

SOMETHING TO SMILE ABOUT



SMILE has the potential to change the way refractive surgery will be performed in the future.

BY RUPAL SHAH, MD

I had the privilege of performing the first single-incision small-incision lenticule extraction (SMILE) procedure in the world, and I have watched this procedure usher in a new paradigm in refractive surgery.

A BRIEF HISTORY OF SMILE

SMILE was developed in 2008 as an extension of the femtosecond lenticule extraction (FLEX) procedure, in which a femtosecond laser was used to cut a flap and a lenticule. The flap was then lifted and the lenticule removed.

In SMILE, the flap is replaced with a small incision. The surgeon uses the VisuMax femtosecond laser (Carl Zeiss Meditec) to cut both surfaces of a lenticule within the cornea (Figure 1). The lenticule shape is determined by the eye's refractive error. The surgeon then removes the lenticule through a small incision that was also made by the femtosecond laser when the lenticule was created (Figure 2).

SMILE offers several advantages over femtosecond LASIK (see *SMILE vs LASIK*). Since 2008, the procedure has seen several refinements. The laser delivery has been improved in a number of ways to decrease visual recovery time: The scanning direction of the laser was changed, the laser speed was increased from 200 to 500 kHz, the spot energy was decreased, the spot and track distances were changed, the instrumentation required for separation and removal of the lenticule has been refined, and the shape of the lenticule and the way astigmatism was corrected were

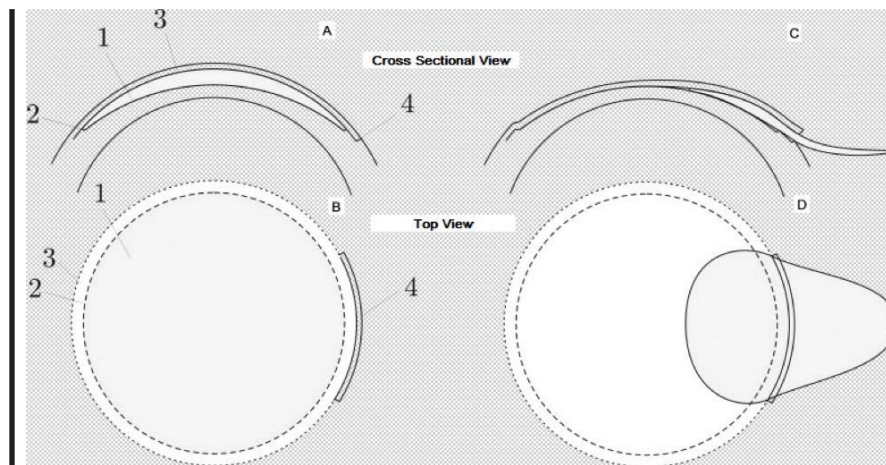


Figure 1. The cross-sectional and top views of the cuts involved in the SMILE procedure.

changed to improve results in the treatment of astigmatism. Further, several surgeons have developed techniques to compensate for cyclorotation of the cornea in the treatment of high astigmatism.

The range of treatments used to be from spherical equivalent of -0.50 D to -10.00 D of myopia. The upper range has now been increased to -12.50 D (Editor's note: outside the FDA-approved (Continued on page 41)

AT A GLANCE

- ▶ Because SMILE uses a small incision and therefore minimizes the cutting of corneal nerves, studies have suggested that it leads to greater corneal sensitivity and a better tear profile postoperatively compared with LASIK.
- ▶ In several published studies, results of SMILE for the treatment of myopia and myopic astigmatism have been equivalent to those for LASIK.
- ▶ A multicenter study is under way evaluating SMILE for the treatment of hyperopia, but this treatment modality is not yet available to surgeons outside the trial.

PATIENT PERSPECTIVE IS KEY

Here's how some patients feel about SMILE compared with LASIK.

BY JODHBIR S. MEHTA, BSc(Hons), MBBS, FRCOPHTH, FRCS(Ed), FAMS



The small-incision lenticule extraction (SMILE) procedure has now been performed more than 1 million times worldwide. Comparative studies compar-

ing SMILE outcomes to those of contemporary LASIK showed equivalent results in most areas with respect to safety and efficacy and superiority in certain areas such as ocular surface rehabilitation.¹

PATIENT-REPORTED OUTCOMES

Recently, there has been growing interest in patient-reported outcomes from surgery. We now understand that surgeons should be focused not only on clinical outcomes but also on the patient experience. This is evident in many facets of life beyond ophthalmology, such as in the airline industry. Some companies have made significant strides in improving one's travel experience to a destination, as opposed to just getting the passengers there on time.

The Patient-Reported Outcomes With LASIK (PROWL) study provided useful information on the patient experience following LASIK surgery.² It reconfirmed, from patients' points of view, something that many refractive surgeons see every day from the majority of our refractive patients: They are happy with the results.

Especially in the era of social media, the following equation applies: overall outcome = achieved result (surgical + experience) – patient expectation. With patient expectations higher than ever, we have to improve the whole journey of their surgical experience.

SMILE VS LASIK

We recently published the results of a study comparing the intra- and postoperative subjective experiences of patients after SMILE and LASIK.³ We used data from a randomized controlled trial in which patients had undergone LASIK in one eye and SMILE in the other.

We had previously published subjective outcomes in LASIK and SMILE patients showing minimal differences, but it is difficult to distinguish subtle differences in procedures unless you have the same patients undergoing both procedures.⁴ This highlights the importance of using the correct trial design to answer relevant questions for any new procedure. Our randomization protocol allowed us to eliminate any issue of first-eye

syndrome, and all cases were done by the same surgeon, who was experienced in both LASIK and SMILE.

PATIENT FEARS

Interestingly, the most frightening part of the refractive procedure for most patients was the excimer ablation, which was rated moderate to very high. Patients also reported being more fearful of flap creation, with respect to docking and suction, compared with lenticule creation. As expected, patients who experienced suction loss had higher fear scores, although the difference did not reach statistical significance due to the low numbers. These results highlight the importance of reducing patient fears and anxieties before the refractive procedure.

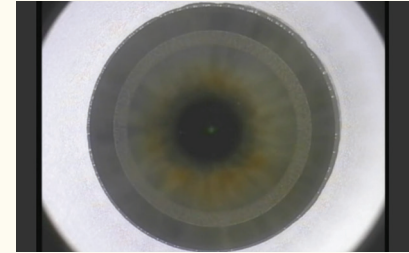
There was also more fear during the first eye surgery than the second, highlighting the importance of study design. We found that patients had significantly less discomfort during the flap lift for LASIK compared with the lenticule manipulation for SMILE, but discomfort scores for both types of tissue manipulation were in the mild range.

SUMMARY

Our study revealed valuable information regarding patients' intraoperative experiences during SMILE and LASIK. The perception of flap creation seems more frightening than that of lenticule creation, and excimer ablation provoked the most fear among patients. The differences we observed may have been due to patients conceptualizing that a small-incision keyhole procedure is less scary than a procedure using a larger incision flap. The higher fear scores in the patients who had suction loss reemphasize the importance of

WATCH IT NOW

Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, FEBO, presents an updated technique for performing SMILE in which the lenticule separation and extraction are done using a single instrument.



► [BIT.LY/SMILENEWTECHNIQUE](https://bit.ly/smilenewtechnique)

preoperative counseling. By addressing patient fears and expectations before treatment, ophthalmologists may increase overall patient satisfaction.

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COMING OF AGE

There are several indications that SMILE has come of age:

- More studies are focusing on the nonrefractive outcomes of the procedure.
- Other companies have now made machines or are in the process of modifying software to allow their own systems to perform the SMILE procedure (personal communication).
- At scientific symposia, there are sessions on SMILE dedicated to discussing outcomes as well as complications and their management.
- Inventive concepts are being developed to advance SMILE further with respect to the software and the use of the lenticule (personal communication).

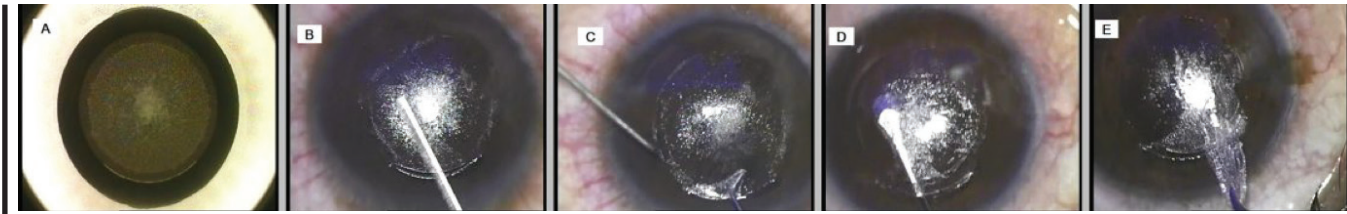


Figure 2. The SMILE procedure: The VisuMax laser cuts both surfaces of a lenticule within the cornea (A); the lenticule is removed through the small incision that was made when the lenticule was created (B-E).

(Continued from page 39)

range in the United States). With more refined instrumentation, the incision size has also been reduced. Many surgeons, myself included, now remove the lenticule through a sub-3-mm incision.

Initially, retreatments with SMILE were a concern, but for several years now software on the VisuMax laser has allowed surgeons to convert the SMILE cap into a flap (*Editor's note: This software is not yet available in the United States*). Retreatments with an excimer laser are then possible after lifting the flap. Techniques are also being developed to perform enhancements using only the femtosecond laser.

STUDY FINDINGS

In several published studies, results of SMILE for the treatment of myopia and myopic astigmatism have been equivalent to those for LASIK.¹ Studies have also reported better results in high myopia with SMILE than with conventional femtosecond LASIK.² Other studies have found that the amount of wavefront aberrations induced after SMILE were less than or equivalent to those induced by wavefront-compensated femtosecond LASIK.³

“IN SEVERAL PUBLISHED STUDIES, RESULTS OF SMILE FOR THE TREATMENT OF MYOPIC ASTIGMATISM HAVE BEEN EQUIVALENT TO THOSE FOR LASIK. STUDIES HAVE ALSO REPORTED BETTER RESULTS IN HIGH MYOPIA WITH SMILE THAN WITH CONVENTIONAL FEMTOSECOND LASIK.”

SMILE VS LASIK

SMILE has several advantages over femtosecond LASIK:

- ▶ It requires only one laser, which reduces both capital costs and the cost per procedure;
- ▶ It improves workflow because the patient does not need to move from one laser to another;
- ▶ The total energy used in SMILE is less than is used in femtosecond LASIK;
- ▶ Because the procedure involves cutting rather than ablation, there is less scatter in the results, as ablation rates are dependent on factors such as the hydration level of the cornea; and
- ▶ The small incision opens the possibility of better biomechanical stability and fewer dry eye symptoms postoperatively.

A multicenter study is under way evaluating SMILE for the treatment of hyperopia, but this treatment modality is not yet available to surgeons outside the trial. Many surgeons have attempted to preserve the lenticules that are removed during SMILE. The lenticules have then been used to treat hyperopia by inserting the lenticule into a pocket created in the cornea with a femtosecond laser. Another use of the lenticules has been to enhance the biomechanical strength of corneas with ectatic disease.

Because SMILE uses a small incision and therefore minimizes the cutting of corneal nerves, studies have

suggested that it leads to greater corneal sensitivity and a better tear profile postoperatively compared with LASIK. This is a major benefit of SMILE and a reason why many patients find the procedure attractive.

SUMMARY

SMILE obtained FDA approval for the treatment of myopia in 2016. Since then, it has become popular in the United States. Worldwide, more than 1 million SMILE procedures have been performed to date. The procedure is well on the road to changing the way that refractive surgery will be performed in the future. ■

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