

MASTERING SMILE AND SMILE-PRO

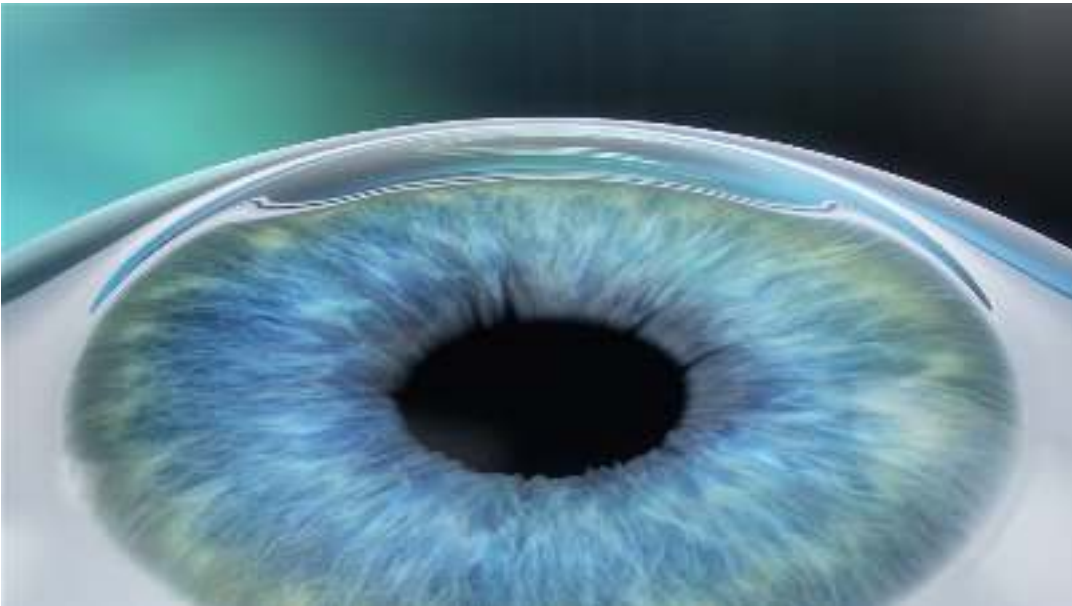
Dr. Jorge L. Alió del Barrio MD, PhD, FEBOS-CR, FWCRS

Medical Director, Vissum (Miranza Group), Alicante (Spain)

Professor of Ophthalmology Universidad Miguel Hernández, Alicante (Spain)

Small Incision Lenticule Extraction (SMILE)

- SMILE received **CE mark in 2009** for the treatment of myopia and myopic astigmatism.
- **1st KLEX technique**
- Just commercially available for hyperopia (2025)
- **VisuMax® 500 (SMILE) & VisuMax® 800 (SMILE-pro)**



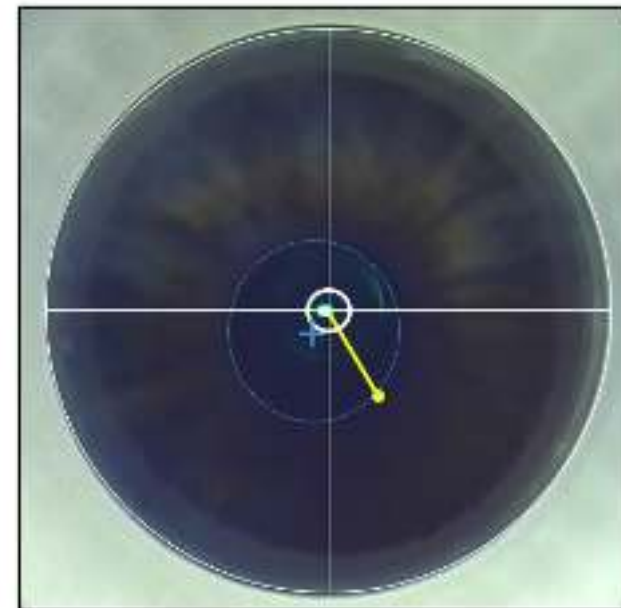
Current Approved Indications (VisuMax)

Parameter	Myopia	Hyperopia
Sphere	-0.50 D to -10.00 D	+0.15 D to +7.00 D
Cylinder	up to 5.00 D	up to 4.00 D
SEQ	-0.50 D to -12.50 D	+0.75 D to +6.50 D

Visumax 800 (New Aids): Centration

CentraLign® - treatment centering assistant

- Intended treatment position is entered during treatment planning
- Manual entry of planning value
- Centering guidance during docking

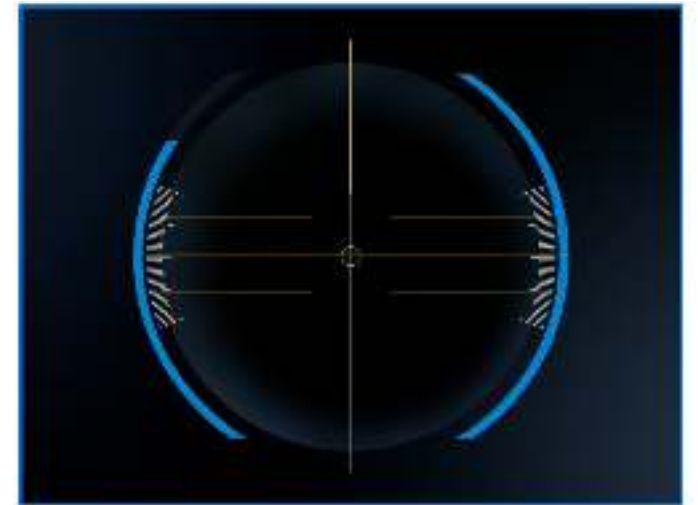
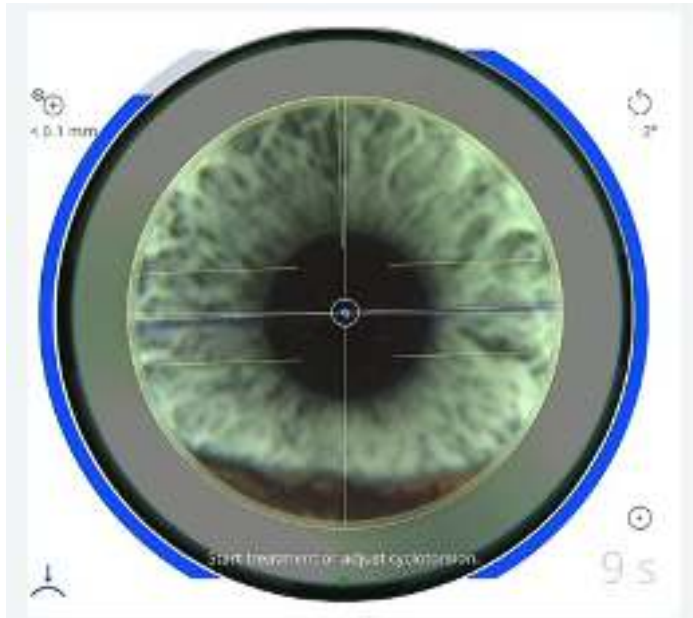


Pupil margin and pupil center indication

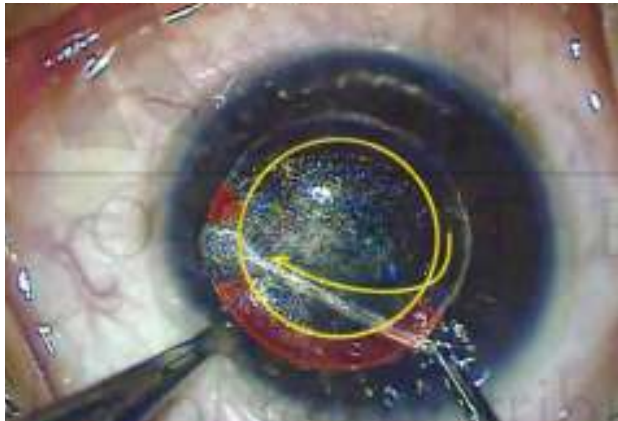
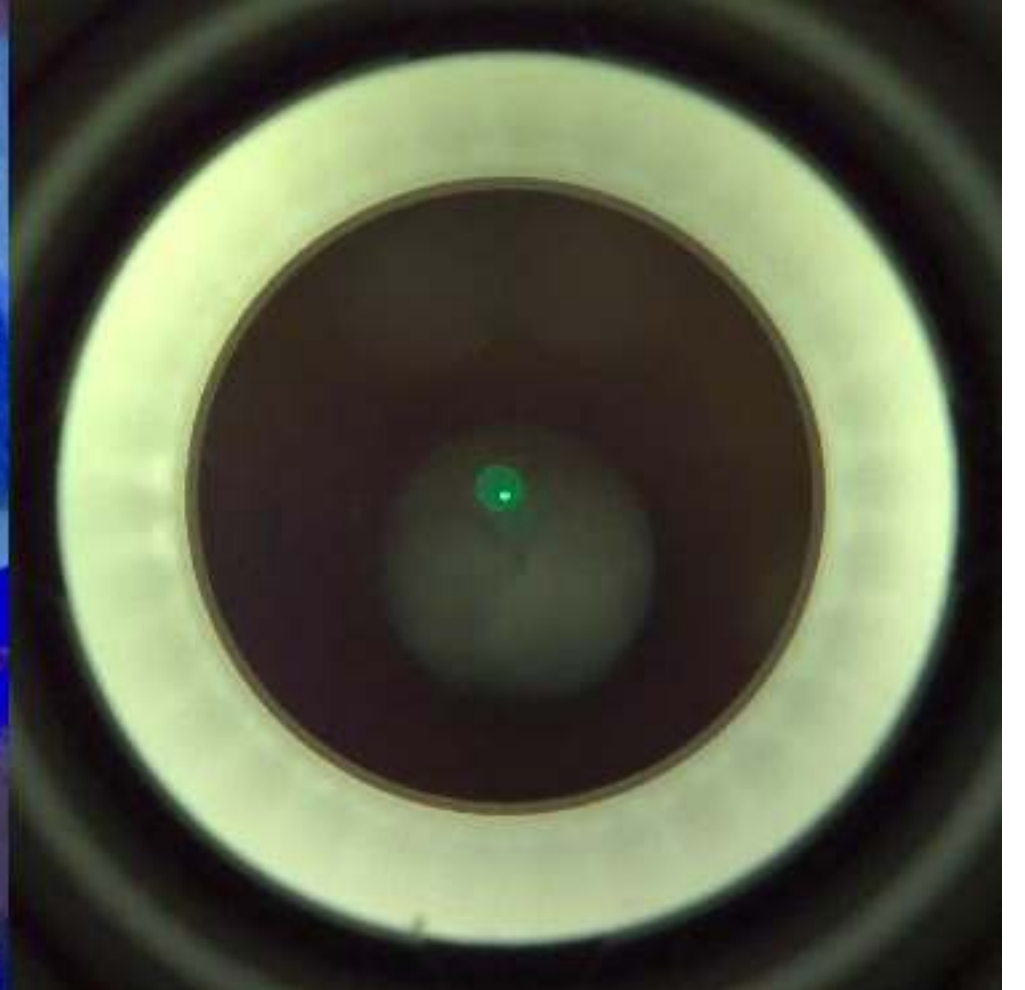
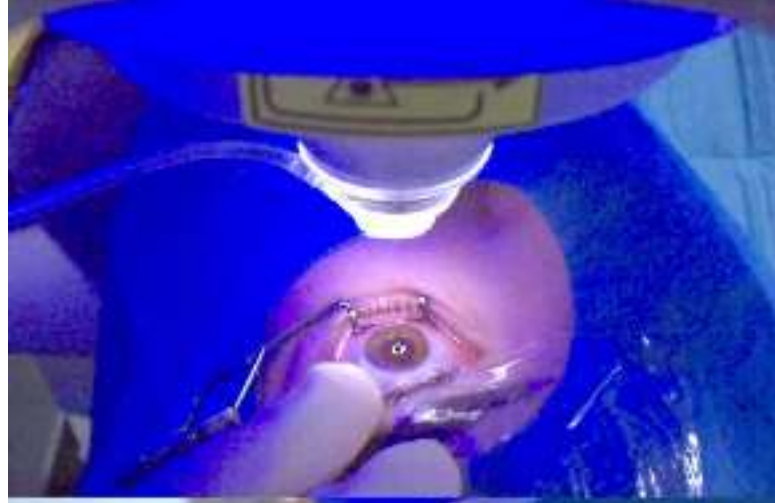


Intended treatment center (dot) and direction indication

Visumax 800 (New Aids): Cyclotorsion



Surgical Technique

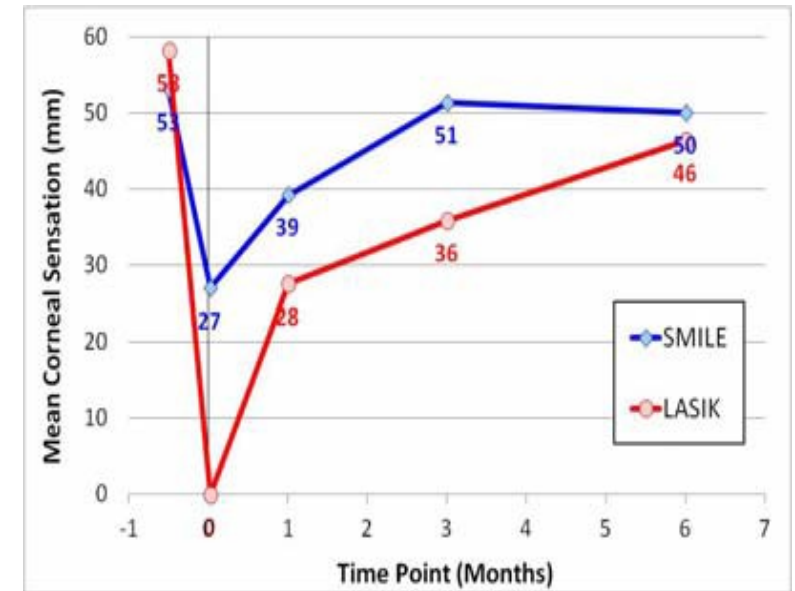


SMILE Advantages over LASIK

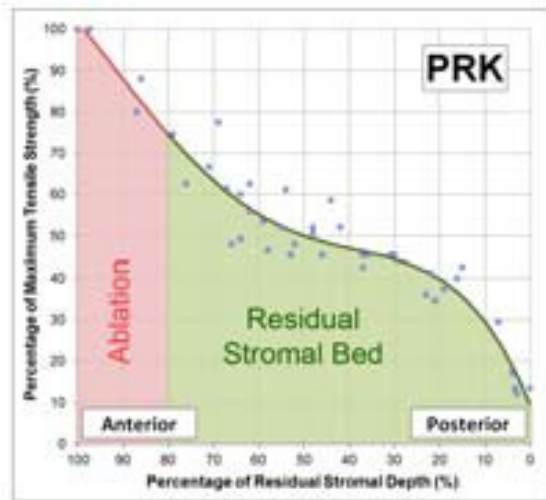
1. Less tissue consumption



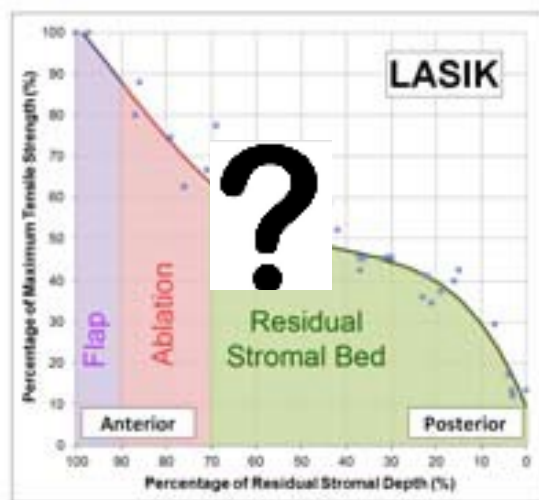
- LASIK: flap stroma (45-55 μ m) + excimer ablation (15 μ mxD)
- SMILE: lenticule stroma [(16 μ mxD) +15 μ m]



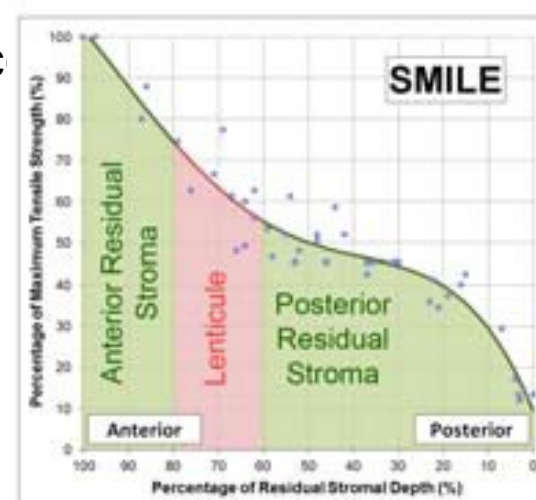
2. Less corneal aberrations



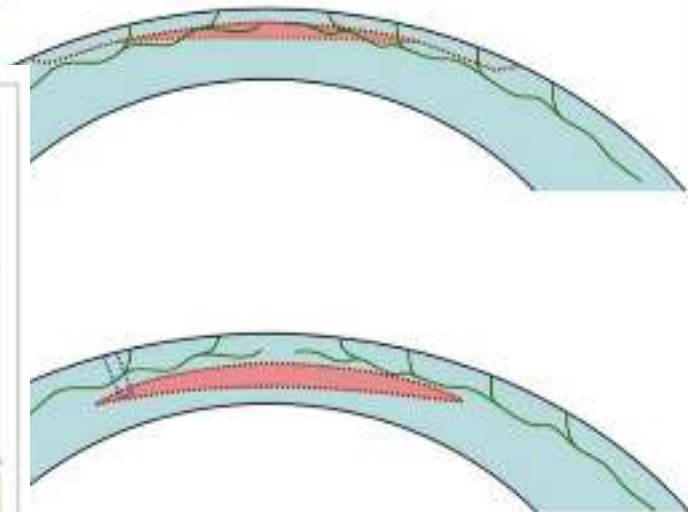
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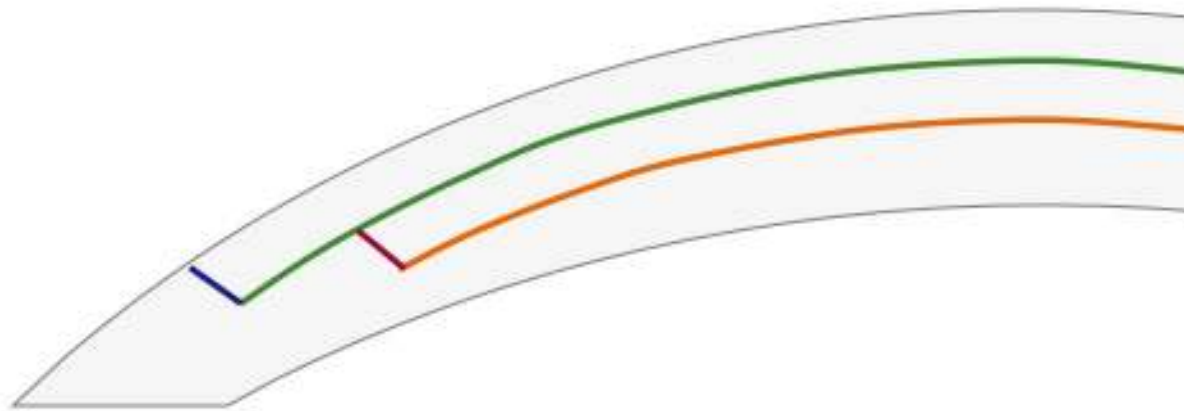
C



LASIK



Technical Details



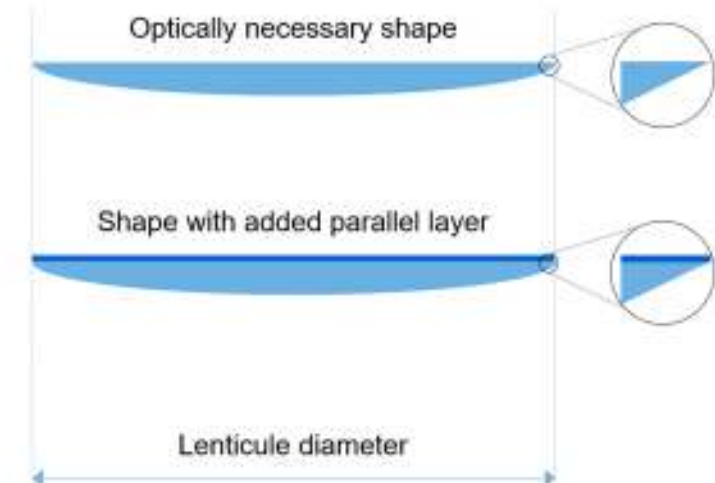
1. Lenticule Cut (underside of lenticule)
2. Lenticule Side Cut
3. Cap Cut (Concurrently upper side of lenticule)
4. Cap Opening Incision



$$\text{Consumption} \\ (\text{Diopters} \times 16\mu\text{m}) + 15\mu\text{m}$$

Lenticule parameters - Minimum thickness

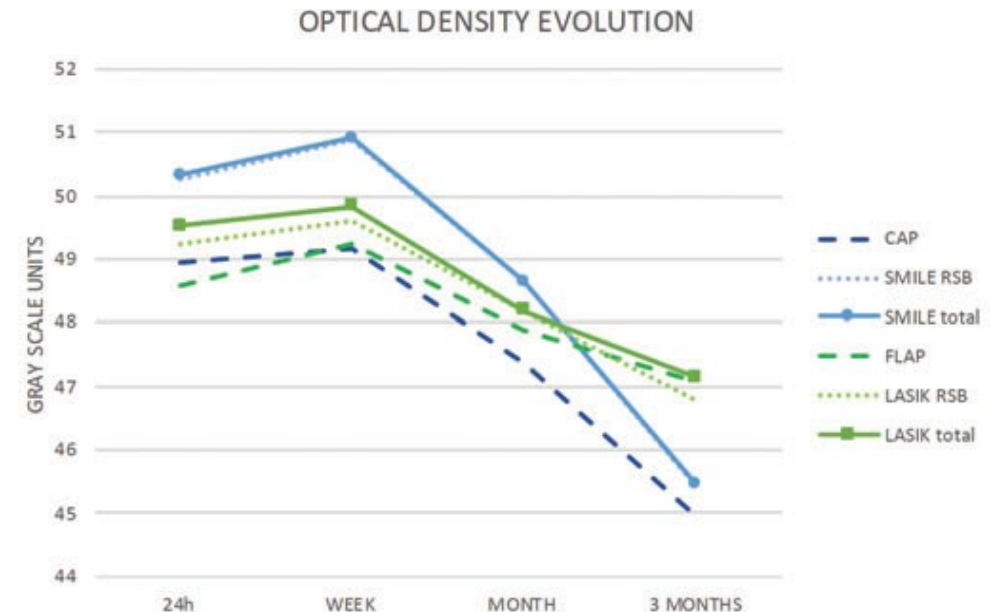
- Thickness of lenticule at lenticule side cut
- **Added refractive neutral tissue layer over complete lenticule diameter for myopic lenticules**
- Range
 - 10 μm to 30 μm
 - Recommended 15 μm



SMILE Disadvantage over LASIK

Delayed visual recovery after SMILE (compared to Femto-LASIK) is due to a **greater increase in the optical density of the corneal stroma in the early postoperative period** (probably due to a greater tissular surgical aggression).

- This increased optical density after SMILE is later reduced within the first 3 months and becomes equal to LASIK values, thus justifying that visual results are equivalent 3 months after surgery.



Dry Eye: SMILE better than LASIK?

- **Early literature suggested that SMILE had a lower risk of postop dry eye compared to FS-LASIK:**

➤ Flap techniques such as LASIK produce a greater ablation of stromal nerves

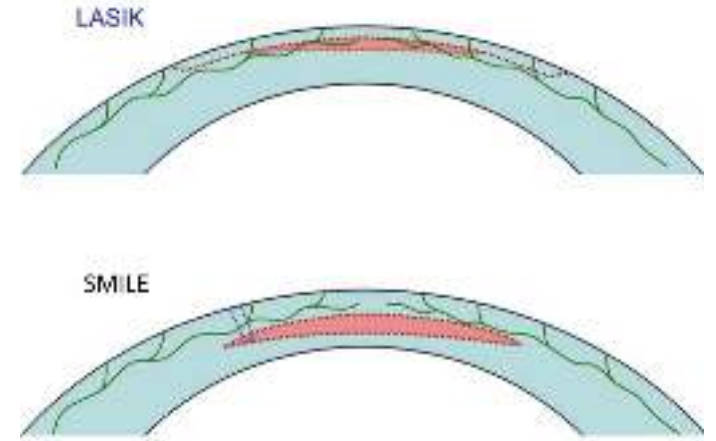
- However, LASIK recovery of corneal sensitivity at 6 months is comparable to the one observed after SMILE.

➤ **Studies have shown no significant differences between the two techniques on this regard with dry eye parameters; including BUT**

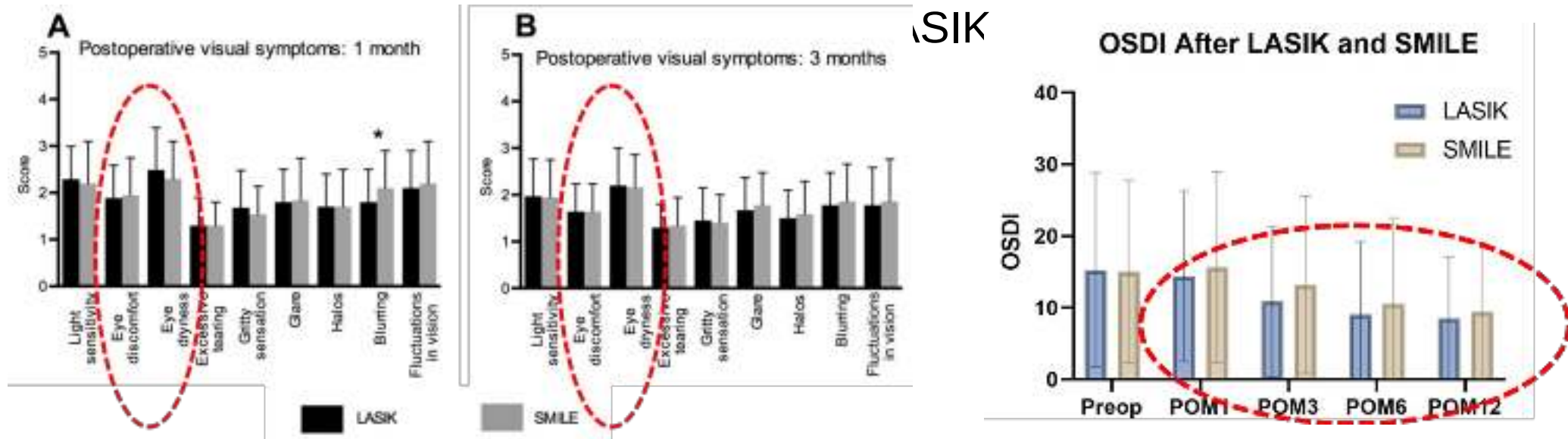
• Demirkok A, Ozguthan EB, Agca A, et al. Corneal sensation after corneal refractive surgery with small incision lenticule extraction. Optom Vis Sci 2013;90(10):1040-7.

• Li M, Zhao J, Shen Y, et al. Comparison of dry eye and corneal sensitivity between small incision lenticule extraction and femtosecond LASIK for myopia. PloS one 2013;8(10):e77797.

• Xu Y, Fang Y. Dry eye after small incision lenticule extraction and LASIK for myopia. Journal of refractive surgery 2014;30(3):186-90.

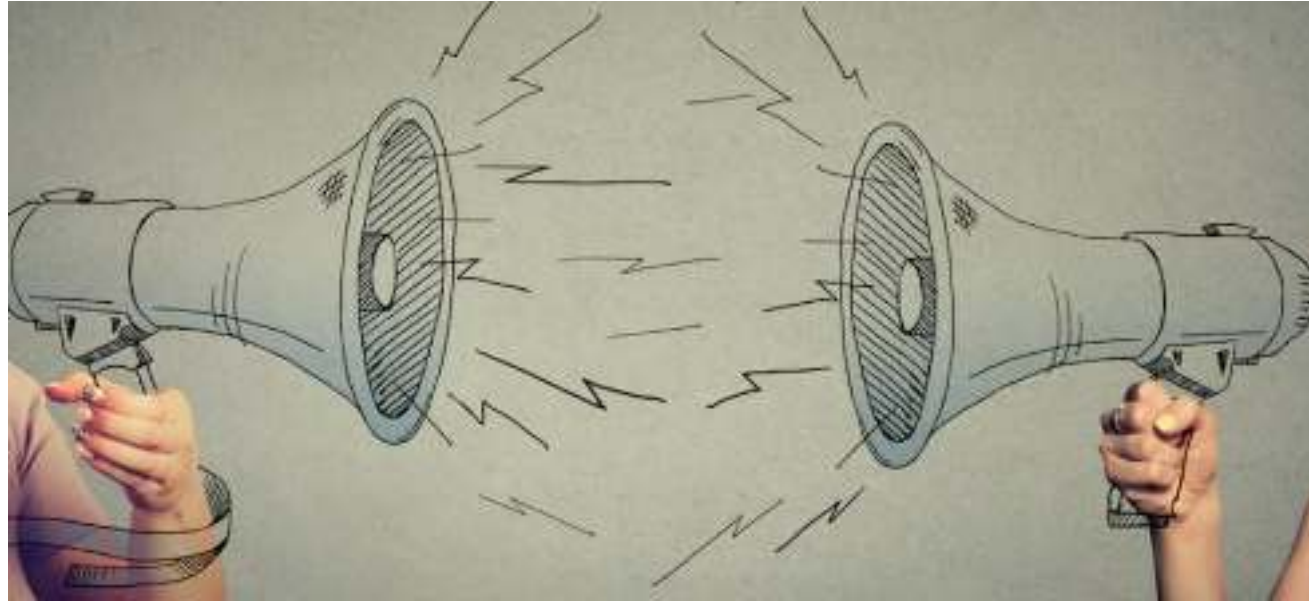


Also recent different **meta-analysis** and **RCT** also showed *no clear competitive advantage of SMILE in terms of ocular surface objective and subjective parameters*



- Xu Y, Yang Y. Dry eye after small incision lenticule extraction and LASIK for myopia. Journal of refractive surgery 2014;30(3):186-90.
- Shen Z, Zhu Y, Song X, et al. Dry eye after small incision lenticule extraction (SMILE) versus femtosecond laser-assisted in situ keratomileusis (FS-LASIK) for myopia: a meta-analysis. PLoS One 2016;11(12):e0168081.
- Ma KK, Manche EE. Corneal Sensitivity and Patient-Reported Dry Eye Symptoms in a Prospective Randomized Contralateral-Eye Trial Comparing Laser In Situ Keratomileusis and Small Incision Lenticule Extraction. American Journal of Ophthalmology 2022;241:248-53.
- Damgaard IB, Ang M, Farook M, et al. Intraoperative patient experience and postoperative visual quality after SMILE and LASIK in a randomized, paired-eye, controlled study. Journal of refractive surgery 2018;34(2):92-9.
- Zhao J, Li Y, Yu T, et al. Anterior segment inflammation and its association with dry eye parameters following myopic SMILE and FS-LASIK. Annals of Medicine 2023;55(1):689-95.

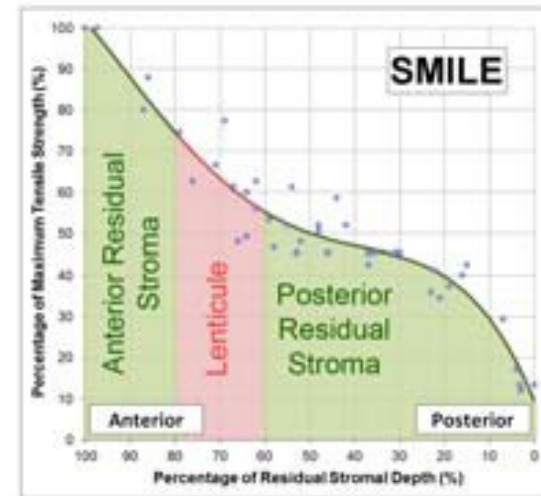
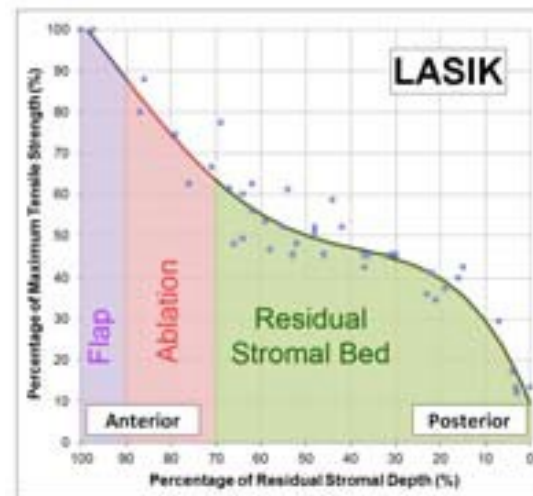
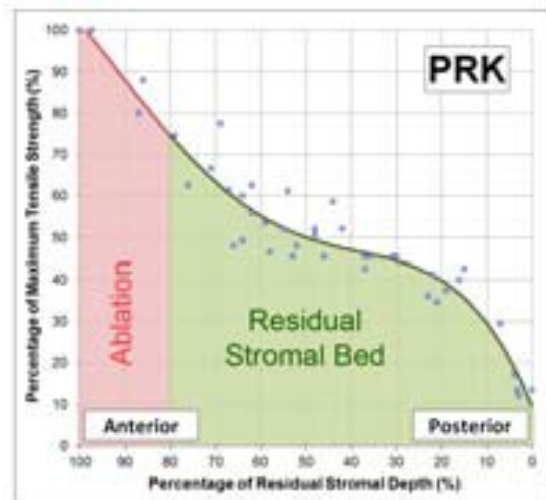
Thus, there is still controversy on the fact of SMILE being superior to FS-LASIK regarding the postoperative risk of ocular surface disease.



Despite theoretical models have suggested that SMILE may result in less corneal nerve damage, **this has not yet been clinically translated into a significant reduction in objective and subjective ocular surface parameters in real-clinical practice**

Biomechanics: SMILE better than LASIK?

- Early evidence based on theoretical models
- Cap is somehow redundant after lenticule removal, biomechanically valid?



LASIK versus SMILE (Spiru B, Kling S, Hafezi F, Sekundo W. Biomechanical Properties of Human Cornea Tested by Two-Dimensional Extensiometry Ex Vivo in Fellow Eyes: Femtosecond Laser-Assisted LASIK Versus SMILE. *J Refract Surg.* 2018 Jun 1;34(6):419-423)

- Compared to a flap-based procedure such as FS-LASIK, the **SMILE technique can be considered superior in terms of biomechanical stability**, when measured experimentally in ex vivo human fellow eye corneas

PRK versus SMILE (Spiru B, Torres-Netto EA, Kling S, Lazaridis A, Hafezi F, Sekundo W. Biomechanical Properties of Human Cornea Tested by Two-Dimensional Extensiometry Ex Vivo in Fellow Eyes: PRK Versus SMILE. *J Refract Surg.* 2019 Aug 1;35(8):501-505)

- SMILE and PRK **may be considered equivalent in terms of biomechanical stability** when measured experimentally in ex vivo human fellow eye corneas

Moderate to High Cylinder

- ✓ SMILE shows acceptable outcomes for the correction of myopic astigmatism
- ✓ However, scientific evidence agrees about the current superiority of the excimer laser-based techniques (PRK/LASIK) for the treatment of low and moderate levels of astigmatism.
- ✓ For high cylinders (over 3 D), both techniques suffer an important loss of efficacy and predictability
 - ✓ But **enhancements after LASIK** (*flap lift*) are easier and involve less **cost** for the clinic than after SMILE (*Circle* or *PRK over cap*).

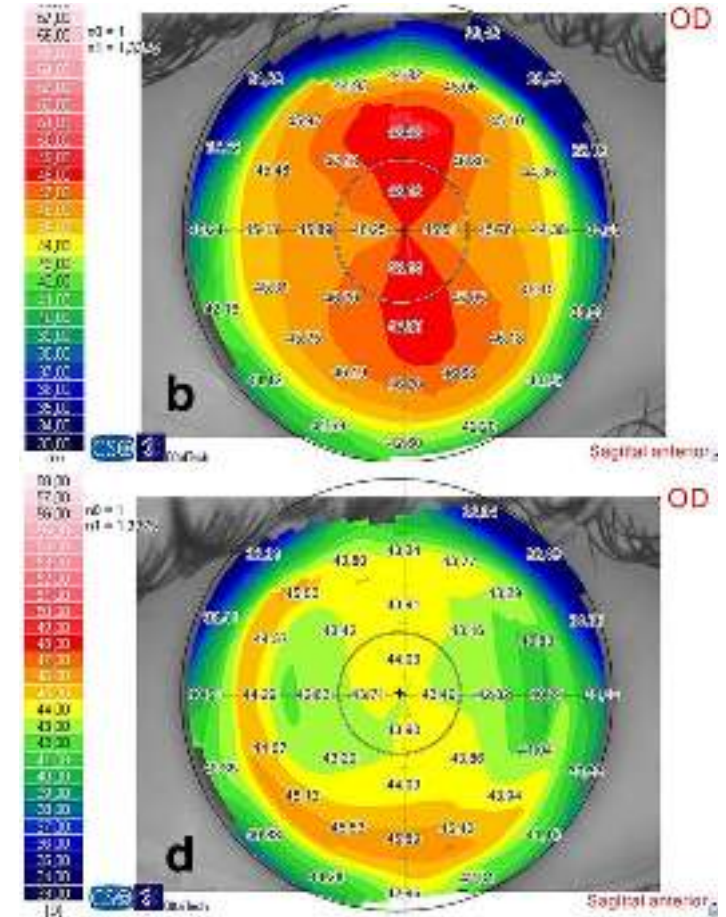


Table 1 SMILE reported outcomes for the treatment of refractive myopic astigmatism with cylinder ≥ 0.75 D

Author	Procedure	N	Mean cylinder (D)	Efficacy index	Safety index	Predictability	Correction index	Difference vector	Magnitude of error	Angle of error ^b	Follow up
Pedersen [20]	SMILE	101	-1.81	NA; 49% of eyes postop UDVA $\geq$ preop CDVA	NA; 9% lost one line in CDVA	70% of eyes within ± 0.5 D of refractive cylinder	0.94	0.31	0.12	0.34	12 months
Chan [23] ^a	SMILE	54	-1.08	0.85; 76% achieved a UDVA of 20/25	0.97; 74% lost one line in CDVA	87% of eyes within ± 0.5 D of refractive cylinder	0.858 ^a	0.349 ^a	-0.225 ^a	6.38 ^a	3 months
Chan [23] ^a	f-LASIK	57	-1.37	0.94; 95% achieved a UDVA of 20/25	0.98; 5.3% lost one line in CDVA	98.2% of eyes within ± 0.5 D of refractive cylinder	1.020 ^a	0.090 ^a	0.037 ^a	-0.72 ^a	3 months
Zhang [24]	SMILE	42	-2.48	93% UDVA $\geq 20/25$	0% lost CDVA lines	Mean postop refractive cylinder of -0.38 ± 0.42 D	0.88	0.36	-0.31	1.22	3 months
Zhang [24]	f-LASIK	22	-2.56	91% UDVA $\geq 20/25$	0% lost CDVA lines	Mean postop refractive cylinder of -0.42 ± 0.45 D	0.94	0.42	-0.23	-1	3 months
Ganesh [27]	SMILE	81	-1.85	NA; 61% of eyes postop UDVA $\geq$ preop CDVA	NA; 0% lost one line in CDVA	86% of eyes within ± 0.5 D of refractive cylinder	0.95	0.33	-0.108	4.09 (absolute AE)	3 months
Qian [30] ^c	SMILE	28 (25)	-1.35 (-2.50)	NA	NA	Mean postop refractive cylinder of $-0.42 (-0.48)$ D	0.94 (0.94)	NA	NA	NA	6 months
Qian [30] ^c	LASEK	17 (14)	-1.27 (-2.55)	NA	NA	Mean postop refractive cylinder of $-0.27 (-0.89)$ D	0.97 (0.77)	NA	NA	NA	6 months

N = number of eyes; NA = Information not available; SMILE = Small incision lenticule extraction; LASEK = laser-assisted subepithelial keratectomy; f-LASIK = femtosecond-assisted laser in-situ keratomileusis; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity

^aOutcomes reported for low and moderate astigmatism; the presented vector analysis is the specific one for the moderate astigmatism subgroup >1.5 D of refractive cylinder; ^bArithmetic Angle of Error; ^cOutcomes reported for moderate (1-2 D of cylinder) astigmatism in periods are shown the outcomes for the high (> 2 D) astigmatism subgroup

Alió del Barrio JL, Vargas V, Al-Shymali O, Alió JL. **Small Incision Lenticule Extraction (SMILE) in the Correction of Myopic Astigmatism: Outcomes and Limitations - An update.** Eye Vis (Lond) 2017; 4:26.

Our Astigmatic Outcomes

Table 1. Visual (LogMAR Scale) and Refractive Outcomes After Myopic LASIK and SMILE.

LASIK total (N = 77)	Preop	1 mo	3 mo	6 mo	P value (preop-1 mo)	P value (1 mo-3 mo)	P value (3 mo-6 mo)
UDVA	1.17	0.00	-0.03	-0.05	<0.001	<0.001	0.008
Sphere	-3.82	0.08	0.26	0.37	<0.001	0.822	0.617
Cylinder	-1.20 ^a	-0.10 ^a	-0.11 ^a	-0.10 ^a	<0.001	0.082	0.712
SC	3.92	0.00	0.21	0.22	<0.001	0.202	0.037
CDVA	-0.02	-0.02	-0.04	-0.05	0.026	<0.001	<0.001

Table 1. Continued

SMILE total (N = 77)	Preop	1 mo	3 mo	6 mo	P value (preop-1 mo)	P value (1 mo-3 mo)	P value (3 mo-6 mo)
UDVA	1.17	-0.01	-0.03	-0.04	<0.001	<0.001	0.005
Sphere	-3.82	0.12	0.12	0.15	<0.001	0.822	0.617
Cylinder	-0.78 ^a	-0.22 ^a	-0.19 ^a	-0.19 ^a	<0.001	0.002	0.712
SC	-4.02	0.01	0.05	0.04	<0.001	0.202	0.887
CDVA	-0.01	-0.02	-0.04	-0.06	0.026	<0.001	<0.001

- Preoperatively equivalent in all parameters
- Except for refractive astigmatism, being lower in the SMILE group ($p < 0.05$)
- Despite that, worse astigmatic outcomes after **SMILE** with **refractive cylinder** being worse at all postoperative time points

($p < 0.05$)

Alió Del Barrio JL, Canto-Cerdan M, El Bahrawy M, Casanova L, García MJ, Cavas F, Alió JL. Corneal stromal thickness changes after myopic laser corneal refractive surgery. J Cataract Refract Surg. 2022 Mar 1;48(3):334-341.

Astigmatism & SMILE: My Advice

I generally avoid SMILE in refractive cylinders >2.0 , where I prefer LASIK/PRK

¿Will Visumax 800 and new SMILE platforms improve astigmatic outcomes by using an automated cyclotorsion control?

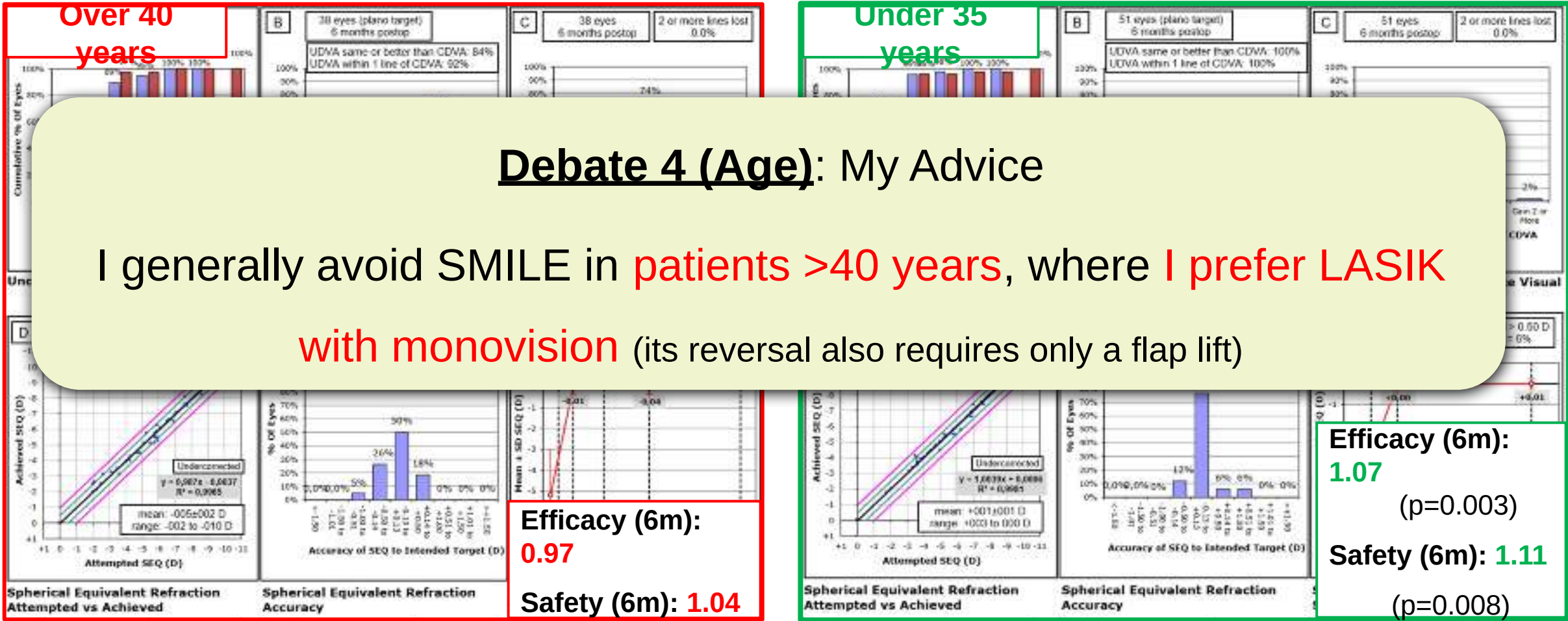
Presbyopic Population

Jod Mehta (2017; Ophthalmology):

*“Risk factors associated with SMILE enhancement included **older age at SMILE procedure**, greater preoperative MRSE, greater preoperative myopia, greater preoperative astigmatism, and the occurrence of intraoperative suction loss”*

Liu YC, Rosman M, Mehta JS. **Enhancement after Small-Incision Lenticule Extraction: Incidence, Risk Factors, and Outcomes.** Ophthalmology. 2017;124(6):813-821. doi:10.1016/j.ophtha.2017.01.053

Patients >40 years show worse refractive outcomes than those patients <35 years ($p<0.05$), with a greater tendency towards astigmatic undercorrection. Probably due to the different stromal stiffness and remodelling



Sx Technique & Conclusions

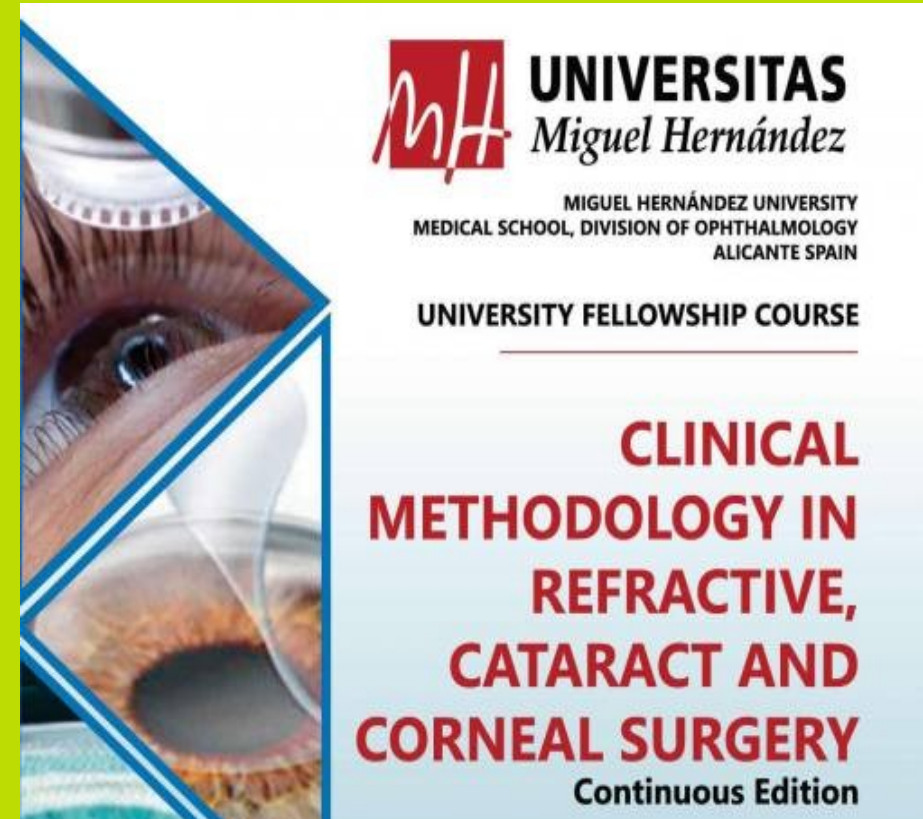
- SMILE is a beautiful safe and effective refractive surgical technique with some advantages over LASIK.
- But it is a growing technique with **still some minor limitations compared to modern excimer LS.**
- So its indiscriminate prescription (usually due to commercial bias) shall be avoided
- A **precise and selective indication enhances further the visual/refractive outcomes,** and so the patient's satisfaction.





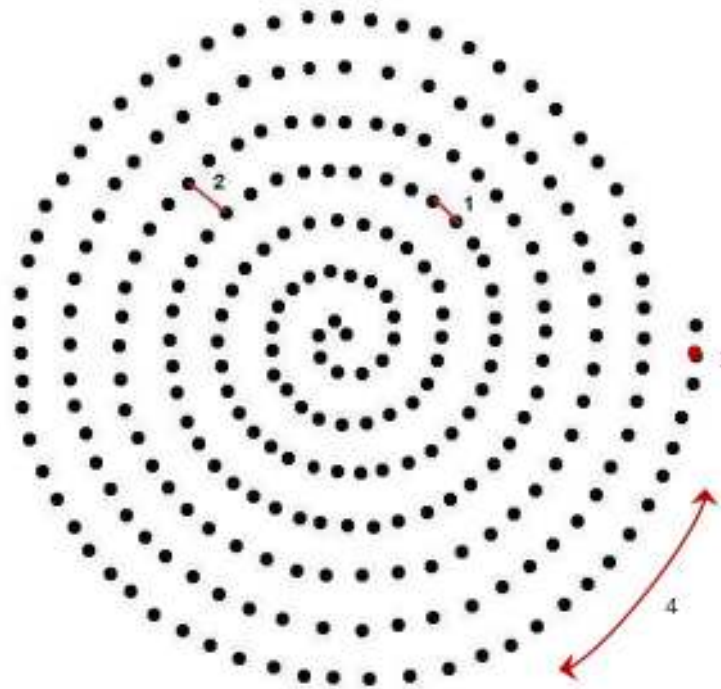
Jorge.aliodelbarrio@vissum.com

VISSUM
GRUPO MIRANZA



Technical Details

Circular spiral scan



Lenticule/Cap Spot/Track distance: 4.5 / 4.5 μm
Side cut Spot/Track distance: 2.0 / 2.0 μm
Energy index: 28
Lasering time: 9 s

Lenticule/Cap Spot/Track distance: 3.1 / 3.1 μm
Side cut Spot/Track distance: 1.0 / 1.0 μm
Energy index: 21
Lasering time: 10 s

SMILE pro parameters: OZ 6.5 mm, Cap diameter 7.5 mm, Cap Thickness 110 μm , Treatment Pack S-size