

SMILE and beyond: CIRCLE into the future

The continuing evolution of SMILE

SMILE has come a long way since the procedure's international launch. In just 4 years, this cutting-edge refractive laser procedure has earned the support of more than 600 pioneering refractive surgeons. The VisuMax femtosecond laser system (ZEISS, Jena, Germany) has been used in more than 200,000 procedures in more than 290 centers across 50 countries around the world.

The procedure is being billed as the 3rd generation of laser vision correction following PRK and LASIK. It quickly became a favorite of some of the world's leading refractive surgeons.

Adding to the already extensive international experience, SMILE is currently further proving its worth in extensive U.S. Food and Drug Administration trials.

FDA: Proving safety, efficacy
William Culbertson, MD, Lou Higgins chair in ophthalmology and professor of ophthalmology, Bascom Palmer Eye Institute, Miami, one of the investigators for the FDA trial, called SMILE the "holy grail" of refractive surgery, explaining that it provides the ability to correct refractive errors through a very small incision, thus preserving corneal strength and integrity to prevent ectasia as well as preserving anterior corneal nerve supply to prevent dry eye.

However, Dr. Culbertson said at the Asia-Pacific Refractive Laser Symposium held in Busan

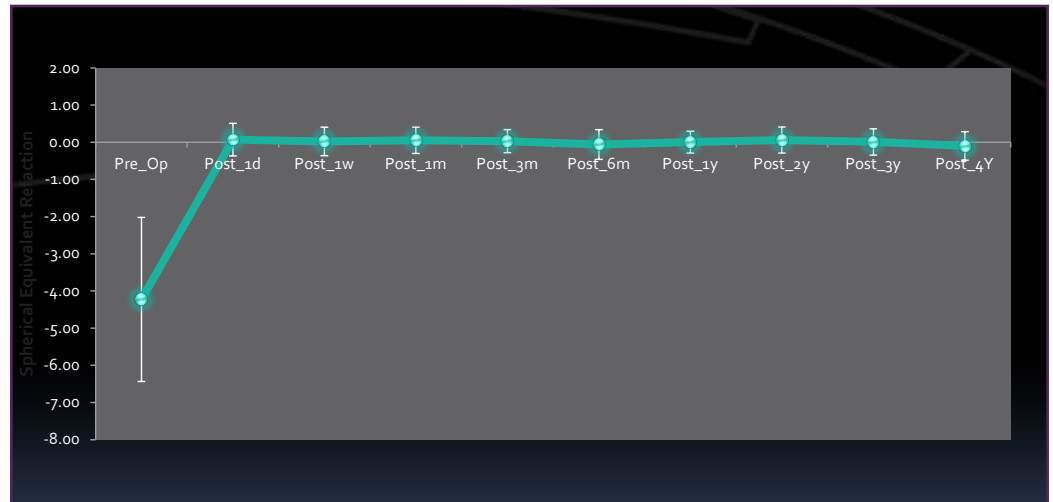


Figure 1. Stability of refractive outcomes following SMILE in Thailand

Source: Ekkhet Chansue, MD

last November, the procedure needs to perform at least as well and be at least as safe as both LASIK and PRK.

Thus, Dr. Culbertson and his colleagues at Bascom Palmer, along with surgeons from 4 other trial sites in the U.S., embarked on the FDA trials—whose famously stringent protocols and requirements ensure the ideal conditions for proving the procedure's safety and efficacy.

Significantly, Dr. Culbertson said, the various sites provide different environmental conditions in terms of altitude, temperature, and humidity in which to test the equipment and procedure. Furthermore, while Dr. Culbertson has had 6 years of experience using the VisuMax together with the MEL 80 excimer laser (ZEISS) for LASIK, the study includes investigators who have had no experience with the VisuMax prior to embarking on the SMILE trials.

Given this variety of conditions that includes environment and surgeon experience, it is impressive, Dr. Culbertson said, that

the results have been so consistent across all 5 trial sites.

At the time of the symposium, the trial had looked into the use of SMILE for correcting myopia in a single eye—with spherical errors from -1.00 D to -10.00 D—of 335 patients. Subjects with cylindrical errors of up to -0.50 D were accepted, but no cylindrical correction was allowed for purposes of the study.

While the results of the study have yet to be released and cannot be disclosed, the efficacy and safety have been at least on par with published data on LASIK.

"That matches up with any LASIK results that I've seen so far," Dr. Culbertson said.

Integrity and sensation

Where SMILE proves better than LASIK, Dr. Culbertson said, is in terms of corneal structural integrity and sensation. Reiterating the conclusion of Dawson and Edlhauser in their experiments with the tensile strength of the cornea—that

the anterior third of the cornea supports 42.5% of eye wall stress¹—Dr. Culbertson said that SMILE leaves the cornea stronger than LASIK by leaving the anterior third relatively intact, as demonstrated by various studies.¹

For instance, looking at -9.00 D treatments, Roy, Dupps, and Roberts found that SMILE incisions could tolerate more stress.² "Interestingly, they brought up the question of making the whole cap thicker in a 9 D correction," Dr. Culbertson said. "They found that this enhanced the strength in these high corrections."

Meanwhile, Kamiya³ and Ibrahim⁴ looked at hysteresis and deformability to confirm better retention of integrity with SMILE.

Other studies have shown that by cutting fewer corneal nerves, SMILE also retains corneal sensation better than LASIK.^{5,6}

A LASIK flap would only preserve the corneal nerve supply through the hinge, leaving the rest of the corneal flap relatively anesthetic, Dr. Culbertson said. This would lead to a neurotrophic dry eye

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state that we call dry eye after LASIK.

In contrast, with the SMILE procedure having just a 30-degree or smaller cut, more of the corneal nerves would be preserved, "perhaps just lost in the area of the side cut," he said.

These qualities allow SMILE to address the complications of corneal ectasia and dry eye, respectively, which have been associated with LASIK.

"I think it's a real life saver for refractive surgery," Dr. Culbertson said, referring to the drop in refractive surgery rates following a combination of bad press, as reports of ectasia following LASIK were exaggerated and spread, and the recent global financial crisis. "It's something to SMILE about, I think, for the whole refractive surgery world."

'Ultra minimal'

While trial investigators in the U.S. continue to build and compile evidence for SMILE's efficacy and safety, surgeons elsewhere are pushing the procedure and the technology to provide even better outcomes.

Tomoaki Nakamura, MD, director, Nagoya Eye Clinic, Japan, explored the possibility of making SMILE an "ultra minimally invasive refractive surgery" by performing it through an even smaller incision.

Dr. Nakamura said small incisions, allow the cornea to retain high resistance to external forces and confer stability to visual function. To this end, he developed instruments for use through a 1-mm incision, such as the 1-mm lenticule separator (Geuder, Heidelberg), preparatory for a potential next step to even smaller incisions.

The current SMILE software, however, does not include the creation of incisions smaller than

2 mm. Nonetheless, **Sri Ganesh, MD**, chairman and managing director, Nethradhama Hospitals Pvt. Ltd., Bangalore, was able to test the possibility of performing SMILE through a 1-mm incision in one of his cases. In this exceptional case, loose conjunctiva in the patient's eye happened to prevent the completion of a full-length incision. Using the incision as a fulcrum and moving the dissector like a windshield wiper, Dr. Ganesh was able to complete the lenticule dissection. He then extracted the lenticule through the sub-1-mm incision using microforceps.

CIRCLE

Dr. Ganesh's case is illustrative of more than just the potential for "ultra minimal" invasiveness of SMILE. As **Rupal Shah, MD**, group medical director, New Vision Laser Centers – Center for Sight, Vadodara and Mumbai, put it: "Most times there is nothing that goes wrong. But sometimes, there are these 'oops' moments." As Dr. Ganesh skillfully demonstrated: "You should know how you can tackle them, so that you can give what you promise to your patients," Dr. Shah said.

One "oops" moment that refractive surgeons might still encounter owing to a number of possible circumstances is the need for retreatment—if your refraction is not what you'd aimed for, what are your retreatment options?

In these cases, you can do surface ablation, or you can perform CIRCLE, a new procedure in which the original SMILE cap is extended into a flap. This procedure requires the precision the VisuMax laser system provides: The femtosecond laser needs to cut exactly along the original plane.

Promising, but difficult to investigate. "We had difficulty in finding a patient to do this

particular procedure," Dr. Shah said. "There were hardly any patients who required retreatment."

Eventually, Dr. Shah did find one patient. In her case, after extending a 6.5-mm cap into a flap, she found the separation to be quite smooth, leaving a smooth bed to work on. **Iain Dunlop, MD**, Canberra Eye Laser, Australia, has also performed CIRCLE once in his practice. In his case, he used the CIRCLE software to extend a 7.5-mm cap into an 8.4-mm flap.

Like Dr. Shah, Dr. Dunlop finds enhancements rarely necessary with SMILE. "Generally, the enhancement rates are 3 to 5%, but with SMILE I'm finding the enhancement rates are much less," he said. "And I will enhance very readily—if people are unhappy I'll do a wee bit more."

However, Dr. Dunlop noted that coming from a large country with a small population, their experience has been with a much smaller number of cases than in other parts of the world.

In contrast, **Ekket Chansue, MD**, founder and medical director, TRSC International LASIK Center, Bangkok, has had relatively extensive experience, even with enhancements in the context of SMILE. Dr. Chansue and his colleagues have performed 73 CIRCLE cases in the last 2 years—an enhancement rate of 2.74% out of about 5,980 eyes undergoing SMILE at the time of the Asia-Pacific Refractive Laser Symposium.

However, having to perform CIRCLE has not been a problem for Dr. Chansue. In his experience, "you will find that [the subsequent incisions or patterns] connect perfectly every time," he said. "This is your 'go ahead' strategy for SMILE, and it's been working perfectly."

Dr. Chansue has followed some of his patients for 4

years, and has found SMILE outcomes stable beginning 1 day postop (Figure 1).

Continuing evolution

As SMILE proves its efficacy and safety in the ongoing U.S. FDA trials, pioneers around the world continue to evolve the procedure. Whether it's pushing the boundaries of the surgery itself by examining options such as performing it through smaller incisions or by exploring different ways to enhance outcomes as needed, SMILE, the 3rd generation of laser vision correction, is poised to ensure that patients achieve the best possible postoperative vision well into the future.

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Practice management: Being different and better

Highlighting patient experience

Practice development is all about “actually seeing through the patient’s eyes.”

Fanny O’Connor, global practice development consultant for ZEISS, spoke to refractive surgeons about practice development at the Asia-Pacific Refractive Laser Symposium.

The objective is to differentiate your practice from others in the patients’ view. Having SMILE certainly help achieve this goal. “It positions your clinic as a premium center,” Mrs. O’Connor said. “It is the cutting edge of technology.”

One of the tricks, she said, is to talk to patients “in their language.” Speaking as a layperson with limited understanding of the clinical

details, Mrs. O’Connor suggested that counselors hone in on those details that would make sense to patients: no flap means a stronger eye; SMILE is the least invasive procedure available; SMILE is a precise procedure; and there is minimal to no postop pain or discomfort.

The trick is to listen: “You don’t have to talk about all of these things, but if you’re listening to your patient during

consultation, you’ll hear their fears and be able to decide what’s right for them.”

“Always look from the patient’s point of view and wonder how you can be different and better,” Mrs. O’Connor said. “Just by the simple fact that you have SMILE, you’re already different. Now let’s become better.”

MEL 90 in the age of SMILE

The excimer laser continues to play a big role in a SMILE-based refractive practice

Having had the VisuMax femtosecond laser system (ZEISS, Jena, Germany) for the last 2 years, **Sri Ganesh, MD**, chairman and managing director, Nethradhama Hospitals Pvt. Ltd., Bangalore, said that he and his colleagues had converted their refractive practice to mostly performing SMILE surgery. Why then did they acquire a MEL 90 excimer laser (ZEISS)?

Speaking at the Asia-Pacific Refractive Laser Symposium held in Busan last November, Dr. Ganesh said he uses the excimer laser to treat patients over 40 with PRESBYOND Laser Blended Vision.

“I think there’s a whole category of patients who are not being treated,” he said. “Presbyopia is a very big market and this is something that you can cater to with the MEL 90 and PRESBYOND Laser Blended Vision.”

Dr. Ganesh thus does SMILE primarily for younger patients, but for patients

on the cusp of developing presbyopia, the VisuMax for flap creation together with the MEL 90 for Laser Blended Vision “has great potential.”

Primary characteristics of the MEL 90, Dr. Ganesh said, are its speed and accuracy. He said that the previous model, the MEL 80, had been the gold standard for ZEISS lasers.

These days, the MEL 90, the VisuMax, and the CRS-Master together provide his clinic with an excellent platform. “The MEL 90 is the latest generation excimer laser,” Dr. Ganesh said. “It’s built on the proven experience of the MEL 80, and it’s a very exciting advancement.”

The MEL excimer lasers use a flying spot laser with a Gaussian beam profile. The MEL 90 features an eye tracker that captures 1050 frames per second.

One significant difference between the MEL 90 and the MEL 80 is the FLEXIQUENCE switch function. This feature allows the surgeon to switch between 250 and 500 Hz. At 500 Hz, the MEL 90 is one of the fastest lasers available today. This setting, Dr. Ganesh said, reduces the ablation time, thereby also reducing the influence of the procedure on stromal dehydration and flap shrinkage, as well as the refractive procedure’s sensitivity to

eye movement and fixation fatigue.

The 250 Hz setting, he said, is used for gentler treatments of the surface. If you want to do surface ablation for any reason, using this lower setting avoids unwanted thermal effects.

The MEL 90 also uses an advanced profile—the Advanced Ablation Algorithm (Triple-A) profile, basically a combination of the 2 profiles used with the MEL 80, aspheric optimization (ASA) and tissue-saving (TSA) profiles.

The MEL 90 includes a component called the cone for controlled atmosphere (CCA+) unit, which maintains constant

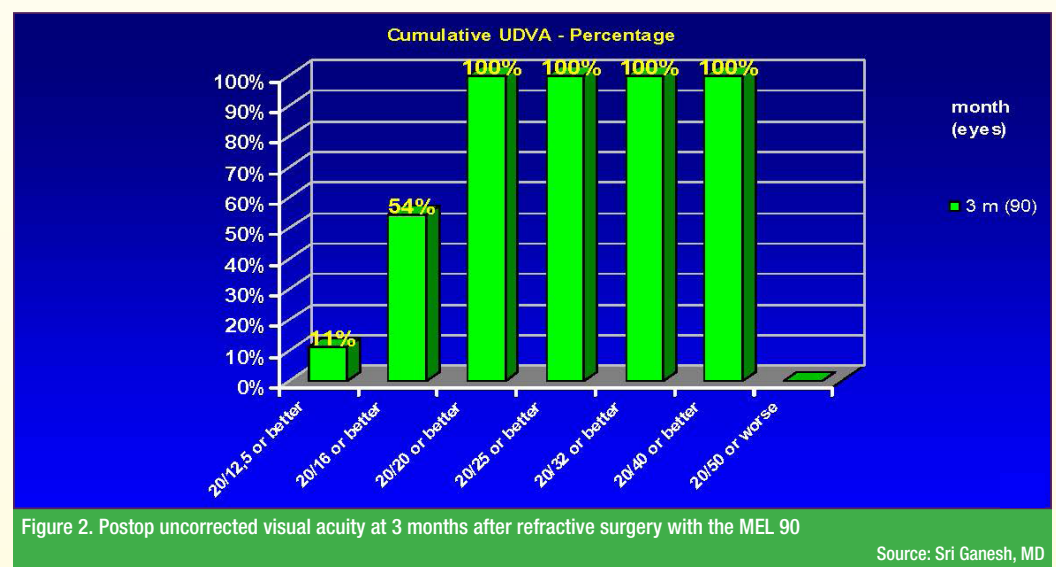


Figure 2. Postop uncorrected visual acuity at 3 months after refractive surgery with the MEL 90

Source: Sri Ganesh, MD

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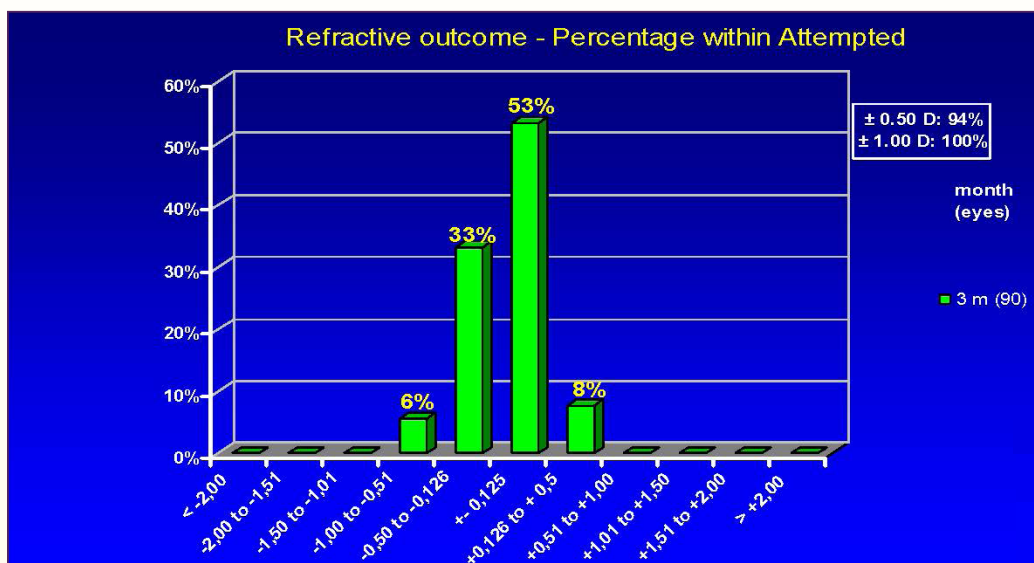


Figure 3. Predictability at 3 months

Source: Sri Ganesh, MD

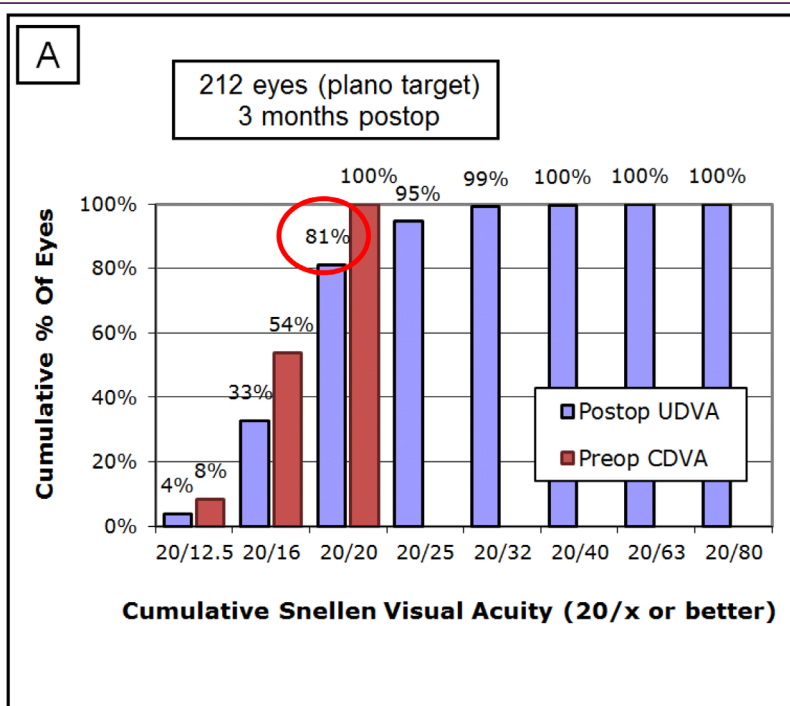


Figure 4. At 3 months, 81% of patients achieved 20/20 or better vision.

Source: Glenn Carp, MD

atmospheric conditions by automatically and intelligently adapting airflow to either 250 or 500 Hz operation modes.

Dr. Ganesh described his experience using the MEL 90. In 112 eyes of 56 patients, he and his colleagues performed alcohol-assisted PRK in 90 eyes and femto LASIK in 22 eyes; 7 patients received PRESBYOND Laser Blended Vision.

From a preop spherical equivalent of -0.50 to -3.00 D in 66.12% and -3.12 to -6.50 D in 33.87% of patients, 87.09% had residual spheres of ± 0.25 D, 6.45% had ± 0.50 D, and 6.45% had ± 0.75 D. At 3 months, 100% of patients achieved 20/20 or better and 54% achieved 20/16 or better postoperative uncorrected visual acuity (Figure 2), while 18.7% had 20/20 and

80.1% had better than 20/20 best corrected visual acuity. Predictability was excellent, with 100% of patients within 1 D and 94% within 0.5 D of attempted correction (Figure 3).

“The MEL 90 excimer laser has high safety and efficacy in treating low to moderate myopia and myopic astigmatism,” Dr. Ganesh said.

Moreover, he added, the MEL 90 integrates well with the VisuMax and CRS-Master to offer a complete platform covering all the needs of refractive patients—including presbyopia.

While Dr. Ganesh restricted his conclusions to his personal experience treating low to moderate myopia and astigmatism, **Glenn Carp, MD**, refractive surgeon, London Vision Clinic, London, presented data at the same symposium on the use of the MEL 90 in 423 hyperopic eyes of 233 patients. They attempted spherical equivalent correction of $+2.32 \pm 1.27$ D ($+0.13$ to $+6.25$ D) and cylinder correction of -0.57 ± 0.55 D (0.00 to -4.00 D).

In this cohort, 93% of patients were within 1 D of target, and 81% achieved 20/20 or better vision at 3 months (Figure 4). In terms of safety, Dr. Carp admitted that 0.9% of patients lost more than 1 line of best corrected visual acuity at 3 months; however, these losses were found to be due mostly to ocular surface pathologies such as SPK and dry eye. “We expect these to improve toward our 1-year results,” he said.

Contrast sensitivity, he added, was “absolutely fine” in this wide hyperopic range.

“I think this may be a big game changer,” Dr. Ganesh said. “It will increase the numbers you can cater to with presbyopic patients, and this is where I think the MEL 90 will play a very big role.”

Conclusion

LASIK still delivers great results and will continue to have a role in the foreseeable future. Nevertheless, SMILE is well on its way as the 3rd generation of laser vision correction, with excellent clinical results, providing great business opportunities and exciting potential for the future.