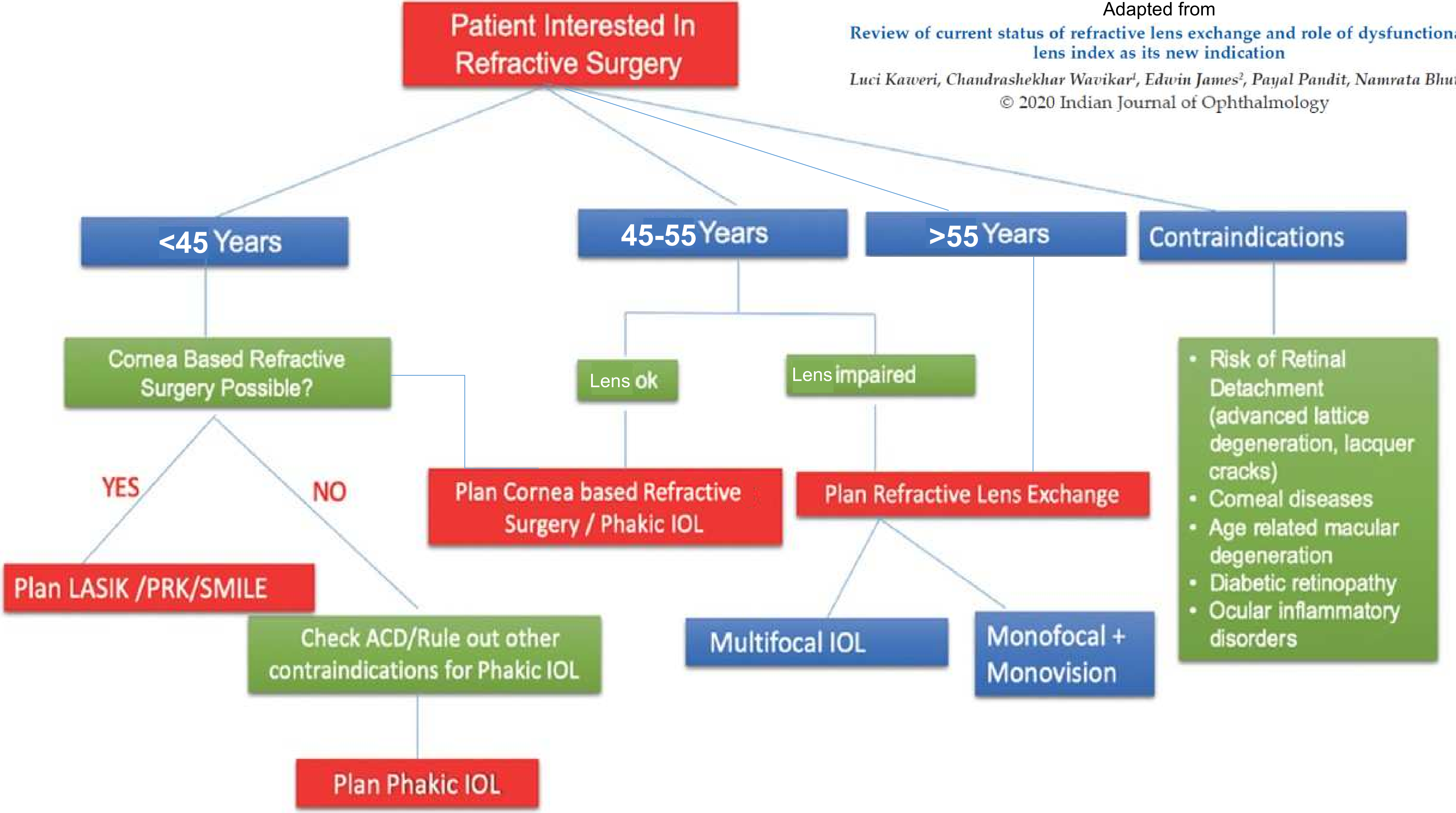
HYPEROPIA

Low hyperopia (+1,00 sph -> +3,00 sph)	Moderate hyperopia (+3,00 sph -> +6,00 sph)	High hyperopia (> +6,00 sph)
PRK LASIK SMILE ICL RLE (age)	LASIK SMILE ICL RLE (age)	ICL RLE (age)
- Age & History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit	- Age & History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit	- Age & History - Corneal parameters - Pupil diameter - ACD & ECD - Patient preference - Cost/benefit

Adapted from

Review of current status of refractive lens exchange and role of dysfunctional lens index as its new indication

Luci Kaweri, Chandrashekhar Wavikar[1], Edwin James[2], Payal Pandit, Namrata Bhuta



Refractive surgery: Paradigm Shift !

SMILE

- All-Femto (no excimer)
- Myopia (from -1 to -10 D) & Hyperopia
- No pain
- No regression
- No dry eye
- No ectasia
- No clinically significant aberrations
- Fast recovery
- Tissue sparing
- Biomechanics preservation (RSB)
- Resistance to trauma

P-ICL

- No corneal surgery
- Myopia and Hyperopia (from ±1 up to ± 20 D)
- No pain
- Fast recovery
- No clinically significant aberrations
- No cataract induction
- No glaucoma (central port)
- Reversible surgery
- Possibility of presbyopia treatment

F-LASIK

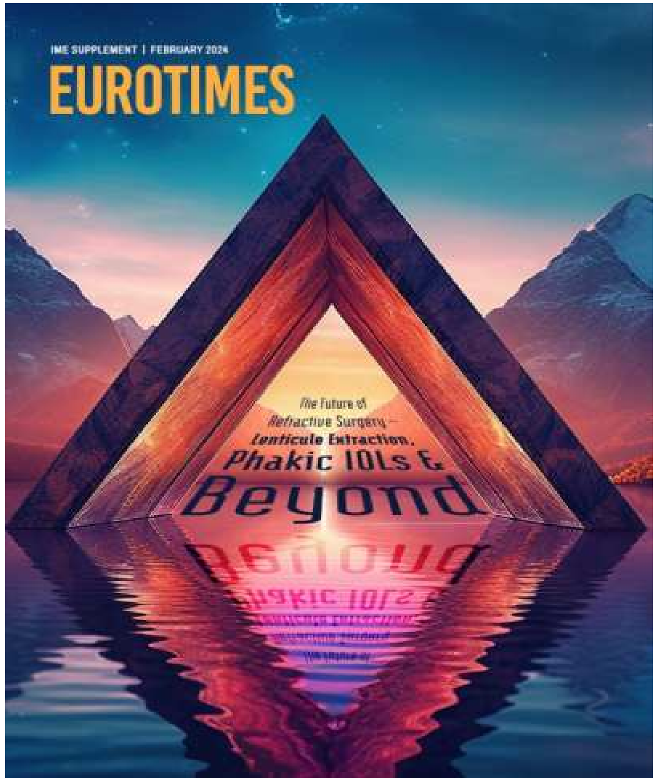
- Low myopia
- Hyperopia (up to 3-4 D)
- Presbyopia

PRK

- Low myopia
- HOA > 0,4 RMS

Refractive Lens Exchange

- Hyperopes with < 2,5 mm ACD and > 45 years
- High/very high myopes > 55 years (with normal fundus)



What to do if all procedures are equally possible?

- ✓ **Patient preference and lifestyle** (expectations)

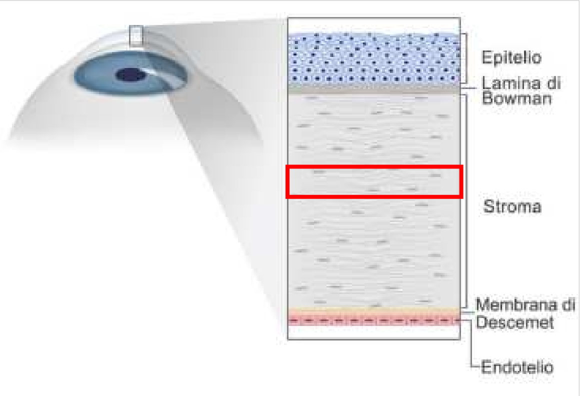
- ✓ **Counselling** («Doc, what would you do if it was your relative?»)

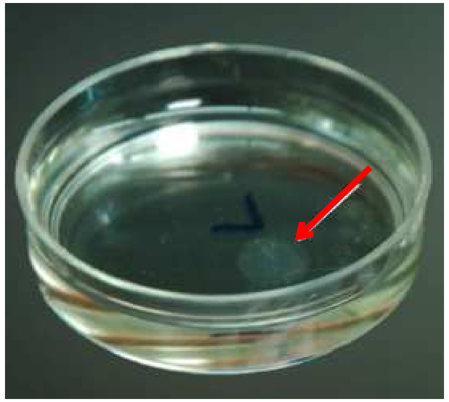
- ✓ **Risk/benefit ratio** (still unclear for PIOL due to low amount of long-term studies on complications in literature)

- ✓ **Surgeon personal expertise in one or more techniques** (can affect outcomes!)

Corneal Stromal Lenticules

SMILE lenticules are neatly cut discs of **native**, **well-organized collagen-rich ECM** that are **ultrathin** (about 30–140 µm thick) **transparent**, **avascular**, and **mechanically strong**, obtained **from young, healthy corneas.** Their **discard** is an enormous **waste** of a **valuable resource of tissue** that can be **reused for therapeutic uses**, moreso with the constantly growing number of SMILE surgeries.





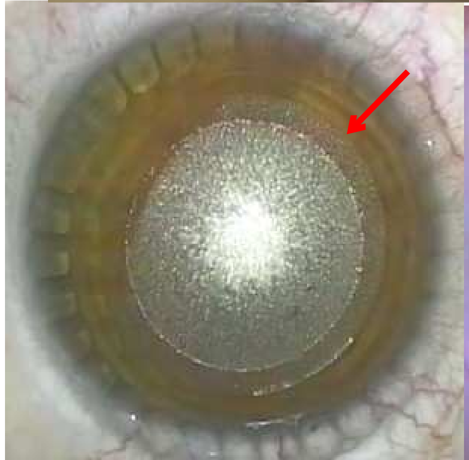

International Journal of Molecular Sciences

Int. J. Mol. Sci. 2022, *23*, 7967.

Review

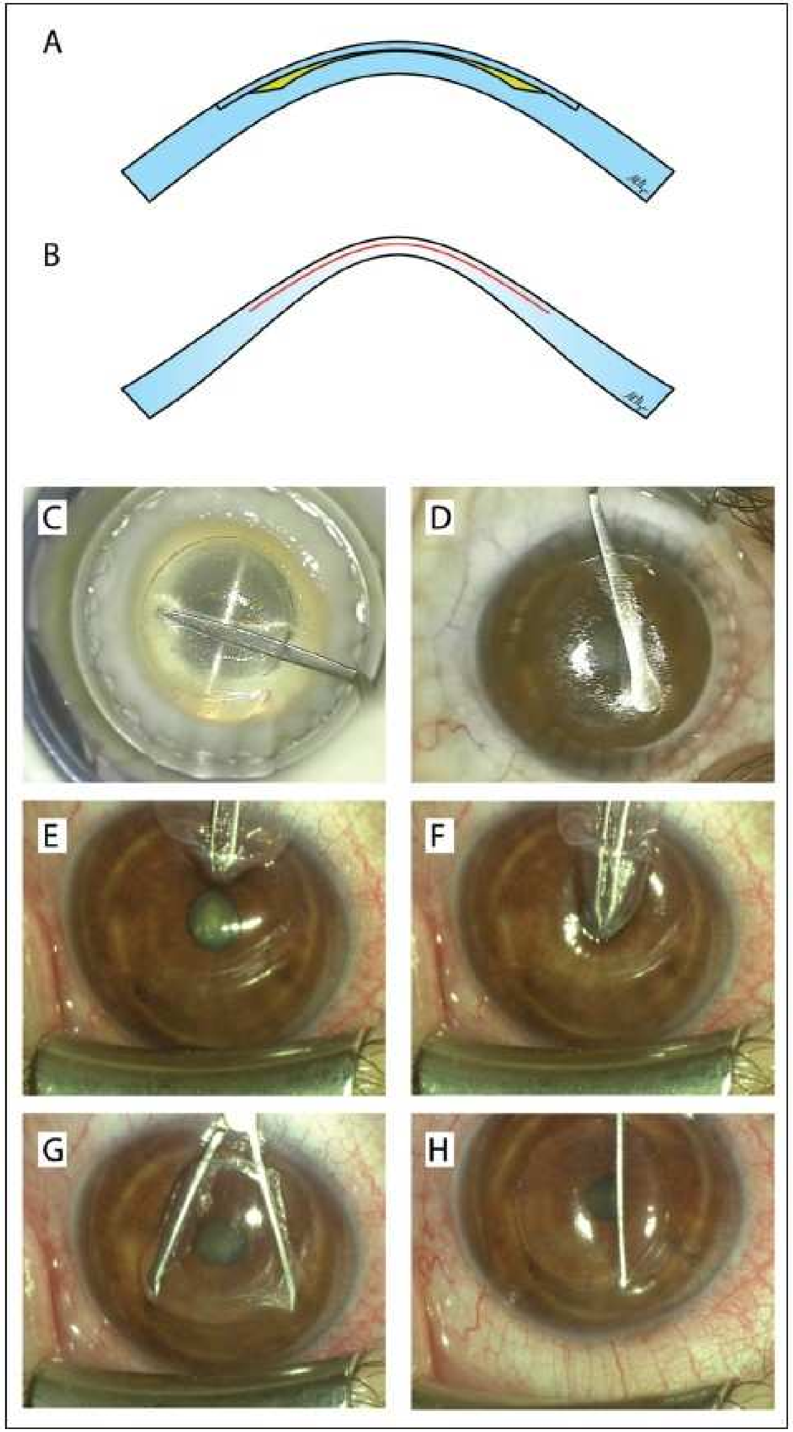
Human SMILE-Derived Stromal Lenticule Scaffold for Regenerative Therapy: Review and Perspectives

Mithun Santra [1], Yu-Chi Liu [2,3], Vishal Jhanji [1] and Gary Hin-Fai Yam [1,2,4,*]



Corneal stromal lenticule provides a possible source of bio-scaffold

- ✓ **Discarded tissue with minor ethical issues**
- ✓ **Natural and biocompatible**
- ✓ **High availability from SMILE procedure**
- ✓ **Possibility to preservation and banking**

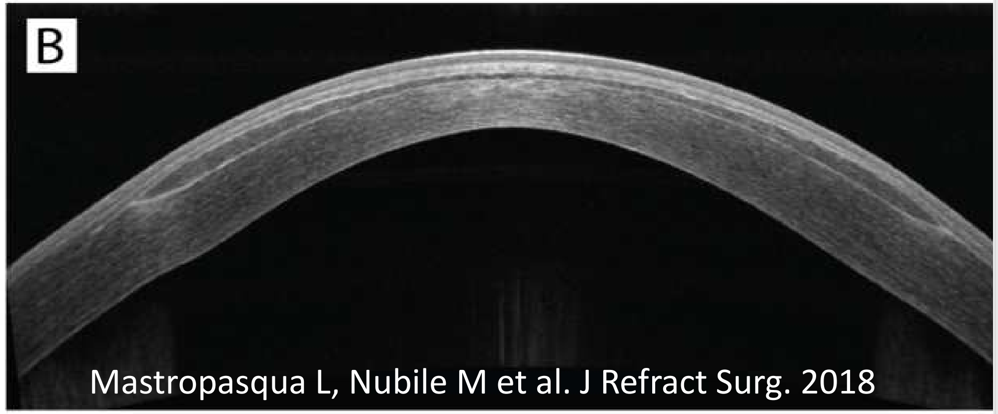


THERAPEUTIC REFRACTIVE SURGERY

SLAK

Femtosecond Laser–Assisted Stromal Lenticule Addition Keratoplasty for the Treatment of Advanced Keratoconus: A Preliminary Study

Leonardo Mastropasqua, MD; Mario Nubile, MD, PhD; Niccolò Salgari, MD; Rodolfo Mastropasqua, MD



Mastropasqua L, Nubile M et al. J Refract Surg. 2018

- 10 cases of **Advanced Keratoconus** (curvature range 55-70 D – CCT: 290-450 microns)
- Transparent cornea
- BSCVA (<20/200)
- Contact lens intolerant
- Stable keratoconus / Candidate for DALK/PK
- LENTICULES were obtained from Eye-bank donor corneas suitable for PK-DALK

Journal of Refractive Surgery

Top cited articles

in current impact factor calculation

	Author(s)	Title	Publication Date	Times Cited
1	Cochener, Beatrice; Boutillier, Guillaume; Lamard, Mathieu; Auberger-Zagnoli, Claire	A Comparative Evaluation of a New Generation of Diffractive Trifocal and Extended Depth of Focus Intraocular Lenses	August 2018	32
2	Wallerstein, Avi; Gauvin, Mathieu; Qi, Susan Ruyu; Bashour, Mounir; Cohen, Mark	Primary Topography-Guided LASIK: Treating Manifest Refractive Astigmatism Versus Topography-Measured Anterior Corneal Astigmatism	January 2019	16
3	Savini, Giacomo; Schiano Lomoriello, Domenico; Balducci, Nicole; Barboni, Piero	Visual Performance of a New Extended Depth-of-Focus Intraocular Lens Compared to a Distance-Dominant Diffractive Multifocal Intraocular Lens	April 2018	14
4	Luft, Nikolaus; Schumann, Ricarda G.; Dirisamer, Martin; Kook, Daniel; Siedlecki, Jakob; Wertheimer, Christian; Priglinger, Siegfried G.; Mayer, Wolfgang J.	Wound Healing, Inflammation, and Corneal Ultrastructure After SMILE and Femtosecond Laser-Assisted LASIK: A Human Ex Vivo Study	June 2018	11
5	Mastropasqua, Leonardo; Nubile, Mario; Salgari, Niccolo; Mastropasqua, Rodolfo	Femtosecond Laser-Assisted Stromal Lenticule Addition Keratoplasty for the Treatment of Advanced Keratoconus: A Preliminary Study	January 2018	10

ORIGINAL ARTICLE [J Refract Surg. 2020;36(8):544-550.]

In Vivo Confocal Microscopy of Stromal Lenticule Addition Keratoplasty for Advanced Keratoconus

Leonardo Mastropasqua, MD; Niccolò Salgari, MD; Erminia D'Ugo, MD; Manuela Lanzini, MD; Jorge L. Alió del Barrio, MD, PhD; Jorge L. Alió, MD, PhD; Beatrice Cochener, MD; Mario Nubile, MD, PhD

TABLE 1
Mean Subbasal Nerve Density (mm/mm^2), Mean Keratocyte Density (cell/mm^2), and Relative Donor-Recipient Interface Reflectivity

		Keratocyte Density		Relative Reflectivity	
Time	Subbasal Nerve Density	Anterior Stroma	Posterior Stroma	Anterior Interface	Posterior Interface
Preoperative	13 ± 3	760 ± 115	583 ± 85	–	–
1 week	4 ± 2	663 ± 98	450 ± 90	46.3 ± 18.1	48.6 ± 20.1
1 month	3 ± 2	699 ± 86	485 ± 97	42.4 ± 15.0	42.1 ± 18.2
3 months	11 ± 2	730 ± 93	505 ± 87	25.6 ± 16.1	28.8 ± 13.0
6 months	12 ± 5	724 ± 107	531 ± 71	25.3 ± 14.3	29.0 ± 15.1
12 months	12 ± 2	748 ± 103	567 ± 73	24.8 ± 10.2	23.9 ± 14.0

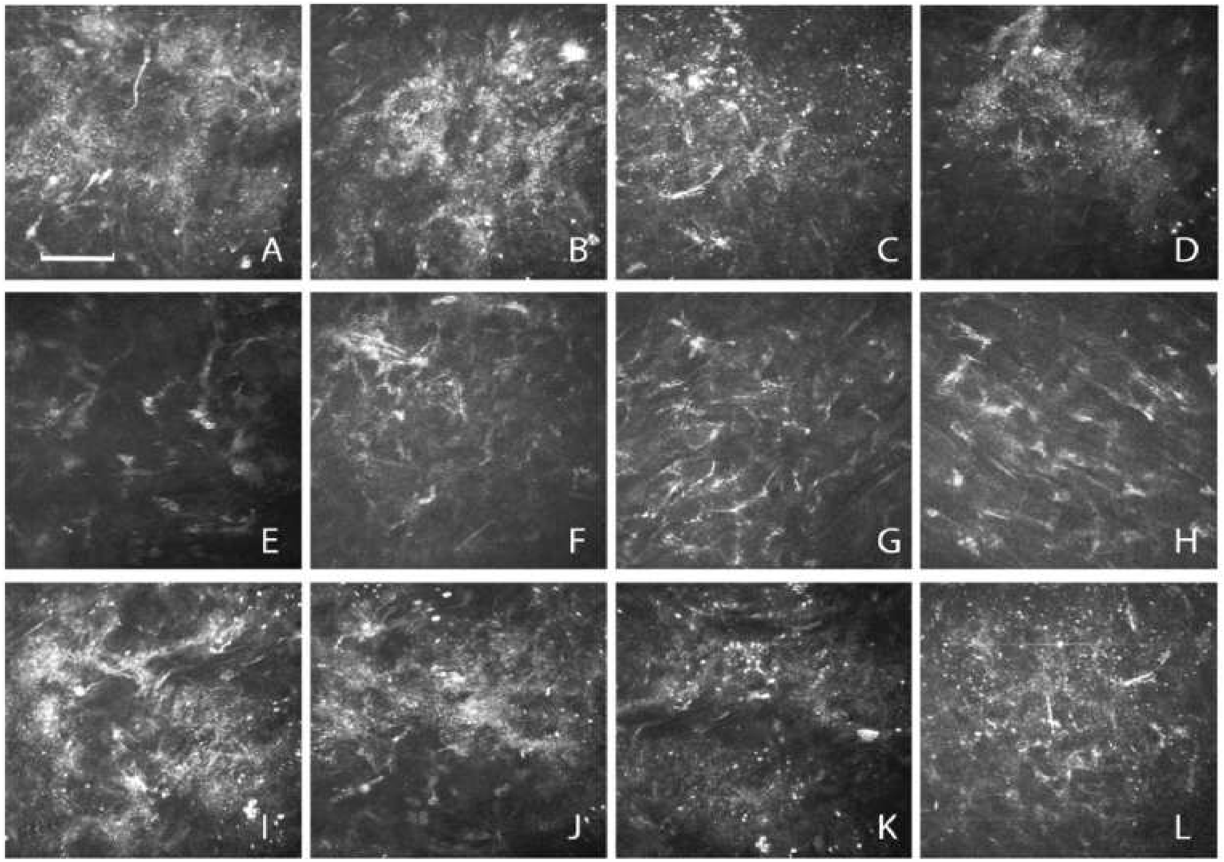


Figure A. Anterior and posterior lenticule interfaces appeared hyperreflective at 1 week (A and I, respectively) with presence of cellular and matrix debris. Reflectivity gradually decreased over time (B and J at 1 month; C and K at 3 months) but was still noticeable at 12 months (D and L). (E) Edema with reduced keratocyte density in lenticule stroma was observed at 1 week. (F) At 1 month, edema subsided but keratocyte nuclei still appeared reduced in number and altered in morphology. Cell density gradually increased and morphology improved over time (G: 3 months) but nuclear shape still appeared irregular at 12 months (H). (Caliper is 100 μm.)

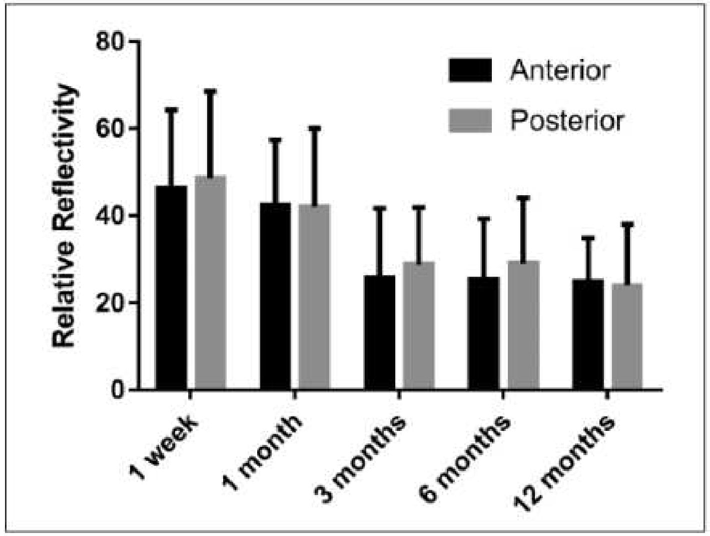


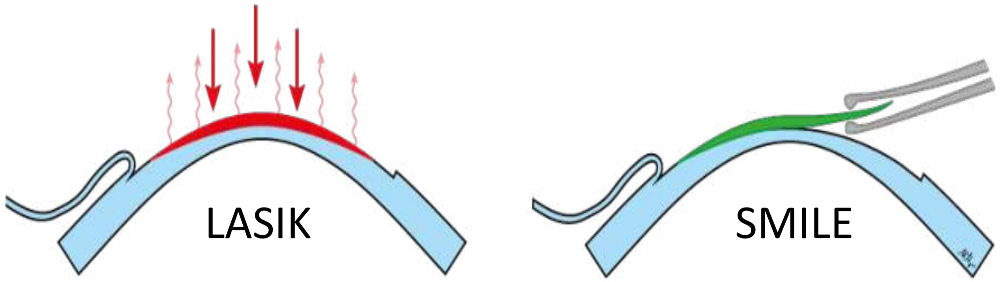
Figure 2. Relative reflectivity level of the anterior and posterior stromal interfaces between donor and recipient.

SLAK:

Mild wound healing reaction, stable interface reflectivity, absence of immune stromal rejection

CONCLUSIONS: Stromal lenticule addition keratoplasty produces transitory nerve plexus density reduction and minor inflammatory reaction that rapidly decreases during the first month. Donor-recipient interface reflectivity is comparable to a femtosecond laser refractive procedure with no sign of stromal opacification or stromal rejection in 1 year of follow-up.

Lenticule banking?



A reversible procedure:

REMOVED TISSUE IS STILL VITAL

The stromal lenticule extracted following ReLEx **maintain keratocyte viability** and overall **collagen structural integrity** in pre- and post- cryopreserved tissue samples.

*Image courtesy of Miracles In Sight Eye Bank (Winston-Salem, North Carolina, U.S.A.

«The potential option of **STROMAL LENTICULE STORAGE AFTER RELEX/SMILE** offers patients the unique opportunity of **bank** their tissue in case of future need, **or to donate** their tissues to others in need».

Risk Evaluation of Human Corneal Stromal Lenticules From SMILE for Reuse

Yanfeng Shang, MD, Yu Li, MD, PhD, Zhiqun Wang, MD, Xuguang Sun, MD, PhD, and Fengju Zhang, MD, PhD

Journal of Refractive Surgery 2020

Preservation of corneal stromal lenticule: review

Martina Nemcokova · Jakub Dite · Yun Min Klimesova · Magdalena Netukova · Pavel Studeny

Cell tissue bank - 2021

Experiment-Based Validation of Corneal Lenticule Banking in a Health Authority-Licensed Facility

Andri K. Riau, Kenny P.Y. Boey, Nur Zahirah Binte M. Yusoff, Tze-Wei Goh, Gary H.F. Yam, Kin F. Tang, Catherine S.H. Phua, Hui-Jun Chen, Yoke F. Chiew, Yu-Chi Liu, and Jodhbir S. Mehta

Journal of Tissue Engineering 2022

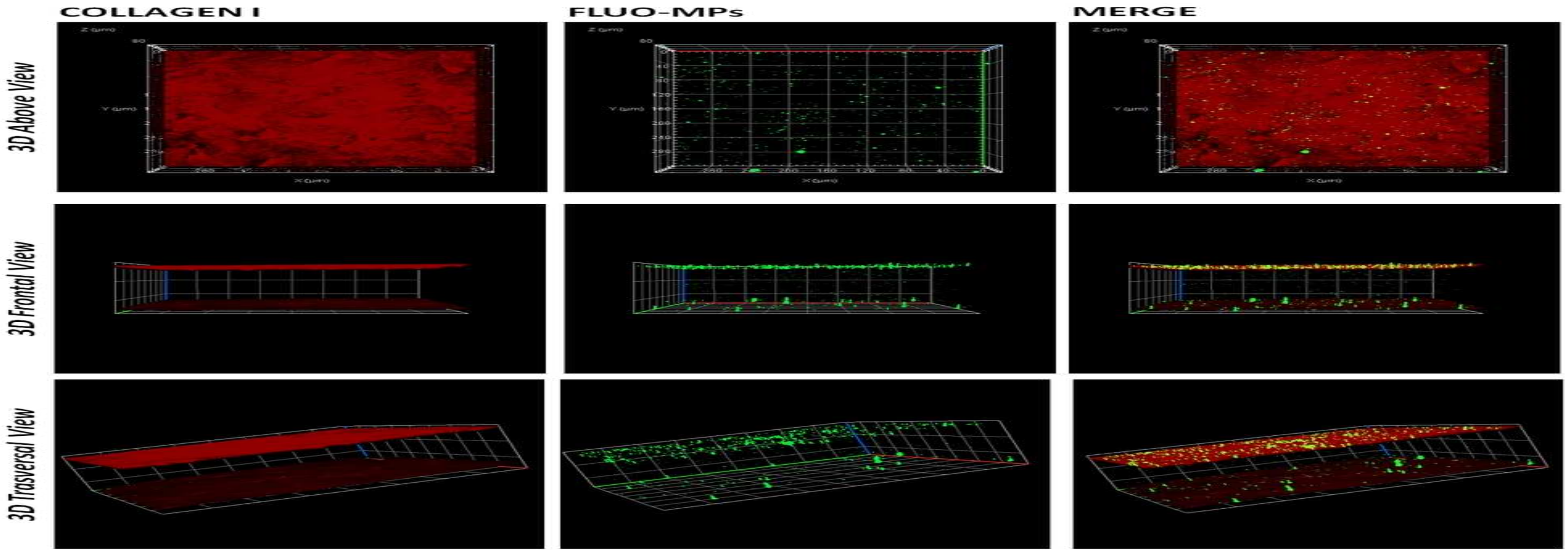
Banking of corneal stromal lenticules: a risk-analysis assessment with the EuroGTP II interactive tool

Esteve Trias · Paola Gallon · Stefano Ferrari · Ana Rita Piteira · Jaime Tabera · Ricardo P. Casaroli-Marano · Mohit Parekh · Alessandro Ruzza · Antonella Franch · Diego Ponzin

Cell tissue bank - 2020

Lenticule Bioengineering: The New Frontier

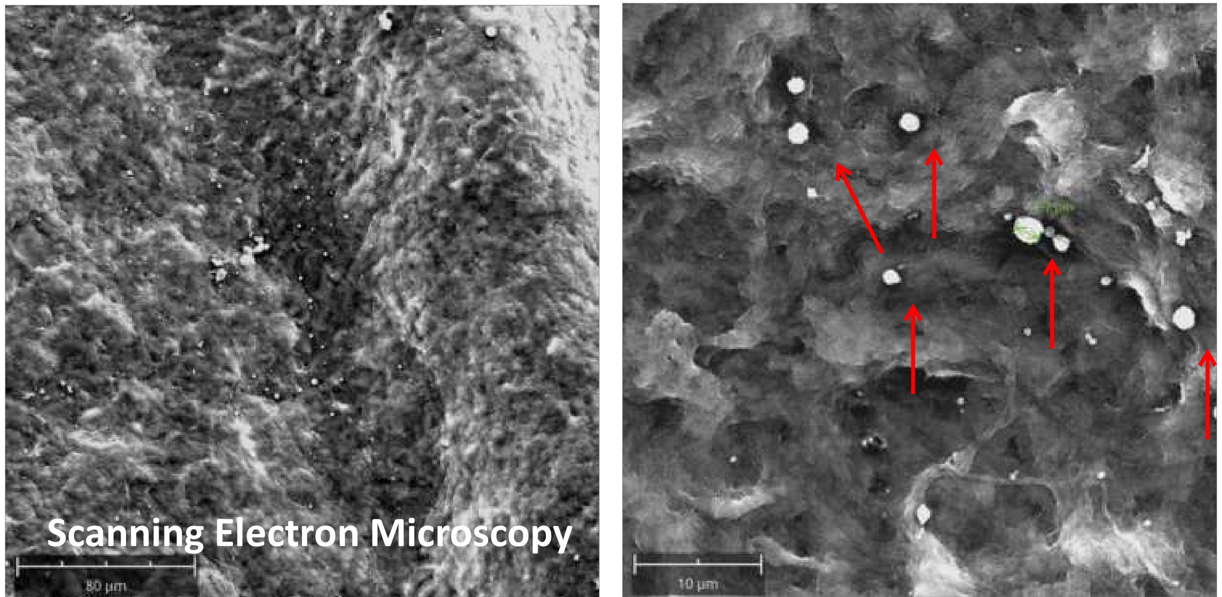
LENTICULE SURFACES | MICROPARTICLES | MERGE



Decellularized human SMILE-derived stromal lenticules with **recombinant human Nerve Growth Factor** (rhNGF) incorporated in **PLGA-microparticles**

3D Trasversal View

Collagen I – Red
Fluo-MPs - Green



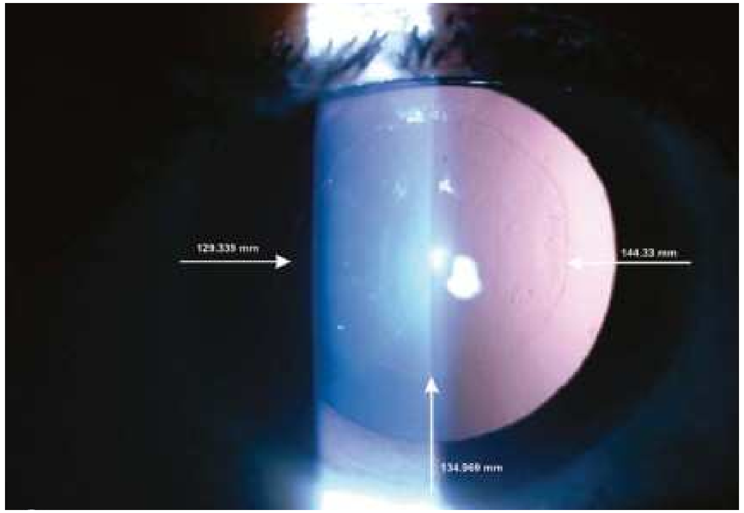
frontiers | Frontiers in Bioengineering and Biotechnology

Bioengineered Human Stromal Lenticule for Recombinant Human Nerve Growth Factor Release: A Potential Biocompatible Ocular Drug Delivery System

ORIGINAL RESEARCH
published: 23 June 2022
doi: 10.3389/fbioe.2022.887414

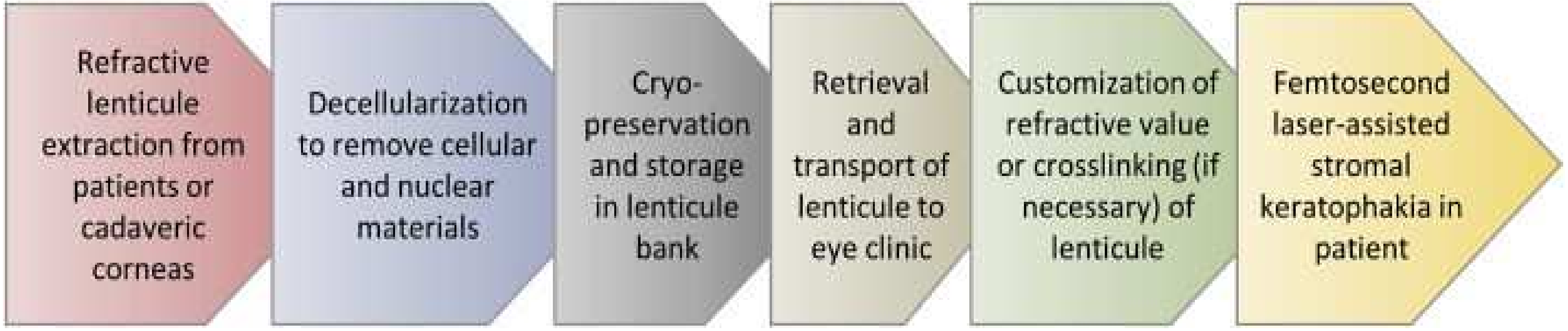
Leonardo Mastropasqua[1†], Mario Nubile[1†], Giuseppina Acerra[2], Nicola Detta[2], Letizia Pelusi[3], Manuela Lanzini[1], Simone Mattioli[2], Manuela Santalucia[3], Laura Pietrangelo[4], Marcello Allegretti[5], Harminder S. Dua[6], Jodhbir S. Mehta[7], Assunta Pandolfi[3†] and Domitilla Mandatori[3†]*

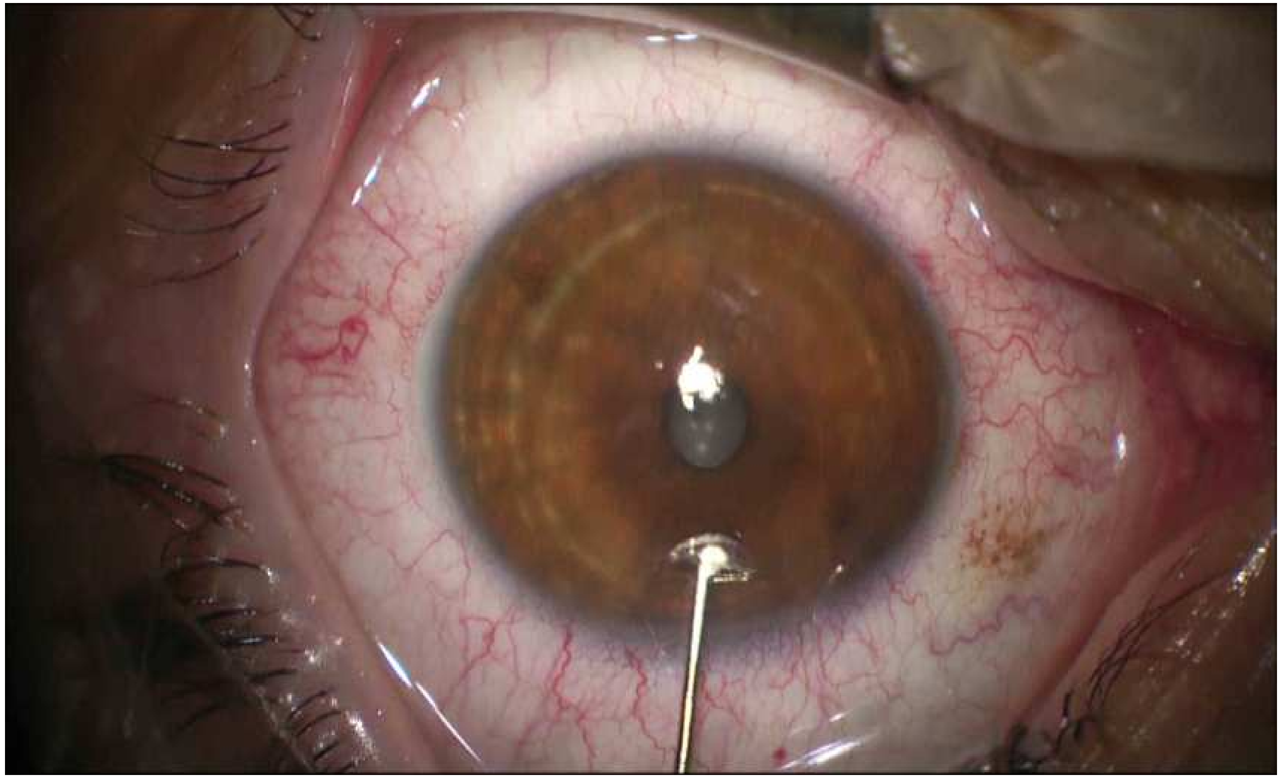
Refractive error correction with lenticule implantation: the future?

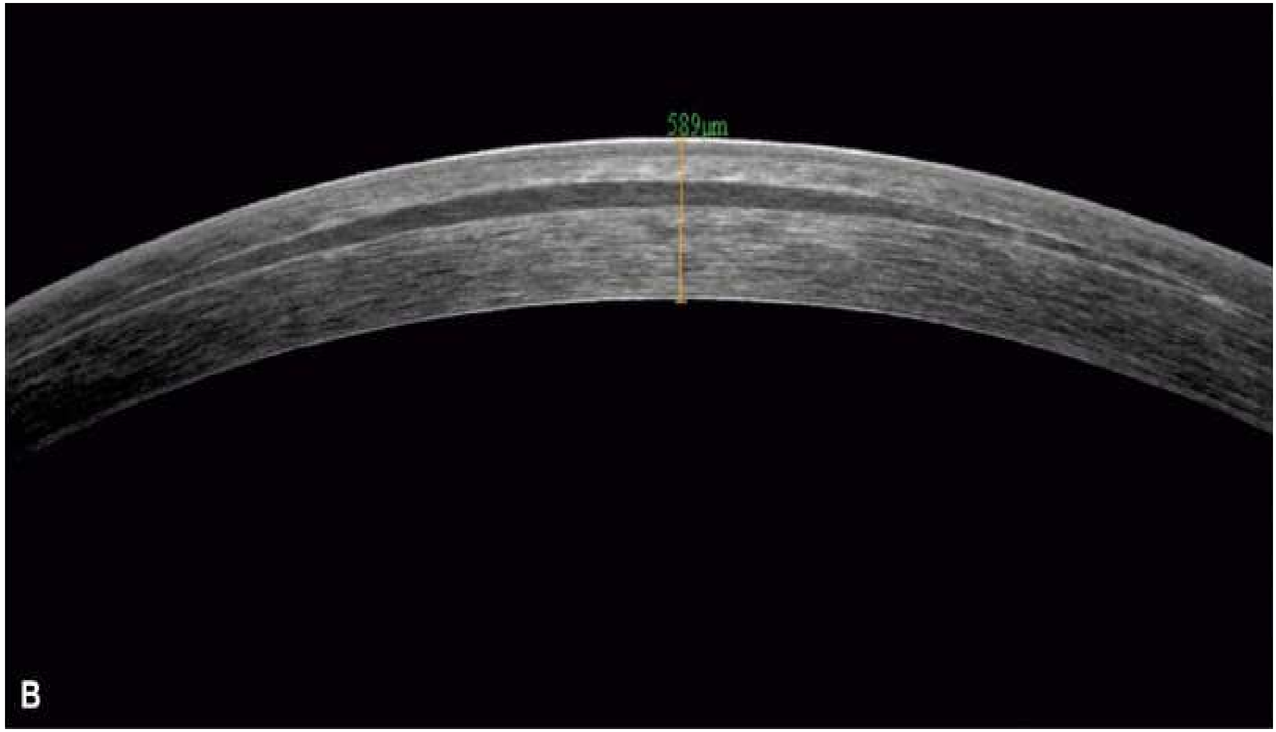


Stromal keratophakia: Corneal inlay implantation Progress in Retinal and Eye Research 2020

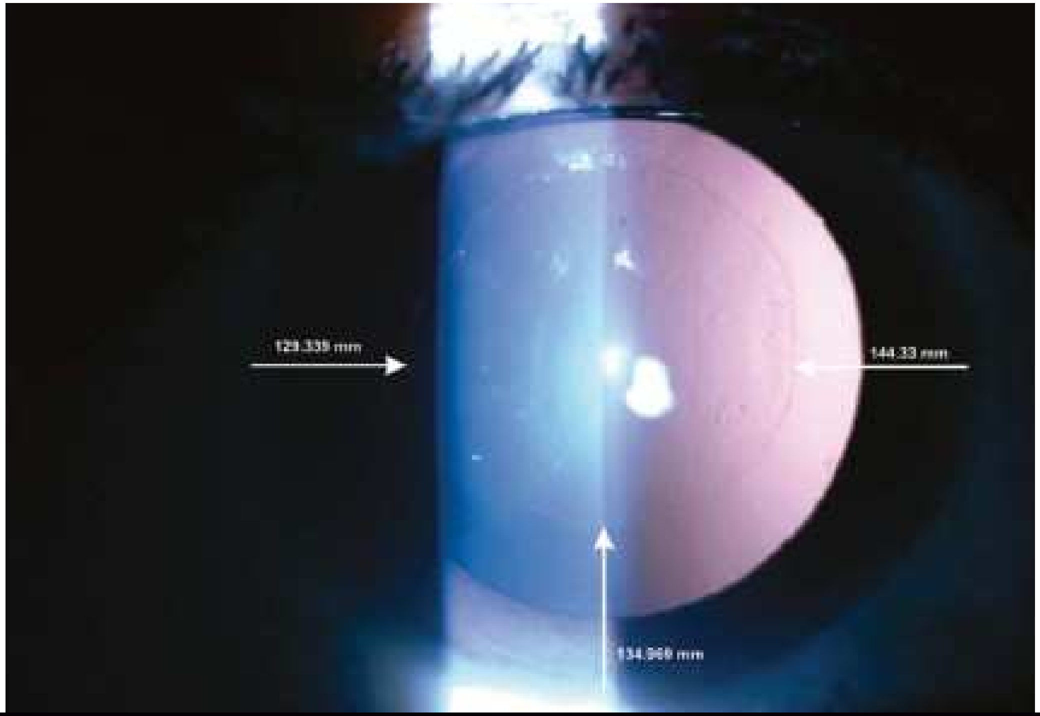
Andri K. Riau [a, 1], Yu-Chi Liu [a, b, c, 1], Gary H.F. Yam [a, b, 1], Jodhbir S. Mehta [a, b, c, 1]

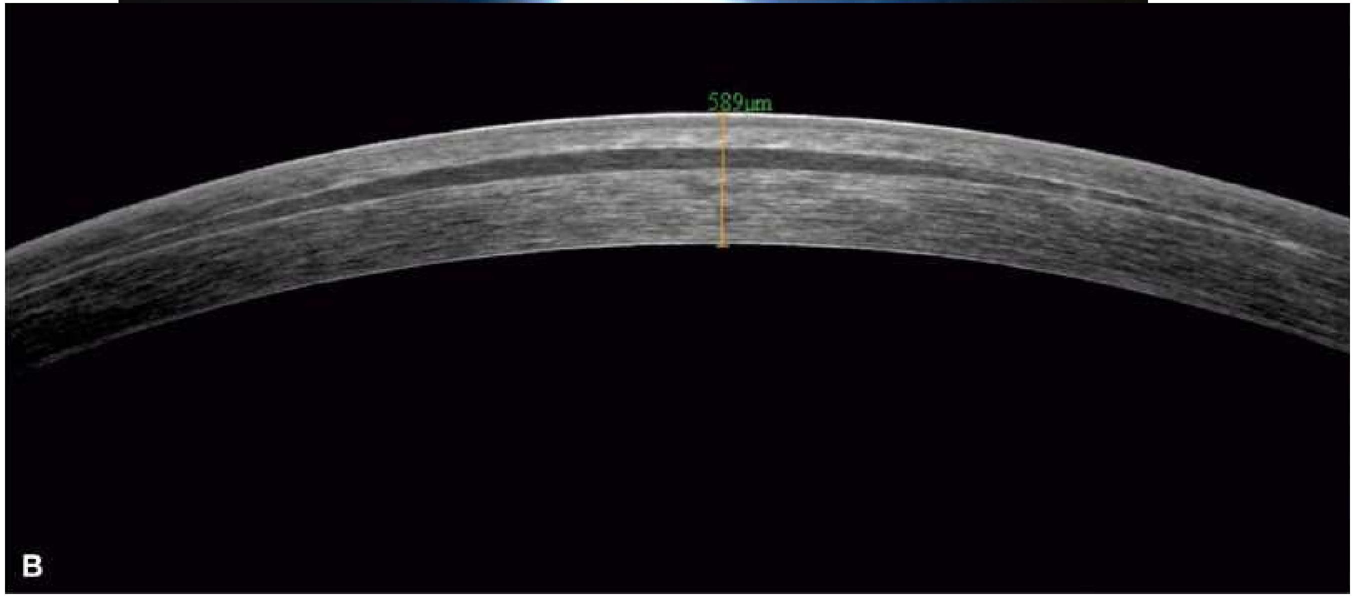






Correction of positive ametropia





Aphakia (first case)

- Pradhan KR, 2013
- Studer HP, 2015

Hyperopia

- Ganesh S, 2014
- Sun L, 2015
- Liu, 2015
- Damgaard, 2017
- Williams GP, 2018
- Moshirfar, 2018
- Zhang, 2021
- Brar, 2022
- Liu, 2022

Presbyopia

- Presbyiopic monovision -
  - Lim CH, 2013
- PEARL – Jacob, 2017
- Liu, 2018

Astigmatism

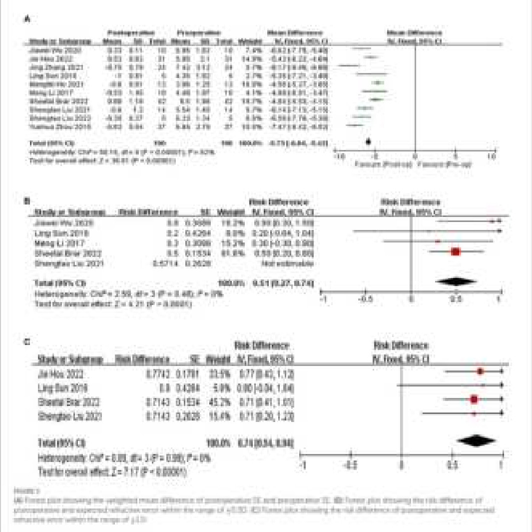
- Damgaard, 2019
- Stodulka, 2020

Allogenic Lenticular Implantation in HYPEROPIA

Efficacy and safety of small-incision corneal intrastromal lenticule implantation for hyperopia correction: a systematic review and meta-analysis

Yue Wang[1], Jingjing Zheng[1], Zuofeng Guo[1] and Xuejun Fang[1,2*]

[1]Ophthalmology, Liaoning Aier Eye Hospital, Shenyang, China, [2]AIER School of Ophthalmology, Central South University, Changsha, China

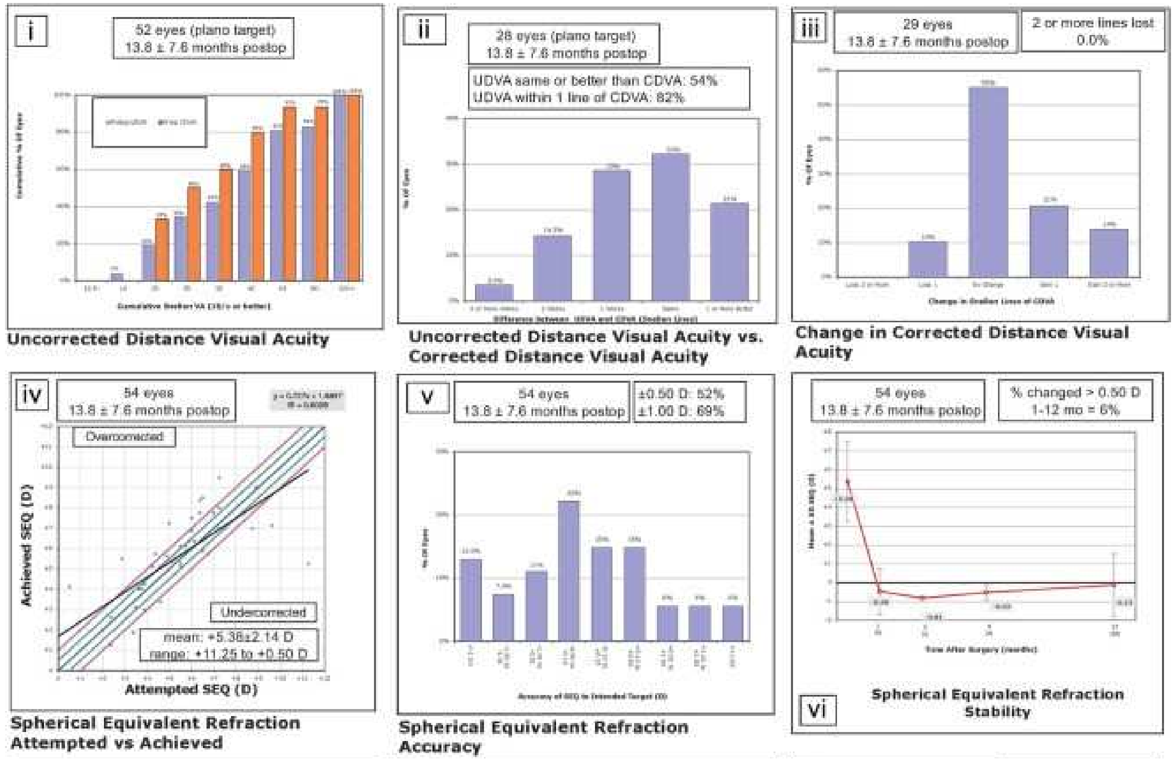


Front in Med 2024

Conclusion: Small-incision intrastromal lenticule implantation may be an effective solution for correcting hyperopia. The effect of improved vision is significant, but further exploration is needed for changes in corneal biomechanics and long-term safety.

A lenticule with a refractive power 1.2 times higher than the estimated power is required.

The equation is as follows: LAC (D) = 1.22 LRP (D) (LAC = lenticule implantation achieved correction, LRP = lenticule refractive power, both measured in diopters).



Moshifar M et al. Allogenic Lenticular Implantation for Correction of Refractive Error and Ectasia – Ophthalmol Ther

VA outcomes were not ideal, with only 60% of patients with 20/40 or better UDVA, only 19% with 20/20 or better UDVA

LENTICULE «MANUAL» CUSTOMIZATION STUDY

Ex Vivo Lenticule Customization for Stromal Lenticule Addition Keratoplasty

iovs investigative ophthalmology & visual science
an ARVO journal
2024

Mario Nubile,[1] Jorge L. Alio del Barrio,[2,3] Luca Cerino,[4] Niccolò Salgari,[5–7] Mona El Zarif,[1,8] Michele Totta,[1] Manuela Lanzini,[1] and Leonardo Mastropasqua[1]

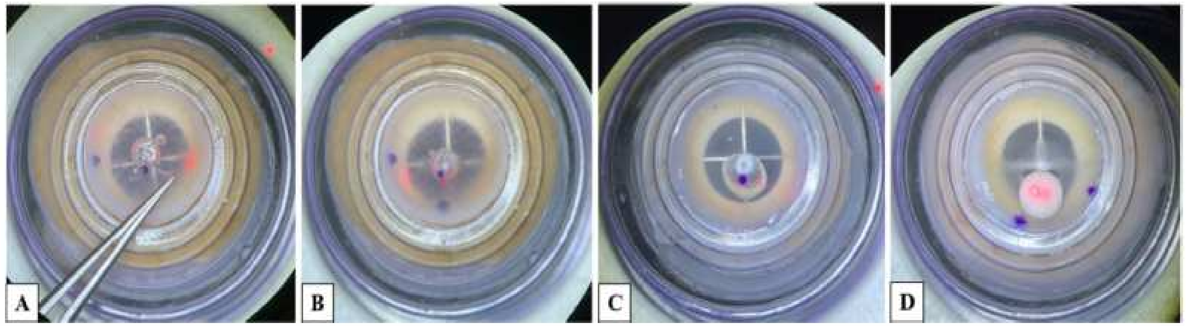


Figure 1 Keratoconus models. (A) Everted cornea is mounted onto the anterior chamber, Descemet membrane, and endothelium are removed before ablation. (B) Off-centered myopic ablation (-18 D) is performed on the posterior surface to simulate posterior ectasia and stromal thinning. (C) In model 1, the cornea is returned to its normal position and the anterior surface hyperopic ablation on the mark (+5 D, 5 mm optical zone) is performed. (D) In model 2, the cornea is returned to the normal position and the anterior surface PTK ablation is performed with a 4 mm mask (8 mm diameter and 100 µm depth).

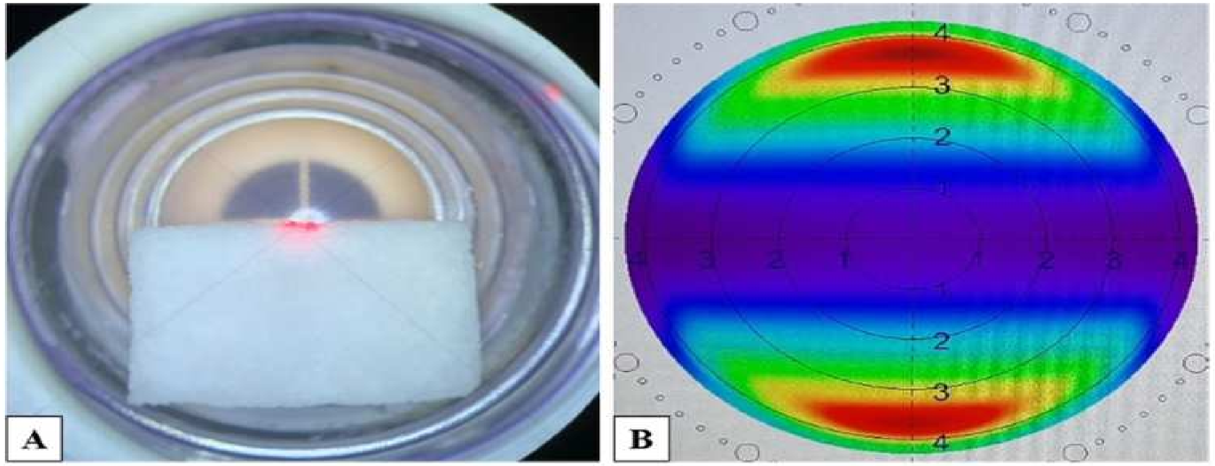


Figure 3 Planar and negative lenticules customization. After placing a 10 mm-wide mask onto the inferior half of the lenticule (A), an astigmatic PRK treatment (B) is performed to produce a bowtie ablation of the superior half only.

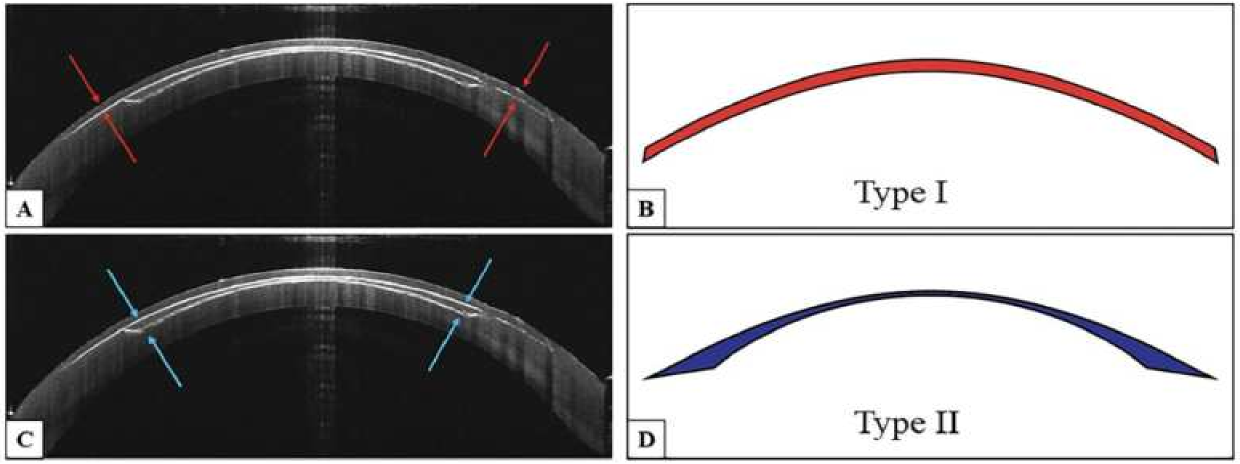


Figure 2 Non-customized lenticules. (A, B) Type I lenticule, with a planar shape (B), is obtained from the 120 µm stromal flap (A; *red arrows*) of the ReLEx-FLEx procedure. (C, D) Type II lenticule, with a negative meniscus shape (D), is sculpted with a +8 D hyperopic FSL ReLEx-FLEx treatment (C; *blue arrows*).

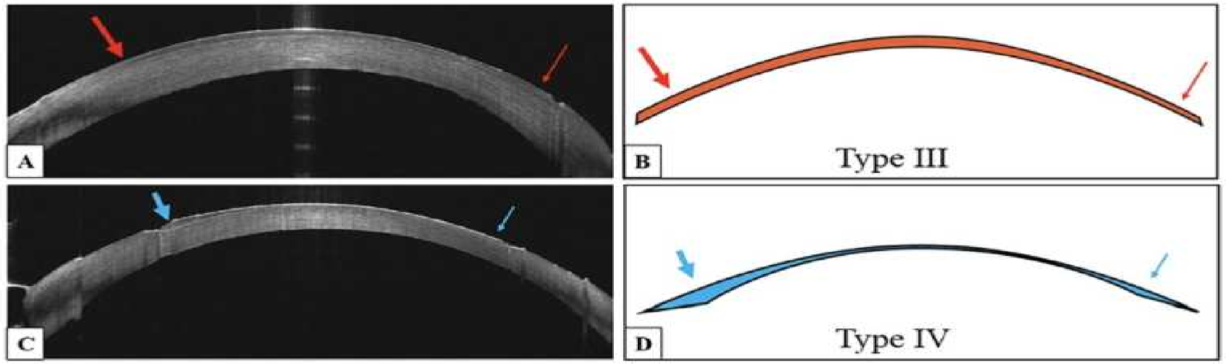


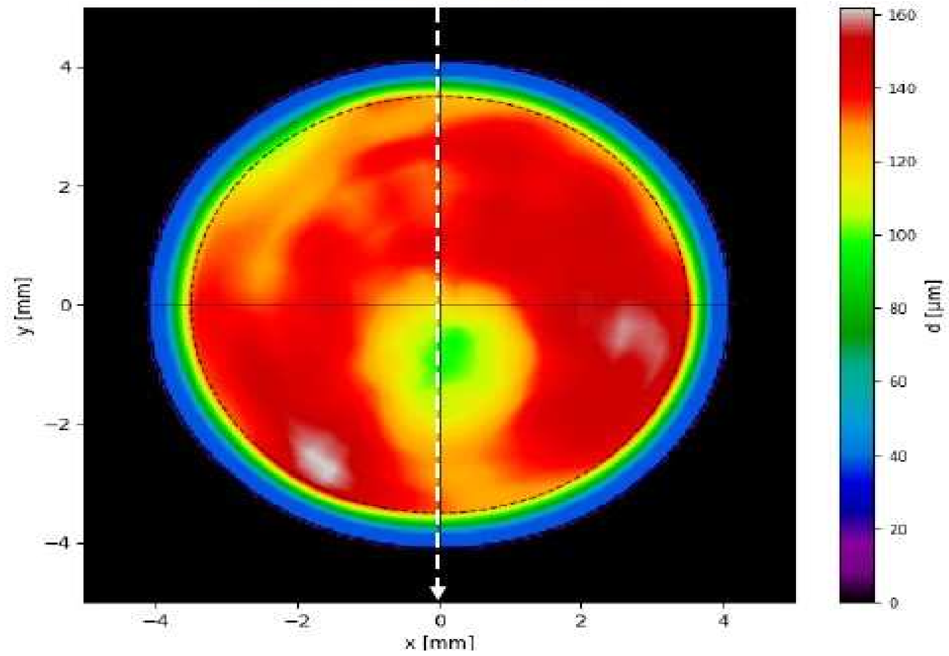
Figure 4 Planar and negative customized lenticules. (A, B) Type III lenticule, with an asymmetric planar shape (B), is obtained through masked excimer laser ablation of the ReLEx-FLEx stromal flap (A). The *thick red arrow* indicates the masked zone, and the *thin red arrow* indicates the ablated zone. (C, D) Type IV lenticule, with an asymmetric negative meniscus shape (D), is obtained through masked excimer laser ablation of the stromal lenticule sculpted with the ReLEx-FLEx treatment after flap removal (C). The *thick blue arrow* indicates the masked zone and the *thin blue arrow* indicates the ablated zone.

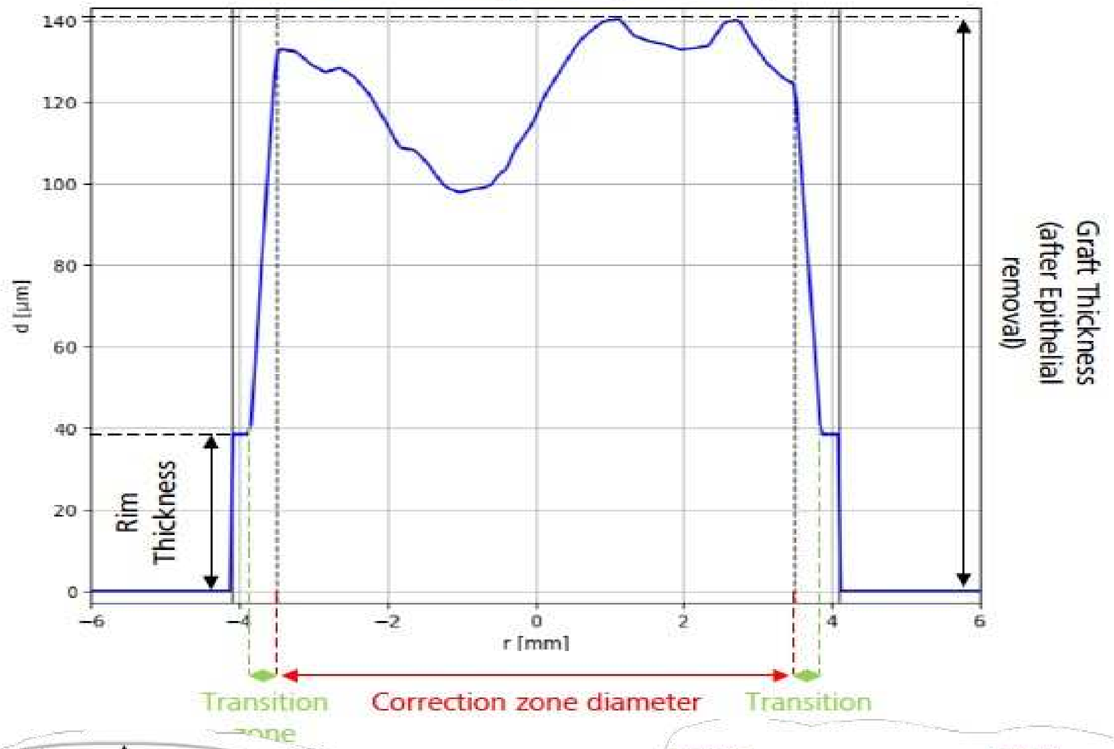
LENTICULE «AUTOMATED» CUSTOMIZATION STUDY

CONFIDENTIAL

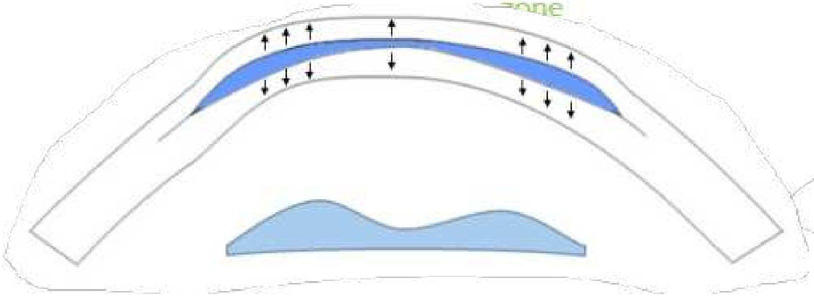
Cornea 231540 (KC-Model CRT 2) – 20.06.2023 (Chieti)
Simulated Implant

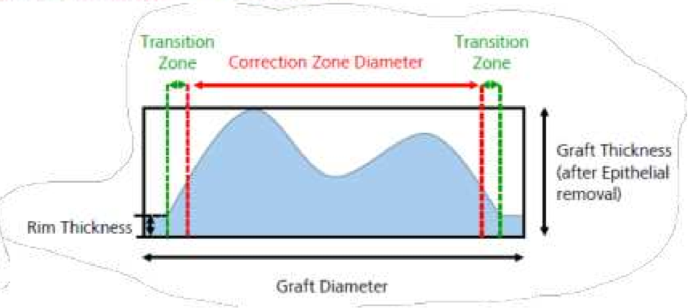
ZEISS





Target corneal radius (post OP):	7.5 mm
Correction zone diameter:	7.0 mm
Rim thickness:	35 µm
Graft Thickness:	162 µm

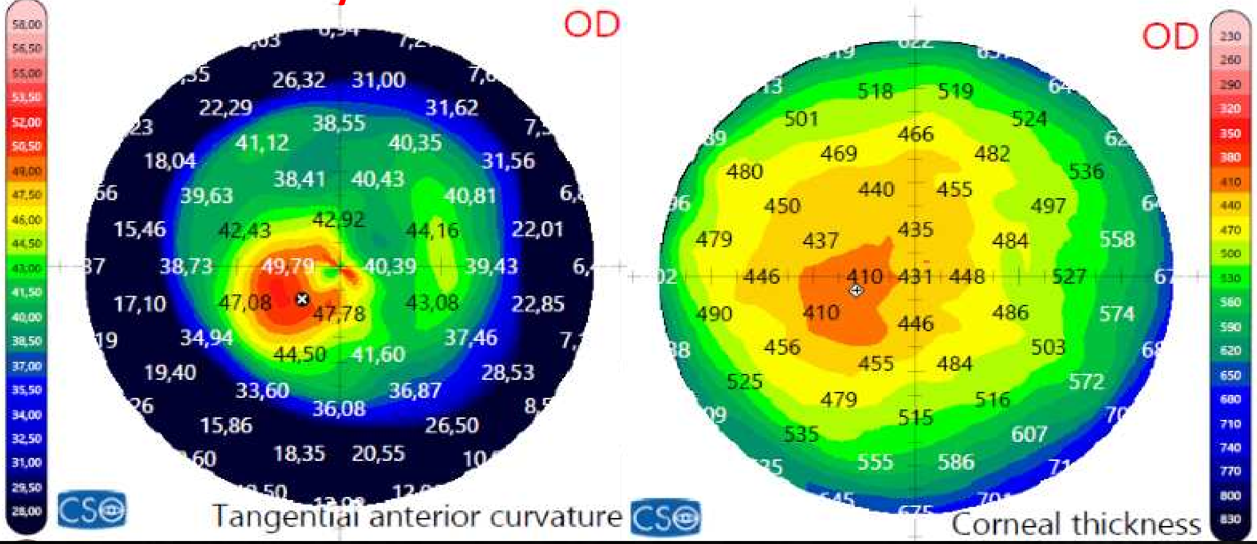




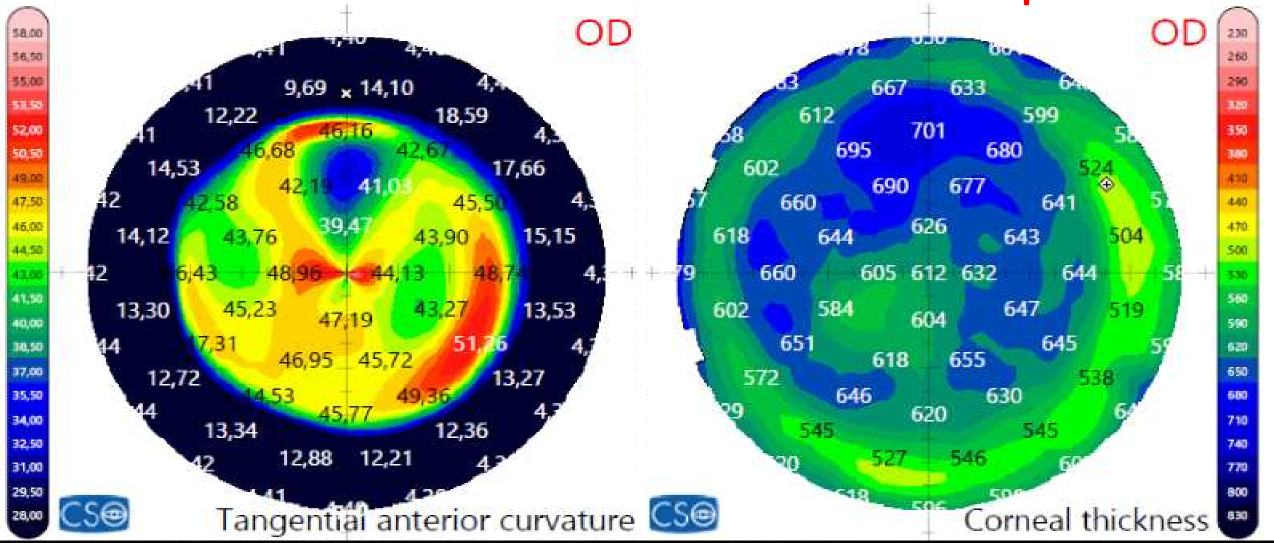
Excimer-laser customization of corneal lenticule based on topography profile to be implanted

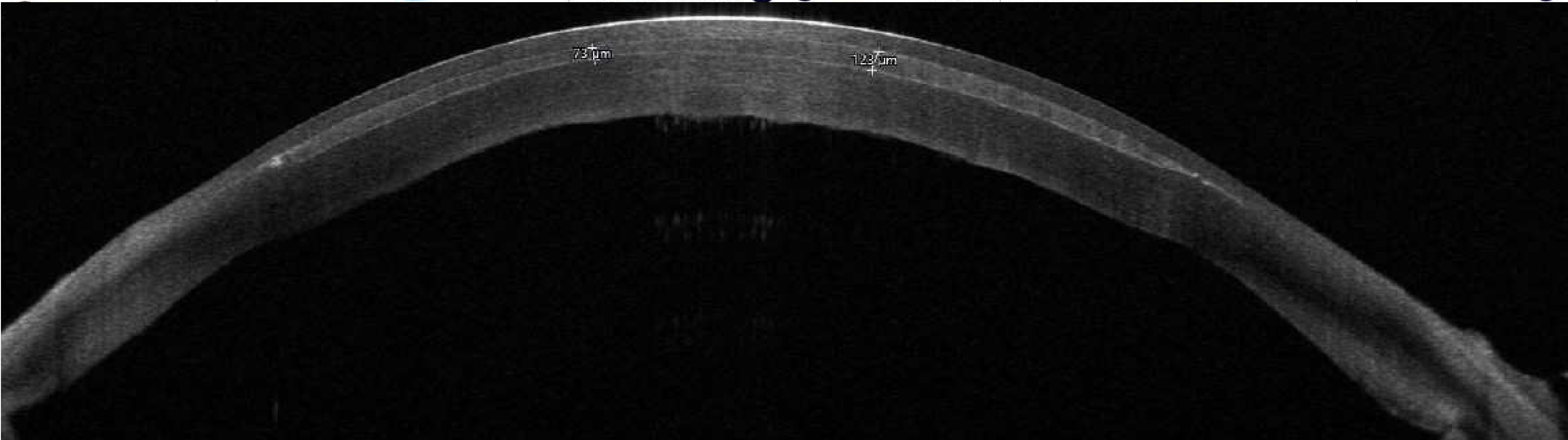
LENTICULE «AUTOMATED» CUSTOMIZATION STUDY

Excimer laser asymmetric KC model



Post excimer laser customized lenticule implantation

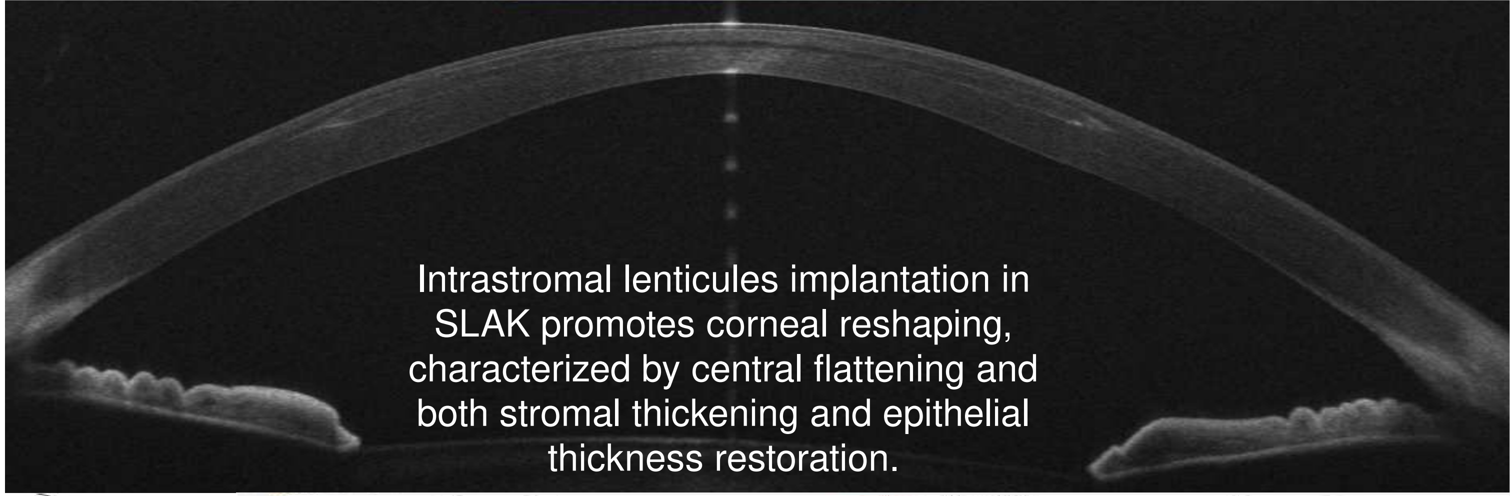


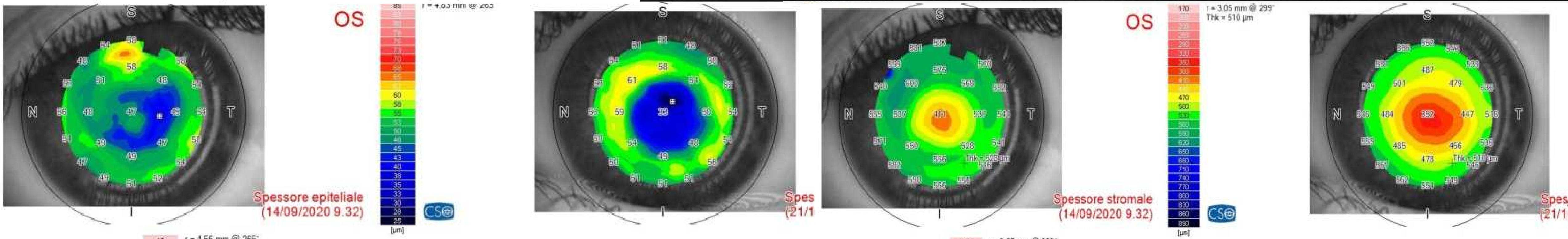


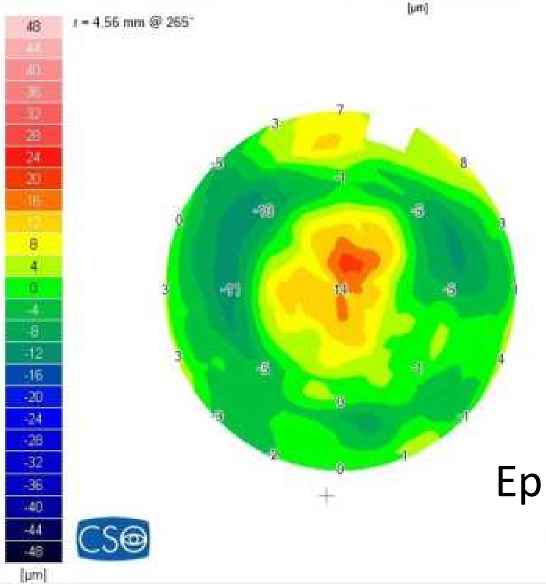
Epithelial and stromal remodelling following femtosecond laser–assisted stromal lenticule addition keratoplasty (SLAK) for keratoconus

scientific reports 2021

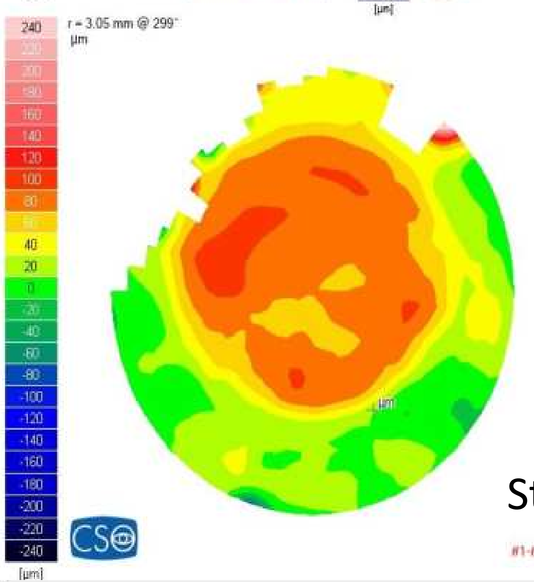
Mario Nubile[1], Niccolò Salgari[1]✉, Jodhbir S. Mehta[2], Roberta Calienno[1], Emanuele Erroi[1], Jessica Bondi[1], Manuela Lanzini[1], Yu-Chi Liu[2] & Leonardo Mastropasqua[1]





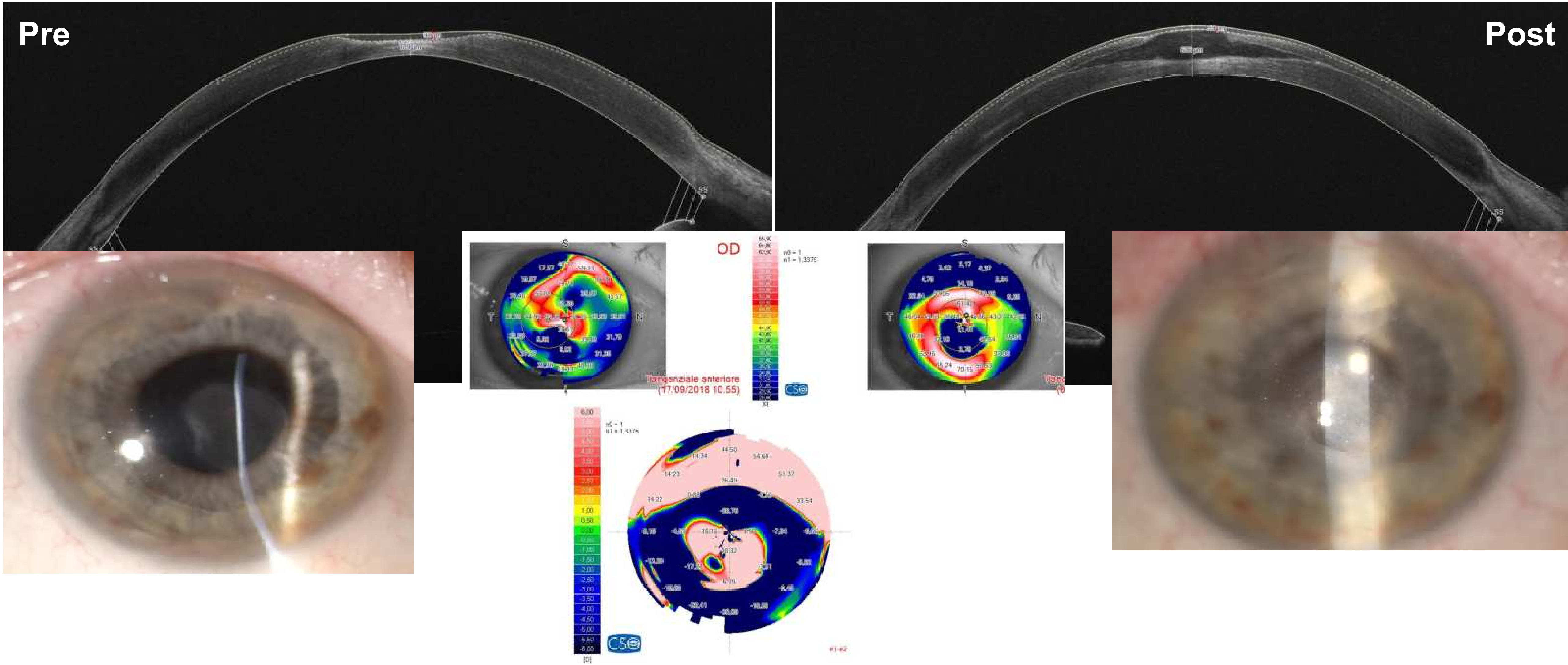


Epithelial thickness



Stromal thickness

Human Corneal Lenticules (hCL) as intrastromal implantation



Stromal Lenticule Addition Keratoplasty with **MYOPIC SMILE** lenticule to re-shape stromal loss in post-HSV stromal scar

Ud'A
Università degli Studi "G. d'Annunzio"

CNAT
Centro Nazionale di Alta Tecnologia in Oftalmologia

EXCELLENCE EYE RESEARCH CENTER
ExÈ

Centro Regionale dei Glaucomi

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Leonardo Mastropasqua, MD

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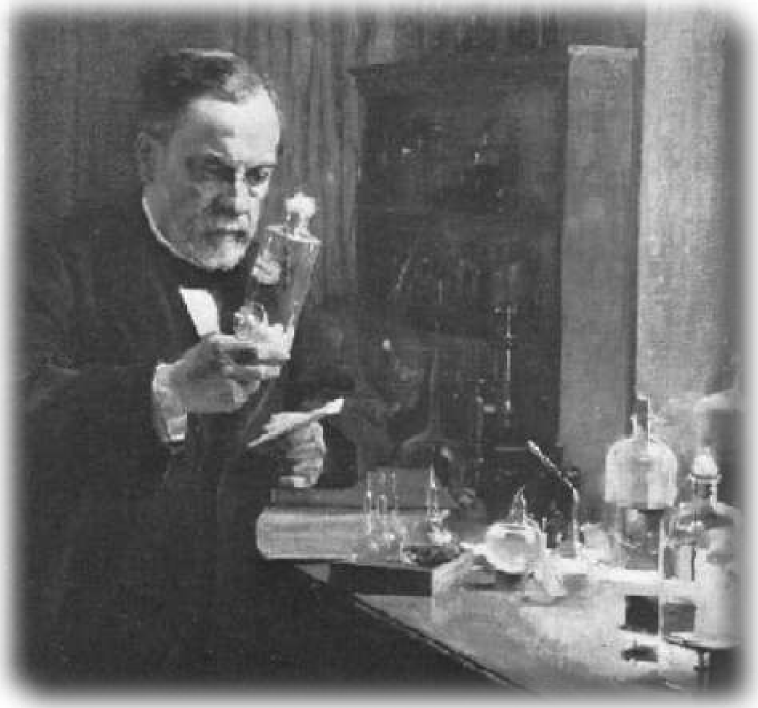
REFRACTIVE SURGERY



"In the fields of observation, chance only favors prepared minds"

Louis Pasteur, 1854