



My 9-year SMILE journey

Rupal Shah, MD, Vadodara, India

It's been a long time since **Rupal Shah, MD**, Vadodara, India, started her journey with SMILE using the VisuMax femtosecond laser. Some things, she said, have remained unfulfilled, but certain dreams did come true.

Dr. Shah started her SMILE journey 9 years ago, and she considers it the most fortunate thing that has happened to her. Performing and being able to contribute meaningfully to the development of the procedure as well as making great friends, traveling, and developing as a person have all made SMILE the most fulfilling part of her professional life.

Changes over the years

Nine years ago, she said, SMILE was just a possibility, beginning as FLEx, femtosecond lenticule extraction. The laser was much slower—just 200 kHz against today's 500 kHz. The laser also used a reverse scanning pattern, higher energy, and lower spot and track spacing. The scanning pattern would begin at the center, moving to the periphery. The second pass would then move from the periphery to the center, taking much longer to complete than the laser does today.

The incision length was also much larger, allowing the surgeon to lift a flap and remove the lenticule. After a few procedures, Dr. Shah realized that FLEx lenticule extraction

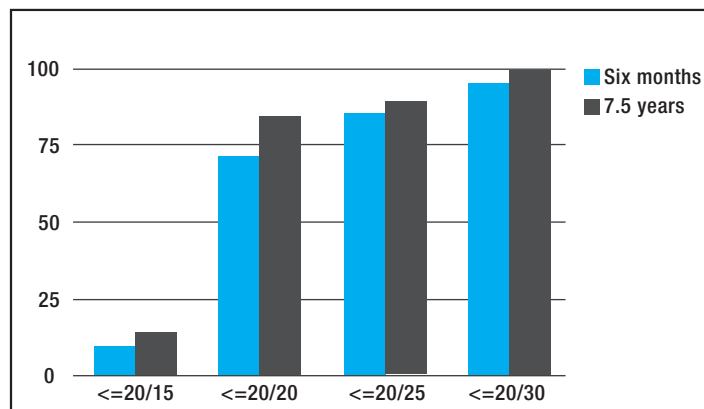


Figure 1. Change in BCVA over time

had few advantages over conventional LASIK surgery, and so proceeded to perform pseudoSMILE within a month from starting FLEx, and SMILE just a few months later.

What made the difference from those early days, Dr. Shah said, was the change in scanning pattern. The original scanning pattern allowed bubbles to accumulate in the center, distorting the tissue before the second incision laser pass. This resulted in distorted corneal topography and delayed visual recovery.

Changing the scanning pattern produced starkly different results—from just 65% achieving a 1-day postop uncorrected visual acuity (UCVA) equivalent to the preop best corrected visual acuity (BCVA) to 83% visual recovery.

This was the procedure's eureka moment, changing the whole scenario.

The test of time

Long-term follow-up is particularly important for establishing the value of SMILE in refractive practice; with the procedure being done primarily for young individuals, refractive changes can occur over the years. Furthermore, SMILE is competing with earlier procedures such as PRK and LASIK, which are more than 20 years in clinical practice.

Dr. Shah has thus been conducting an ongoing study to see how the procedure stands the test of time. To date, out of 132 patients who underwent SMILE or FLEx for myopia or myopic astigmatism with spherical equivalent less than -10 D between August 2008 and 2009, 30 returned for a follow-up in April and May 2016. All patients had been treated with the 200-kHz laser, most with the old scanning pattern.

The results, Dr. Shah said, even with the older techniques, were astonishing.

In 7.5 years, the refraction remained stable, with very little deviation from that achieved at 6 months and 1 year postop. In terms of efficacy and safety, the UCVA and BCVA, respectively, changed very little over time, with a non-statistically significant improvement in BCVA over time (Figure 1).

Topography studies further showed true 6-mm zones, while induced higher order aberrations were equal to or less than LASIK treatment.

In terms of subjective satisfaction, 100% of patients reported satisfaction with the procedure, saying they would recommend the procedure to friends or relatives, four patients reported dryness or grittiness in their eyes, and two patients reported difficulties driving at night. No other subjective symptoms were reported.

SMILE: 9 years on

SMILE has come a long way over the years, with better surgical techniques and a faster laser with better energy parameters and an improved scan pattern. However, early results are, in Dr. Shah's experience, as good as or better than other competing refractive procedures—even after several years.

In April 2017, Carl Zeiss Meditec (Jena, Germany) conducted a user meeting in Singapore. More than just a showcase for their latest technologies, the company's user meeting has grown into a venue for peer-to-peer sharing of information among the world's top ophthalmic surgeons.

The first symposium of the meeting focused on SMILE, small incision lenticule extraction, performed with the ZEISS VisuMax femtosecond laser, and how this cutting-edge procedure is redefining the field of refractive surgery.

Vision after refractive surgery

Pravin Krishna Vaddavalli, MD, Hyderabad, India

Traditionally, when we talk about visual acuity measurements, we talk about measuring vision in one eye, said **Pravin Krishna Vaddavalli, MD**, Hyderabad, India. It is, he said, the quickest and fastest way to measure vision in the clinic. Rarely is visual acuity discussed in both eyes together.

Furthermore, studies and published reports on SMILE performed with the VisuMax femtosecond laser and other refractive procedures also tend to only measure and compare vision in one eye, whether to demonstrate predictability, accuracy, or safety. One tenth of studies look at binocular vision after surgery, Dr. Vaddavalli said. Yet, he added, actual vision uses both eyes, and binocular visual field is much more important in terms of visualization.

How binocular is better

A few years ago, when Dr. Vaddavalli looked into the image quality in patients who were undergoing refractive surgery, they measured the higher order aberrations (HOAs) after surgery, comparing them with the same subjects before surgery.¹ They also back calculated to estimate the visual acuity and clarity the patients would have with these measurements and attempted to correlate whether their calculations were similar to what patients were actually seeing in the clinic.

Dr. Vaddavalli found that

HOAs patients had, the computational depth of focus was less than the actual depth of focus. This means that when you look at binocular vision and the ability to read at close distances with good stereoacuity, patients had better stereoacuity than could be predicted based on HOAs—presumably, he said, due to depth of focus.

Prospective study

Dr. Vaddavalli then performed a prospective randomized control trial on 106 patients—40 LASIK, 26 PRK, 40 SMILE—to assess optical quality, looking at bilateral visual performance. They measured optical parameters—objective refraction, aberrations, and computational reconstruction of image quality using aberrometry—and perceptual parameters—high and low contrast distance logMAR acuity, near visual acuity, and random dot stereoacuity. Subjects were evaluated preop and postop 1 day, 1 week, 1 month, 3 months, and 6 months.

While mean preop refractions were similar in all three groups (LASIK -5.44 D, PRK -4.78 , SMILE -5.38 D), 6-month postop refractions were slightly hyperopic in the LASIK (0.21 D) and PRK (0.33 D) groups. At 6 months, HOAs were also significantly higher postop after LASIK (from 0.26 μm preop to 0.66 μm postop) and PRK (from 0.25 μm to 0.70 μm), and not as high after SMILE (from 0.22 μm to 0.30 μm). High and low contrast visual acuities were comparable across the three groups.

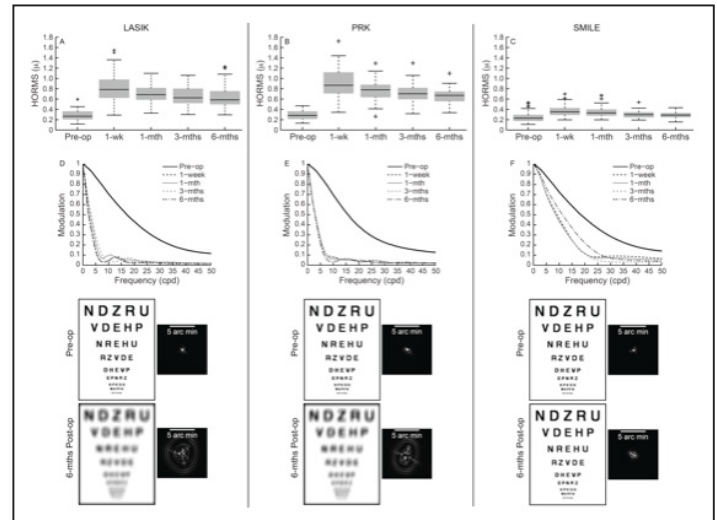


Figure 1. Expressing computed HOAs as a visual function, SMILE patients had better quality of vision.

When Dr. Vaddavalli back calculated clarity of vision, expressing computed HOAs as a visual function, SMILE patients had better quality of vision (Figure 1).

Furthermore, postop stereoacuity worsened after LASIK (from 41 arc sec preop to 73.6 arc sec postop) and PRK (from 36 arc sec to 74 arc sec) but improved after SMILE (from 38.5 arc sec to 23 arc sec). This may be accounted for by lower aberrations and a smaller difference in aberrations between eyes after SMILE compared with either LASIK or PRK.

Finally, the defocus curves after SMILE were more consistent with preop curves than with either LASIK or PRK.

SMILE for binocular vision

In conclusion, Dr. Vaddavalli said that while the accuracy of refractive correction, HCVA, and LCVA were similar in all three procedures, SMILE induced less aberrations than either LASIK or PRK, with no significant drop in image quality and better stereoacuity—apparently even better than preop stereoacuity in Dr. Vaddavalli's patients, perhaps enhanced by the lower variability in interocular aberrations.

SMILE therefore appears to perform better than either LASIK or PRK from the point of view of binocular visual acuity.

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Clinical experience of 36,000 SMILE procedures

Xingtao Zhou, MD, Shanghai, China

Everyone wants beautiful eyes with sharp vision, but myopia has become a significant problem in China, said **Xingtao Zhou, MD**, Shanghai, China. With one of the largest populations in the world, the country, he said, may also have the largest number of myopic patients.

Fortunately, China has been catching up with the rest of the world in terms of refractive surgery. While PRK was first performed in the country in 1993, Prof. Zhou began investigating FLEx and SMILE 7 years ago.

As of April 2017, surgeons in China had performed an impressive 320,000 SMILE procedures—36,000 of them by Prof. Zhou's surgical team.

SMILE safety and efficacy

Prof. Zhou discussed the procedure's advantages, including better refractive outcomes and visual quality, safety from flap complications, and tectonic preservation of the anterior corneal stromal layer.

His team did some research on the safety and efficacy of the procedure in their patients. They found that the procedure had an efficacy index of 1.10 with stable results requiring no enhancements for regression; resulted in 92% of patients within ± 0.50 D of target; and had a safety index of 1.05. In terms of complications, suction loss occurred in 0.058% of cases and diffuse lamellar keratitis (DLK) in 1.6%; otherwise, there were

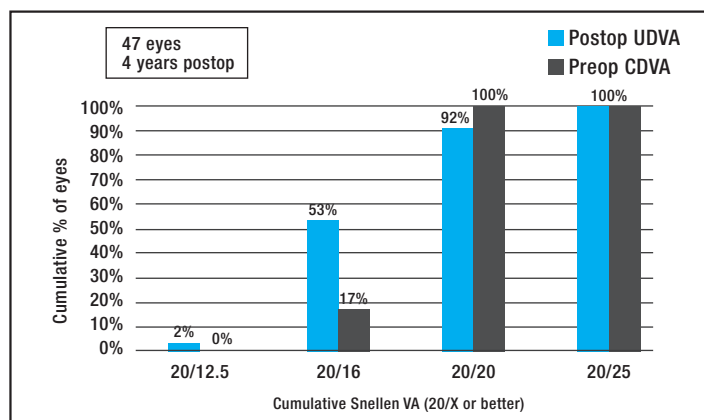


Figure 1. UDVA at 4 years after SMILE

no infections, and no lenticular residual induced astigmatism.

Overall, he said, the efficacy, stability, predictability, and safety were very satisfactory.

Predictability and stability over 4 years

Prof. Zhou studied the predictability and stability over time in a 4-year observational study on 47 eyes in 26 patients who underwent SMILE, measuring refractive outcomes and wavefront aberrations. Of these eyes, 92% achieved uncorrected distance visual acuity of 20/20 or better, while 53% achieved 20/16 or better (Figure 1); 9% gained two lines, 57% gained one line, and no eyes lost any lines of vision; 89% were within ± 0.50 D and 100% within ± 1.0 D of refractive target.

Spherical equivalent decreased from -0.01 ± 0.33 D at 6 months to -0.09 ± 0.39 D at 4 years, but this change was not statistically significant.

There were increases in total higher order aberrations, coma, spherical aberration,

and higher order astigmatism, while trefoil and tetrafoil were unchanged. Coma was most affected, possibly due to the centration of the lenticule on the visual axis. No significant differences were detected over 4 years of follow-up.

Prof. Zhou noted that previous studies on LASIK and PRK have shown a significant decline in spherical equivalent over 10 years; nevertheless, in their study at least, SMILE provides a predictable and stable correction of moderate to high myopia at least up to 4 years. However, long-term changes in aberrations need further study.

3-year stability of posterior corneal surface elevation

Prof. Zhou also studied the stability of posterior corneal surface elevation 3 years after SMILE. They looked at posterior central elevation (PCE), posterior mean elevation (PME), and posterior elevation at the thinnest point preoperatively (PTE).

Significant differences from preop values were found in terms of PCE and PTE at 3 years, but no difference was seen in terms of PME.

No statistically significant linear relationship was seen between changes in posterior corneal elevation at the last follow-up and residual bed thickness, corneal hysteresis, thinnest corneal thickness preoperatively, or spherical equivalent.

Their study showed that the posterior corneal surface was stable up to 3 years after SMILE; however, the cause of the slight change in PCE and PTE needs further study.

Pilot study: SMILE for hyperopia

Recently, Prof. Zhou published a pilot study on hyperopic SMILE, performing the procedure on an eye bank eye. They examined the hyperopic SMILE eye under a slit lamp and via OCT imaging at 3 minutes and 30 minutes after lenticule creation and after lenticule extraction. They then examined the various surfaces of the lenticule, cap, and stromal bed by electron microscopy. They concluded that it is possible to produce good quality hyperopic SMILE lenticules with smooth surfaces.

Room for innovation

Safety, said Prof. Zhou, is the highest principle of refractive surgeries. SMILE has good visual predictability and stability, as well as structural stability. Nevertheless, SMILE is an interesting procedure for further LVC innovation in the future.

Can SMILE replace LASIK?

Hyung Jin Koo, MD, Seoul, South Korea



According to **Hyung Jin Koo, MD**, Seoul, South Korea, the total number of vision correction surgeries is decreasing in Korea. He quoted a recent survey of ASCRS members confirming a decrease of 13% in the average volume of laser vision correction surgery from 2013 to 2015.

Ophthalmologists around the world, he said, are thus looking for a new breakthrough in laser vision correction.

Refractive history

When LASIK first appeared, Dr. Koo said that the refractive market boomed. However, when femto LASIK began replacing microkeratome LASIK in 2005, the market failed to grow.

In fact, he said, femto LASIK did not even compensate for the drop in refractive surgery practices around the world following the financial crisis in the U.S.

In 2015, he added, SMILE accounted for less than 10% of the total number of refractive surgeries. The remaining 90% of procedures were LASIK and PRK.

Since femto LASIK failed to invigorate the market, Dr. Koo said that SMILE should take on the role of stimulating the field's growth.

Practice booster

In December 2016, Dr. Koo's clinic posted a video on Facebook demonstrating the characteristics and advantages of SMILE. The video describes how unlike the excimer laser, the femtosecond laser penetrates the cornea to remove as much tissue as needed.

Since the video was posted, Dr. Koo said, the social media website has recorded more than 2 million views, with 20,000 comments and 15,000 shares—a “surprising record” and a “huge response” in South Korea.

More to the point, the total number of SMILE procedures in Dr. Koo's clinic in the following months of January, February, and March increased 50% compared to the same period the previous year.

Significantly, while the video itself might not seem so special on the surface, Dr. Koo said that it addresses the concerns patients have regarding refractive surgery that, at least in South Korea, played a large part in the drop in refractive procedures over the years—mainly, the complications that have all too often been emphasized by the media, creating a negative impression of laser vision correction in general.

By reducing this concern, he added, SMILE will be able to replace LASIK and “reactivate” the refractive market.

SMILE advantages in theory and practice

In theory, SMILE provides certain biomechanical advantages over LASIK and PRK. As illustrated by a graph that **Dan Reinstein, MD**, created through mathematical modeling,¹ SMILE preserves more tensile strength than either LASIK or PRK by preserving the anterior corneal lamella, which Dr. Koo said provides 50% more tensile strength than the posterior lamella. In addition, the finite-element model created by Roy et al.² indicates that following a –9.0 D correction with a 100- μ m

flap or cap, LASIK appears to redistribute stresses toward the residual stromal bed, whereas the stress distribution between SMILE and a geometry analog were similar. This, said Dr. Koo, suggests that SMILE may induce less biomechanical weakening than LASIK.

However, Dr. Koo said that looking at biomechanics in vivo using the Ocular Response Analyzer (ORA, Reichert Technologies, Depew, New York) and the OCULUS Corvis ST (Oculus, Wetzlar, Germany) has shown no significant differences between SMILE and LASIK. When it comes to keratectasia and SMILE, he said, more scientific evidence is needed.

Dry eye is another matter. Because SMILE does not cut a flap, SMILE corneas retain more functional corneal innervation. Morphologically, these corneas retain greater nerve density, with higher numbers and branching than LASIK corneas. This, Dr. Koo said, results clinically in fewer dry eye symptoms with less need for tear substitute eye drops as well as better ocular surface disease index, tear film break-up time, tear osmolarity, and dry eye severity than LASIK.

However, Dr. Koo said that the most common complaint after SMILE is relatively slower visual recovery than LASIK and blurred vision.

Blurring, he said, may have to do with increased backscatter after SMILE, as reported by Agca et al.³ Whatever the reason is, he said, patients would be more enthusiastic about SMILE if faster visual recovery and less blurring were made possible.

Can SMILE replace LASIK or PRK?

Dr. Koo thinks SMILE can replace LASIK and PRK and even invigorate the refractive surgery market—provided the following conditions are met.

First, doctors need to provide more scientific evidence of SMILE's advantages over LASIK in terms of keratectasia and dry eye symptoms, as well as improve visual recovery to at least the level of LASIK.

Second, the cost of the technology and the procedure need to become more reasonable.

Finally, Dr. Koo said that the importance of communication cannot be overemphasized.

“We live in the age of the 4th Industrial Revolution,” he said. “Power already has fallen into the hands of the public, not our hands.”

Doctors need to invest more time and effort in communicating with their patients and educating them further on refractive surgery.

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View EWAR (EyeWorld Augmented Reality) code by downloading the free EyeWorldAR app in your Android or Apple store