

Frequently Asked Questions About SMILE

INTERVIEW WITH JOHN F. DOANE, MD, FACS, WHO PRACTICES AT DISCOVER VISION CENTERS IN KANSAS CITY, MISSOURI.



Small Incision Lenticule Extraction, or SMILE, is the fastest growing refractive procedure since the introduction of the excimer laser. More than 2 million eyes have been treated worldwide. Approved by the FDA in September 2016,

SMILE became commercially available in the United States in March 2017.

As one of five refractive surgeons in the United States who participated in the clinical trials, John F. Doane, MD, FACS, often hears from colleagues who are considering offering SMILE to their patients. Below, he answers some of their most frequently asked questions.

How should I describe SMILE vision correction to my patients?

Most patients understand that surgeons in all medical specialties have been moving toward smaller incisions, whether for appendectomies, cholecystectomies, or even joint replacements. The same is true of eye surgeons. Typically, for LASIK surgery, the surgeon makes a 270° or 300° incision to create a corneal flap. SMILE is performed using a 60° or 90° incision, and the visual results are comparable to those I achieve with LASIK.¹ SMILE is less invasive and potentially more biomechanically stable as the small side cut created with SMILE leaves a greater amount of the anterior corneal stroma intact compared to a larger incision associated with a LASIK flap. The anterior corneal stroma is thought to play an important role in corneal biomechanics. Being less invasive than LASIK, and having a shorter recovery time than PRK, SMILE offers less discomfort, and advantages that resonate with patients.

Tell me about the SMILE technology.

Unlike LASIK, which requires a femtosecond laser to create the flap and an excimer laser to change the curvature of the cornea, SMILE requires only the VisuMax femtosecond laser (ZEISS) to create two planes within the cornea. Those planes

come together to create a lens-like shape that is removed through a small incision. The result is a 3D confirmational shape that flattens the cornea to treat myopia.

What type of patient is a candidate for SMILE?

In my practice, anyone who is a candidate for LASIK is a candidate for SMILE.

Does SMILE correct astigmatism?

Yes. In the United States, we can use SMILE to correct from -0.75 D to -3.00 D of refractive astigmatism, when refractive spherical equivalent is no greater in magnitude than 10.00 D. With the advent of astigmatism correction, I think our SMILE cases will account for about 85% of our total refractive surgery volume.

Are there possible complications with SMILE?

Possible postoperative complications for SMILE are essentially the same as they are for LASIK. Although rare, diffuse lamellar keratitis and infection would be most concerning. Epithelial defects and discomfort are possible. Decentration is highly unlikely because of the patient interface with corneal vertex fixation. Instances of undercorrection or overcorrection are relatively low within my practice. As some practices may refract differently, if there is a need to make a nomogram adjustment this can be done.

How much do you charge patients for SMILE surgery?

In my practice, we found that giving patients too many options can be confusing for them, particularly discussions of technology versus refraction versus special treatments. For simplicity, we base our fee on the patient's refractive error—the higher the power, the higher the price. The cost for SMILE is the same as for LASIK or PRK. We recommend the procedure we consider best for the individual patient.

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How does SMILE differ from LASIK in preoperative and postoperative considerations?

There are no great differences. We use all of the same diagnostic equipment preoperatively, regardless of which procedure is chosen, and the schedule for postoperative drops is identical.

Are your instructions to patients about returning to physical activity any different for SMILE versus LASIK?

Because there is no hinge or flap with SMILE, the cornea is potentially more stable biomechanically. Therefore, I have no problem with patients returning to most forms of physical activity on postoperative day 1 after SMILE. In addition, I am completely comfortable with patients not wearing a shield on postoperative day 0 or at night after SMILE surgery.

My LASIK results are near-perfect. Why should I buy another laser to incorporate SMILE?

I believe SMILE has the potential to change our approach to refractive surgery. It is the first true competitor to LASIK. The 12-month data for SMILE are equivalent to the best data we have for LASIK to date.¹

The benefits of SMILE are significant. Patients appreciate that the incision is small, and no flap is created. In my practice, I have found this to be a potential benefit for people who are in the military, combat martial arts, boxing, or wrestling.

How is the patient's WOW factor for SMILE compared to LASIK after surgery?

Early on, in my practice, about 25% of our eyes treated with SMILE had postoperative visual acuity of 20/20 on day 1. Now, about 75% of eyes treated with SMILE are 20/20 uncorrected on day 1, and I expect this percentage to increase with continued optimization of laser energy parameters. The recent approval of spherocylindrical myopia also included the ability to further optimize laser energy parameters. With the new settings, we expect the WOW factor to be equivalent to LASIK. These new settings allow the laser to be optimized to reduce the overall distribution of energy into the cornea.

Based on my years of experience with LASIK, I have found that our SMILE outcomes after 18 months are equivalent to what

LASIK outcomes achieve after 22 years of laser development. This is based upon comparative FDA data between recent SMILE and LASIK PMA data.

Percentage of eyes with 20/20 visual acuity, percentage of eyes that are +/- 0.50 D and +/- 1.00 D from target, gained or lost lines of best vision, stability over time, all are virtually identical for spherical myopia and compound myopic astigmatism compared to excimer laser results.²

How should I position SMILE to optometrists?

I usually discuss my experiences with SMILE and emphasize how motivated and optimistic I am by the outcomes I have achieved, not only for the short term but also for the long term. Over the last 18 months, I have converted most of my patients seeking refractive surgery to SMILE, because I believe I can deliver a great result. I would not be performing SMILE if I did not feel I was achieving the same quality of refractive outcomes while also providing the benefits of SMILE.

When should an optometrist refer a patient back to the surgeon?

The great thing about SMILE, in my experience, is that the enhancement rate is definitely lower than with LASIK. As with LASIK, if the optometrist has any concerns, the surgeon should be available to give guidance or see the patient personally.

When do you feel comfortable having a patient return to the referring optometrist?

I typically see all patients at postoperative day 1, and I feel completely comfortable having the patient see the referring optometrist at week 2. ■

1. Data on file.
2. Data on file.

JOHN F. DOANE, MD, FACS

- Cornea and Refractive Surgeon, Discover Vision Centers, Kansas City, Missouri
- Clinical Assistant Professor, Department of Ophthalmology, Kansas University Medical Center, Kansas City, Kansas
- jdoane@discovervision.com
- Financial disclosure: Consultant (Carl Zeiss Meditec)