# THE FUTURE OF LASER VISION CORRECTION

Something to smile about in keratorefractive surgery!

## BY WILLIAM W. CULBERTSON IV, MD



When LASIK was first introduced, it appeared to promise a precise refractive alteration of the corneal contour and the accuracy of the excimer laser without the discomfort, delayed recovery of vision, and corneal haze often associated with PRK. Postoperative complications such as corneal ectasia and neurotrophic dry eye disease soon became apparent with LASIK.

Ultimately, word of these problems spread via the Internet, causing fear and apprehension among potential patients and a sharp reduction in LASIK procedures performed in the United States. Various alternative strategies were envisioned for intracorneally collapsing the corneal stroma using picosecond and femtosecond lasers without making a flap, but these methods never achieved functional efficacy.

SMILE, short for small-incision lenticule extraction, is a minimally invasive technique performed with the VisuMax femtosecond laser (Carl Zeiss Meditec; Figure 1). Two intersecting coronal planes—a deeper variable refractive plane and a more superficial, planar, "cap cut" at a depth of 120 to 160  $\mu$ m—are made in the cornea (Figure 2). The resultant corneal lenticule is extracted via a 45° to 90° access cut (Figures 3A). The strongest part of the cornea, which is the anterior 120  $\mu$ m stromal layer with Bowman membrane along with the superficial corneal nerve supply, is preserved for over 270° to 315°. Conceptually, if preserving the anterior corneal lamella makes the cornea more resistant to ectasia<sup>1-3</sup> and neurotrophic dry eye disease,<sup>4,5</sup> then the two major complications associated with LASIK could be avoided or reduced in frequency with SMILE.

Recent studies have shown that unaided visual acuity after SMILE is very close to that achieved with modern LASIK for both low and high levels of simple myopia and myopic astigmatism.<sup>6,7</sup> Hyperopic treatment with SMILE is presently under investigation internationally. The SMILE procedure is not approved in the United States.

### **ADVANTAGES**

Unlike LASIK, in which patients are moved from a femtosecond to excimer laser, SMILE is performed with only one laser. The cap is not vulnerable to traumatic displacement, because there is only a 30° to 90° access cut versus a 300° to 315° side cut with LASIK. As a result, patients can resume sports activities almost immediately after undergo-



Figure 1. The Visumax femtosecond laser was designed for the SMILE procedure.

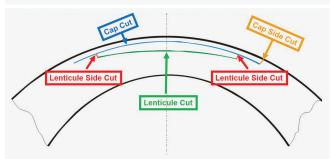


Figure 2. Diagram of the SMILE procedure. The variable refractive plane is cut in the deeper cornea, and the cap cut is parallel to the corneal surface at a depth of 120 to 160  $\mu$ m. The access side cut can vary from 30° to 90° in arc length, depending on the surgeon's preference and experience.

ing SMILE. Additionally, because the outcome is not environmentally dependent (humidity, temperature, or altitude), strict environmental stability in the treatment room or an environment-based nomogram adjustment is not necessary. The results are the same whether SMILE is performed in Miami, Kansas, Denver, or Kathmandu.

#### **DISADVANTAGES**

Enhancements after SMILE are not as straightforward as after LASIK. With SMILE, the majority of enhancements to date have been performed with surface excimer laser ablation. Alternatively, the cap can be fashioned into a LASIK-

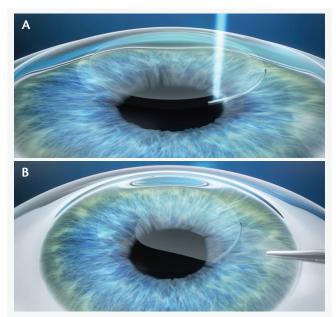


Figure 3. The Visumax creates the lamellar planes and side cuts sequentially (A). The lenticule is manually separated by the surgeon and extracted from the cornea through the access side cut (B).

like flap by making an additional side cut, then applying an excimer laser treatment to the bed for the correction. Hyperopic SMILE is still in development. Complications may include difficulty dissecting out the lenticule, tearing the cap during extraction of the lenticule, or leaving epithelium in the interface, but these problems do not result in serious vision loss.<sup>67</sup>

#### **INTERNATIONAL ACCEPTANCE**

SMILE has gained acceptance overseas among both surgeons and potential patients. Internationally, SMILE has been marketed to patients as a unique procedure that is different from and more advanced than LASIK. Although SMILE



- For SMILE, the VisuMax femtosecond laser is used to create a lenticule inside the intact cornea, which can then be extracted through a small incision. A flap is not created.
- The procedure has been shown to make the cornea resistant to ectasia and neurotrophic dry eye disease.
- Complications may include difficulty dissecting out the lenticule, tearing the cap during extraction of the lenticule, or leaving epithelium in the interface.

is akin to small-incision LASIK or flapless LASIK, the term *LASIK* has been avoided in marketing efforts due to negative connotations. In English-speaking countries, the term *SMILE* has naturally been confused with dental procedures such as teeth whitening, but this has not appeared to inhibit patients' understanding or acceptance of the procedure.

SMILE has been positioned in refractive surgery practices as a premium procedure much like premium cataract surgery with a charge of 25% to 33% over LASIK. Tiered pricing for keratorefractive surgery from lowest to most expensive is PRK, microkeratome LASIK, femtosecond LASIK, and SMILE. Patients undergoing SMILE are often given first-class treatment, with some practices offering "SMILE lounges."

#### **PROSPECTS IN THE UNITED STATES**

In my opinion, the availability of a LASIK-like procedure with fewer serious complications could bring patients back into the US market. I believe both practitioners and patients will welcome SMILE if it is presented as a new procedure that is distinct from LASIK.

SMILE requires surgeons to purchase or lease the Visumax femtosecond laser, which was designed from the ground up to perform SMILE. Surgeons who have experienced a significant decline in their LASIK surgery volumes may be reluctant to commit to a large capital purchase until they see SMILE gain traction in the marketplace. It is very possible, however, that this procedure is just what the doctor ordered to bring keratorefractive surgery back in the United States. It will be important for surgeons to avoid overpromising results and promoting unrealistic outcomes and instead stick to the significant fundamental advances that SMILE represents.

1. Roy A, Dupps WJ, Roberts C. Comparison of biomechanical effects of small incision lenticule extraction and laser in situ keratomileusis: finate element analysis. *J Cataract Refract Surg.* 2014;40:971–979.

 Kazutaka K, Shimizu K, Igarashi A, et al. Intraindividual comparison of changes in corneal biomechanical parameters after femtosecond lenticule extraction and small-incision lenticule extraction. *J Cataract Refract Surg.* 2014;40;963-970.
 Ibrahim O. Biomechanical changes pre- and post-SMILE vs femto-LASIK by assessment of corneal deformation response. Paper presented at: The ASCRS/ASOA Symposium and Congress; April 19; 2015; San Diego, CA.
 Li M, Zhou Z, Shen Y, et al. Comparison of corneal sensation between small incision lenticule extraction (SMILE) and femtosecond laser-assisted LASIK for myopia. *J Refract Surg.* 2014;30:94–100.

1ethiosecolor laser-assisted cAsic tori hypota. J Aeritad Surg. 2014;30:34–100.
5. Wei S, Wang Y. Comparison of corneal sensitivity between FS-LASIK and femtosecond lenticule extraction (ReLEx flex) or small-incision lenticule extraction (ReLEx smile) for myopic eyes. *Graefes Arch Clin Exp Ophthalmol.* 2013;251:1645-1654.
6. Vestergaard A, Ivarsen A, Asp S, Hjortdal JØ. Femtosecond (FS) laser vision correction procedure for moderate to high myopia: a prospective study of ReLex flex and comparison with a retrospective study of FS-laser in situ keratomileusis. Acta Ophthalmol. 2013;91:355-362.

 Lin F, Xu Y, Yang Y. Comparison of the visual results after SMILE and femtosecond laser-assisted LASIK for myopia. JRefract Surg. 2014;30:248–254.

#### William W. Culbertson IV, MD

- professor of ophthalmology, Lou Higgins distinguished chair, and director of refractive surgery and the Cornea Service, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, Miami, Florida
- wculbertson@med.miami.edu
- financial disclosure: coinvestigator for the Zeiss SMILE US multicenter trial and has received travel grants and honoraria from Carl Zeiss Meditec