

# THE LITERATURE



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## Five-Year Results of Small Incision Lenticule Extraction (ReLEx SMILE)

Blum M, Täubig K, Gruhn C, et al<sup>1</sup>

### ABSTRACT

Blum and colleagues evaluated the 5-year outcomes of 56 eyes with myopia and myopic astigmatism that underwent small-incision lenticule extraction (SMILE). The investigators assessed UCVA, BCVA, manifest refraction, and the health of the ocular surface.

They found that no eye had lost 2 or more lines of BCVA. Compared with the 6-month data,<sup>2</sup> 32 of the 56 eyes had gained 1 to 2 lines of BCVA. In terms of stability, no clinically significant change in manifest refraction had occurred compared with the 6-month data.

The researchers concluded that SMILE was safe, effective, and stable for the treatment of myopia and myopic astigmatism over a 5-year period.

### DISCUSSION

SMILE is an innovative, minimally invasive approach to treat myopia. The procedure has been commercially available in the United States since early March 2017. Outside this country, more than 750,000 SMILE procedures have been performed since its commercial introduction in 2011. Nevertheless, to our knowledge, Blum and colleagues published the first long-term study to find that SMILE using the 200-kHz VisuMax laser (Carl Zeiss Meditec) was safe, effective, and stable in the treatment of myopia and myopic astigmatism.

The investigators found a safety index of 1.2 and an efficacy index of 0.9 over the 5-year period, with a preoperative mean spherical equivalent of  $-4.75 \pm 1.56$  D.<sup>3</sup> In addition to achieving excellent vision results, no patient in this study reported dry eye symptoms at the 5-year follow-up visit.

## Enhancement After Small-Incision Lenticule Extraction

Liu YC, Rosman M, Mehta JS<sup>4</sup>

### ABSTRACT

Liu and colleagues retrospectively reviewed the charts of 307 patients (524 eyes) who underwent SMILE. The investigators sought to identify the incidence, risk factors, and outcomes of enhancements performed after the initial procedure.

They found the incidence of enhancements to be 2.1% and 2.9% at 1 and 2 years, respectively. Significant risk factors for needing an enhancement were an age older than 35 years, a preoperative mean refractive spherical equivalent greater than  $-6.00$  D, preoperative myopia higher than  $6.00$  D, preoperative astigmatism greater than  $3.00$  D, and intraoperative suction loss. The 14 eyes that required enhancements had a UCVA ranging from 20/25 to 20/80, with a mean attempted spherical equivalent at the time of enhancement of  $-0.50 \pm 0.86$  D. The investigators reported that 92.9% of patients who underwent an enhancement, all PRK, showed an improvement in UCVA.

### DISCUSSION

The initial SMILE procedure reported by Liu and colleagues used a nomogram adjustment of  $+0.25$  to  $+0.50$  D to achieve a target of plano. The investigators observed a 2.7% prevalence of patients who required enhancements overall.

The need for an enhancement increased with age. Patients with a higher preoperative refractive error also had higher enhancement rates. Epithelial hyperplasia with increased refractive error, along with stromal wound-healing responses, may play a role in the decreased predictability of SMILE in patients undergoing higher refractive correction. It is important to note



## AT A GLANCE

- A prospective study found small-incision lenticule extraction (SMILE) to be safe, effective, and stable in the correction of myopia and myopic astigmatism over a 5-year period.
- A retrospective study found the 2-year incidence of enhancement after SMILE to be 2.9%. Older age, greater preoperative myopia, higher preoperative astigmatism, greater preoperative mean refractive spherical equivalent, and intraoperative suction loss were risk factors for needing an enhancement. PRK with mitomycin C achieved good clinical outcomes.
- In a meta-analysis, there was no difference in safety and efficacy when comparing SMILE with femtosecond laser-assisted LASIK, but SMILE created fewer short-term dry eye symptoms.
- The results of these three studies are encouraging, but randomized, double-blind, long-term prospective studies are needed.

that no regression was observed in patients undergoing an enhancement, because all of these procedures were performed on individuals who exhibited a primary over- or underresponse.

Currently in the United States, SMILE is not capable of correcting moderate or high amounts of astigmatism, but Liu and colleagues shared valuable data showing that an under-response is more likely to occur when astigmatism exceeds 3.00 D. Patients who experienced intraoperative suction loss were also more likely to need a postoperative enhancement than those without suction loss.

Various approaches for enhancements after SMILE have been reported, but given current US limitations in software approvals for the VisuMax laser, most surgeons here will consider surface ablation. Ivarsen and Hjortdal reported that two of five SMILE patients developed significant anterior stromal haze after a PRK enhancement,<sup>5</sup> but Liu and colleagues found PRK with adjunctive mitomycin C to be a successful technique after primary SMILE.

To our knowledge, the study by Liu et al is the first to analyze risk factors for needing an enhancement after SMILE. US surgeons should assess whether the treatment nomogram should be adjusted to reduce the need for enhancements in patients at increased risk. Limitations of this study include its retrospective design and specific patient population.

### Clinical Outcomes of SMILE and FS-LASIK Used to Treat Myopia: a Meta-analysis

Zhang Y, Shen Q, Jia Y, et al<sup>6</sup>

#### ABSTRACT

Zhang and colleagues performed a large-scale meta-analysis to compare the clinical outcomes of SMILE and femtosecond laser-assisted LASIK (FS-LASIK) for the correction of myopia and myopic astigmatism. The investigators evaluated patients' visual acuity, refractive error, tear breakup time (TBUT), and corneal sensitivity.

Using Cochrane Collaboration methodology, the researchers identified 102 studies, of which 11 met the selection criteria. A total of 1,101 eyes were included; 532 eyes (48.32%) underwent SMILE, and 569 eyes (51.68%) underwent FS-LASIK. The investigators found no significant difference between the two procedures in terms of final refractive spherical equivalent ( $P = .72$ ), the proportion of eyes losing 1 or more lines of corrected distance visual acuity after surgery ( $P = .69$ ), the proportion of eyes achieving an uncorrected distance visual acuity of 20/20 or better ( $P = .35$ ), or a refractive spherical equivalent within  $\pm 1.00$  D of the target values ( $P = .70$ ). The TBUT was longer in the SMILE group than the FS-LASIK group 1 and 6 months after surgery ( $P = .004$  and  $P = .02$ , respectively). Corneal sensitivity was significantly higher in the SMILE group than in the FS-LASIK group 1 week ( $P < .00001$ ), 1 month ( $P < .0001$ ), 3 months ( $P < .00001$ ), and 6 months ( $P < .003$ ) after surgery.

The investigators concluded that SMILE and FS-LASIK were comparable with regard to safety and efficacy, but they stated that SMILE may create fewer short-term dry eye symptoms and that patients may have greater corneal sensitivity after this procedure than FS-LASIK at 6 months.

#### DISCUSSION

The pooled results in this meta-analysis showed no difference between SMILE and FS-LASIK in terms of safety, efficacy, and predictability, but the longest follow-up time was 6 months.

Many surgeons have postulated that the ocular surface profile is better after SMILE than FS-LASIK, because the former preserves the anterior stromal nerve plexus.<sup>7-9</sup> Zhang and colleagues found that, over a 6-month period, TBUT was longer after SMILE compared to FS-LASIK and patients had better corneal sensitivity after SMILE compared to FS-LASIK. Recent meta-analyses have found similar differences in the first 3 months but no significant difference at 6 months.<sup>10,11</sup> ■

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