

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

Rupal Shah, MS (Ophthalmology)

**Abstract:** Small incision lenticule extraction (SMILE) is a new paradigm for refractive surgery, and was first performed by Sekundo and Blum in 2008. It uses only a femtosecond laser to carve out a lenticule within the corneal stroma, and then achieves refractive correction by extracting the lenticule through a small incision. A number of studies have shown that SMILE leads to stable and efficacious outcomes, combined with high safety. Long-term studies also indicate that SMILE has excellent outcomes combined with high safety. Although relatively safe, SMILE can have some intraoperative and postoperative complications, including suction loss during the procedure, lenticule tears, incision tears, epithelial ingrowth, diffuse lamellar keratitis, and residual refractive error. Studies indicate that SMILE leads to less postoperative dry eyes. It is thus preferred over laser-assisted in-situ keratomileusis (LASIK) in cases wherein there is mild dry eye preoperatively. It is also preferred over LASIK in cases wherein the patient is likely to engage in contact sports. LASIK may be preferred over SMILE for the treatment of hyperopia, and in cases of significant higher order wavefront aberrations or topographic irregularities.

**Key Words:** LASIK, refractive lenticule extraction, small incision, small incision lenticule extraction, SMILE

(*Asia Pac J Ophthalmol (Phila)* 2019;8:371–376)

Automated lamellar keratoplasty<sup>1</sup> (ALK) was a technique used for the correction of myopic refractive errors, which was popular in the late 1980s and early 1990s, before the advent of the excimer laser. It involved the creation and extraction of a lenticule from within the corneal stroma, to flatten the central cornea and thus correct myopia. In ALK, a specially designed mechanical microkeratome was used to complete the entire procedure. The microkeratome<sup>2</sup> is an instrument designed to cut a fixed thickness planar slice of the cornea. The microkeratome used in the ALK technique allowed the surgeon to vary the depth and diameter of the cut based on the requirements of the correction. The microkeratome was first used to create an 8 to 9 mm free cap of the cornea, with a thickness of around 160  $\mu\text{m}$ . This would expose the corneal stroma. In a second pass, the microkeratome was used to create a 4- to 5-mm

diameter slice of stroma. The thickness of this second slice was determined by the amount of refractive correction required. The free cap was then placed back on the cornea, and sutured in place. In a later variation, instead of a free cap, a hinged flap was created first, lifted to one side, and then the second cut was performed on the exposed stroma. The corneal flap was then refloated in place, and allowed to heal at the edges, without any suturing.

Although lamellar keratoplasty has a long intellectual history, beginning with the efforts of Barraquer<sup>3</sup> in the 1950s, it was only much later that mechanical microkeratomes reached a level of refinement, which allowed ALK to be used by the average ophthalmologist. However, the technique suffered from many limitations. First, the thickness of the lenticule was subject to high levels of unpredictability. The refractive outcomes were not, therefore, very predictable. Second, ALK could not treat astigmatism, as mechanical microkeratomes were not designed to change the size or thickness of the lenticule along a particular axis. Third, the lenticule was a fixed thickness planar lens, which was not physiological, as the lenticule needed to be removed would be spherocylindrical in shape. Finally, mechanical microkeratomes of that era had a high rate of complications.<sup>4</sup> As a result of these problems, ALK remained a niche technique to treat high myopia, and did not gain much traction among patients or eye surgeons.

The excimer laser was introduced in 1983 as a tool to perform corneal surgery.<sup>5</sup> By 1988, it was used to perform excisional correction of refractive errors.<sup>6</sup> A refractive lenticule was ablated to reshape the cornea, using the photoablative properties of the excimer laser. Thus, the excimer laser could be used to treat refractive errors. The initial technique used with the excimer laser was known as photorefractive keratectomy<sup>7</sup> (PRK). PRK involved mechanical scraping of the corneal epithelium followed by reshaping of the remaining corneal bed with the excimer laser. The corneal epithelium was then allowed to regrow. The refractive lenticule was not removed as a single intact lenticule of the corneal stroma. Rather, the excimer laser's photoablative properties were used to convert corneal tissue into a gaseous plume, with small amounts of tissue removed with every laser pulse. The laser pulses were directed into the corneal stroma in a way that, overall, a refractive lenticule was removed with a shape corresponding to the refractive change desired.

PRK was a procedure which met with a high amount of success, as the excimer laser could remove tissue from the cornea with great accuracy. This led to a high predictability of the refractive outcomes with the procedure. Although initially it was used to treat only spherical myopia, it was quickly adapted to treat astigmatism and hyperopia. It obtained US Food and Drug Administration (FDA) approval in 1995, and quickly became the procedure of choice to treat refractive errors. The success of the

From the Vadodara, India

Submitted May 30, 2019; accepted July 30, 2019.

The author receives study and travel fees from Carl Zeiss Meditec.

The authors have no conflicts of interest.

Correspondence: Dr. Rupal Shah, Centre for Sight, 101, Tower A, Atlantis K10, Genda Circle, Vadodara 390023, India. E-mail: rupalbrd@gmail.com.

Copyright © 2019 Asia-Pacific Academy of Ophthalmology. Published by Wolters Kluwer Health, Inc. on behalf of the Asia-Pacific Academy of Ophthalmology.

This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

ISSN: 2162-0989

DOI: 10.1097/01.APO.0000580132.98159.9a

excisional PRK procedure also displaced the incisional procedure of radial keratotomy<sup>8</sup> (RK).

However, PRK also had its share of problems.<sup>9</sup> As the corneal epithelium was scrapped off before the laser ablation, the patient experienced a high amount of pain during the first postoperative day. Subsequently, the visual recovery was delayed as the regrown corneal epithelium took some time to achieve full thickness, and there was a hyperopic overshoot for the first postoperative month. Third, in some patients especially with high amounts of refractive error, PRK is followed by corneal haze and regression of the treatment. Today, despite significant improvements in laser ablation profiles, medication, wound healing modulation regimes, and surgical technique, PRK is performed on <20% of all refractive surgery patients.

In the early 1990s, Buratto et al<sup>10</sup> and Pallikaris et al<sup>11</sup> combined ALK with the excimer laser into a procedure known as LASIK. It was proposed that a mechanical microkeratome to be used to make a hinged flap of the cornea. Excimer laser reshaping could then be done on the exposed corneal stroma, and finally the hinged flap could be refloated back on the cornea, and it allowed patients to heal in place without any sutures. As the first cut with the microkeratome was only to expose the corneal stroma, its accuracy was not very critical; and because the refractive lenticule was ablated with the help of the excimer laser, its shape and size could be accurately controlled. As a result, the accurate correction of all types of refractive errors became possible. Most of the disadvantages of ALK could be overcome by using the excimer laser to ablate the refractive lenticule.

LASIK quickly became the default choice of treating refractive errors. Its advantages—short period of patient discomfort, rapid visual recovery, and minimal wound healing reaction—led to very quick clinical acceptance of the procedure, and millions of LASIK procedures have been performed in the last 20 years.

Although LASIK with the mechanical microkeratome is still popular, the mechanical microkeratome is also the reason behind the majority of LASIK complications.<sup>12</sup> Some of these complications include free caps, incomplete flaps, irregular flaps, and flap displacements. Also, mechanical microkeratomers sometimes make flaps which are thicker than intended, which in some cases leads to kerectasia, a progressive thinning and subsequent irregular steepening of the cornea. Many surgeons have therefore shifted to the femtosecond laser as their primary means for making LASIK flaps.

A femtosecond laser<sup>13</sup> produces tiny pulses of laser light, with pulse widths of around 200 femtoseconds. When such laser is used with high-quality optics to focus the laser light intracorneally, it does not damage the surface but produces an intense energy field within the cornea. Nonlinear tissue interactions occur only above a sharp laser intensity threshold, which limits the effects to a very small area. Atoms are stripped off from their electrons, producing a plasma. This plasma expands rapidly, creating a gas bubble within the tissue. The whole process is so fast that there is no significant heat diffusion to surrounding tissues. A femtosecond laser can be rapidly scanned with a pulse frequency of hundreds of kilohertz and a small distance between adjacent pulses. A cleavage plane can be created within the cornea, with tiny tissue bridges between the gas bubbles. The tissue bridges can then be broken mechanically to completely separate the cleavage plane from the underlying tissue.

The first viable clinical application of the femtosecond laser was the corneal flap.<sup>14</sup> In this application, the femtosecond laser has many advantages over the mechanical microkeratome. The thickness of the flap can be more precise. Complications like free caps, buttonholes, and irregular flaps<sup>12</sup> can be eliminated or reduced. Fewer flap displacements occur as there is a well defined gutter at the edge, allowing the flap to be “locked in.” LASIK flaps made with a femtosecond laser are relatively more aberration neutral. All these advantages have led to the femtosecond laser gaining rapid traction as a flap making tool in the LASIK procedure. Over a number of years, the femtosecond laser has also evolved into a tool for keratoplasty and for creating corneal tunnels for placing intracorneal rings.

The use of the femtosecond laser in making corneal flaps during the LASIK procedure has some disadvantages, however. Two lasers are needed to complete the LASIK procedure: the femtosecond laser to make the flap and the excimer laser to perform the corneal reshaping. This leads to higher capital cost, and also higher maintenance and consumable costs. For a busy surgeon, it also means a significant workflow disruption, as the patient has to be moved from under one laser to another.

In recent years, a new femtosecond laser is available (Visu-Max, Carl Zeiss Meditec AG, Jena, Germany), which can carve out a lenticule within the cornea. This procedure of carving out a refractive lenticule within the cornea, and its subsequent mechanical extraction from the cornea to perform corneal reshaping is called femtosecond lenticule extraction, or ReLEx. The lenticule can then be extracted from within the corneal stroma, either by creating and lifting a hinged flap as in ALK or LASIK, or by extricating it from within the cornea through a small incision in the cornea. The former technique is usually called FLEx, and the latter is called SMILE. Most experienced surgeons use SMILE only, and FLEx is generally a technique used during the learning curve.

SMILE is therefore akin to ALK, in that a whole refractive lenticule is created in the corneal stroma, and then removed from the cornea to achieve corneal reshaping. However, the femtosecond laser has several advantages over mechanical microkeratome for the lenticule creation procedure. Unlike a mechanical microkeratome, a femtosecond laser can scan the cornea in all 3 dimensions, and thus the refractive lenticule created is more physiological in shape. Second, the femtosecond laser is more accurate. Studies indicate that for Femto-LASIK, the standard deviation of the flap thickness is around 10 to 12  $\mu\text{m}$ .<sup>15</sup> In contrast, the standard deviation of mechanical microkeratomers used in ALK or LASIK was around 24  $\mu\text{m}$ .<sup>16</sup> Third, with the femtosecond laser, the shape of the lenticule can be varied in thickness or diameter along a particular axis. Thus, astigmatic corrections are possible. Finally, the femtosecond laser offers a better safety profile than a mechanical microkeratome.

SMILE requires only a femtosecond laser to perform the entire refractive procedure, and it has various clinical, practical, and economic advantages over the more traditional and well known 2-laser solution of LASIK.

## HISTORY

In 2002, a German government taskforce appointed to find novel uses of the femtosecond laser first proposed the use of the femtosecond laser to cut lenticules within the cornea for refractive

correction. By 2004, Carl Zeiss Meditec had formed a team to create such laser.

In 2005, animal trials were commenced to check the proof of the lenticule extraction concept. Dr. Walter Sekundo from a University in Marburg, and Dr. Markus Blum from the HELIOS Ophthalmic Hospital Erfurt, were involved in the initial animal studies. These studies demonstrated feasibility and safety of lenticule extraction. However, due to the limitations of using animal eyes, predictability still needed to be established.

The first clinical studies were commenced in 2006. The initial clinical studies included studies on FLE<sub>x</sub> and SMILE. The first SMILE patient underwent the operation on April 24, 2007. These initial SMILE operations were done with 2 to 3 incisions from which the lenticule was extracted. The results of the initial studies were published in 2008<sup>17</sup> and 2010.<sup>18</sup>

The first clinical studies outside Germany were carried out by Dr. Rupal Shah in India in 2008. She performed SMILE with a single incision, and published her results on SMILE in 2010.<sup>19</sup>

Although the first studies indicated feasibility of the procedure, high predictability, and safety, they indicated that the new procedure compared poorly with LASIK in terms of visual recovery.

However, several improvements, including changing the direction of the scan pattern of the femtosecond laser,<sup>20</sup> raising the laser frequency from 200 to 500 kHz, optimizing the track and spot spacing of the laser,<sup>21</sup> and reducing the laser energy, all led to an improvement of the procedure. This led to the release of the laser for widespread use of the procedure in 2011. After completion of clinical trials, SMILE was also approved by the US FDA for the treatment of spherical myopia in 2016. By 2017, more than a million SMILE procedures had been performed worldwide.

## RESULTS

### Visual and Refractive Outcomes

There are several studies which have studied the visual and refractive outcomes after SMILE surgery for the treatment of myopia and myopic astigmatism.

Table 1 provides a summary of the studies on SMILE since 2010.<sup>20,22–32</sup> This is only a partial list which was deemed representative of the nearly 100 hundred studies, which have been published till date.

These studies indicate that SMILE leads to predictable and efficacious outcomes, combined with high safety.

There are a number of studies which compare the results after SMILE with the results of LASIK performed for myopia and myopic astigmatism.

Zhang et al<sup>33</sup> performed a systematic review and metaanalysis for comparing the results of SMILE with the results of FS-LASIK. The authors identified 11 studies from a review of 102 articles, involving a total of 1101 eyes, of which 532 eyes (48.32%) underwent SMILE and 569 eyes (51.68%) underwent FS-LASIK. No significant difference between the 2 procedures was evident in terms of final refractive spherical equivalent ( $P = 0.72$ ), the proportion of eyes losing  $\geq 1$  lines of corrected distance visual acuity after surgery ( $P = 0.69$ ), the proportion of eyes achieving an uncorrected distance visual acuity of 20/20 or better ( $P = 0.35$ ), and a refractive spherical equivalent within  $\pm 1.00$  D of the target

TABLE 1. Representative Summary of Results Published on the Results of SMILE for Myopia and Myopic Astigmatism

Study	Eyes	Follow-Up	Preoperative Spherical Equivalent, D	Postoperative Spherical Equivalent	SpEq within $\pm 0.5$ D, %	PreOP CDVA 20/20 or Better, %	PostOp UDVA 20/20 or Better, %	Loss of CDVA > 2 Lines, %
Sekundo et al <sup>22</sup> (2014)	54	1 y	-4.68 $\pm$ -1.29		92	98	88	0
Shah and Shah <sup>20</sup> (2011)	51	6 mo	-4.87 $\pm$ -2.16	+0.03 $\pm$ 0.30	91	67	62	0
Hjortdal et al <sup>23</sup> (2012)	670	3 mo	-7.19 $\pm$ 1.30	-0.25 $\pm$ 0.44	80	88	61	2.4
Kamiya et al <sup>24</sup> (2014)	26	6 mo	-4.21 $\pm$ 1.63	0.01	100	100	96	0
Agca et al <sup>25</sup> (2014)	40	1 y	-4.03 $\pm$ 1.61	-0.33 $\pm$ 0.25	95	NA	65	0
Ganesh and Gupta <sup>26</sup> (2014)	50	3 mo	-4.95 $\pm$ 2.09	-0.14 $\pm$ 0.28	96	96	96	0
Kim et al <sup>27</sup> (2015)	125	1 y	-7.67 $\pm$ -1.01	-0.24 $\pm$ -0.35	88	NA	80	0.3
Chansue et al <sup>28</sup> (2015)	318	1 y	-4.96 $\pm$ -1.88	+0.09 $\pm$ -0.31	93	98	90	0
Zhang et al <sup>29</sup> (2015)	98	1 y	-5.55 $\pm$ -1.39	NA	NA	96	80	0
Hansen et al <sup>30</sup> (2016)	722	3 mo	-6.43 $\pm$ -1.59	-0.06 $\pm$ -0.01	88	88	58	1.6
Messerschmidt-Roth et al <sup>31</sup> (2017)	50	3 y	-6.18 $\pm$ -1.91	-0.18 $\pm$ -0.39	78	86	47	0
Agca et al <sup>32</sup> (2019)	54	5 y	-4.11 $\pm$ -0.98	-0.13 $\pm$ -0.29D	93	93	80	0

CDVA indicates corrected distance visual acuity; UDVA, uncorrected distance visual acuity.

values ( $P=0.70$ ). The authors concluded that SMILE and FS-LASIK were comparable in terms of both safety and efficacy.

A more recent study<sup>34</sup> compared the safety and efficacy of topography-guided LASIK and contralateral eye SMILE for myopia and myopic astigmatism correction. The study concluded that topography-guided LASIK was superior in all visual performance parameters studied, both subjectively and objectively. However, it should be noted that the uncorrected distance visual acuity and the refractive outcomes in this study after SMILE were worse than in other studies, as shown in Table 1.

A few studies<sup>24,26,35</sup> have compared the induction of higher-order aberrations after SMILE and FS-LASIK. Most authors agree that there is an induction of higher-order aberrations after both SMILE and FS-LASIK. However, there is equivalent or less induction of higher aberrations after SMILE procedures compared with that after FS-LASIK procedures.

### COMPLICATIONS

As shown in Table 1, SMILE is a relatively safe procedure. However, complications (both intraoperative and postoperative) can occur.

Common intraoperative complications<sup>36</sup> which have been reported after SMILE include a) suction loss during the procedure, b) decentration of the treatment, c) incision tear or cap perforation during the SMILE procedure, d) tearing of the lenticule during the extraction process and subsequent retention of some lenticule tissue within the cornea, e) opaque bubble layer leading to difficult extraction of the lenticule, f) uncut areas of the lenticule owing to some foreign body or fluid between the contact glass and the cornea, g) lenticule adherence to the cap, resulting in a difficult extraction procedure, h) bleeding at the incision site, and i) epithelial defects.

Although the reported incidence of such complications varies in the literature, presumably because of the learning curve of the surgeon, from our experience, the incidence of all intraoperative complications put together is <1%.

Postoperative complications include corneal haze, diffuse lamellar keratitis, epithelial, ectasia, postoperative dry eyes, undercorrection or over-correction, and infection.

Several cases of ectasia<sup>37-40</sup> after SMILE have been reported in the literature, although it is not always clear from the reports whether these were because of the SMILE procedure being performed on undiagnosed cases of forme fruste keratoconus or because of weakening of the cornea owing to the procedure.

**TABLE 3.** Absolute and Relative Contraindications of SMILE

Absolute Contraindications	Relative Contraindications
Corneal thinning disorders like keratoconus or pellucid marginal degeneration	Age <18 y
Pregnancy or lactation	Diabetes mellitus
Cataract with CDVA <6/6	Autoimmune disorders
Uncontrolled glaucoma/uveitis	History of herpes simplex keratitis
Severe dry eye/blepharitis/severe ocular allergy	Mild dry eye/mild ocular allergy
Corneal scarring or opacity which would prevent laser penetration into deeper areas of corneas	Irregular cornea or irregular corneal astigmatism
Active eye inflammation or infection	Immunodeficient status
	One eyed/single eye functionality
	Epithelial basement membrane dystrophy

CDVA indicates corrected distance visual acuity; SMILE, small incision lenticule extraction.

**TABLE 2.** Indications for SMILE

Refractive error	Within $-0.5D$ to $-12D$ spherical equivalent, with upto $-5D$ of astigmatism
Age	>18 y
Mesopic pupil size	<7 mm
Residual stromal bed	>250 $\mu\text{m}$
Central corneal thickness	>475 $\mu\text{m}$
Stability of refraction	>1 y
Keratometry	Expected keratometry after procedure >35D and <47D

SMILE indicates small incision lenticule extraction.

### Postoperative Dry Eyes

There are a number of studies, which have compared postoperative dry eyes after SMILE and FS-LASIK. It is generally accepted that because SMILE cuts a smaller number of corneal nerve fibers compared with FS-LASIK, SMILE causes less dry eyes than FS-LASIK.

In an animal study, Mohamed-Noriega et al<sup>41</sup> found that SMILE results in less nerve damage and faster nerve recovery than LASIK. Ganesh et al<sup>42</sup> found significantly higher tear osmolarity after LASIK compared with that after SMILE. They also found that SMILE eyes have a longer tear film breakup time than LASIK eyes. Li et al<sup>43</sup> showed that the decrease in subbasal nerve fiber density was less severe in the first 3 months after SMILE than that after LASIK. Reinstein et al<sup>44</sup> demonstrated that recovery of central corneal sensitivity to baseline was reached by 6 months after SMILE and corneal sensation after SMILE was higher than after LASIK for the first 6 months after surgery.

### Indications and Contraindications of SMILE

Currently, SMILE is available for myopia ranging from  $-0.5 D$  to  $-12 D$  spherical equivalent, with myopic astigmatism up to  $-5 D$ . Within this range, the indications of SMILE are similar to LASIK generally. The indications are summarized in Table 2.

There are several contraindications for SMILE. Many of these are again similar to LASIK. Both absolute and relative contraindications of SMILE are summarized in Table 3.

There are several situations where SMILE could be preferred over LASIK. Similarly there are some situations in which LASIK or PRK may serve the patients' need better than SMILE.

SMILE could be the preferred choice for all patients who are likely to play contact sports, such as boxing, soccer, and martial

arts. The lack of a flap would be of significant advantage for such patients. As SMILE has been shown to cause less dry eyes, it may be the preferred choice in patients who have a long history of contact lens wearing and/or mild dry eye disease. SMILE has also shown higher stability in high myopia and thus would be a preferred choice for high myopia.

PRK or LASIK would be preferred over SMILE in cases with epithelial basement membrane dystrophy or in cases of corneal opacity. LASIK would be the preferred choice in the treatment of hyperopia. It would also be appropriate to use LASIK for cases of high wavefront aberrations or eyes with topographic irregularities. It would also be the preferred choice where there is a large difference between the pupil center and the visual axis. In such cases, topographically guided LASIK would be a more appropriate choice.

## CONCLUSIONS

Introduced in 2007, SMILE has established itself as a new paradigm to perform refractive surgery. It is currently available for the treatment of myopia and myopic astigmatism. It has excellent visual outcomes and a good safety profile. There is less dry eye after SMILE. It is an appropriate choice for the treatment of myopia in the absence of epithelial disorders or significant corneal irregularity.

## REFERENCES

- Ibrahim O, Waring III S, Salah T, et al. Automated in situ keratomileusis for myopia. *J Refract Surg.* 1995;11:431–441.
- Haimovici R, Culbertson W. Optical lamellar keratoplasty using the Barraquer microkeratome. *J Refract Surg.* 1991;7:42–45.
- Barraquer JJ. The history and evolution of keratomileusis. *Int Ophthalmol Clin.* 1996;36:1–7.
- Slade SG, Updegraff SA. Complications of automated lamellar keratectomy [letter]. *Arch Ophthalmol.* 1995;113:1092.
- Trokel SL, Srinivasan R, Braren B. Excimer laser surgery of the cornea. *Am J Ophthalmol.* 1983;96:710–715.
- McDonald MB, Kaufman HE, Frantz JM, et al. Excimer laser ablation in a human eye: case report. *Arch Ophthalmol.* 1989;107:641–642.
- Munnerlyn CR, Koons SJ, Marshall J. Photorefractive keratectomy: a technique for laser refractive surgery. *J Cataract Refract Surg.* 1988;14:46–52.
- Leaming D. Practice styles and preferences of ASCRS members—1996 survey. *J Cataract Refract Surg.* 1997;23:527–535.
- Lipshitz I, Loewenstein A, Varssano D, Lazar M. Late onset corneal haze after photorefractive keratectomy for moderate and high myopia. *Ophthalmology.* 1997;104:369–373.
- Buratto L, Ferrari M, Rama P. Excimer laser intrastromal keratomileusis. *Am J Ophthalmol.* 1992;113:291–295.
- Pallikaris IG, Papatzanaki ME, Siganos DS, et al. A corneal flap technique for laser in situ keratomileusis: human studies. *Arch Ophthalmol.* 1991;109:1699–1702.
- Tham VM, Maloney RK. Microkeratome complications of laser in situ keratomileusis. *Ophthalmology.* 2000;107:920–924.
- Kurtz RM, Horvath C, Liu HH, Krueger RR, Juhasz T. Lamellar refractive surgery with scanned intrastromal picosecond and femtosecond laser pulses in animal eyes. *J Refract Surg.* 1998;14:541–548.
- Ratkay-Traub I, Ferencz IE, Juhasz T, Kurtz RM, Krueger RR. First clinical results with the femtosecond neodymium-glass laser in refractive surgery. *J Refract Surg.* 2003;19:94–103.
- Reinstein DZ, Archer TJ, Gobbe M, Johnson N. Accuracy and reproducibility of artemis central flap thickness and visual outcomes of LASIK with the Carl Zeiss Meditec VisuMax Femtosecond Laser and MEL 80 Excimer Laser Platforms. *J Refract Surg.* 2010;26:107–119.
- Yildirim R, Aras C, Ozdamar A, et al. Reproducibility of corneal flap thickness in laser in situ keratomileusis using the Hansatome microkeratome. *J Cataract Refract Surg.* 2000;26:1729–1732.
- Sekundo W, Kunert K, Russman C, et al. First efficacy and safety study of femtosecond lenticule extraction for the correction of myopia: six month results. *J Cataract Refract Surg.* 2008;34:1513–1520.
- Sekundo W, Kunert KS, Blum M. Small incision corneal refractive surgery using the small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism: results of a 6 month prospective study. *Br J Ophthalmol.* 2011;95:335–339.
- Shah R, Shah S, Sengupta S. Results of small incision lenticule extraction: all-in-one femtosecond laser refractive surgery. *J Cataract Refract Surg.* 2011;37:127–137.
- Shah R, Shah S. Effect of scanning patterns on the results of femtosecond laser lenticule extraction refractive surgery. *J Cataract Refract Surg.* 2011;37:1636–1647.
- Meyer B, Wiltfang R. Management of Laser Settings for Better SMILE Surgery. Small Incision Lenticule Extraction (SMILE) (Ed. Walter Sekundo): 107–112.
- Sekundo W, Gertner J, Bertelmann T, Solomatin I. One-year refractive results, contrast sensitivity, high-order aberrations and complications after myopic small-incision lenticule extraction (ReLEx SMILE). *Graefes Arch Clin Exp Ophthalmol.* 2014.
- Hjortdal JO, Vestergaard AH, Ivarsen A, Ragunathan S, Asp S. Predictors for the outcome of small-incision lenticule extraction for myopia. *J Refract Surg.* 2012;28:865–871.
- Kamiya K, Shimizu K, Igarashi A, Kobashi H. Visual and refractive outcomes of femtosecond lenticule extraction and small-incision lenticule extraction for myopia. *Am J Ophthalmol.* 2014;157:128–134.
- Ağca A, Demirok A, Cankaya Kİ, et al. Comparison of visual acuity and higher-order aberrations after femtosecond lenticule extraction and small-incision lenticule extraction. *Cont Lens Anterior Eye.* 2014;37:292–296.
- Ganesh S, Gupta R. Comparison of visual and refractive outcomes following femtosecond laser-assisted LASIK with smile in patients with myopia or myopic astigmatism. *J Refract Surg.* 2014;30:590–596.
- Kim JR, Kim BK, Mun SJ, Chung YT, Kim HS. One-year outcomes of small-incision lenticule extraction (SMILE): mild to moderate myopia vs. high myopia. *BMC Ophthalmol.* 2015;15:59.
- Chansue E, Tanehsakdi M, Swasditbutra S, McAlinden C. Efficacy, predictability and safety of small incision lenticule extraction (SMILE). *Eye Vis (Lond).* 2015;2:14.
- Zhang J, Wang Y, Wu W, Xu L, Li X, Dou R. Vector analysis of low to moderate astigmatism with small incision lenticule extraction (SMILE): results of a 1-year follow-up. *BMC Ophthalmol.* 2015;15:8.
- Hansen RS, Lyhne N, Grauslund J, Vestergaard A. Small-incision lenticule extraction (SMILE): outcomes of 722 eyes treated for myopia and myopic astigmatism. *Graefes Arch Clin Exp Ophthalmol.* 2016;254:399–405.
- Messerschmidt-Roth A, Sekundo W, Lazaridis A, Schulze S. Three years follow-up study after refractive small incision lenticule extraction (SMILE)

- using 500kHz femtosecond laser in “fast mode”. *Klin Monbl Augenheilkd.* 2017;234:102–108.
32. Ağca A, Tülü B, Yaşa D, Yıldırım Y, Yıldız BK, Demirok A. Long-term (5 years) follow-up of small-incision lenticule extraction in mild-to-moderate myopia. *J Cataract Refract Surg.* 2019;45:421–426.
33. Zhang Y, Shen Q, Jia Y, Zhou D, Zhou J. Clinical outcomes of SMILE and FS-LASIK used to treat myopia: a meta-analysis. *J Refract Surg.* 2016;32:256–265.
34. Kanellopoulos AJ. Topography-guided LASIK versus small incision lenticule extraction (SMILE) for myopia and myopic astigmatism: a randomized, prospective, contralateral eye study. *J Refract Surg.* 2017;33:306–312.
35. Lin F, Xu Y, Yang Y. Comparison of the visual results after SMILE and femtosecond laser-assisted LASIK for myopia. *J Refract Surg.* 2014;30:248–254.
36. Ivarsen A, Asp S, Hjordtal J. Safety and complications of more than 1500 small-incision lenticule extraction procedures. *Ophthalmology.* 2014;121:822–828.
37. Mattila JS, Holopainen JM. Bilateral ectasia after femtosecond laser-assisted small incision lenticule extraction (SMILE). *J Refract Surg.* 2016;32:497–500.
38. El-Naggar MT. Bilateral ectasia after femtosecond laser–assisted small-incision lenticule extraction. *J Cataract Refract Surg.* 2015;41:884–888.
39. Sachdev G, Sachdev MS, Sachdev R, Gupta H. Unilateral corneal ectasia following small-incision lenticule extraction. *J Cataract Refract Surg.* 2015;41:2014–2018.
40. Wang Y, Cui C, Li Z, et al. Corneal ectasia 6.5 months after small-incision lenticule extraction. *J Cataract Refract Surg.* 2015;41:1100–1106.
41. Mohamed-Noriega K, Riau A, Lwin N, Chaurasia S, Tan D, Mehta J. Early corneal nerve damage and recovery following small incision lenticule extraction (SMILE) and laser in situ keratomileusis (LASIK). *Invest Ophthalmol Vis Sci.* 2014;55:1823–1834.
42. Ganesh S, Gupta R. Comparison of visual and refractive outcomes following femtosecond laser-assisted LASIK with smile in patients with myopia or myopic astigmatism. *J Cataract Refract Surg.* 2014;30:590–596.
43. Li M, Niu L, Qin B, Zhou Z, Ni K, Le Q, Xiang J, Wei A, Ma W, Zhou X. Confocal comparison of corneal reinnervation after small incision lenticule extraction (SMILE) and femtosecond laser in situ keratomileusis (FS-LASIK). *PLoS One.* 2013;8:e81435.
44. Reinstein DZ, Archer TJ, Gobbe M, Bartoli E. Corneal sensitivity after small incision lenticule extraction (SMILE). *J Refract Surg.* 2015;41:1580–1587.