

CRST EUROPE

Cataract & Refractive Surgery Today

ReLEx SMILE – Broadening the vision of success





Table of Contents

A Decade of Innovation and Advancement 4

Looking back at the success of SMILE.

BY WALTER SEKUNDO, MD, PhD

How SMILE Changed My Practice 6

Increased patient volume and word-of-mouth referrals can result from the clinical benefits of SMILE.

BY IAN CHAN, MD

SMILE is a Driver in My High-Volume Clinic 7

Patients love the quick recovery of their visual acuity.

AN INTERVIEW WITH XINGTAO ZHOU, MD, PhD

Keys to a Successful Refractive Surgery Center 9

Two of the most important elements are patient satisfaction and high-end technology.

**BY ANDREI FILIP, MD, PhD; MIRCEA FILIP, MD, PhD; MIRUNA NICOLAE, MD, PhD;
RALUCA MOISESCU, MD; EUGEN ROTARU; AND ERZSEBET FILIP**

Ten Steps to Perfect Patient Counseling 12

Tips from one clinic on how to successfully counsel patients about SMILE.

BY MARTIN BECHMANN, MD

SMILE: Another Opportunity to Make LVC Great 14

First experiences in the United States.

BY GREGORY D. PARKHURST, MD, FACS

A Decade of Innovation and Advancement

Looking back at the success of SMILE.

BY WALTER SEKUNDO, MD, PhD



Small incision lenticule extraction, or SMILE, has become a widely accepted method of laser vision correction, and we are very close to 1 million procedures completed worldwide. Even though we do not know the exact date the first SMILE surgery was performed, we know it was some time in April 2007. Something

I can remember, though, was the day that I performed the first iteration of the SMILE procedure, femtosecond lenticule extraction, or FLEx, for the first time. This was May 3, 2006.

Once FLEx was an established technique, Marcus Blum, MD, and I started to reduce the incision size required of the procedure. The first SMILE had two opposite incisions that were each 5 mm. It was Rupal Shah, MD, who then made the next step in the progression of SMILE by performing it through a single incision. Since this time, the technique has continued to advance dramatically. Now that SMILE has been approved by the US FDA, we can say that the procedure is now embraced by the entire corneal refractive surgery community.

TRACKING THE FIRST PATIENTS

Not only have 5-year results of both SMILE and FLEx been published by our group,¹ but peer-reviewed 4-year results with the current VisuMax 500 kHz-laser (ZEISS) have also been published.² Several 3-year studies from us and other investigators are also available.³⁻⁵

SMILE has become a hot topic; in a recent PubMed search, I found 280 citations on SMILE, including five major reviews⁶ and

three large meta-analyses.⁷⁻⁹ Moreover, two books, one in Chinese and one in English, are already available, and another book in English and Spanish is due to be released. Dr. Blum and I are privileged to be the first in the world to perform SMILE surgery, and we are currently preparing a 10-year follow-up study of the first patients treated in 2007.

We were also able to track some of the patients who had undergone FLEx in Marburg, Germany, 10 to 11 years ago. The most impressive outcome was that BCVA has not deteriorated (Figure 1). In terms of stability (Figure 2), 1-month and 10-year mean spherical equivalent was -0.58 and -0.70 D, respectively. The remarkable stability of the first five eyes ever treated raise hopes that our 10-year SMILE study will also provide similarly good long-term results.

A LONG-LASTING EFFECT

In my opinion, several considerations will have a long-lasting effect on the refractive market. There is, for instance, no doubt that SMILE, when performed through a true small incision size between 2 and 3 mm, has less destructible effect on corneal sensation in the short-term.¹⁰ Further, theoretical, experimental and clinical studies for high myopia have shown that SMILE has less short- and long-term weakening effects on corneal biomechanics compared with other laser vision correction procedures.¹¹

The centration issue that has been discussed for a considerable time is no longer relevant since several studies showed that patient's self-centration yields better results

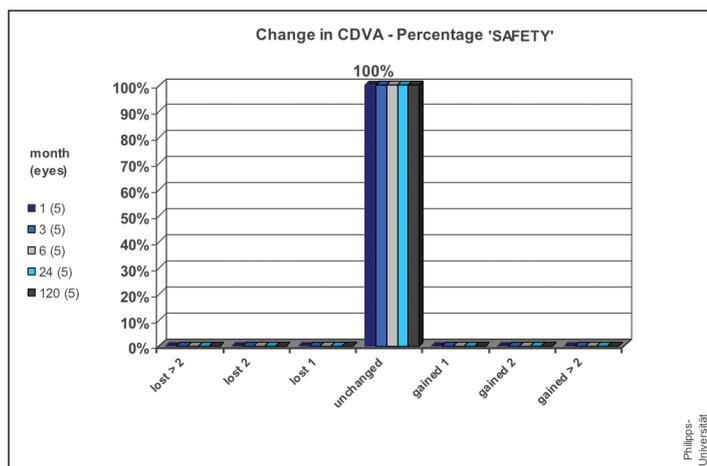


Figure 1. BCVA at 1, 3, 6, 24, and 120 months postoperative.

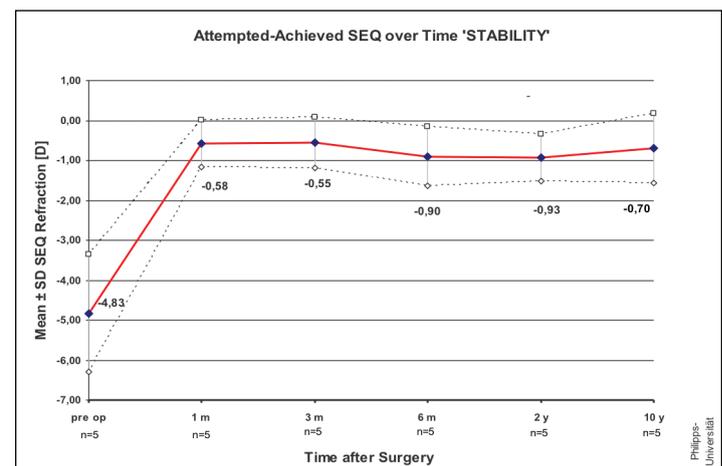


Figure 2. Mean spherical equivalent at 1, 3, 6, and 24 months and 10 years.

than surgeon-controlled eye-tracker centration with excimer laser ablations.¹²⁻¹⁴

The issue of cyclotorsion has at least been partially resolved by an idea proposed by several groups of surgeons, including Ivarsen and Hjortdal, of Aarhus, Denmark, who have provided guidance on how to mark the cornea and rotate the suction cone according to the marks. Although this is controversial, Dr. Ivarsen's method has proved to be extremely effective in daily routine practice as shown by Brar and Ganesh.¹⁵ Of course, an automatic cyclotorsion and adjustment control would further increase the acceptance of SMILE surgery.

Another major step was an investigator-initiated trial, led by Kishore Raj Pradhan, MD, to introduce hyperopic SMILE. At the same time, our group had successfully finished a hyperopic FLEEx study, and the final results were released at the beginning of 2017. We are in the process of publication now.

Energy management with the VisuMax femtosecond laser has allowed surgeons to expand the capabilities of SMILE and has also improved the cutting quality and shortened the surgical time. Helpful rescue software included in the laser aids novice surgeons in making the right decisions in critical situations, such as suction loss. Last but not least, the idea of lenticule implantation and autotransplantation has been studied by several investigators, and it has proved to be useful in certain special situations.¹⁶

A FIRST-CHOICE PROCEDURE

Taken together, there is no wonder that SMILE is on the way to becoming a first-choice refractive procedure, in particular for higher myopia and in young patients. At the same time, it does not mean in any way that femtosecond LASIK is not a good procedure. It has some advantages and disadvantages compared to SMILE and should be considered as one of the assets for safe,

patient-oriented, comfortable refractive surgery. Together these procedures have the potential to hopefully drive the refractive market to new heights. ■

- Blum M, Taeubig K, Gruhn C, Sekundo W, Kunert KS. Five-year results of small incision lenticule extraction (ReLex SMILE). *Br J Ophthalmol*. 2016;100(9):1192-1195.
- Han T, Zheng K, Chen Y, Gao Y, He L, Zhou X. Four-year observation of predictability and stability of small incision lenticule extraction. *BMC Ophthalmol*. 2016;16(1):149.
- Messerschmidt-Roth A, Sekundo W, Lazaridis A, Schulze S. Three years follow-up study after refractive small incision lenticule extraction (SMILE) using 500 kHz femtosecond laser in "fast mode." *Klin Monbl Augenheilkd*. 2017;234(1):102-108.
- Pedersen IB, Ivarsen A, Hjortdal J. Three-year results of small incision lenticule extraction for high myopia: Refractive outcomes and aberrations. *J Refract Surg*. 2015;31(11):719-724.
- Han T, Zhao J, Shen Y, Chen Y, Tian M, Zhou X. A three-year observation of corneal backscatter after small incision lenticule extraction (SMILE). *J Refract Surg*. 2017;33(6):377-382.
- Reinstein DL, Morshifrar Shen Z et al. *PLoS One*. 2016.
- Wang JS, Xie HT, Jia Y, Zhang MC. Small-incision lenticule extraction versus femtosecond lenticule extraction for myopic: a systematic review and meta-analysis. *Int J Ophthalmol*. 2017;10(1):115-121.
- Ağca A, Demirok A, Yıldırım Y, Demircan A, Yaşa D, Yeşilkaya C, Perente I, Taşkapılı M. Refractive lenticule extraction (ReLex) through a small incision (SMILE) for correction of myopia and myopic astigmatism: current perspectives. *Clin Ophthalmol*. 2016;10:1905-1912.
- Shen Z, Shi K, Yu Y, Yu X, Lin Y, Yao K. Small incision lenticule extraction (SMILE) versus femtosecond laser-assisted in situ keratomileusis (FS-LASIK) for myopia: A systematic review and meta-analysis. *PLoS One*. 2016;11(7):e0158176.
- Cai WT, Liu QY, Ren CD, Wei QQ, Liu JL, Wang QY, Du YR, He MM, Yu J. Dry eye and corneal sensitivity after small incision lenticule extraction and femtosecond laser-assisted in situ keratomileusis: a meta-analysis. *Int J Ophthalmol*. 2017;10(4):632-638.
- Spiru B, Kling S, Hafezi F, Sekundo W. Biomechanical differences between femtosecond lenticule extraction (FLEEx) and small incision lenticule extraction (SMILE) tested by 2D-extensometry in ex vivo porcine eyes. *Invest Ophthalmol Vis Sci*. 2017;58(5):2591-2595.
- Lazaridis A, Droutsas K, Sekundo W. Topographic analysis of the centration of the treatment zone after SMILE for myopia and comparison to FS-LASIK: subjective versus objective alignment. *J Refract Surg*. 2014;30(10):680-686.
- Reinstein DZ, Pradhan KR, Carp GI, Archer TJ, Gobbe M, Sekundo W, Khan R, Citron K, Dhungana P. Small incision lenticule extraction (SMILE) for hyperopia: Optical zone centration. *J Refract Surg*. 2017;33(3):150-156.
- Reinstein DZ, Gobbe M, Gobbe L, Archer TJ, Carp GI. Optical zone centration accuracy using corneal fixation-based SMILE compared to eye tracker-based femtosecond laser-assisted LASIK for myopia. *J Refract Surg*. 2015;31(9):586-592.
- Brar S. Paper presented at: the European Refractive Symposium; June 2016; Potsdam, Germany.
- Ganesh S, Brar S, Rao PA. Cryopreservation of extracted corneal lenticules after small incision lenticule extraction for potential use in human subjects. *Cornea*. 2014;33(12):1355-1362.

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How SMILE Changed My Practice

Increased patient volume and word-of-mouth referrals can result from the clinical benefits of SMILE.

BY IAN CHAN, MD



I am a solo practitioner in Perth, Australia. As a corneal subspecialist, one-third of my practice is devoted to corneal surgery, one-third to refractive surgery, and one-third to cataract and related general ophthalmic surgery. I have been performing refractive surgery since 2008 and small incision lenticule extraction, or SMILE, since 2015. In my years of practice, no other procedure has had the same kind of impact as quickly as SMILE has.

THE GROUNDWORK

Our team at Aculase consists of one surgeon (me), two receptionists, one optometrist, one practice manager, and five part-time laser nurses (Figure 1). When we purchased the VisuMax femtosecond laser (ZEISS) 2 years ago, we expected to perform about 100 SMILE procedures in the first year. The volume of SMILE procedures that we have actually performed, however, has well exceeded those expectations. Right now, I use SMILE in 98% of myopic patients who elect refractive surgery. For hyperopic patients, I still perform LASIK.

Because of my background in corneal surgery, and because of my experience with lamellar keratoplasty specifically, the technical adoption of SMILE was easy, and it only took me a handful of surgeries to become completely comfortable with the procedure.

Likewise, it did not take patients long to warm up to the idea of SMILE as a solution to their visual needs. Because SMILE provides patients with a flapless option with only a keyhole incision for laser vision correction, we have found that many are drawn to this surgical procedure. Patients are clearly more worried about the corneal flap than I have previously appreciated. I think patients also like the fact that SMILE is performed entirely under the same laser, instead of under two laser platforms like LASIK, and that there is a lower risk of dry eye postoperatively. Many patients who have dry eyes issues with contact lenses are drawn to the lower risk of dry eye with SMILE.

With that said, when we initially introduced SMILE to the patients in our market, we had to keep in mind that we were dealing with an audience that had never heard of the procedure before. Therefore, we focused our marketing efforts on educating patients about the SMILE procedure. The small wound size and the minimal laser treatment time (25 sec) seem to resonate with patients. Now that patients in our market are educated on SMILE and are aware of its benefits, many have come to our practice for refractive surgery simply because we offer SMILE.

Once the procedure is explained to patients clearly (Figure 2), SMILE really sells itself. In the beginning, we had many patients in their 30s come into Aculase inquiring about



Figure 1. Dr. Chan and some of the staff at Aculase.



Figure 2. Dr. Chan talking with a patient.

SMILE; now, however, we are seeing many more younger patients. Additionally, we have seen an increase in the number of health professionals including doctors, nurses, and dentists, who are interested in SMILE because they can particularly appreciate the benefits of keyhole surgery.

As the procedure continues to penetrate and grow the refractive surgery market, I expect that the number of patients coming to our practice specifically asking for SMILE will increase. Right now, we use SMILE to treat myopia and myopic astigmatism between -0.50 and -10.00 D sphere and up to 4.00 D astigmatism; however, in the future that indication might expand and it will probably also be possible to treat patients with a corneal graft, even higher levels of myopia, and, hopefully, hyperopia.

SMILE is a Driver in My High-Volume Clinic

Patients love the quick recovery of their visual acuity.

AN INTERVIEW WITH XINGTAO ZHOU, MD, PhD



How many years have you been performing refractive surgery in general and ReLex SMILE in particular?

Dr. Zhou: I have been performing PRK for 21 years, LASIK for 20 years, LASEK for 19 years, epi-LASIK for 13 years, and SMILE for about 5 years.

For what reasons did you want to try SMILE?

Dr. Zhou: I liked that the procedure is minimally invasive and that it provides excellent vision quality.

Please share your clinical outcomes with SMILE.

Dr. Zhou: Along with my colleagues, I recently conducted a 4-year observational study of the predictability and stability of SMILE.¹ In that study, we concluded that, in the long-term, SMILE provided a predictable and stable correction of moderate to high myopia. What we specifically found was that UDVA was 20/20 or better in 92% of eyes and that 89% were within ± 0.50 D of the intended refraction. The safety and efficacy indices were 1.16 ± 0.14 and 1.07 ± 0.16 , respectively. Further, there was no significant change in the spherical equivalent at any of the follow-ups (1, 3, and 6 months and 1, 2, and 4 years).

Has performing ReLex SMILE been an advantage to your practice?

Dr. Zhou: Yes, of course.

Have you noticed any changes in your surgical volume since offering SMILE? What about patient demographics?

Dr. Zhou: We are now able to treat a larger range of patients, including those with up to -12.50 D spherical equivalent. At the Eye and ENT Hospital of Fudan University, we have treated patients as young as 18 years and as old as 60 years with SMILE.

What is the price of SMILE compared to LASIK and PRK?

Dr. Zhou: Patients pay the same price for SMILE as they do for LASIK and PRK.

Have you noticed an increase in revenue after SMILE?

Dr. Zhou: I believe that our overall revenue has been similar.

How does the postoperative management for SMILE patients compare to LASIK?

Dr. Zhou: The postoperative management process is similar for both surgeries.

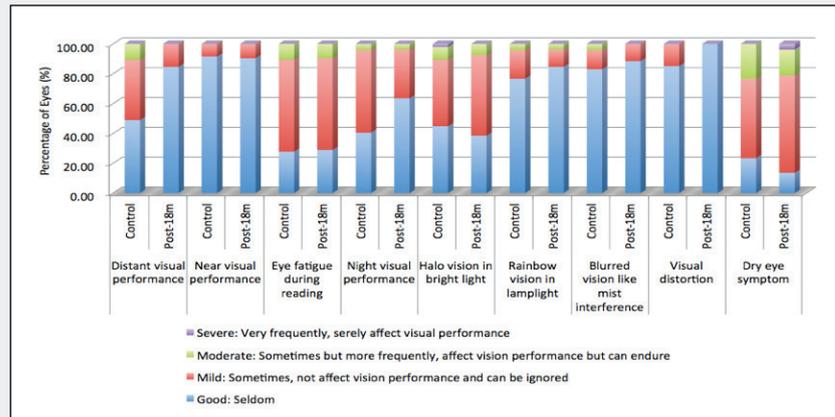


Figure 1. Patient satisfaction and visual quality after SMILE.

In your practice, what is the main “wow” effect for patients?

Dr. Zhou: With SMILE, the biggest “wow” factor that patients communicate is the quick recovery of their visual acuity without any discomfort.

In your clinic, what is the current procedural volume for SMILE?

Dr. Zhou: About 92% of the procedures we perform are laser vision correction. The other approximate 8% is phakic IOLs.

How do you maintain such a high volume of SMILE procedures?

Dr. Zhou: The visual quality after SMILE surgery is the most important factor in why we suggest the procedure to our patients (Figure 1).

What is your preferred method of marketing to attract patients to your clinic?

Dr. Zhou: We do not use marketing efforts in my hospital. With that said, I do my best to serve every patient with my whole heart, and our team does its best to achieve good visual quality after every surgery.

1. Han T, Chen Y, Gao Y, He L, Zhou X. Four-year observation of predictability and stability of small incision lenticule extraction. *BMC Ophthalmol.* 2016;16:149-156.

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PRICING STRATEGY AND PROFIT MARGINS

At Aculase, we do charge a premium for SMILE, with a price point 15% higher than that of LASIK and 30% higher than that of PRK. Although this has obviously had an impact on our profitability, the main increase in revenue is the higher patient volume. SMILE is also a much quicker procedure than other laser vision correction surgeries; I can perform two SMILE cases in the same time it takes me to perform one LASIK case. In short, more patients are coming through our doors now that we offer SMILE, and we can perform more surgery within the same amount of theater time.

Most patients who come into our practice end up choosing SMILE, despite the premium price. We present all three options to our patients (SMILE, LASIK, and PRK), and our recommendation relates directly to their circumstances. For instance, in a patient who has no preexisting dry eye and requires a low-power correction, I often tell the patient that he or she will be fine with LASIK or SMILE. Ultimately, they decide on the surgical option based on their preference and budget. Even in the event that a patient does not elect SMILE, he or she still undergoes other surgery at our center, again boosting volume and our profit margin.

We have always treated and will always treat patients equally, whether they decide on SMILE, LASIK, PRK, or any other procedure. However, I find that less chair time is required with SMILE than with procedures like LASIK and PRK, but we maintain similar appointment schedules regardless of procedure.

THE PATIENT EXPERIENCE

As I mentioned, we have been performing SMILE at our practice for 2 years now. One thing that we notice time and again is that patients really have no complaints about the procedure or the recovery process. Patients like that SMILE is quick and painless, that they do not need to wear dressings or goggles on their eyes immediately postoperatively, and that they can resume daily activities relatively right away.

I have heard before that SMILE does not have the same “wow” effect as LASIK; however, in my experience patients have similar visual acuities on day 1 postoperative after SMILE and LASIK. Vision on day 1 postoperative seems to improve with more surgical experience in SMILE. Further, there is no deterioration in vision from dry eye symptoms that some LASIK patients seem to notice 1 week after surgery.

On the other hand, we have a high incidence of dry eye in Australia. A proportion of LASIK patients have deterioration in vision from dry eye symptoms 1 week after surgery; however, SMILE patients do not have this vision-reduction pattern from dry eyes.

SMILE consistently exceeds patient expectations, and therefore they are generally smiling all the way through the procedure and at their follow-up appointments. Because SMILE presents such a strong patient experience, our number of word-of-mouth referrals has also increased. I have treated whole families, several coworkers in the same office, and lunch groups—all from patient referrals.

Further, we have some strong advocates for SMILE in the patients who we have already been treated. I think some of them are bursting at the seams to share how happy they are, and they do this on social media. Also being among the first patients in Perth to have a new procedure is something they are proud of. Having that presence on social media certainly helps our practice.

PROFESSIONAL SATISFACTION

Seeing the joy on our patients’ faces after such a short treatment keeps a smile on my face at postoperative visits. Beyond the clinical benefits of SMILE, there are other rewards in being involved in a successful new procedure. For instance, I had the exciting opportunity to design a dissecting forceps and suggest a new method to perform SMILE to an international audience. Professionally I find it a rewarding experience on many different levels.

I think communication and patient education are still the keys to success with any procedure. We do spend marketing efforts on promoting SMILE specifically, but more importantly patients are learning about SMILE and its benefits through word of mouth and through our educational efforts. Once patients are through the door, we take time to go through the process and discuss the advantages of SMILE as well as the minor side effects they may encounter.

I believe in being realistic with patients instead of over-promising and under-delivering. Also, understanding each patient’s circumstance and tailoring the treatment plan accordingly is important.

I have always been open to trying new procedures, and I always present to patients balanced, educational material about the various procedures that we offer. I do not believe that we have altered the patient workflow or counselling specifically for SMILE patients, but we have seen a natural preference for this minimally invasive laser procedure. Since we began offering SMILE, we have seen an increase in our patient volume. ■

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Keys to a Successful Refractive Surgery Center

Two of the most important elements are patient satisfaction and high-end technology.

BY ANDREI FILIP, MD, PhD; MIRCEA FILIP, MD, PhD; MIRUNA NICOLAE, MD, PhD; RALUCA MOISESCU, MD; EUGEN ROTARU; AND ERZSEBET FILIP

In recent years, there has been much development in corneal refractive laser surgery techniques and technologies. With the resultant increase in surgical capabilities, patient demands and expectations have also increased. Therefore, we believe that patient satisfaction must always be a key element in the evaluation of the overall success of any refractive surgery procedure.

ReLEx small incision lenticule extraction, or SMILE, has become our first choice for corneal refractive surgery in myopic patients. We have been performing the procedure for 3 years and have witnessed its many advantages over LASIK, including high predictability, being virtually painless, fast healing, and the reduced risk of dry eyes due to the elimination of a corneal flap. In more ways than one, SMILE continues to meet the expectations of our highly demanding refractive surgery patients.

A BRIEF HISTORY

In 2005, we started performing PRK with the MEL 70 G-Scan excimer laser (ZEISS). In 2010, we purchased the MEL 80 and, in 2014, the VisuMax femtosecond laser (ZEISS). At that time, we started to perform femtosecond LASIK (femto-LASIK) and SMILE. Today, we continue to perform PRK, femto-LASIK, and SMILE, although our indications have changed (see *Treatment Protocols at Ama Optimex Eye Clinic* for more information).

In short, usually when we make a recommendation to a patient, we consider a sum of medical criteria including diopter range, indications, and contraindications as well as subjective factors like occupation, patient expectations, and financial considerations. In our clinic, we use a range of refractive surgery procedures including corneal laser surgery and refractive lens exchange, with the sole purpose of completely addressing the patient's needs.

INTRODUCING A HIGH-END PROCEDURE, OBTAINING PATIENT FEEDBACK

About the same time that we introduced SMILE at our clinic, the refractive surgery market in Romaina was in decline, like everywhere else. Being the first to introduce a high-end procedure such as SMILE gave us the opportunity to make the procedure known to the public and to inform and educate patients through intense marketing campaigns.

The typical profile of a refractive surgery patient is young, active on the internet (especially with social media), and well educated. For these reasons, we have found that a targeted

Treatment Protocols at Ama Optimex Eye Clinic

PRK

- Myopia up to -5.00 D
- Myopic astigmatism up to -2.00 D
- SEQ up to -5.00 D
- Hyperopia up to 1.50 D
- No hyperopic astigmatism treatments performed as PRK

Femto-LASIK

- Myopia up to -7.00 D
- Myopic astigmatism up to -5.00 D
- SEQ up to -7.00 D
- Hyperopia up to 4.00 D*
- Hyperopic astigmatism up to 4.00 D*
- Spherical equivalent up to 4.00 D*

SMILE

- Myopia up to -10.00 D
- Myopic astigmatism up to -5.00 D
- SEQ up to -12.50 D

Abbreviations: SEQ = spherical equivalent

*Out of CE-approved range

marketing strategy that engages with patients mainly online is very fruitful. We have designed a dedicated website for refractive surgery, describing every refractive surgery technique available in our clinic. The main message to patients is that we can find a solution for anyone who wants to achieve spectacle independence. We have also invested in search engine optimization and in our presence on social media. All of this has resulted in a constant increase of refractive surgery patients presenting in our clinic.

We strongly believe that setting realistic patient expectations is one key to ensuring that patients are both satisfied and cooperative. In order to better understand the needs and satisfaction levels of our patients, we developed an online survey

Results of the Patient Questionnaire

SMILE Group:

- Most patients gathered information about the procedure from the practice's dedicated webpages and Facebook but also from friends, family, and medical forums
- Reasons for having surgery were: becoming spectacle independent (71%), decreased tolerance for spectacles or contact lenses (21%), because of their profession (19%)
- The advantages of SMILE: painless during and after the procedure (80%); minimally invasive, flapless technique (73%); rapidly resume normal daily routine (69%); correction of high myopia and astigmatism (69%); safety (57%); rapid visual recovery (59%)
- The day of the surgery: feeling safe/surrounded by a pleasant environment (61%); concerns were rapidly put to rest by medical staff (41%); surgery was much easier than expected (45%)
- Immediate postoperative period: blurry vision (50%); minimal discomfort (40%); no concerns about recovery (40%)
- Postoperative treatment: easy to administer and painless (93%)
- Visual recovery: visual improvement in a few hours after surgery (35%); visual improvement after few days (40%); good visual acuity but fluctuating sometimes (18%); other answers (7%); no future concerns (36%); concerned about regression (39%); concerned about presbyopia (25%)
- Other: happy about the decision of having SMILE (98%); willing to recommend the procedure to family and friends (97%)

Femto-LASIK Group:

- Most patients gathered information about the procedure from the practice's dedicated webpages and Facebook but also from friends, family, medical forums, and medical info webpages
- Reasons for having surgery were: becoming spectacle independent (59%), decreased tolerance for spectacles or contact lenses (30%)
- The advantages of femto-LASIK, rapid visual recovery (56%); painless during and after the procedure (56%); only technique appropriate for them (48%)
- The disadvantages of femto-LASIK: eye rubbing (50%); sustaining some type of injury prone to dislodging the flap (48%); creation of the flap (19%); postoperative limitations (22%)
- Immediate postoperative period: involuntary eye rubbing (48%); foreign body sensation requiring the use of artificial tears (41%); blurry vision (30%); dry eye sensation (15%)
- Postoperative treatment: painless and easy to apply (81%); fast or very fast recovery (70%)
- Future concerns: none (44%); regression (27%); that the flap might be torn or displaced after minor eye injury (15%); presbyopia (11%)
- Other: happy with their decision and they would recommend the clinic to friends and family (93%)

that was sent to all of our femto-LASIK and SMILE patients who had surgery between 2014 and now. Most of our femto-LASIK patients were hyperopic and therefore could not have been treated with SMILE.

A study, based on multiple choice and open-answer patient questionnaires, was created to establish the degree of patient satisfaction after SMILE and femto-LASIK. It evaluated key parameters in patient satisfaction, such as comfort during surgery and the immediate postoperative period, the rate at which normal activity can be resumed after surgery, the impact of postoperative treatment, and limitations on lifestyle. Also, we aimed to establish each patient's preoperative expectations and future concerns and the subjective perception on visual recovery speed and postoperative quality of vision.

The survey was designed to reveal the main information sources used by patients to learn about each technique and the degree of awareness in terms of suitability, safety, and stability that patients acquired prior to surgery. We included some questions about the overall opinion on the quality of medical services and the availability of medical personnel; both questions were found to be particularly useful for improving our daily practice.

RESULTS

The results of the survey showed that patients perceive SMILE as a friendly, virtually painless, and safe procedure that provides fast visual recovery. It also indicated that SMILE is capable of meeting patient needs and expectations and that patients have less concerns for the future, like risk of flap dislocation, dry eye, or regression. On the other hand, results of the survey indicated that questions about femto-LASIK included the existence of the flap, its possible dislocation after trauma or certain sports and activities, the longer period of restrictions after surgery, and the risk for dry eye disease (DED).

Also relevant is that, in my practice, I perform SMILE more often than other procedures because I think it better corrects a larger range of myopia and myopic astigmatism compared to other refractive surgery techniques, such as femto-LASIK. A more thorough look at the study results can be found in the *Results of the Patient Questionnaire* box above.

CONCLUSION

The results of the questionnaire indicated that SMILE was superior to femto-LASIK in terms of patient satisfaction, especially when

addressing topics such as potential complications, intraoperative comfort, visual recovery, postoperative restrictions, and DED. Based on our own treatment protocol, SMILE not only corrects a large range of refractive errors, but it also has less incidence of dry eye symptoms postoperatively and allows patients to resume their normal daily activities with no limitations more quickly than other refractive surgery procedures.

Patients also recognized the advantage of having a safe and stable procedure that requires only a 72-hour period of postoperative restrictions, compared with a flap-based procedure that lengthens the period of postoperative restrictions to several weeks and comes with concerns about flap dislocation during sports or eye contact. (The 72-hour window is our recommendation, but some other clinics have even fewer hours of restriction after SMILE.)

Performing the SMILE procedure in our clinic for the past 3 years has increased the indication range for refractive surgery, placing us at the top of the Romanian refractive surgery provider list. Increasing patient awareness by means of dedicated web and social media pages has facilitated contact between refractive surgery candidates and medical personnel, allowing the former to make correct and informed decisions about the type of refractive surgery best suited to their needs.

Based on the consultation with the patient and his or her test results, only then will the surgeon make the recommendation for the appropriate laser technique, which in the majority of our myopic patients is SMILE. ■

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Ten Steps to Perfect Patient Counseling

Tips from one clinic on how to successfully counsel patients about SMILE.

BY MARTIN BECHMANN, MD



In our Smile Eyes Clinics, patients have had access to the latest laser vision correction surgical procedure via small incision lenticule extraction, or SMILE, since 2012. This procedure is attractive to many types of patients because it can be performed with one laser system, the VisuMax femtosecond laser (ZEISS), and because instead of requiring a flap in the cornea it only requires a keyhole incision through which a lenticule of tissue is removed.

The percentage of SMILE treatments we perform has steadily increased over the past 5 years, from 52% in 2012 to 67.6% in 2016. Because of this, and because the procedure has less capital investment and per-procedure costs to both the practice and the patient, the impact that SMILE has had on our revenue stream has been quite significant (Figure 1).

STRUCTURE YOUR PROCESS

Part of the reason we have seen continued success and rising patient acceptance of SMILE in particular is that we use a structured patient counseling process. In 10 simple steps, patients can be both educated on SMILE and counseled on why the procedure is right for them.

Step No. 1: The opening. During the initial conversation with the patient, it is important that he or she receives a warm welcome to the practice. We always ask, “Who should we thank for the referral to our practice?” This can be used to create a connection with the patient and also provide insight into why he or she is interested in SMILE. Also during the first dialogue, we start the patient’s file and go over specific treatment plans that we offer.

Step No. 2: What can we do for you? Using an open-ended question like this can give the patient the opportunity to articulate exactly what it is that he or she is looking for in a treatment. The most common answer we hear is, “Because I want to get rid of my glasses.”

Step No. 3: Ask a follow-up question. That simple statement—“Because I want to get rid of my glasses.”—does not provide enough information to select the best procedure for the patient. Therefore, it is important to follow-up with, “Can you tell me why?” During this point in the patient counseling process, the patient should be doing 80% of the talking, and the clinician should listen and only lead the conversation

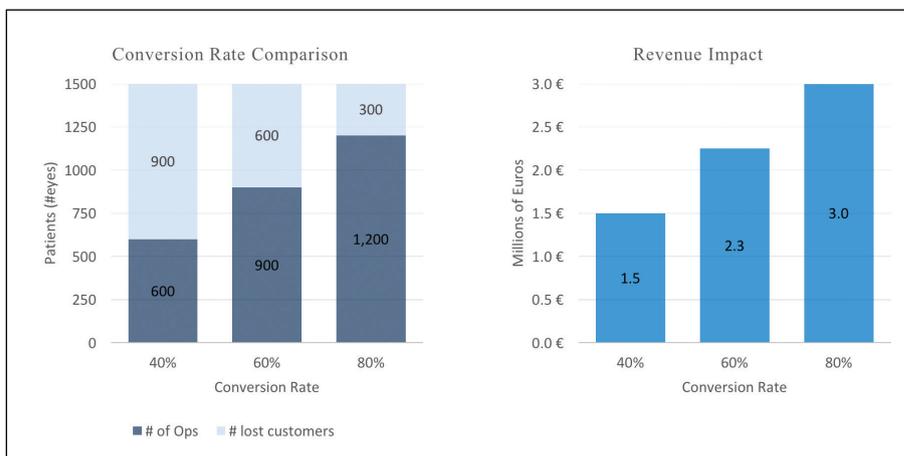


Figure 1. Conversion rate to SMILE and the impact on revenue at Smile Eyes.

when necessary. Throughout the process, the clinician must encourage positive thinking and provide a safe space for the patient to talk freely.

Step No. 4: Gauge the patient’s knowledge base. Has the patient done research on the internet? Has he or she heard about SMILE from family or friends? Has he or she seen brochures, visited a competitor, or attended an informational session about the procedure? Eliciting this information can help the surgeon to learn more about the patient, including the way he or she thinks about the procedure and what his or her fears are. This information also provides insight into the success of our marketing and into which marketing tools are successful and which are not.

Step No. 5: Determine and explain the patient’s suitability. An ocular examination including corneal tomography is a great tool to explain the suitability of the patient for laser vision correction. Symmetry of the topography, corneal thickness, and the traffic light appearance of the Belin Ambrosio tool (Figure 2) are easy for the patient to understand when explained properly. This understanding ensures the patient that there is a clear rationale why he or she is a good candidate for refractive surgery.

Step No. 6: Introduce the procedure in more detail. Once it is decided that the patient is a good candidate for SMILE, the clinician should then provide a thorough introduction to the procedure. At Smile Eyes, we like to provide a complete overview on the evolution of laser vision correction, from microkeratome LASIK to femtosecond LASIK to SMILE. It gives the patient a sense of how far refractive surgery has come and how we take years of knowledge and experience into account when selecting the right procedure for him or her. At this point in

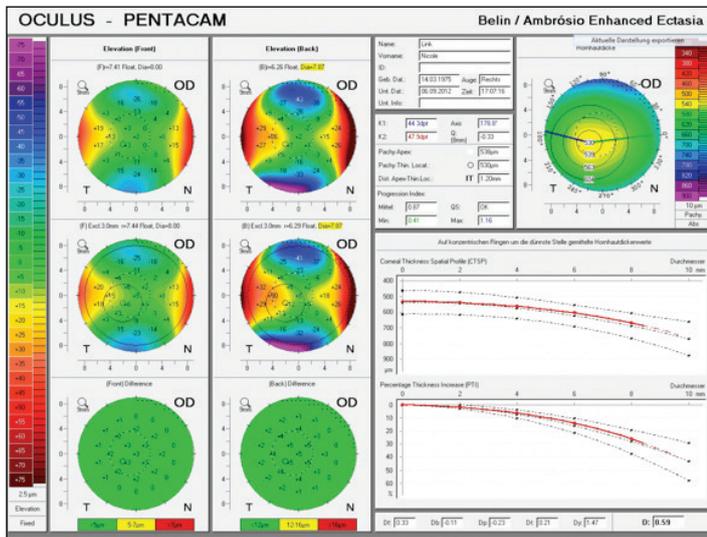


Figure 2. The Belin Ambrósio tool on corneal topography.

the counseling process, we ask that the patient watches a video about SMILE as another means of educating him or her about the procedure. This is important because some patients are visual learners. The key point here is the principle of evolution and not revolution in the technology. I always make it clear to patients that the basic principle of tissue removal has not changed since the beginning of laser vision correction. The only thing that has improved dramatically is the way in which we achieve this goal.

One mistake that can be made when being too enthusiastic about a new procedure is that the older procedures are pinned as negative. Instead, we should make it very clear that laser vision correction has always been successful and reliable and has even continued to improve over the years.

Step No. 7: Identify the risks. We always suggest to the patient what procedure we think is best for him or her. But no matter what procedure the patient selects, an essential part of the counseling process is identifying the risks associated with the procedure. With SMILE, those risks include infection, suction loss during the procedure, postoperative refractive errors, dry eye, and the presence of halos or glare after surgery. We are also sure to let patients know that the risk of infection is extremely small and that all of the other risks have an easy solution.

Step No. 8: Take time to answer any questions. All patients have some fear surrounding refractive surgery. Taking the time to ask if the patient has any questions and to acknowledge that it is OK to feel nervous or anxious about surgery can go a long way in reassuring patients. Talking about the reality of fear with the patient and letting him or her voice any specific concerns is a great way to reinforce the trust that has been built between you. One thing that I have found helpful is to cite a recent study by Kezirian et al,¹ which showed that refractive surgeons are more than four times more likely to have had refractive surgery than the general population and that 91% have recommended refractive surgery to their immediate family members.

Step No. 9: Schedule the procedure. Once the patient has had the opportunity to ask questions, it is now time to schedule the procedure. At this point, it is best if the clinician leads the conversation. Ask, “When would you like to have surgery?” and give him or her the choice of different appointment dates and times.

Step No. 10: Closing. Confirm the appointment time with the patient, and then provide reassurance that he or she is making the right decision. Easing patient fears and providing positive dialogue at this stage strengthens the patient’s feelings about the procedure.

CONCLUSION

In the past 6 years, we have seen significant gains in the volume of SMILE procedures we have performed and in the profitability that our clinic has enjoyed. In fact, we have seen a 10% gain in our laser vision correction volume since offering SMILE. In order to ensure we can maintain the momentum we have created behind this procedure, we believe that following a structured patient counseling process like the one described here is necessary. ■

1. Kezirian GM, Parkhurst DG, Brinton JP, et al. Prevalence of laser vision correction in ophthalmologists who perform refractive surgery. *J Cataract Refract Surg.* 2015;41:1826-1832.

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SMILE: Another Opportunity to Make LVC Great

First experiences in the United States.

BY GREGORY D. PARKHURST, MD, FACS



At Parkhurst NuVision, one of our fundamental philosophies is that refractive surgery is more about meeting the goals and needs of our patients than it is about the particular procedures we offer. We spend a lot of time listening to patients and thinking, examining, and educating them on what their anatomy tells us about the potential upsides and downsides of any given intervention unique to their optical system. Only after we have a good understanding of the patient's needs, desires, and anatomy do we think about selecting a procedure.

A FULL MENU OF OPTIONS

Because our strategy is fitting the procedure to the patient, rather than the patient to the procedure, having a full menu of options has always been important to the way we approach refractive surgery. Whenever we decide to add a new procedure, first we study it and get a sense for what its advantages are. We read about it, and we talk to, and then visit, surgeons who have experience performing the procedure.

For example, I went to Singapore this past year to consult with Jodhbir S. Mehta, BSc(Hons), MBBS, FRCOphth, FRCS(Ed), FAMS, who has been performing small incision lenticule extraction, or SMILE, with the VisuMax femtosecond laser (ZEISS) for several years. I also talked to some surgeons from Southeast Asia about their experiences with SMILE and traveled to Europe to observe more procedures and to collect information on European

results with SMILE. After talking with surgeons I trust, I became convinced that SMILE is going to be an important procedure for refractive surgery in the United States, just as it has been in Europe and Asia.

I performed my first SMILE in March 2017, and the day was especially memorable because it happened to be my 40th birthday. Being early adopters of advanced technology is part of our core values at Parkhurst NuVision, so we were proud to be one of the first 10 practices in the country to launch the procedure commercially. I had been using the VisuMax laser for LASIK flaps for 1 year prior to that, so I had adequate time to get used to the platform and its nuances, and I really love the platform for making flaps. The VisuMax continues to be the main laser I use, whether I am performing modern LASIK or whether I am performing SMILE. I really like that the platform is so versatile, meaning I can perform a variety of procedures depending on what is best for each individual patient.

Thus far in my experience, patient satisfaction has been excellent. I can recall one patient specifically who said that the SMILE surgery was so gentle that it was almost like nothing had happened, except that afterward she could see better. She related the patient experience to going in for an eye exam, but coming out with clear vision. The surgery is so comfortable that it is almost like a nonevent, which is a different experience than what patients are used to on the day of surgery with almost any other refractive procedure.

MORE INDICATIONS TO COME

Right now, we are finding that only about 25% to 30% of our current refractive surgery patients are eligible for SMILE. That is going to grow dramatically, and it is going to grow soon. The reason that we have not performed SMILE more often thus far is because the current indication in the United States is only for spherical myopia between -1.00 and -8.00 D. This means that, in the United States, we are not able to treat patients with greater than 0.50 D astigmatism. As one can expect, that limits the patient pool significantly. Once the astigmatism indication is approved by the US FDA, I expect the volume of SMILE procedures that I perform to increase dramatically.

Currently I find that SMILE works best in patients who have moderate to high myopia (-3.00 to -8.00 D). This is because, when getting used to dissecting and extracting the lenticule, a higher treatment gives you a little more tissue to grasp ahold of and get into.



Figure 1. Dr. Parkhurst (right) performing SMILE with the VisuMax.

MARKETING REFRACTIVE SURGERY

Rather than marketing one specific procedure as the best laser eye surgery available, we choose to focus our messaging on the fact that we have all the different options to ensure that the best surgical solution is chosen for each individual patient. There are situations when a patient is better suited for SMILE and others when a patient is better suited for modern LASIK. We want our patients to know what all of their options are before they make the transformative decision to undergo refractive surgery.

One thing we have done since we started performing SMILE is to do some TV interviews educating the community about what SMILE is. We have done some optometric seminars to introduce SMILE, so referring optometrists understand what it is, what it can offer their patients, and how it differs compared to some of our other procedures.

Our marketing strategy may seem a bit subtle, but it has been very effective. It is different from the way new technologies have been introduced into refractive surgery in the past. Take for instance what happened when the femtosecond laser was introduced for LASIK flap creation. The common messaging across the United States was, "Hey, you should get all-laser LASIK, and you should not trust the surgeon down the street who is still using a microkeratome blade. Come to me, because we do it all by laser." That was an underlying negative message, and it was a market-share play by the surgeons who invested in that laser technology. But what resulted from that negative messaging was fear and stagnation in the refractive surgery market, not growth. This time around, any marketing should be positive, and surgeons should try to be strategic about not positioning SMILE as the one procedure that everybody should get. Rather they should alert patients and doctors that they need to know about SMILE because it is in fact an optimal procedure for many people desiring to undergo laser vision correction.

CONCLUSION

There are a lot of people in this world who would benefit from refractive surgery who simply do not know it yet. Anything we can do to educate our patients about the transformative potential of refractive surgery and to bring excitement back into the specialty is beneficial. Introducing a new laser vision correction procedure to augment the surgeon's already expanding toolbox gives people another reason to think about refractive surgery again.

I believe SMILE, among other procedures, will be a catalyst of growth for refractive surgery. We have already seen some of this effect, as laser vision correction volume is up in many centers by 20% or more so far in 2017 and there has been a lot more positive messaging and chatter around refractive surgery in the United States in the past 12 to 18 months. I would attribute some of that to the introduction of SMILE, and perhaps even more to the collaboration and positive messaging taking place among refractive surgeons looking to expand the refractive surgery space.

I think the future of SMILE will have a much broader scope than it currently has in the United States, mostly because of the limitations in the indications for treatment that we can perform right now. By the time that the procedure has FDA approval for astigmatism correction, SMILE is going to become a really important procedure for refractive surgery patients because of the quick recovery, the comfort during surgery, and the excellent quality of vision it provides postoperatively. ■

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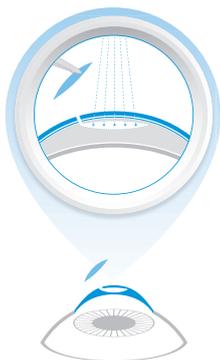
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Creating success with a SMILE.

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Over 1 million
treated eyes
worldwide



Minimally invasive refractive surgery.

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