



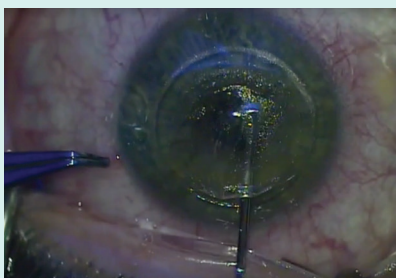
SMILE 2.0: WHAT'S NEW?

The recent expansion of indications
will allow more patients to be treated
with greater flexibility.

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Small-incision lenticule extraction (SMILE), approved by the FDA in 2016, is the latest addition to mainstream corneal refractive surgery. Tissue depth per diopter of correction with SMILE is roughly equivalent to that with PRK and LASIK. Unlike in LASIK and PRK, however, in SMILE a femtosecond laser (VisuMax, Carl Zeiss Meditec) is used to dissect a lens-shaped portion of stromal tissue for refractive correction, followed by manual removal of that lenticule (See *Watch It Now*).

▶ WATCH IT NOW ◀



▶ [BIT.LY/0619SMILE2](https://bit.ly/0619SMILE2)

In October 2018, the FDA approved two significant expansions to the indications for SMILE. One was the addition of astigmatic correction so that the approved range of correction now includes spherical myopia from 1.00 to 10.00 D and cylinder from 0.75 to 3.00 D. The other change now allows surgeons to make a smaller entrance incision, potentially reducing disruption of corneal nerves and the corneal surface.

This expansion, which we are calling *SMILE 2.0*, will allow us to treat more patients—now including those with up to 3.00 D of astigmatism—and to have more flexibility in the parameters we use. In this article, we discuss the

clinical trial results that led to the recent approval and describe how we incorporate SMILE into our two separate laser refractive surgery practices.

CLINICAL TRIAL RESULTS

In the initial clinical trials for approval of SMILE for spherical myopia, 99.7% of eyes achieved 20/40 or better UCVA at 6 months postoperative, and 87.5% had 20/20 or better UCVA.¹ Similarly, in data supporting the recent premarket approval, which included both spherical and astigmatic corrections (NCT02430428), 98.6% of eyes achieved a UCVA of 20/40 or better, and 84.2% had 20/20 or better UCVA at 6 months.²

These 6-month UCVA results fit nicely among the data for most of the recent LASIK FDA approvals. This is impressive considering that LASIK has had more time to become a mature technology and that it was not this accurate from the start.

Although patients can have 20/20 or 20/25 UCVA 1 day after SMILE, our clinical experience and the SMILE data from these approvals indicate that some patients' visual recovery can take longer. The trial data showed that it can take from 3 to 6 months for patients' vision to stabilize and establish a new baseline UCVA. In the spherical SMILE study, for example, only 63.3% of eyes achieved 20/20 UCVA at 1 week, improving to 87.5% at 6 months.¹

FINE-TUNING THE SETTINGS

In our clinical experience with SMILE outside of the FDA trials, the ease of lenticule dissection is directly related to the speed of the patient's visual recovery. Typically, the less force needed, the faster the recovery.

This is where the second element of the recent FDA labeling expansion becomes relevant.

The initial approval mandated femtosecond laser spot and track spacing of 3 μm , a transition zone of 0 μm , and a 90° incision angle. With the recent change, spot spacing, track spacing, and laser energy level are adjustable, and the surgeon has the ability to expand the transition zone of the lenticule dissection. Additionally, the incision angle may now be as small as 60°, representing a potential one-third reduction in the cutting of superficial nerves.

A common observation is that not all femtosecond lasers are the same. Mirrors become worn over time, or environmental factors can alter effectiveness. The result is a lack of plug-and-play setting optimization. Each laser must be separately optimized. Most US SMILE surgeons are now in the process of optimizing their settings, which holds promise for achieving smoother dissections and allowing faster visual recovery in the future.

As they optimize their settings, many surgeons are finding success using spot and track spacing in the range of 4.2 to 4.5 μm and energy levels of 125 to 150 nJ. Most are now also using the smaller, 2-clock-hour incision angle.

If SMILE surgeons are now able to achieve significant improvements in healing speed as the lasers are optimized, it would not be the first time the refractive market has noted such improvements. Early ophthalmic femtosecond lasers used for LASIK flap creation struggled to compete with microkeratomes regarding corneal clarity. Today, however, femtosecond lasers provide excellent visual results with a level of safety that no microkeratome could ever match.

SIX TIPS FOR GETTING STARTED WITH SMILE

- **Tip No. 1: Start with moderate to high myopes.** Because the nonrefractive component of the lenticule cannot yet be modified in the United States, selecting these patients allows use of a thicker lenticule and permits easier dissection. Energy settings that have not been optimized can more easily affect the results with thinner lenticules.
- **Tip No. 2: Optimize energy settings.** This is where SMILE and LASIK flaps differ. Because in SMILE the refractive treatment is done by the femtosecond rather than the excimer laser, improper energy settings can cause a rougher interface and an opaque bubble layer, which results in difficult dissection and slower visual recovery. In general, lower is better, but setting the energy too low can result in black spots of incomplete treatment, leading to rougher surfaces and difficult dissection. This all affects the patient's rate of visual recovery and the final result.
- **Tip No. 3: Recognize the importance of cap distention.** Microdistortions cause slow visual recovery and poor visual outcomes,¹ as they do in LASIK. In the experience of one of us (R.L.R.), this process requires more manipulation than a LASIK flap would require.
- **Tip No. 4: Pay attention to centration.** There is no pupil tracker or iris registration for SMILE. This allows the surgeon to have perfect control over the treatment centration, but it also *requires* the surgeon to have perfect control over the treatment centration.

The importance of this step cannot be overstated. There are many devices that help with centration, including the AcuTarget HD (Visiometrics), Pentacam (Oculus Optikgeräte), Orbscan (Bausch + Lomb), and others. Corneas should be marked at 0° and 180° (and more axes if needed) to account for cyclorotation. One of us (O.B.W.) particularly advises first becoming comfortable with the low-suction, curved interface of the femtosecond laser for LASIK flaps before attempting the first SMILE case.

- **Tip No. 5: Have a strategy—including dissecting the anterior plane first—but know how to make a rescue.** Most surgeons will find themselves in the posterior plane before the anterior plane at some point. This does not affect visual recovery, but it can make dissecting the anterior plane more difficult. Learn the rescue technique, as demonstrated in http://bit.ly/0619SMILE2_2 and depicted in Figures 1 through 3.
- **Tip No. 6: Have an excimer laser available.** It is not a failure to convert to LASIK if you encounter an opaque bubble layer, a suction break, or a difficult dissection. Many times, LASIK can be performed on the same day, but waiting for another day can sometimes be a better option. This is a possibility we discuss with all SMILE patients as part of the informed consent process out of an abundance of preparation and precaution.

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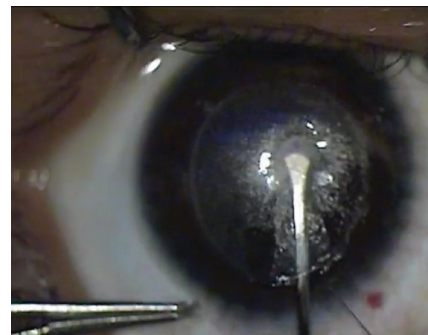


Figure 1. Perceived anterior dissection but in the posterior plane.



Figure 2. A visible bubble in the anterior segment is a clue that you are in the posterior plane.

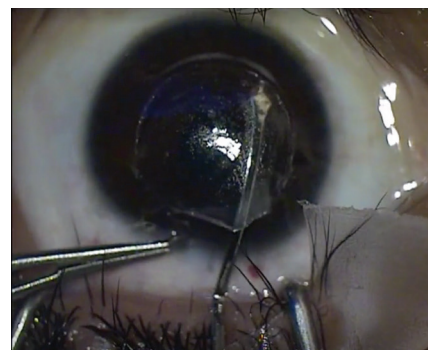


Figure 3. Rescue technique to find and dissect the anterior plane.

We now can inspect flap quality before the tissue bridges are released upon lifting the flap.

STARTING TO SMILE

Proper training for SMILE is imperative. Poor technique and planning can greatly affect visual results. Some tips for getting started are included in the above sidebar.

We are often asked how we position SMILE in our practices. We each practice in comprehensive vision correction centers that offer all forms of laser vision correction as well as phakic IOLs, corneal inlays, refractive lens exchange, cataract surgery, and CXL.

Most patients have at least heard of LASIK, which essentially now serves as a proprietary eponym for all forms of

surgical vision correction, even lens-based. It is up to us to provide the singular and best recommendation for each patient who walks through our doors. Having SMILE as an option increases our ability to do so.

When we ask patients why they haven't had vision correction already, the answer is almost invariably one of two things: fear or money. For the

“WHEN WE ASK PATIENTS WHY THEY HAVEN’T HAD VISION CORRECTION ALREADY, THE ANSWER IS ALMOST INVARIABLY ONE OF TWO THINGS: FEAR OR MONEY. FOR THE LATTER, THERE ARE FINANCING OPTIONS. FOR THE FORMER, THIS IS REALLY WHERE SMILE SHINES.”

latter, there are financing options. For the former, this is really where SMILE shines. Patients like that there is no flap involved and no mechanical cutting—just the laser.

It is important to stress to patients that LASIK is better than ever. It can treat nearsightedness, farsightedness, astigmatism, and aberrations (which we sometimes call *hills and valleys*). In this context, SMILE can and should be brought up and offered as another option that may be better in a particular patient’s case. At least in theory, SMILE could offer the following potential benefits.

No. 1: A more comfortable postoperative period. The subbasal nerve plexus is affected less in SMILE than with a LASIK flap, and the incision typically lies under the upper eyelid.

No. 2: Faster return to physical activities. Although cap dislocation can occur, it is rare. SMILE may be preferred by mixed martial arts fighters and oil and gas workers, among individuals with other athletic interests and physically demanding careers. Patients may also go back to wearing eye makeup sooner after SMILE than after LASIK or PRK.

No. 3: A stronger cornea. SMILE most likely leaves the cornea stronger than either LASIK or PRK.³ Ectasia can still happen, but it may be less likely.

No. 4: Useful in eyes with large pupils. Patients still ask about this. Effective optical zones have been shown to be larger after SMILE than LASIK even when the same optical zone is programmed.⁴

It is equally important to discuss the potential cons.

No. 1: Potentially slower visual recovery. Although it can improve with surgeon experience and optimized parameters, visual recovery after SMILE tends to be slower.⁵

No. 2: Future enhancements. Given that the cap for SMILE is locked in at 120 μm in the United States, thin-flap LASIK is difficult, especially after any epithelial remodeling. PRK is the recommended enhancement strategy. Future options may include Circle (converting the SMILE cap to a LASIK flap) and a second SMILE procedure.

No. 3: Limited range. Astigmatic correction is limited to the range of 0.75 to 3.00 D programmed, and hyperopia cannot yet be treated.

SMILE 3.0?

SMILE is impressive in that it has already become a rival to LASIK in a short time. Just like other forms of vision correction, it will continue to improve. LASIK, PRK, phakic IOLs, and lens-based refractive surgery are all significantly better today than their first generations, and SMILE is already better than it was just a few years ago.

There are many things to look forward to in the future of SMILE.

Unlocking parameters. We look forward to having the ability to vary the thickness of the lenticule, change the location and size of the primary incision, vary the cap thickness to allow LASIK enhancements, and change energy settings even further.

Treating hyperopia and aberrations. Studies are already being done for hyperopia.

Developing new techniques. New ideas are always being generated. It is important to stay current.

CONCLUSION

It is exciting to have another option for laser vision correction. There are many reasons that SMILE is growing so quickly in popularity, and we are proud to offer it in our practices.

As the articles in this cover focus look to the future of ophthalmology, it is helpful to keep in mind that SMILE will perform best when we evaluate each patient as an individual to determine the optimal personalized treatment modality for that patient. The procedure will not thrive so well in an environment in which competition leads practitioners to express negativity about certain laser vision correction options (because they don’t happen to offer them but the practice across town does). Let us hope that the future of ophthalmology makes room for all safe and effective refractive surgical options so that we can best serve each and every patient.

We look forward to SMILE 3.0 and other future iterations. ■

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