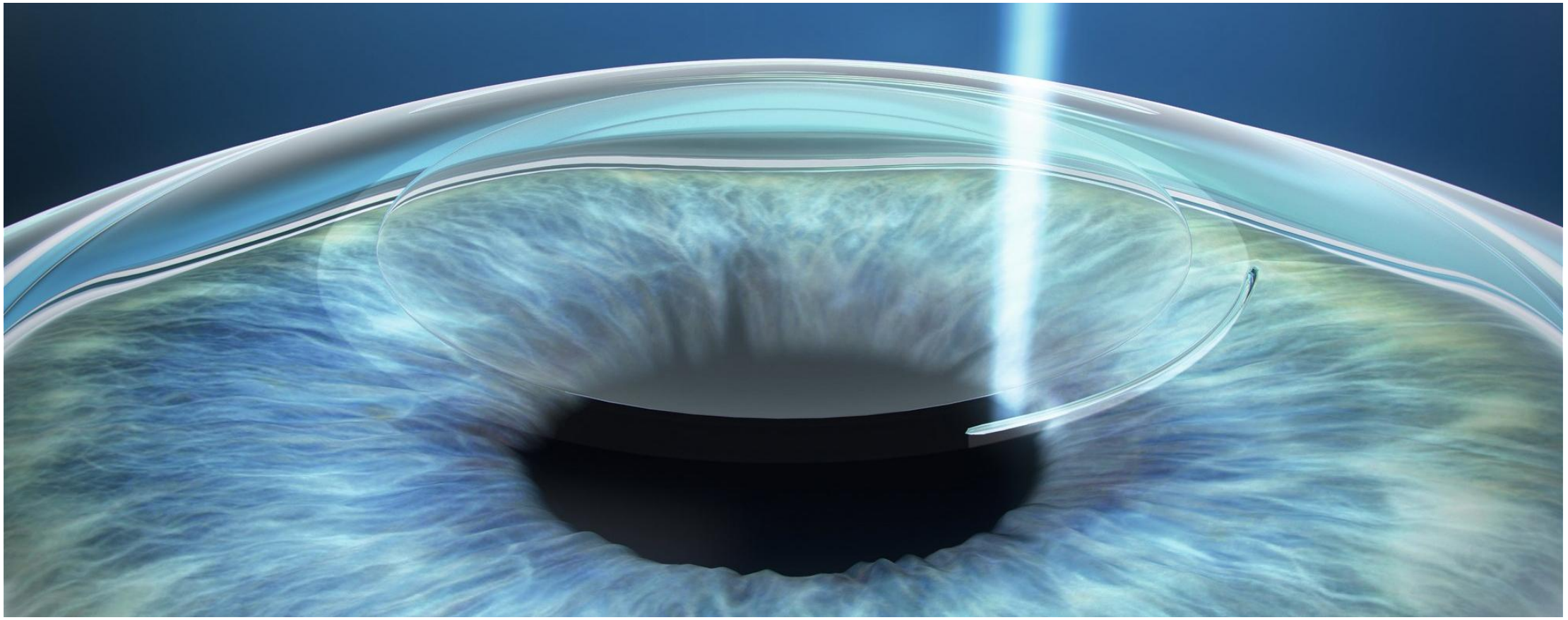
SMILE™: The Next Iteration

Thanh Nguyen, OD – GULFCOAST EYE CARE, TAMPA BAY, FL



My Journey

- University of West Florida – BS Chemistry/Biochemistry
- Nova Southeastern College of Optometry – Davie, FL
- Baltimore VAMC/Wilmer Eye Institute - Residency

GULFCOAST EYE CARE

- TAMPA BAY, FL

Financial Disclosure

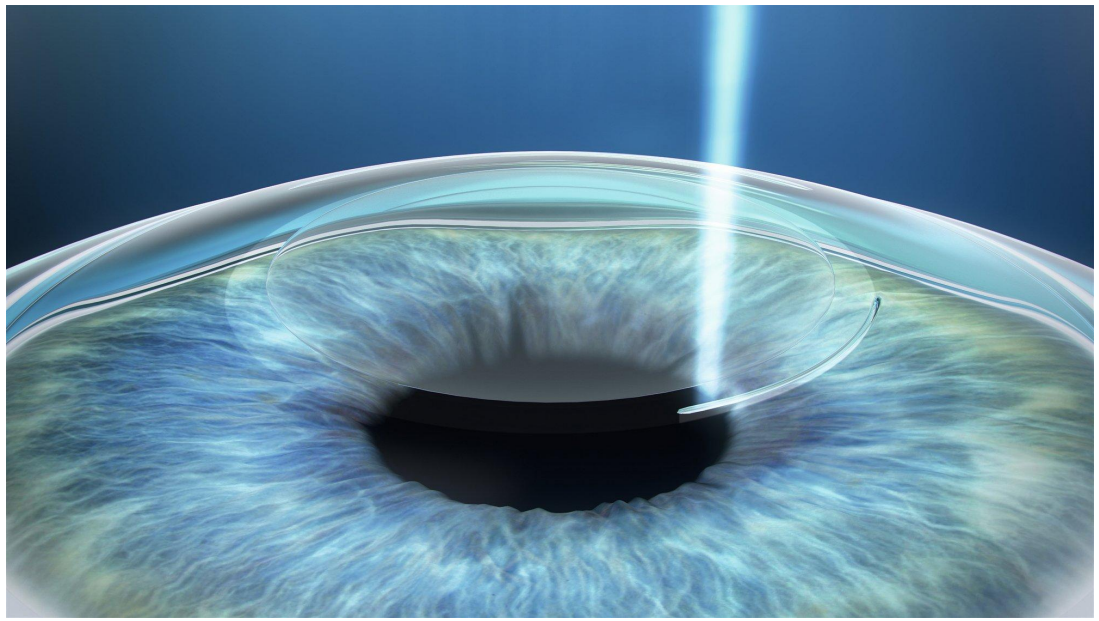
- Alcon Honorarium

What is SMILE

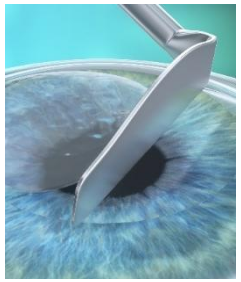
Webster's Dictionary - *noun*

- *a facial expression in which the eyes brighten and the corners of the mouth curve slightly upward and which expresses especially amusement, pleasure, approval, or sometimes scorn*
- *a pleasant or encouraging appearance*

Small Incision Lenticule Extraction

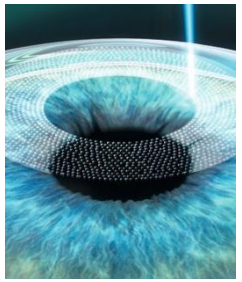


Timeline of Laser Vision Correction



1995

PRK IS FDA APPROVED

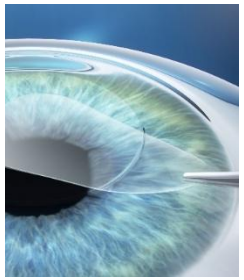


1998

LASIK IS FDA APPROVED

2001

FEMTOSECOND LASER IS FDA APPROVED



SEPTEMBER 2016

SMILE GAINS FDA APPROVAL IN US

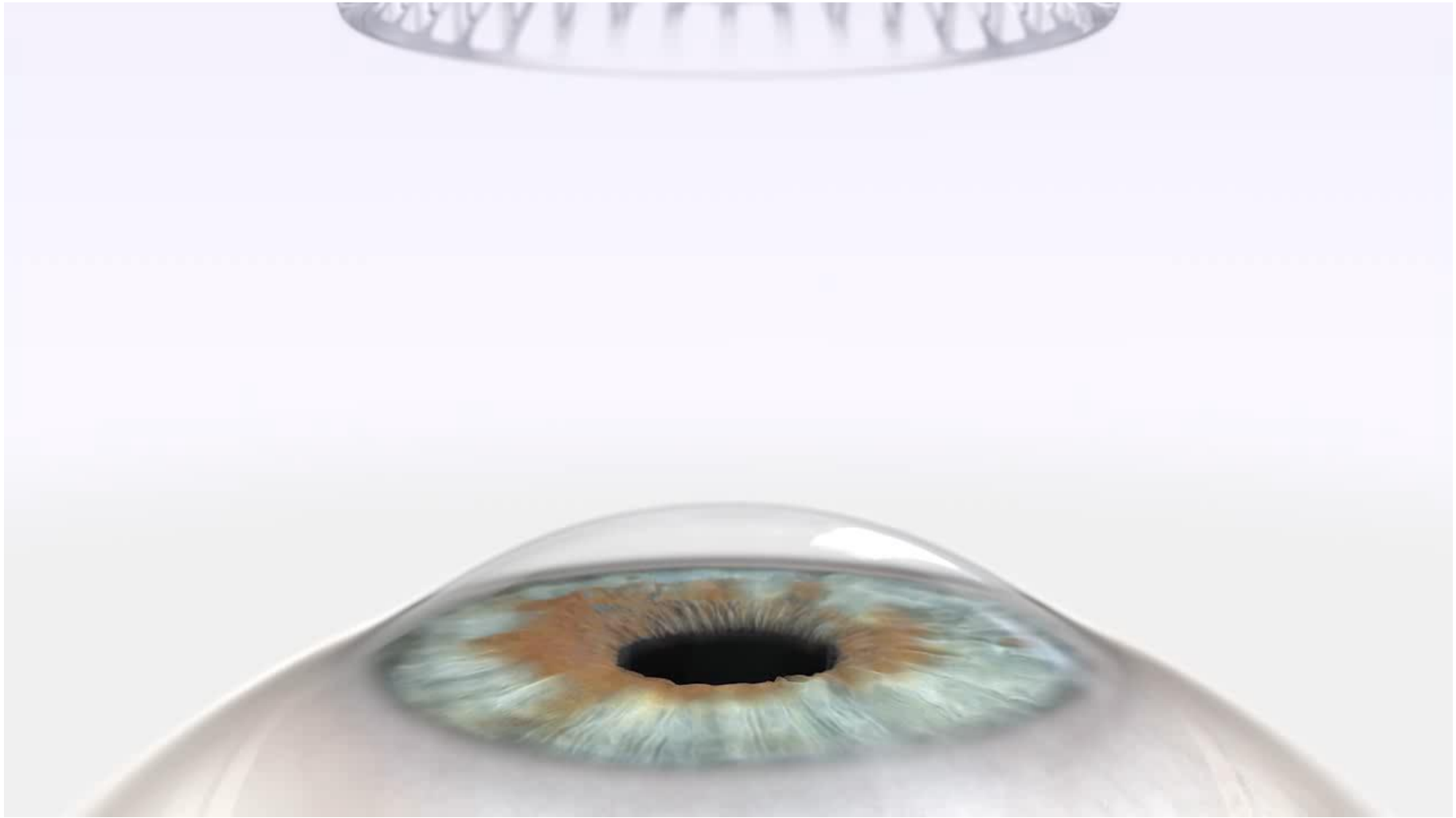
MARCH 1, 2017

FIRST SMILE CASES PERFORMED IN US

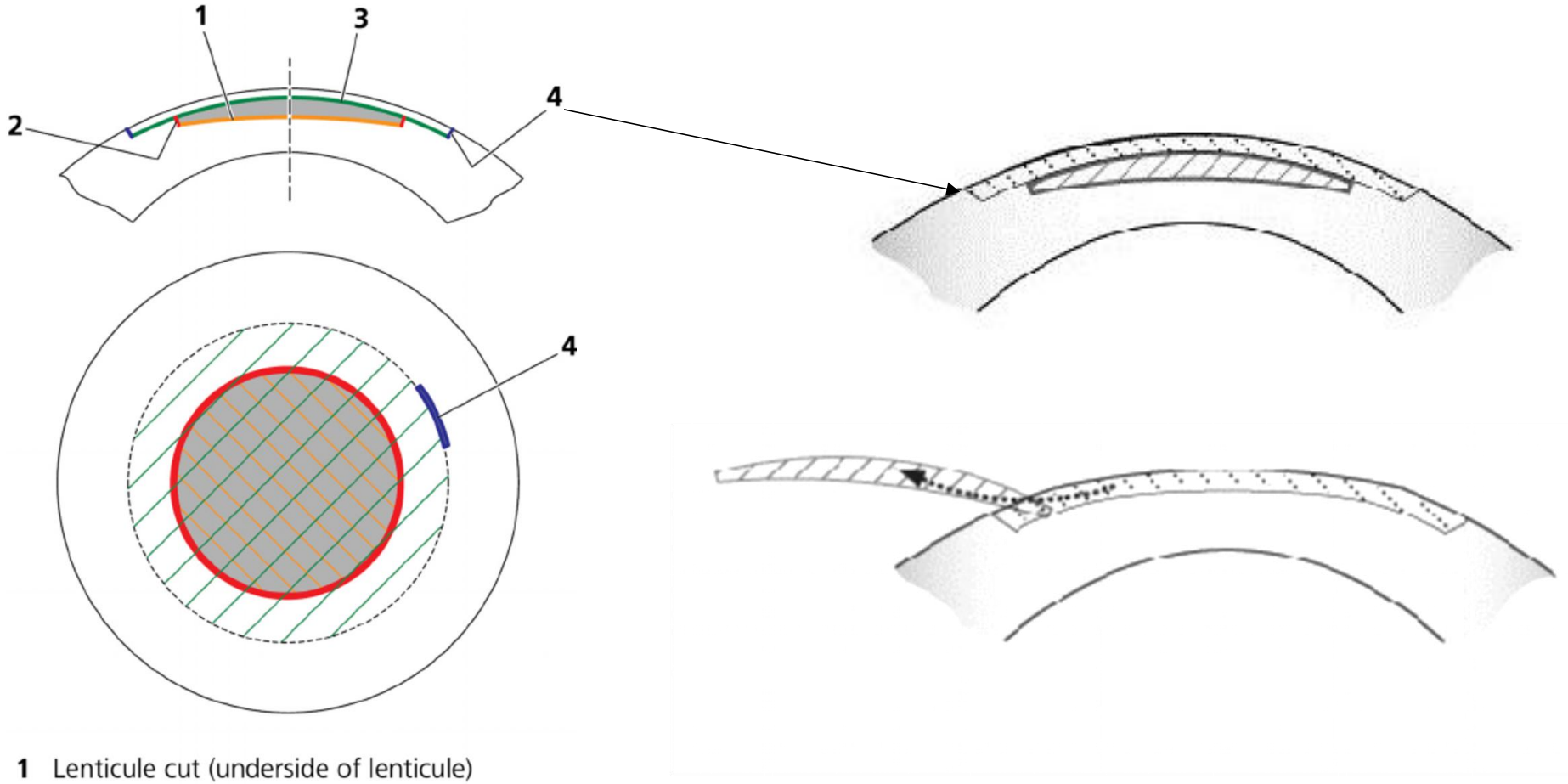
OCTOBER 4, 2018

FDA APPROVED SMILE TO TREAT ASTIGMATISM

SMILE Procedure



SMILE Procedure

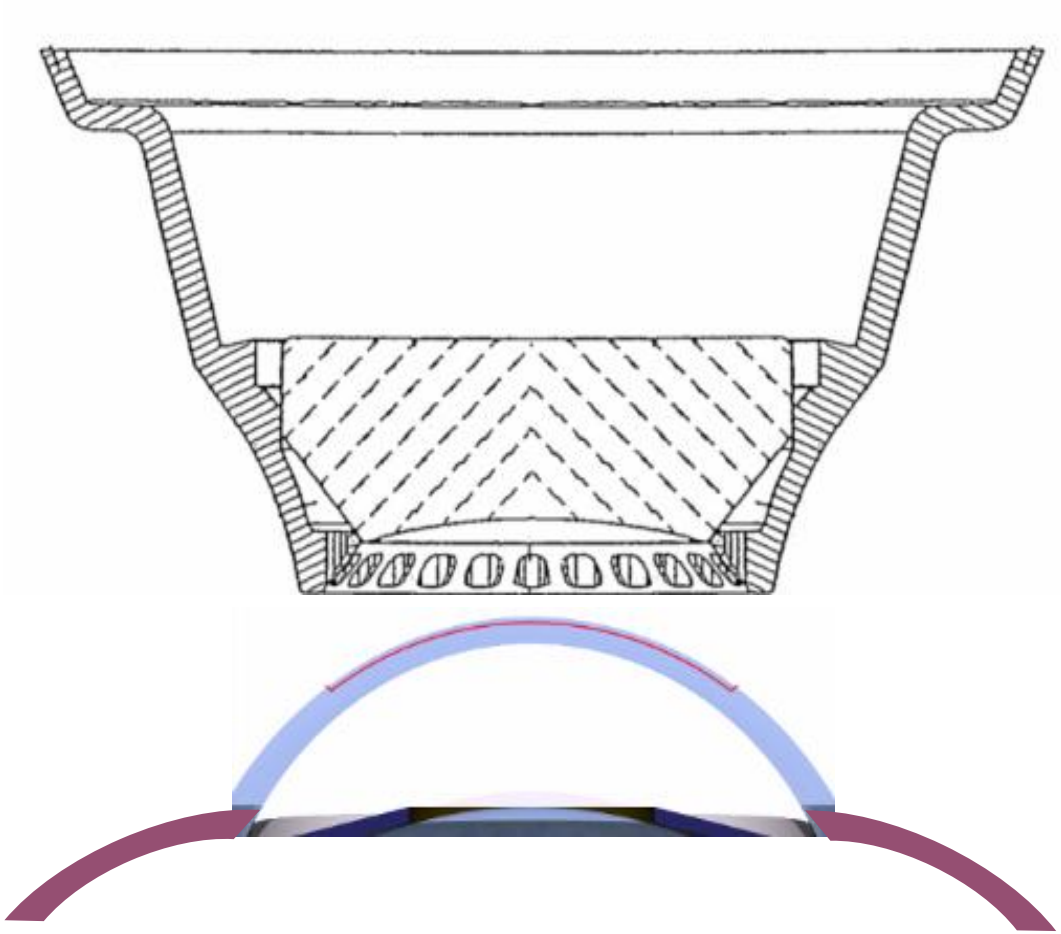


1 Lenticule cut (underside of lenticule)
2 Lenticule side cut
3 Cap cut (concurrently upper side of lenticule)
4 Cap opening incision

VisuMax Features

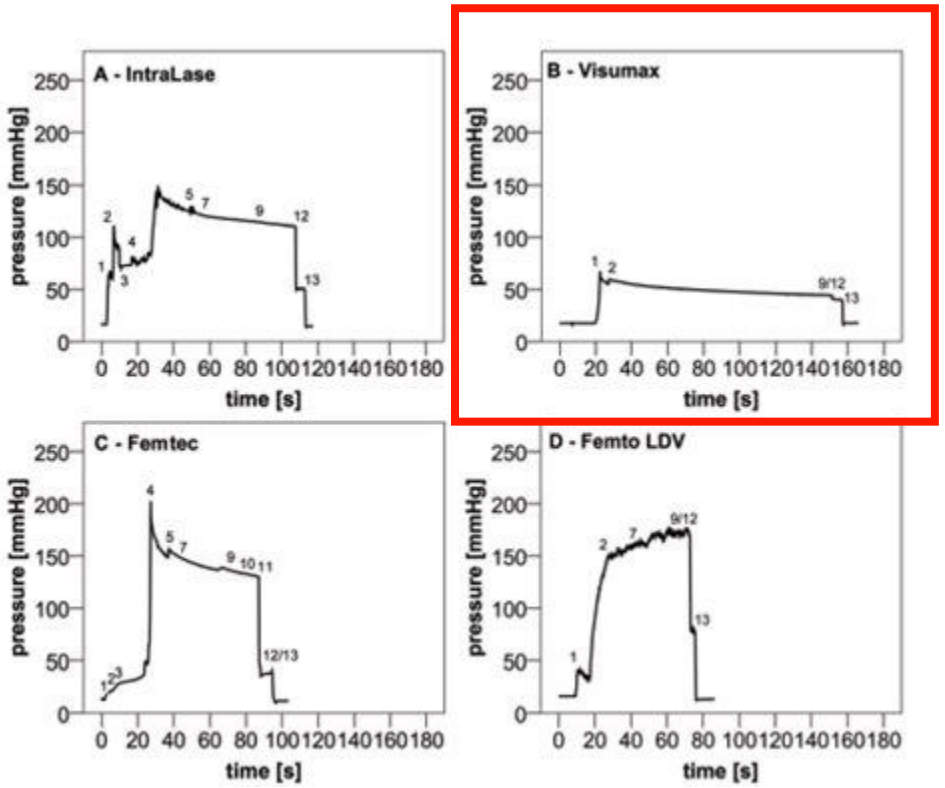
- Curved interface
- Lower deformation of corneal tissue
  - needed for precise lenticule creation
- Lower IOP increase
- Improved patient comfort

- Corneal suction
- Suitable for small palpebral fissure
- Lower chance of subconjunctival hemorrhage



VisuMax Features

- Corneal suction
  - Low IOP increase
    - 85mmHG
  - No temporary loss of vision
    - Maintains intraocular circulation
  - Patient comfort
    - Lower incidence of subconj heme



* Vetter JM, Holzer MP, Teping C, et al. Intraocular pressure during corneal flap preparation: Comparison among four femtosecond lasers in porcine eyes. J Refract Surg. 2011;27(6):427-433.

FDA Approved Indications for SMILE

Indications for use:

For use in the reduction or elimination of myopia with or without astigmatism for spherical refractive error from -1.00D to -10.00D, for astigmatism from -0.75D through -3.00D, and when the MRSE is no greater than -10.0D in the eye to be treated.

SMILE is indicated for patients who are 22 years of age or older with documentation of a stable manifest refraction over the past year as demonstrated by a change in the sphere and cylinder of less than or equal to .50D in magnitude.

SMILE Pre-Operative Considerations

- Pupil size
- Corneal thickness
- Ideally a pachymetry map should be available
- Limbus diameter (white to white)
- K-readings examination
- Topography
- Manifest and cycloplegic refractions
- Awareness of contraindication
- Dry eye testing

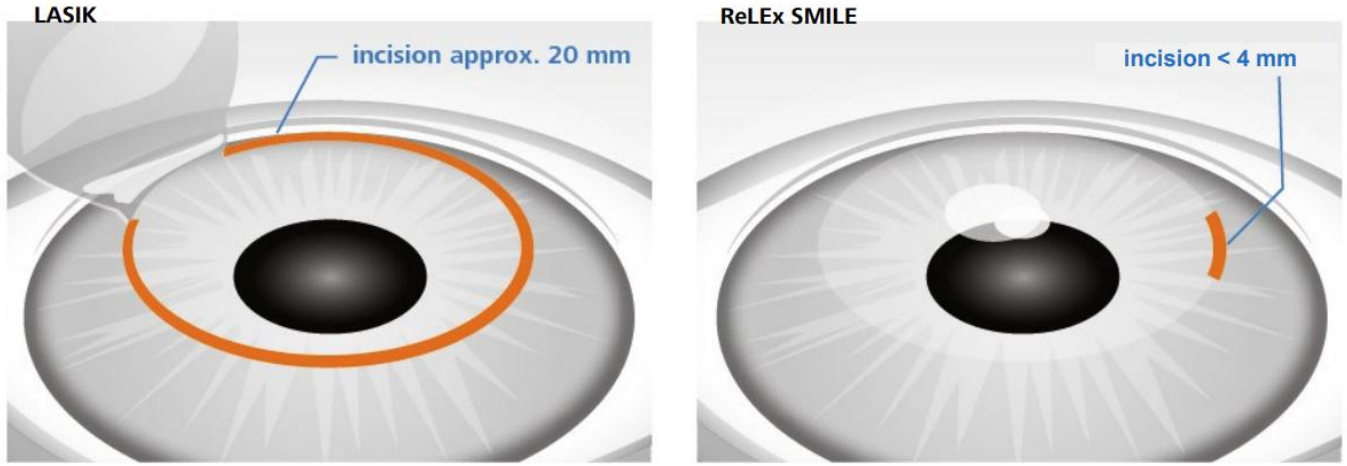
Some Common Contraindications for Laser Vision Surgery

- Insufficient corneal tissue thickness for correction needed
- Abnormal topography
- Unstable prescription – Ocular Maturity
- Active eye infection or inflammation
- Active autoimmune disease or connective tissue disease
- Uncontrolled glaucoma
- Uncontrolled diabetes
- Pregnancy
- Severe dry eye

Small Incision Lenticule Extraction

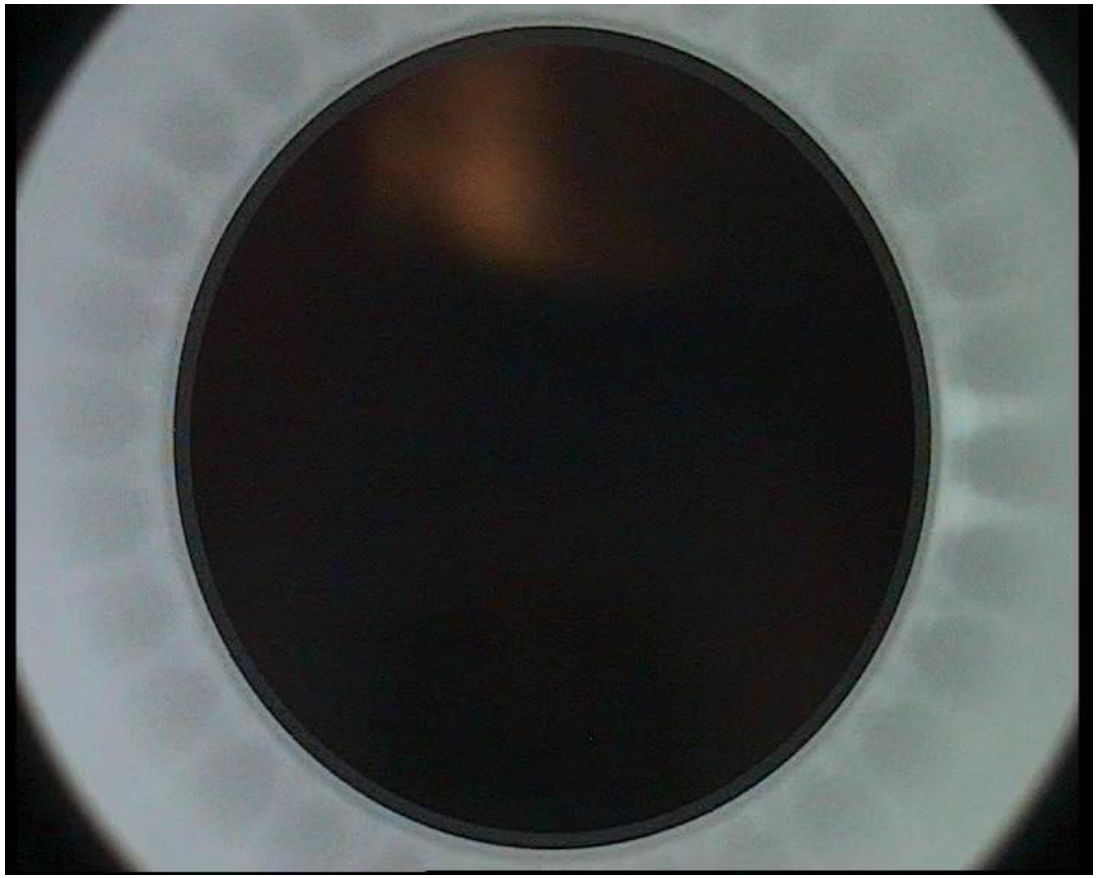
LASIK-like outcomes with a one-step, minimally-invasive procedure

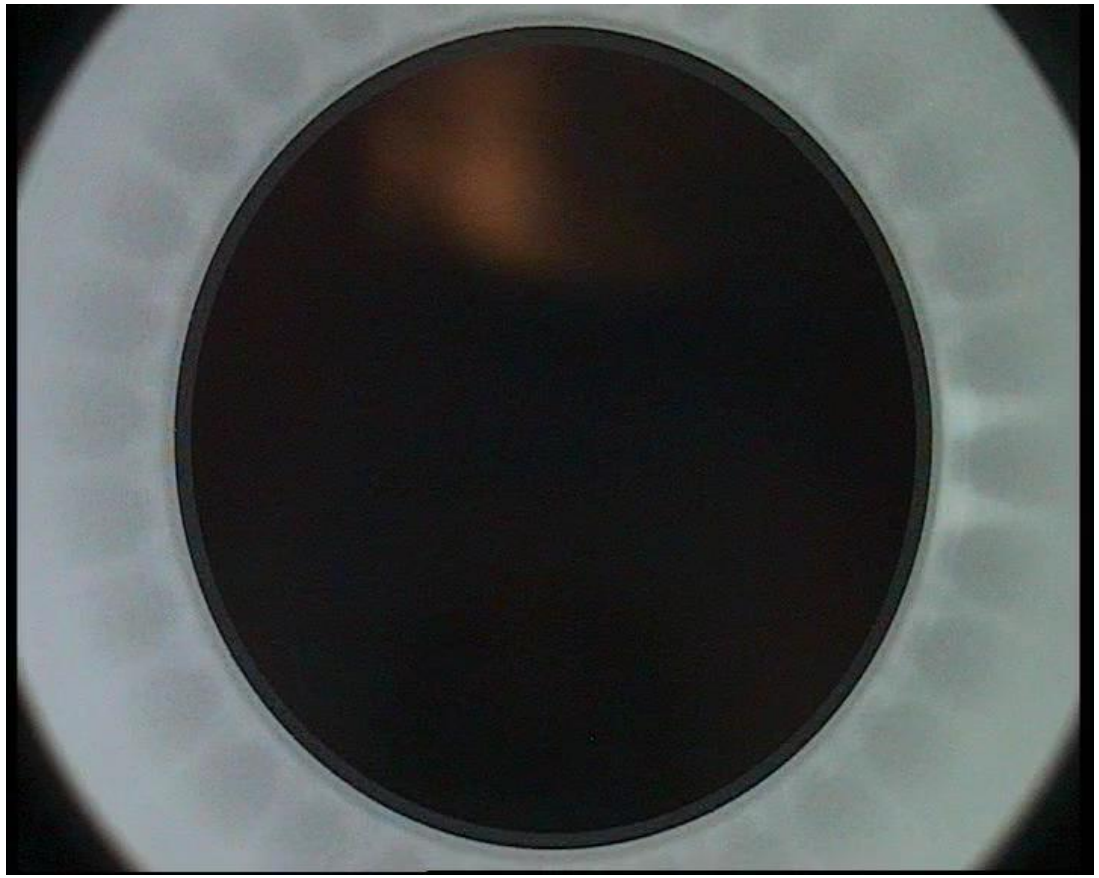
- No flap-related complications (e.g., flap detachment)
- All-femtosecond laser procedure in one step without need to move the patient
- 80% smaller side cut, 30% smaller cap cut may result in a stronger cornea post-op



Comparison of visual ad refractive outcomes following femtosecond laser assisted LASIK with SMILE in patients with myopia or myopic astigmatism. Journal of Refractive Surgery 2014 Sep, Sri Ganesh, Rishika Gupta.

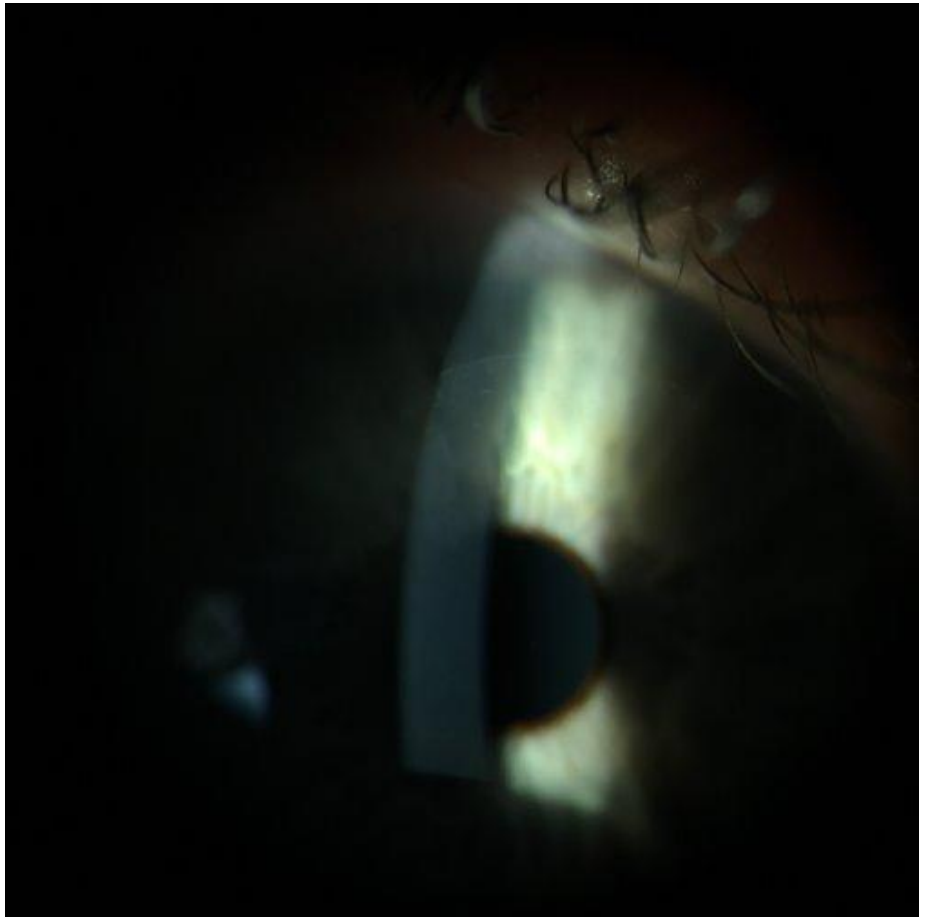
SMILE – In Real Life (IRL)

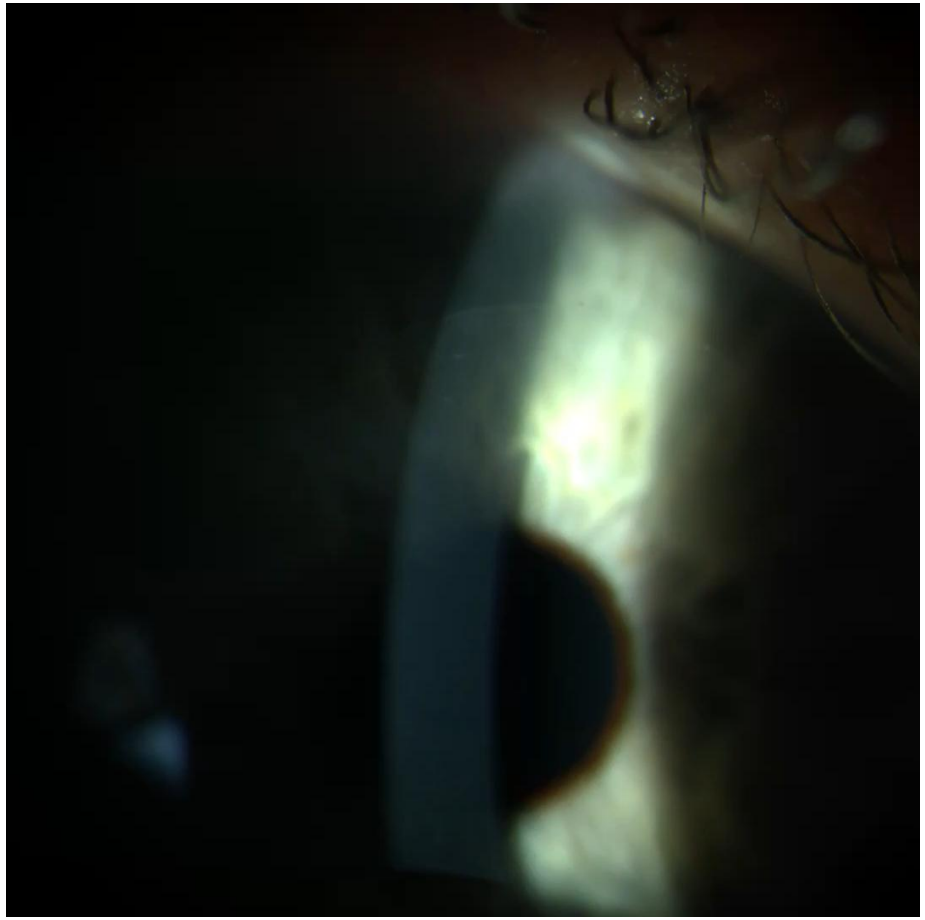




Video Courtesy of Gulfcoast Eye Care

SMILE – In Real Life (IRL)





SMILE – In Real Life (IRL)

- 24yo/Female
- Flight Attendant
- Pre Operative MR:
  - OD -3.00-0.75x170 20/20
  - OS -3.25-1.00x160 20/20
- 3 day Post Operative Appt:
  - OD 20/20
  - OS 20/20

Recovery With A Smile

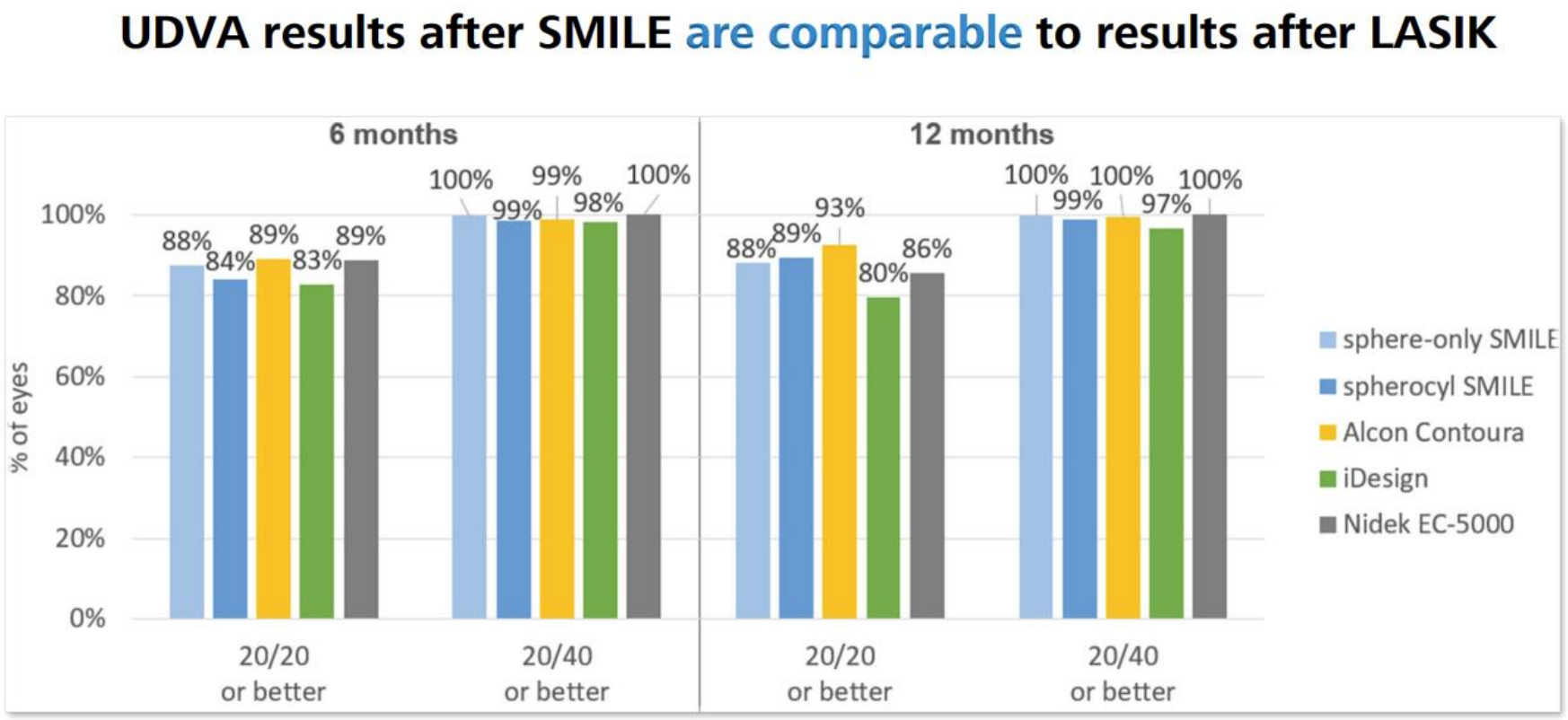
Fast Healing

While overall visual recovery closely parallels LASIK, the minimally invasive nature of SMILE may enable more rapid resumption of regular activities.

Post Operative Care

- Post operative visits
  - 3 day (NO FLAP)
  - 1 month
  - 3 month
- Medications and artificial tears
  - Moxifloxacin
  - Prednisolone
- Shields
  - Day of surgery
- Resume activities

SMILE Results: Comparison To Most Recent LASIK FDA Approvals



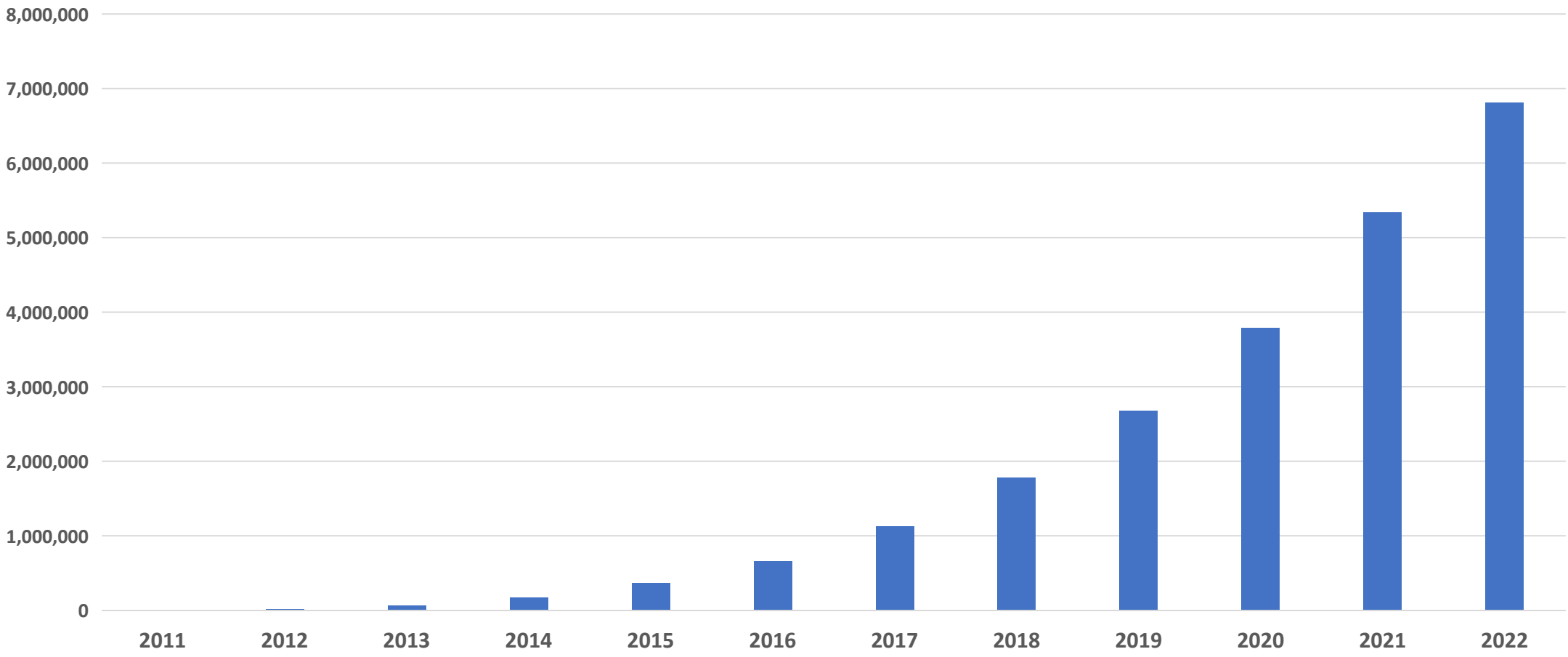
1. US Food and Drug Administration. Summary Of Safety And Effectiveness Data (SSED): VisuMax Femtosecond Laser – P150040/S003.
2. US Food and Drug Administration. Summary Of Safety And Effectiveness Data (SSED): STAR S4 IR Excimer Laser System iDesign Advanced WaveScan Studio System.
3. US Food and Drug Administration. Summary Of Safety And Effectiveness Data (SSED): ALLEGRETTO WAVE Eye-Q Excimer Laser
4. US Food and Drug Administration. Summary of Safety And Effectiveness Data (SSED): Nidek EC-5000 Excimer Laser System.

Comparison of LVC Outcomes in FDA Studies
Astigmatism Correction

Cylinder	SMILE	Topo-guided LASIK	WFG LASIK
Preop mean ± SD	-1.53 ± 0.67 D	-1.19 ± 1.23 D	-1.77 ± 1.65 D
Postop mean ± SD	-0.22 ± 0.33 D	-0.19 ± 0.30 D	-0.33 ± 0.36 D
Within ± 0.50 D	88%	90%	85%
Within ± 1.00 D	97%	97%	94%

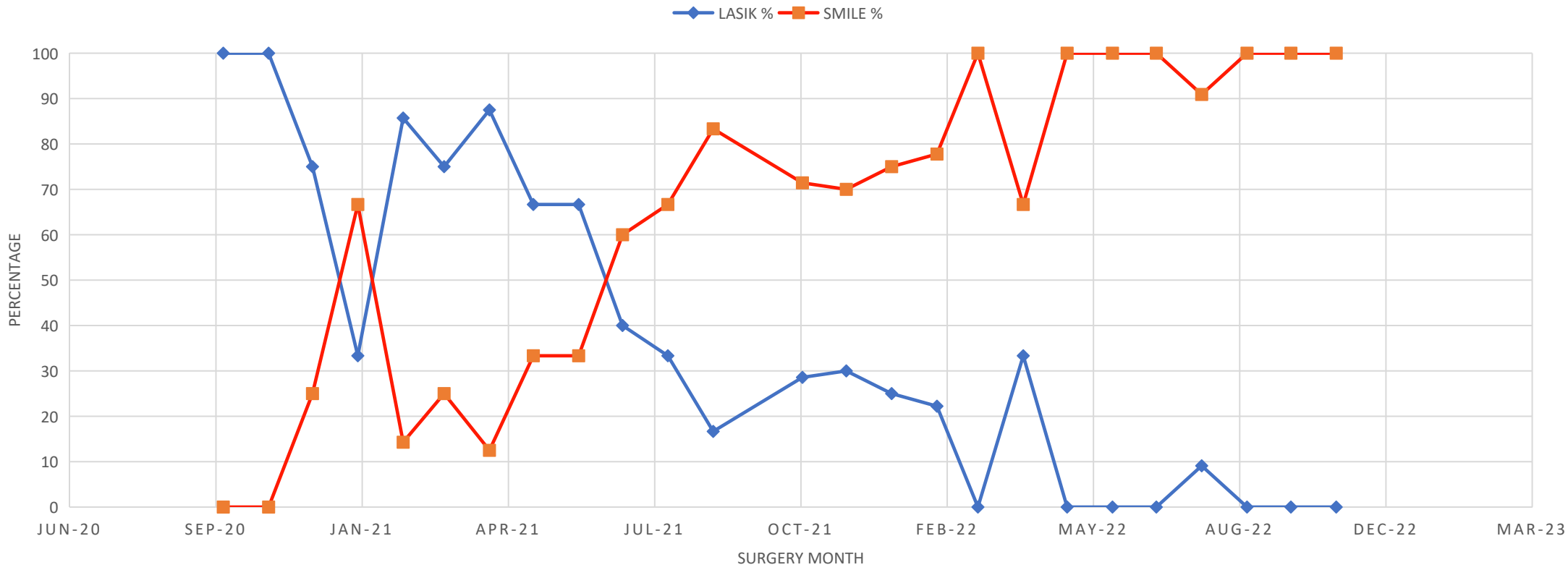
Schallhorn JM, Seifert S, Schallhorn SC. SMILE, topography-guided LASIK: review of clinical outcomes in premarket approval FDA studies. J Refract Surg. (2019) 35:690–8. 10.3928/1081597X-20190930-02

Cumulated SMILE Procedures - Global



GULFCOAST EYE CARE

GULFCOAST EYE CARE, LASIK V. SMILE TREND



Enhancement Rates

Conclusion: Following SMILE, ophthalmologists may anticipate an enhancement rate of one to seven percent In these cases, PRK is a safe and effective procedure for enhancement of SMILE.

Clinical Ophthalmology

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ORIGINAL RESEARCH

Photorefractive Keratectomy Enhancement (PRK) After Small-Incision Lenticule Extraction (SMILE)

Majid Moshirfar[1–3], Mark T Parsons[4], Nicholas A Chartrand[4], Chap-Kay Lau[4], Seth Stapley[5], Nour Bundogji[2], Yasmyne C Ronquillo[1], Phillip C Hoopes[1]

[1]Hoopes Vision Research Center, Hoopes Vision, Draper, UT, USA; [2]John A. Moran Eye Center, University of Utah School of Medicine, Salt Lake City, UT, USA; [3]Utah Lions Eye Bank, Murray, UT, USA; [4]University of Arizona College of Medicine – Phoenix, Phoenix, AZ, USA; [5]Arizona College of Osteopathic Medicine, Midwestern University, Glendale, AZ, USA

Correspondence: Majid Moshirfar, Hoopes Vision Research Center, 11820 S. State Street Suite #200, Draper, UT, 84020, USA, Tel +1 801-568-0200, Fax +1 801-563-0200, Email cornea2020@me.com

Purpose: To determine rates of enhancement and visual prognosis following photorefractive keratectomy (PRK) enhancement of small-incision lenticule extraction (SMILE).

Patients and Methods: This retrospective, single-site study reviewed all cases of primary SMILE at Hoopes Vision in Draper, Utah between March 14, 2017 and April 8, 2022 to identify any cases that required follow-up enhancement. Primary SMILE was performed using Visumax 500 kHz femtosecond laser (Carl Zeiss Meditec, Jena, Germany). All enhancements were performed with alcohol-assisted PRK, using a WaveLight EX500 excimer laser (Alcon Laboratories, Inc., Fort Worth, TX).

Results: Four hundred and five eyes underwent primary SMILE, of which 15 later underwent PRK enhancement (enhancement rate of 3.7%). No significant difference in pre-SMILE data was identified between the enhancement and non-enhancement groups. The average age of those who underwent PRK enhancement was 33.8±6.3 years old and ranged from 25 to 45. Following primary SMILE, 13 eyes (87%) had an uncorrected distance visual acuity (UDVA) of 20/40 or better, and none had a UDVA of 20/20 or better. After one year of post-enhancement follow-up, all eyes had a UDVA of 20/40 or better, and 13 eyes (87%) had a UDVA of 20/20 or better (Figure 1). All were within one diopter of target spherical equivalent (SEQ), 13 (87%) were within 0.50 D, and 10 (67%) were within 0.25 D. Of those with 12-month follow-up data, none had UDVA worse than corrected distance visual acuity (CDVA), and none had lost lines of CDVA. Efficacy and safety indices were 1.03 and 0.99, respectively.

Conclusion: Following SMILE, ophthalmologists may anticipate an enhancement rate of one to seven percent. In these cases, PRK is a safe and effective procedure for enhancement of SMILE.

Enhancement Rates

Conclusions: The 2-year incidence of enhancement after SMILE was 2.9%. Risk factors associated with enhancement included older age at SMILE procedure, greater preoperative MRSE, greater preoperative myopia, greater preoperative astigmatism, and the occurrence of intraoperative suction loss. Clinical outcomes of using PRK with application of MMC for enhancement were good.

. 2017 Jun;124(6):813-821. doi: 10.1016/j.ophtha.2017.01.053. Epub 2017 Mar 15.

Enhancement after Small-Incision Lenticule Extraction: Incidence, Risk Factors, and Outcomes

Yu-Chi Liu [1], Mohamad Rosman [1], Jodhbir S Mehta [2]
Affiliations expand

- PMID: 28318639
- DOI: 10.1016/j.ophtha.2017.01.053

Abstract

Purpose: To report the incidence, risk factors, and outcomes of enhancement after small-incision lenticule extraction (SMILE).

Design: Retrospective cohort study.

Participants: Five hundred twenty-four eyes of 307 patients who underwent SMILE at Singapore National Eye Center between February 2012 and March 2016.

Methods: The data collected included patient age at primary SMILE, gender, race, preoperative and postoperative manifest refraction spherical equivalent (MRSE), preoperative and postoperative uncorrected distance visual acuity and corrected distance visual acuity, the occurrence of suction loss during the procedure, and the need for enhancement. All enhancements were carried out by performing an alcohol-assisted photorefractive keratectomy (PRK) procedure with application of mitomycin C (MMC).

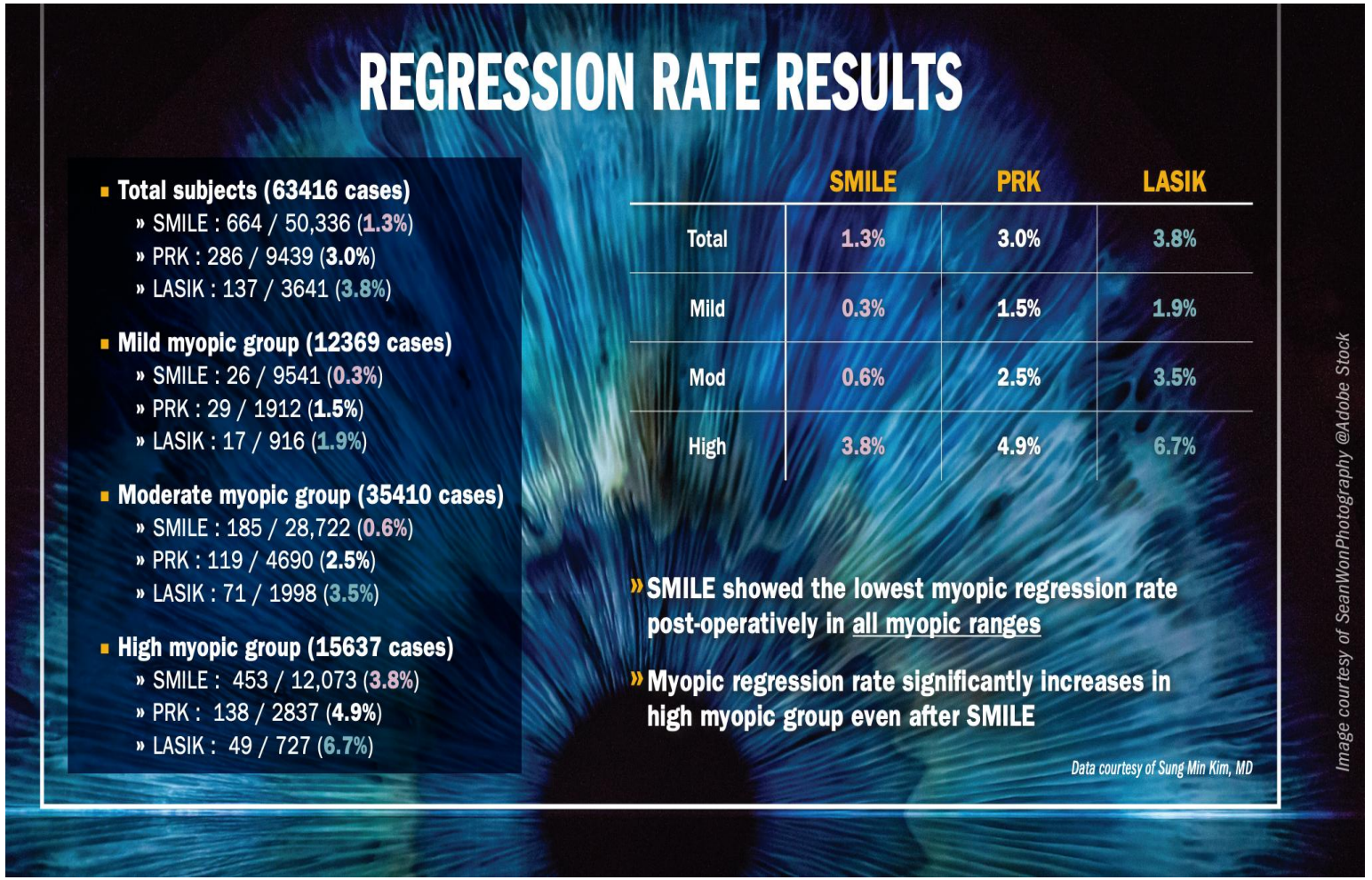
Main outcome measures: Incidence, prevalence, preoperative and intraoperative risk factors for enhancement, and outcomes after enhancement.

Results: The prevalence of enhancement was 2.7%, and 71.4% eyes had enhancement within 1 year of primary SMILE. The incidence of enhancement was 2.1% and 2.9% at 1 and 2 years, respectively. Age older than 35 years, preoperative MRSE more than -6.00 diopters (D), preoperative myopia more than 6.00 D, preoperative astigmatism more than 3.00 D, and intraoperative suction loss were significant risk factors for enhancement after SMILE after adjusting for all other covariates (odds ratios, 5.58, 4.80, 1.41, 3.06, and 2.14, respectively; P = 0.004, 0.021, 0.022, 0.002, and 0.020, respectively). In the patients who underwent bilateral SMILE, the first-operated eye had a marginal trend toward significance for enhancement (P = 0.054). There was no gender or racial difference. In the 14 eyes requiring enhancement, the uncorrected distance visual acuity before enhancement ranged from 20/80 to 20/25, and the mean attempted enhancement spherical equivalent was -0.50±0.86 D. The uncorrected distance visual acuity improved in most patients (92.9%) after enhancement.

Conclusions: The 2-year incidence of enhancement after SMILE was 2.9%. Risk factors associated with enhancement included older age at SMILE procedure, greater preoperative MRSE, greater preoperative myopia, greater preoperative astigmatism, and the occurrence of intraoperative suction loss. Clinical outcomes of using PRK with application of MMC for enhancement were good.

Enhancement Rates

- **SMILE offers low enhancement rate after nomogram adjustment**



Lynda Charters; Reviewed by Sung Min Kim, MD. SMILE offers low enhancement rate after nomogram adjustment. Ophthalmology Times, : March 15, 2021, Volume 46, Issue 5

Why It Matters To Patients??

- Does LASIK/SMILE wear off??
- Will I have to wear glasses again??
- Milestones

Dry Eye: Post Refractive Surgery

Dry Eye Disease after Refractive Surgery

Comparative Outcomes of Small Incision Lenticule Extraction versus LASIK

Alexandre Denoyer, MD, PhD,[1,2,3] Elise Landman, MD,[1] Liem Trinh, MD,[1,4] Jean-François Faure, MD,[1,4] François Auclin, MD,[1] Christophe Baudouin, MD, PhD[1,2,3,5]

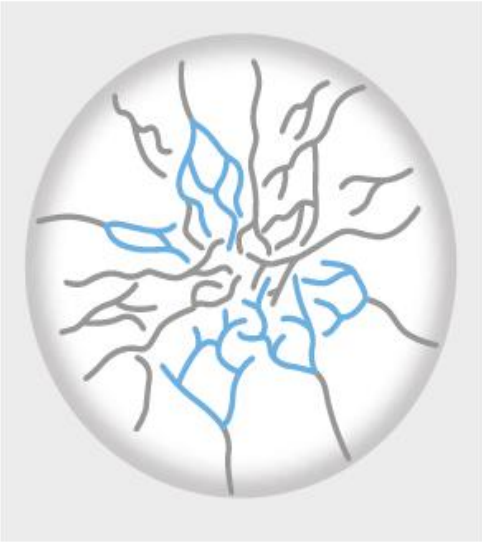
Table 2. Dry Eye Disease 1 and 6 Months after Refractive Surgery

	1 Month			6 Months		
	SMILE	*LASIK*	*P*	*SMILE*	*LASIK*	*P*
OSDI (0–100)	19.7±12.7	23.9±14.8	0.09	**7.5±4.5**	**20.6±20.8**	**<0.01**
TBUT (s)	5.9±1.7	5.1±1.9	0.16	**7±1.8**	**5.2±1.8**	**0.01**
Schirmer I test (mm/5′)	13.2±6.1	19.9±10.5	0.08	17.3±8.2	16.9±7.8	0.85
Oxford score (0–5)	0.08±0.28	0.27±0.55	0.16	0	0.4±0.6	0.06
Tear osmolarity (mOsm)	**305.1±12.5**	**316.3±11.6**	**<0.01**	**300.3±11.4**	**315.0±11.9**	**<0.01**
Dry eye severity score (0–4)	1.0±0.8	1.5±0.9	0.06	**0.2±0.4**	**1.2±1.1**	**<0.01**

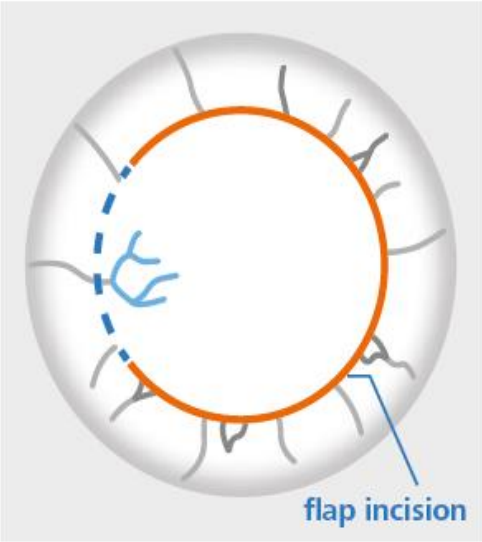
OSDI = Ocular Surface Disease Index; SMILE = small incision lenticule extraction; TBUT = tear film breakup time.
The dry eye severity score was calculated according to the modified Delphi approach.[3,10] Data are reported as mean ± standard deviation. Boldface indicates statistical significance ($P < 0.01$).

Dry Eye: Corneal Plexus

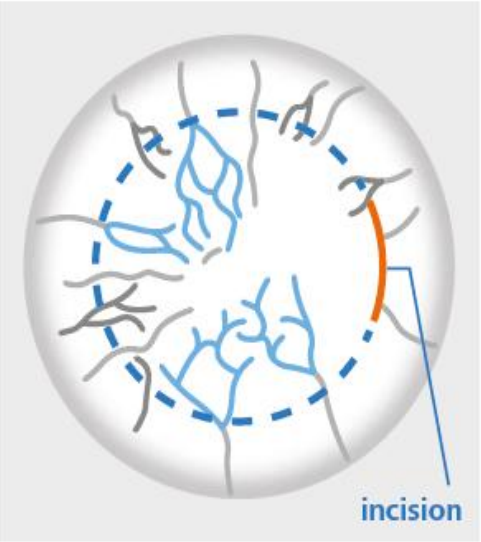
- Removing tissue from deeper corneal layers results in less impact on the corneal surface and nerves.



Normal Nerve Network



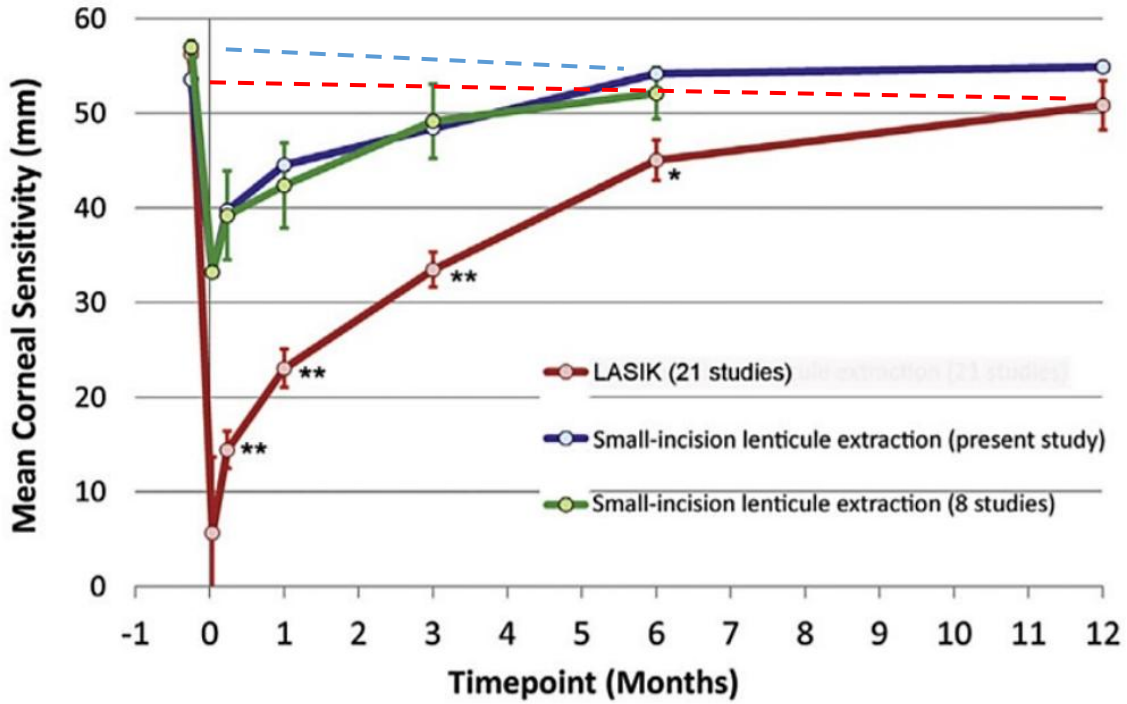
LASIK



SMILE

Dry Eye: Corneal Sensitivity

Recovery of central corneal sensitivity to baseline was reached by 6 months after small-incision lenticule extraction and was higher than after LASIK for the first 6 months after surgery



Reinstein DZ, Archer TJ, Gobbe M, Bartoli E. Corneal Sensitivity after Small Incision Lenticule Extraction (SMILE). J Cataract Refract Surg. 2015

Corneal Integrity

Computational modeling study.

Small-incision lenticule extraction (SMILE) may present less biomechanical risk to the residual bed of susceptible corneas than comparable corrections involving LASIK flaps. Deeper corrections in the stroma may be possible in small-incision lenticule extraction without added risk for ectasia.

Comparative Study
J Cataract Refract Surg; 2014 Jun;40(6):971-80; doi: 10.1016/j.jcrs.2013.08.065.

Comparison of biomechanical effects of small-incision lenticule extraction and laser in situ keratomileusis: finite-element analysis

Abhijit Sinha Roy [1], William J Dupps Jr [1], Cynthia J Roberts [2]

Abstract

Purpose: To theoretically compare the corneal stress distribution of laser in situ keratomileusis (LASIK) with the stress distribution of small-incision lenticule extraction.

Setting: Cleveland Clinic Cole Institute, Cleveland, and The Ohio State University, Columbus, Ohio, USA.

Design: Computational modeling study.

Methods: A finite-element anisotropic collagen fiber-dependent model of myopic surgery using patient-specific corneal geometry was constructed for LASIK, small-incision lenticule extraction, and a geometry analog model with unaltered material properties from preoperative but with postoperative geometry including thickness. Surgical parameters, magnitude of myopic correction, LASIK flap thickness, and lenticule depth in small-incision lenticule extraction were varied. Two sets of models, 1 with uniform and 1 with depth-dependent material properties, were constructed.

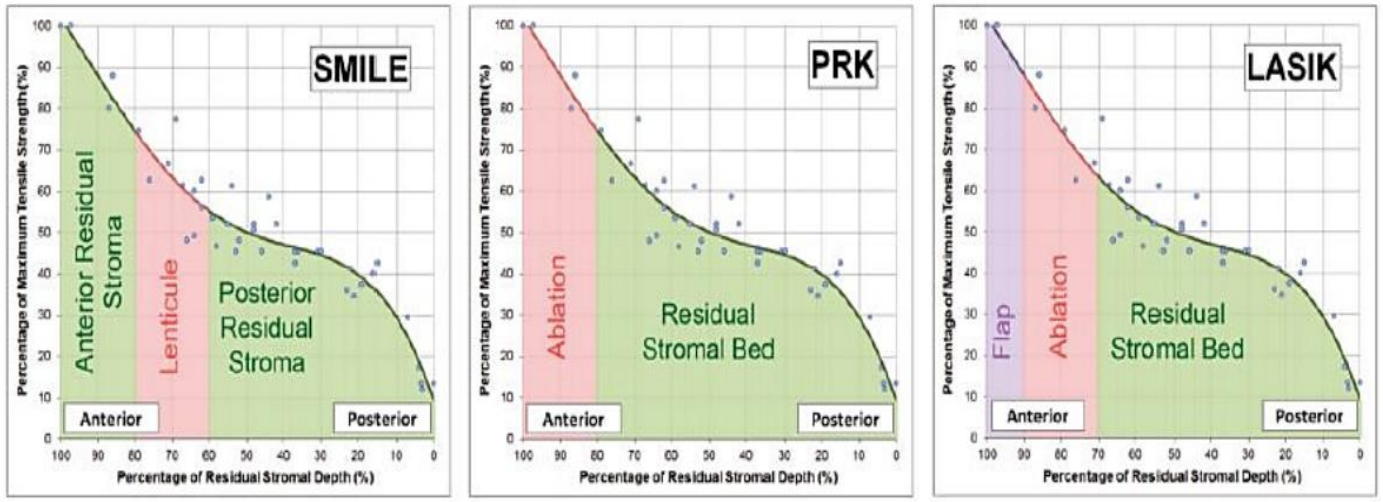
Results: Stress distribution between small-incision lenticule extraction simulations and the geometry analog model were similar. In contrast, LASIK consistently reduced stress in the flap and increased stress in the residual stromal bed (RSB) compared with the geometry analog model. An increase in flap thickness or lenticule depth resulted in a greater increase in RSB stress in the LASIK model than in the small-incision lenticule extraction model.

Conclusions: Small-incision lenticule extraction may present less biomechanical risk to the residual bed of susceptible corneas than comparable corrections involving LASIK flaps. Deeper corrections in the stroma may be possible in small-incision lenticule extraction without added risk for ectasia.

Corneal Integrity

This mathematical model predicts that the postoperative TTS is considerably higher after SMILE than both PRK and LASIK, as expected given that the strongest anterior lamellae remains intact.

Consequently, SMILE should be able to correct higher levels of myopia.



75% SMILE (130-µm cap) 68% PRK 54% LASIK (110-µm flap)

TTS = Total tensile stength

Dan Z. Reinstein, MD, MA(Cantab), FRCOphth; Timothy J. Archer, MA(Oxon), DipCompSci(Cantab); J. Bradley Randleman, MD; Mathematical Model to Compare the Relative Tensile Strength of the Cornea After PRK, LASIK, and Small Incision Lenticule Extraction. Journal of Refractive Surgery • Vol. 29, No. 7, 2013

Why It Matters To Patients??

- Convenient Post Operative Schedule
- Potentially less dryness symptoms than LASIK
- Faster recovery in corneal sensitivity
- Martial Arts/Sports/Occupation

Contact Lens Intolerance

Current or previous experience with contact lenses was reported by 453 (62%) of the subjects. Of these subjects, 119 (26.3%) reported that contact lenses were not the ideal form of visual correction for them (contact lens dissatisfaction) and another 109 (24.1%) had permanently discontinued contact lens wear.

A significant number of contact lens wearers are not satisfied with contact lenses and are at risk for discontinuation.

Cornea. 2007 Feb;26(2):168-74.
doi: 10.1097/01.ico.0000248382.32143.86.

Frequency of and factors associated with contact lens dissatisfaction and discontinuation

Kathryn Richdale[1], Loraine T Sinnott, Elisa Skadahl, Jason J Nichols

Abstract

Purpose: To determine the frequency of and factors associated with contact lens dissatisfaction and discontinuation.

Methods: A cross-sectional survey of 730 subjects was conducted using a self-administered survey instrument. The survey collected information about present age and sex, history of contact lens wear, types of lenses worn, age at starting wear, current wearing schedule (hours per day, days per week), self-perceived contact lens satisfaction, and contact lens-related problems. A variety of statistical analyses including analysis of variance, logistic regression, and repeated-measures logistic regression were used to model the data.

Results: Current or previous experience with contact lenses was reported by 453 (62%) of the subjects. Of these subjects, 119 (26.3%) reported that contact lenses were not the ideal form of visual correction for them (contact lens dissatisfaction) and another 109 (24.1%) had permanently discontinued contact lens wear. Dissatisfied contact lens wearers had reduced self-reported wearing times compared with satisfied contact lens wearers. Previous lens wearers were more likely than current lens wearers to be men, older (by approximately 9.5 years), have started contact lens wear at a later age (approximately 4-5 years later), and have tried either rigid or both soft and rigid lenses. The primary self-reported reason for both contact lens dissatisfaction and discontinuation was ocular symptoms (dryness and discomfort), followed by preference for another corrective modality.

Conclusion: A significant number of contact lens wearers are not satisfied with contact lenses and are at risk for discontinuation.

Contact Lens Intolerance

Primary reasons for discontinuation were discomfort (24%), dryness (20%), red eyes (7%), and expense (7%).

About 23% of those surveyed had discontinued CL wear permanently. The primary reasons for dropping out continue to be discomfort and dryness. Dropout rates were lower in silicone hydrogel wearers.

Eye Contact Lens. 2013 Jan;39(1):93-9. doi: 10.1097/ICL.0b013e318271caf4.

The impact of contemporary contact lenses on contact lens discontinuation

Kathy Dumbleton, Craig A Woods, Lyndon W Jones, Desmond Fonn

Abstract

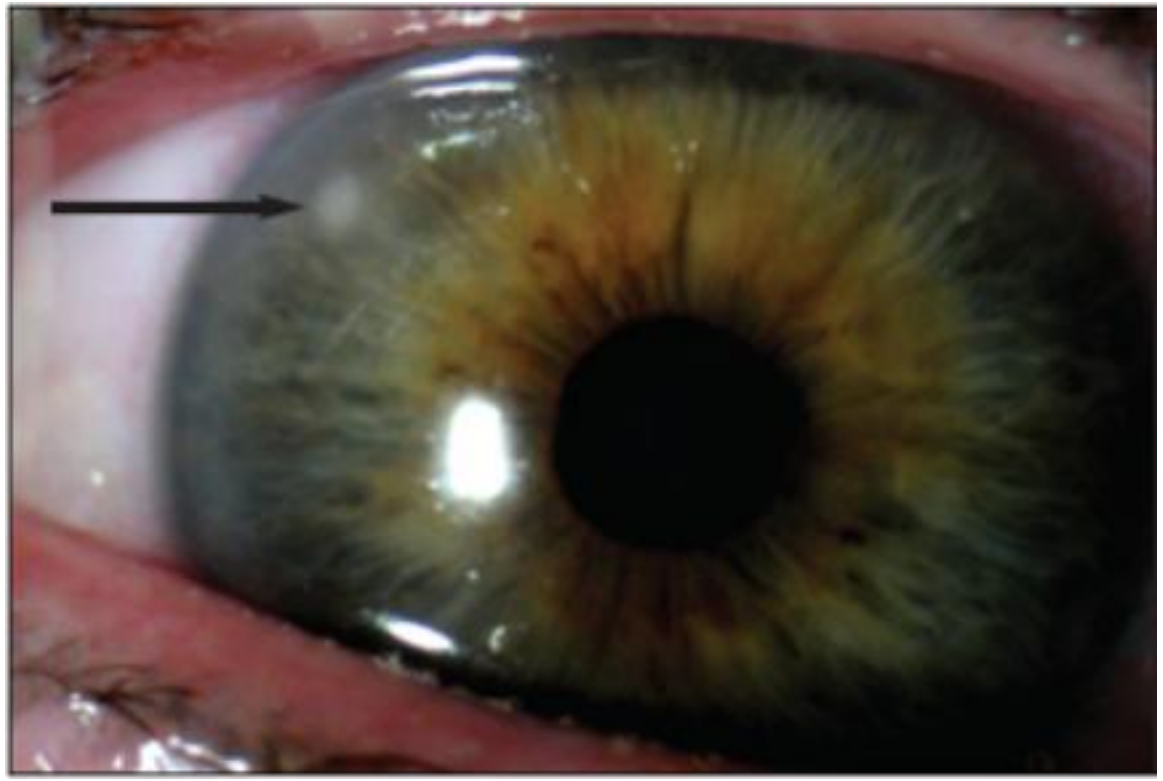
Objectives: Discontinuation or "dropout" from contact lens (CL) wear continues to afflict the CL industry. This study was conducted to determine whether the advent of new CL materials and designs has impacted the dropout rate and the reasons for discontinuation.

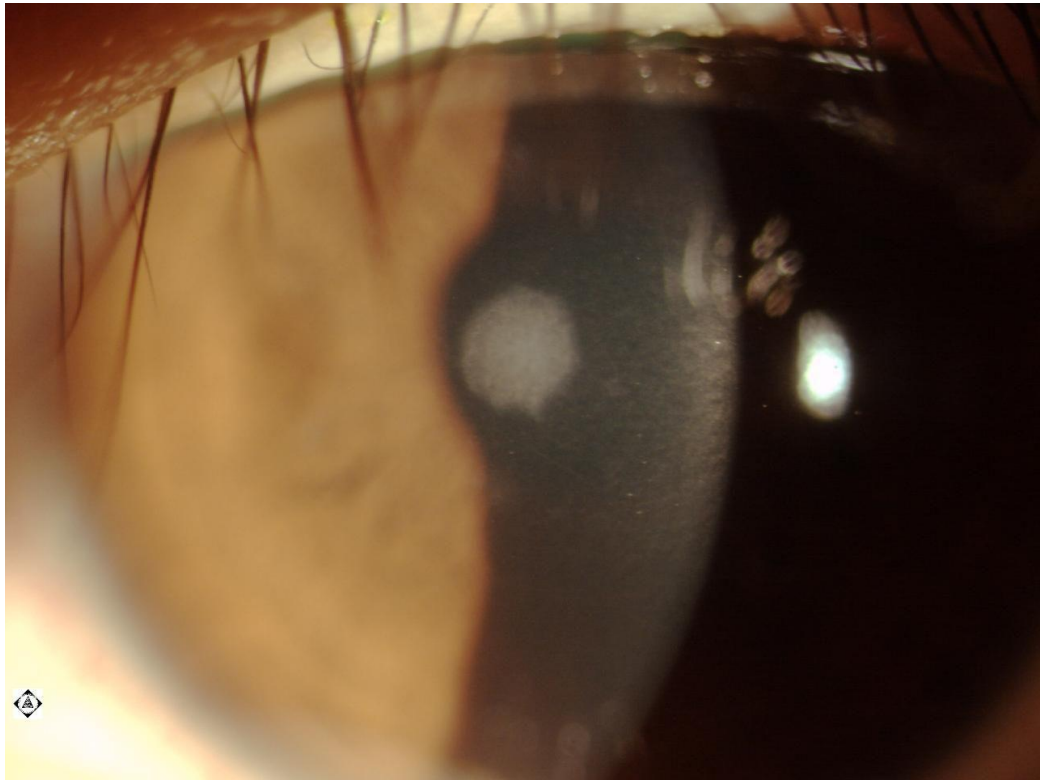
Methods: Current and lapsed CL wearers residing in Canada were recruited using Facebook to take part in an on line survey investigating CL wearing experiences during 2008 to 2010 and to establish the percentage of participants who temporarily and permanently discontinued CL wear during the period surveyed.

Results: Four thousand two hundred seven eligible surveys were received (64% female; median age 27 years). Forty percent had lapsed from lens wear for at least 4 months; however, 62% of the lapsed wearers (LWs) resumed wear. There were no differences between LWs and nonlapsed wearers (NLWs) with respect to gender; however, LWs were older, started lens wear when older, and had not worn lenses for as long as NLWs (all $P<0.001$). More NLWs than LWs wore silicone hydrogel CLs (49% vs. 38%, $P<0.001$) and more LWs than NLWs wore daily disposable lenses and hydrogel CLs (24% vs. 19% and 22% vs. 18%, respectively, $P\leq0.001$). Primary reasons for discontinuation were discomfort (24%), dryness (20%), red eyes (7%), and expense (7%). Compliance with lens replacement was no different between LWs and NLWs (48% vs. 45%).

Conclusions: About 23% of those surveyed had discontinued CL wear permanently. The primary reasons for dropping out continue to be discomfort and dryness. Dropout rates were lower in silicone hydrogel wearers.

Contact Lens Related Keratitis





Why It Matters To Patients??

- Corneal Infection/Scar reduces the chance of candidacy for SMILE
- May be able to pivot to LASIK/PRK
- Alternative to wear CLs

Three-Year Longitudinal Survey Comparing Visual Satisfaction with LASIK and Contact Lenses

Marianne O Price [1], David A Price [2], Frank A Bucci Jr [3], Daniel S Durrie [4], William I Bond [5], Francis W Price Jr [6]

Affiliations + expand

PMID: 27208981 DOI: 10.1016/j.ophtha.2016.04.003

Results: Of 1800 subjects, 694 (39%) comprised the control group who continued contact lens wear, 819 (45%) wore contacts at baseline and had LASIK, and 287 (16%) wore glasses at baseline and had LASIK. Most contact lens users had worn them successfully ≥5 years. The proportion expressing strong satisfaction with their current vision correction method decreased from 63% at baseline to 54% at year 3 in the contact lens control group, whereas 88% of former contact lens wearers and 77% of former glasses wearers were strongly satisfied with LASIK at year 3. Patients 40 years of age or younger when they had LASIK were somewhat more likely to be strongly satisfied than older patients. LASIK significantly reduced difficulties with night driving and nighttime visual disturbances among former contact lens users and former glasses users. The proportion with dry eye symptoms at 1, 2, or 3 years after LASIK was not significantly increased relative to baseline contact lens wear but was significantly increased relative to baseline glasses use, consistent with many glasses users having tried and abandoned contact lenses because of latent dry eye problems. Compared with continued contact lens wear, LASIK significantly reduced the self-reported rates of eye infections, ulcers, and abrasions each year.

Conclusions: Compared with contact lens wear, current LASIK technology improved ease of night driving, did not significantly increase dry eye symptoms, and resulted in higher levels of satisfaction at 1, 2, and 3 years follow-up.

1800 subjects
694 (39%) control group who continued contact lens wear, ≥5 years
819 (45%) wore contacts at baseline and had LASIK
287 (16%) wore glasses at baseline and had LASIK

Percent Satisfaction:
Control: 63% to 54%
CL-LASIK: 63% to 88%
Glasses-LASIK: 63% to 77%

Patients 40 years of age or younger when they had LASIK were somewhat more likely to be strongly satisfied than older patients.

Benefits of LASIK

- Compared to SMILE
  - Similar outcomes
  - Availability – Only VisuMax is currently FDA Approved for SMILE
  - Name recognition – Everyone knows somebody
  - Proven track record
  - Fast return to normal activities
  - Some initial dry eye, improves with time
  - Corneal Scar – some small faint scars could be considered

Benefits of SMILE

- Compared to LASIK
  - Similar outcomes
  - One laser
  - No flap
  - Potential better biomechanical stability
  - Faster return to normal activities
  - Less induction of higher order aberrations
  - Less dry eye issues

Our Role
Supply and Demand

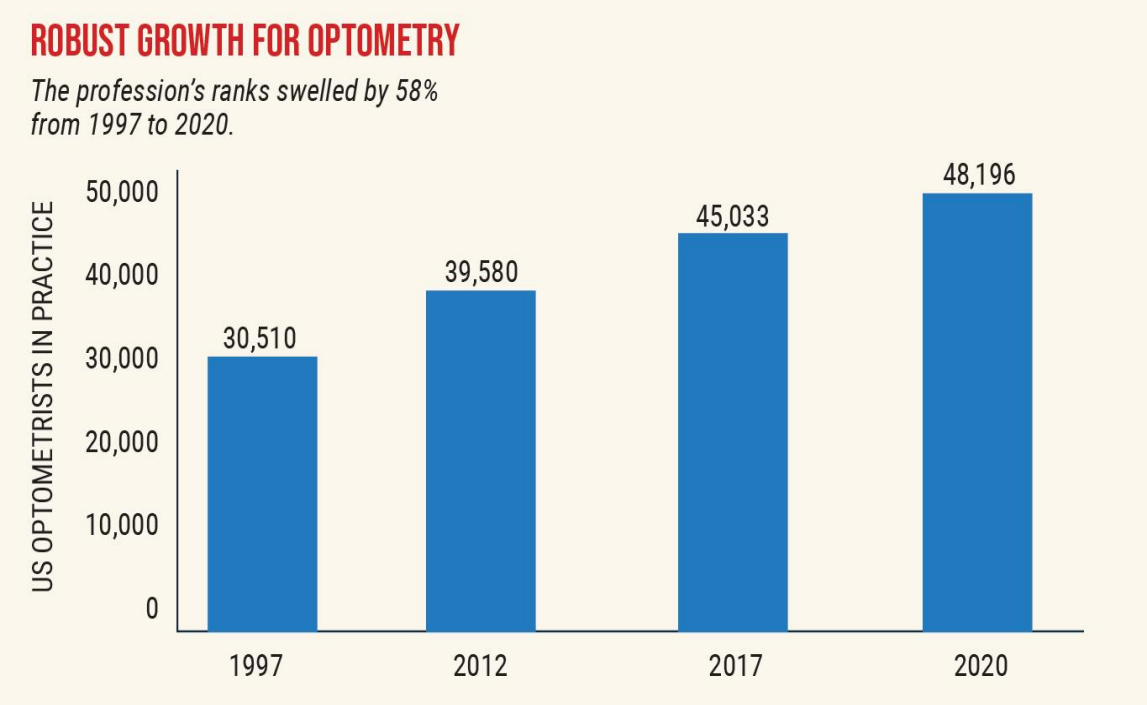


Exhibit 1: National Estimates of Supply and Demand of Surgical Specialty Physicians, 2013 -2025

Specialty[a]	Baseline Estimates (FTEs, 2013)	Projections (FTEs, 2025)		
	Supply = Demand[b]	Supply	Demand	Difference[c]
General Surgery	28,190	30,760	33,730	-2,970
Colon/Rectal Surgery	1,710	2,120	1,990	130
Neurological Surgery	5,160	4,930	6,130	-1,200
Ophthalmology	18,470	16,510	22,690	-6,180
Orthopedic Surgery	25,420	24,350	29,400	-5,050
Cardiothoracic Surgery	4,490	3,600	5,410	-1,810
Otolaryngology	9,440	9,190	10,810	-1,620
Plastic Surgery	7,720	7,280	8,770	-1,490
Urology	9,910	8,830	12,460	-3,630
Vascular Surgery	3,050	3,410	3,930	-520
Total	**113,560**	**110,980**	**135,320**	**-24,340**

Notes: Numbers may not sum to totals due to rounding. All estimates are rounded to the nearest 10.
[a] Specialties reflect physicians' primary reported discipline.
[b] Supply and demand for 2013 surgical specialty physicians were assumed to be in approximate equilibrium at the national level.
[c] Difference = (supply – demand); a negative difference reflects a shortage (i.e., supply is less than demand), while a positive difference indicates a surplus (i.e., supply is greater than demand).

Supply 2022:
40,640

Supply 2022:
18,948

Association of American Medical Colleges. The Complexities of Physician Supply and Demand: Projections from 2019 to 2034. https://www.aamc.org/media/54681/download?attachment . Accessed Dec. 7, 2022.

Health Resources & Services Administration. National and Regional Projections of Supply and Demand for Surgical Specialty Practitioners: 2013-2025. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/surgical-specialty-report.pdf . Accessed Dec. 7, 2022.