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Tomorrow's vision today: Part II Asia-Pacific Refractive Laser Symposium 2014

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The science of SMILE: dispelling myths

Using science to dispel misconceptions about SMILE and examine its future directions

In just a little over 4 years, SMILE—the refractive procedure performed with the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany)—has been performed in 200,000 procedures in more than 290 centers across 50 countries around the world, becoming the preferred procedure of some of the best and brightest minds in refractive surgery.

"In our practice, we've converted largely in terms of the myopic cases to SMILE," said **Glenn Carp, MD**, refractive surgeon, London Vision Clinic, London. Some practices, he said, are now performing the procedure in up to 85% of myopic cases.

Nevertheless, some surgeons may remain reluctant to adopt such a relatively new procedure. Much of this reluctance has to do with what used to be perceived as the procedure's disadvantages—a lot of which, Dr. Carp said, "are not really disadvantages anymore."

"In a very short space of time, we've managed to overcome many of these issues," he said.

Dispelling myths

Dr. Carp took the opportunity to dispel "myths" about the SMILE procedure in his talk at the Asia-Pacific Refractive Laser Symposium held in Busan last November.

These misconceptions include a slower recovery of visual acuity; the inability to treat high cylinder and control cyclotorsion; the limited retreatment options; the difficulty of the technique; and the inability to treat hyperopia.

Initially, Dr. Carp admitted that recovery of visual acuity "did seem to be slower" with SMILE, possibly due to some increased postop edema as revealed by retroillumination in some of his cases. However, Dr. Carp said the discrepancy was only evident in terms of recovery to 20/20 or better uncorrected distance visual acuity (UDVA, Figure 1), and the difference has become even less with improved instruments and techniques that minimize manipulation and procedure-induced trauma.

Moreover, SMILE patients caught up to LASIK patients by 1 week postop.

Other misconceptions simply aren't supported by Dr. Carp's experience and the scientific evidence.

In terms of centration, with double verification of the vertex using the first Purkinje reflex with the Hirschberg test—marked off at the consent with the patient sitting up—and then the eye image from the ATLAS 9000 topographer (Carl Zeiss Meditec), 99% of 100 consecutive SMILE patients at Dr. Carp's clinic were within 0.5 mm of the corneal vertex—no different from the LASIK control group (Figure 2).

High cylinder and cyclotorsion also have not been a problem. Dr. Carp and his colleagues have treated 316 patients with an average cylinder of –1.33±0.72 D (–0.75 to –5.75 D), and they control cyclotorsion simply by marking the eye before docking and rotating the contact glass as necessary.

In terms of retreatment, surgeons can perform a PRK on top of the SMILE, or convert the cap into a flap with a larger diameter through the CIRCLE option.

In addition to dispelling these myths, Dr. Carp said that SMILE has advantages over LASIK in terms of corneal biomechanics and the induction of spherical aberration.

"Corneal weakening occurs in the side cut in LASIK," he said. "If you do a 90-µm flap you get a 9% weakening; if you do a 160-µm flap you get a 32% weakening."

On the other hand, he said, doing away with the side cut and performing delamination only with SMILE at any depth results in just a 5% weakening. "It's the side cut in LASIK that causes most of the weakening in the cornea."

In addition, because they were able to create wider optical zones with SMILE, they induced 64% less spherical aberrations than with LASIK.

"These optical zones are powerful in limiting spherical aberration induction," he said.

Further experience

Dr. Carp's data comes from an analysis of just 100 of their SMILE eyes, but the experience from a growing number of cases around the world support his conclusions. **Wang Yan, MD, PhD**, and colleagues at the Tianjin Eye Hospital & Institute in China, for instance, had performed SMILE on 3,700 eyes at the time of the symposium, with great results.

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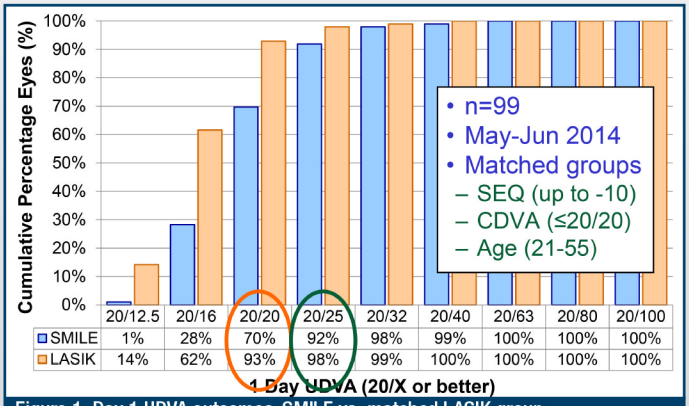

Figure 1. Day 1 UDVA outcomes, SMILE vs. matched LASIK group
Source: Glenn Carp, MD

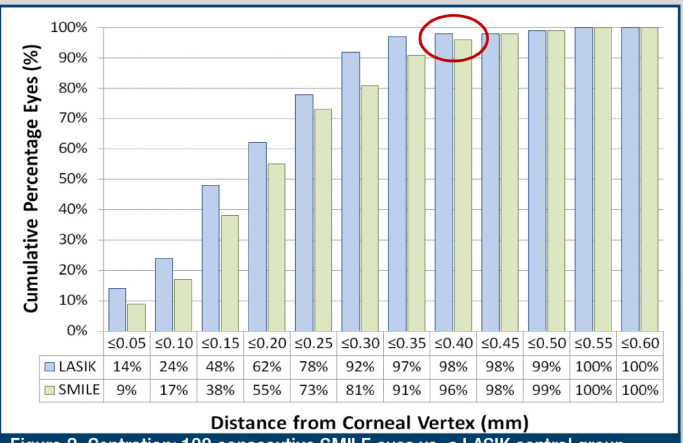

Figure 2. Centration: 100 consecutive SMILE eyes vs. a LASIK control group matched for SEQ treated
Source: Glenn Carp, MD

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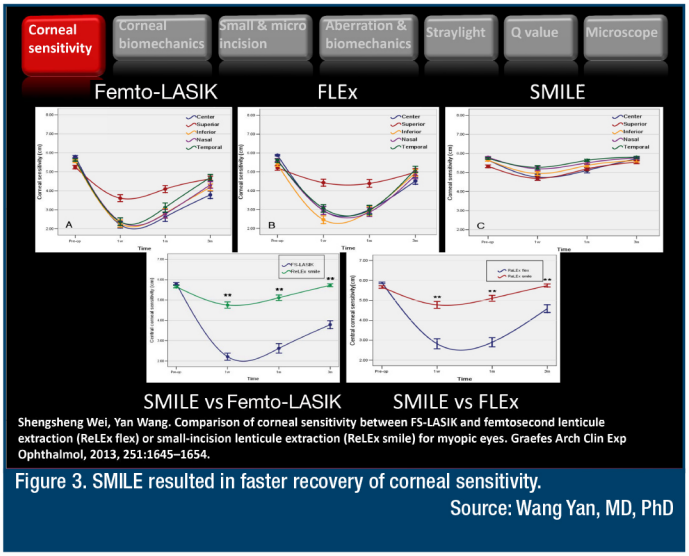

Figure 3. SMILE resulted in faster recovery of corneal sensitivity.
Source: Wang Yan, MD, PhD

In terms of safety, corrected distance visual acuity (CDVA) was unchanged in 51.56% of eyes at Dr. Wang's institute; 37.50% gained 1 line, 6.25% gained 2 lines, and 1.60% gained more than 2 lines. These results were highly predictable and remained stable with up to 3 years of follow up.

Dr. Wang also conducted research comparing SMILE with femtosecond LASIK. Her research found that because the procedure severed fewer corneal nerves than LASIK, SMILE resulted in faster recovery of corneal sensitivity (Figure 3).

She also found that while both SMILE and LASIK caused biomechanical changes, changes in corneal viscoelastic properties—corneal resistance factor (CRF) and corneal hysteresis (CH), measured using the Ocular Response Analyzer (ORA, Reichert Technologies, Depew, N.Y.)—were less after SMILE.

Elsewhere in China, **Xingtao Zhou, MD**, Department of Ophthalmology, Eye & ENT Hospital, Fudan University, and Key Lab of Myopia, Ministry of Health, had performed 8,900 SMILE procedures. In a prospective study involving 66 of their cases, Dr. Zhou evaluated optical quality by examining MTF cutoff, Strehl ratio, and intraocular scatter using the objective scatter index (OSI).

Dr. Zhou said that the MTF cutoff and Strehl ratios were not significantly different from preoperative values. Initially, OSI "significantly increased after SMILE, but decreased with time"—but always remaining within normal range.

"SMILE had minimal negative impact on patients' retinal image quality in moderate to high myopia correction," he said, concluding, "Patients with younger age and lower intraocular scattering will achieve better optical quality after SMILE."

Learning curve?

Regardless of these outcomes, newcomers may nonetheless find the idea of having to learn an additional procedure daunting. In this regard, the experience of **Kishore Pradhan, MD**, refractive surgeon, Tilganga Institute of Ophthalmology, Kathmandu, Nepal, is instructive.

Dr. Pradhan attended a 6-month refractive laser observership—without performing a single surgery—at Dr. Carp's clinic. Upon returning to Nepal, Dr. Pradhan's first case was a SMILE procedure.

"In [Dr. Pradhan's] opinion, SMILE was easier, and in fact it was hard to push him toward doing more LASIK in the beginning," Dr. Carp said. "As a beginner surgeon it was easier just to get on with SMILE."

This might not be true for every surgeon, but Dr. Pradhan's experience demonstrates that it is not necessarily as daunting as beginner surgeons might fear.

Hyperopic SMILE

Dr. Pradhan has since gone on to work on one of SMILE's remaining limitations: treating hyperopia.

To begin with, he cited the work of Prof. Marcus Blum, which revealed that increasing the transition zone resulted in better results, minimizing loss of lines and regression.[1,2]

Proceeding from this work, Dr. Pradhan and his colleagues are currently in the final phase of a 4-phase clinical trial on SMILE for hyperopia. Dr. Pradhan presented some of their results at the Asia-Pacific Refractive Laser Symposium.

Comparing the hyperopic SMILE eyes in their study with the ATLAS 9000 topographies of other excimer laser treatments, including hyperopic LASIK with the VISX (Abbott Medical Optics, Abbott Park, Ill.), hyperopic SMILE created larger optical zones than any of the other treatments, with centration that was qualitatively "at least as good, if not better" than hyperopic LASIK.

Among its advantages, Dr. Pradhan said hyperopic SMILE eliminates fluence projection errors and the risk of ablation zone truncation that can occur with LASIK if the flap is not perfectly centered.

Surgically, Dr. Pradhan said, "dissection is no more difficult than myopic cases."

The preliminary results are promising, and Dr. Pradhan is certain hyperopic SMILE will soon be a reality.

FILI for hyperopia

Rather than removing tissue, **Sri Ganesh, MD**, chairperson, managing director and medical director, Nethradhama Super Specialty Eye Hospital, Bangalore, India, has been working on adding tissue for hyperopia through a procedure called femtosecond intrastromal lenticular implantation (FILI).

"When you look at a child making a mound by the seaside and you ask the child to steepen the mound, what does he do?" he asked the audience at the Asia-Pacific Refractive Laser Symposium. "He will put more sand, and then steepen it."

This, he said, is the basic concept behind FILI. Dr. Ganesh and his colleagues conducted a prospective, non-randomized, non-comparative study in which they took cryopreserved lenticules and inserted them into their patients' corneas to treat hyperopia.

In 18 eyes of 11 patients with moderate to high hyperopia, Dr. Ganesh and his colleagues observed no adverse reactions or rejections after a mean follow-up period of 9 months.

Significantly, there was no loss of BCVA in any of the subjects. In fact, from a mean preop BCVA of 20/32, the mean postop uncorrected VA in their patients at 9 months was 20/26.

"With hyperopia and lasers, usually you have a loss of best corrected vision," Dr. Ganesh said. "Here with tissue addition you're actually having an improvement."

Compared with other options such as hyperopic LASIK and PRK, which leave corneas hyperprolate, FILI

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"maintains the prolate corneal shape, minimizes the chances of regressions and aberrations," Dr. Ganesh said. "We have not had any significant regression at almost 1 year."

Best of all, he added, the procedure is reversible.

Other horizons

Femtosecond lasers present the opportunity to explore an "entirely different horizon," said **Osama Ibrahim, MD**, professor of ophthalmology, Department of Ophthalmology, Faculty of Medicine, Alexandria University, Egypt.

Dr. Ibrahim was speaking about intracorneal ring implantation at the Asia-Pacific Refractive Laser Symposium.

While nothing new, "the real revolution happened with the introduction of the femtosecond laser," particularly with the accuracy of ZEISS optics. Femtosecond laser systems, Dr. Ibrahim said, allow surgeons to customize the diameter, width of tunnel, depth, and the size and shape of the access cut.

Intracorneal rings are indicated for keratoconus, pellucid marginal degeneration, and post-LASIK ectasia, as well as irregular astigmatism in a variety of cases, such as following PK, radial keratotomy, and even trauma.

These indications, Dr. Ibrahim said, need more investigation; nonetheless, "once the VisuMax is there you can use it for anything."

In terms of myopia treatment, SMILE is already at least as good as LASIK. When these new directions for the procedure in particular and the VisuMax laser in general become a reality for patients, the future of refractive surgery certainly looks like something refractive surgeons will want to SMILE about.

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LBV to enhance your practice

Laser Blended Vision (LBV)—available through technology provided by Carl Zeiss Meditec (Jena, Germany)—saved the practice of **Andrew Logan, MD**, Wellington Eye Centre, Wellington, New Zealand, from the global financial crisis (GFC).

Dr. Logan said that the number of refractive surgeries performed dropped off consistently since 2007 following the GFC. The number of surgeons performing at least 75 LASIK cases per month—the definition of "high volume"—dropped from 27% in 2001 to 9% in 2012.

While Dr. Logan had given up on LASIK prior to 2001—"I got disenchanted with some of the problems we had with microkeratomes," he said—he and his colleagues managed to push their numbers along with surface laser procedures right through to 2007, at which point the practice bottomed out. "We were in trouble, and if it kept on going like this I think I'd have been out of the game," he said.

In 2009, with the idea of targeting presbyopes to expand his practice, Dr. Logan made the decision to invest in a VisuMax femtosecond laser (Carl Zeiss Meditec) and on LBV, which uses the MEL 80 excimer laser, the CRS-Master, and LBV software (all Carl Zeiss Meditec).

LBV increases depth of field by adjusting spherical aberration. LBV is the latest iteration, offering customization based on a patient's accommodative amplitude.

"Lo and behold, our numbers recovered, and they have held up very well," he said. "In fact, our numbers are going up again" (Figure 4).

Since 2013, Dr. Logan has been treating patients between 40 and 72 years of age, 69% myopes, 31% hyperopes. He has treated quite significant refractive errors—dominant eyes with preoperative spherical equivalents from +3 to –11.0 D, non-dominant eyes from +4.0 to –11.25 D.

While Dr. Logan admits that his own results are not quite as good as others have achieved, he said that 98% of his patients "never wear glasses at all, and 2% have occasional wear of glasses."

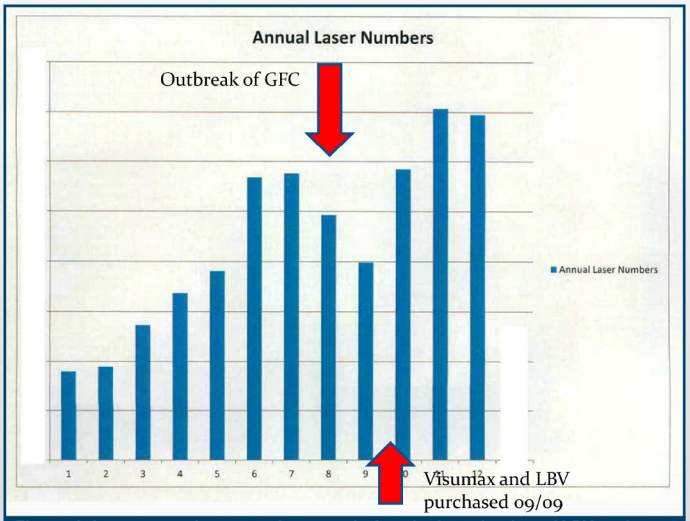

Figure 4. Laser procedure rates increased after the introduction of LBV at the Wellington Eye Centre post-GFC.

Source: Andrew Logan, MD

"I think that's pretty fantastic," he said. "If you're a 60-year-old and you're hardly ever wearing glasses, that's a pretty good outcome. Certainly patients respond to that very well."

This led to a significant number of word-of-mouth referrals. "I think it's probably what kept me in the game," Dr. Logan said. "It's been our main revenue source since the start of the GFC."

By extending a practice to include presbyopes, Dr. Logan said, LBV increases the numbers of potential laser candidates.

"There's high satisfaction rates, good visual acuity … and older patients have different financial constraints than younger patients," he added. "This can shield you a little bit from financial and economic events."

PRESBYOND LBV: Bringing spherical aberration under control

Employing spherical aberration to increase depth of field to treat presbyopia

In the young eye during accommodation, "spherical aberration is part of what happens to give you near vision," said **Patrick Versace, MD**, partner and medical director, Vision Eye Institute, Bondi Junction, Australia. "It's not just a change in refractive power in the crystalline lens."

If you have some spherical aberration with some monovision, Dr. Versace said, you will get better quality of vision than if you only had the myopia by itself.

This combination together with some pupillary miosis, he said, is the concept behind PRESBYOND Laser Blended Vision (LBV, Carl Zeiss Meditec, Jena, Germany).

According to **Glenn Carp, MD**, refractive surgeon, London Vision Clinic, London, PRESBYOND LBV "really sets the MEL 90 [excimer laser, Carl Zeiss Meditec] apart from all other lasers," providing surgeons with a way "where we can bring a lot more to our patients, bearing in mind half our patients are over the age of 45."

PRESBYOND LBV uses spherical aberration control to increase depth of field. "This is a naturally occurring aberration in the eye," Dr. Carp said, a point echoed by Dr. Versace. "It increases with age and increases during accommodation as well."

Dr. Carp explained the effect of spherical aberration on vision at the Asia-Pacific Refractive Laser Symposium in Busan last November. "If you take an eye without any spherical aberration, the object that you're looking at will be perfectly in focus, but objects in front or behind that will be completely out of focus," he said. "As you dial in some spherical aberration, you then slowly degrade your primary objective gaze—but only by a very small amount—and you greatly enhance the objects in front and behind."

In other words, dialing in some spherical aberration increases the depth of field.

"In practical terms, if you have a patient set to a –1.50 D reading boost and you dial in some spherical aberration, at the same time you know the pupil mioses during accommodation … you also in the process enhance the image quality," he said. "You get a far greater resolution of the image compared to an unspherically aberrated eye."

Central neural processing—neuroadaptation—then "cleans up" the image.

With PRESBYOND, spherical aberration is "dialed in" on top of micromonovision. The dominant eye is targeted for distance while the non-dominant eye is brought to a slightly myopic "reading position" of –1.50 D. The overlap is the "blend zone"—hence "blended vision" PRESBYOND.

Induced spherical aberration, however, is "a double-edged sword," said **Beom-Jin Cho, MD**, HanGil Eye Hospital, Incheon, South Korea. While depth of field increases, he said, visual quality decreases.

The limit of spherical aberration beyond which visual quality is affected is about 0.56 μm, he said.

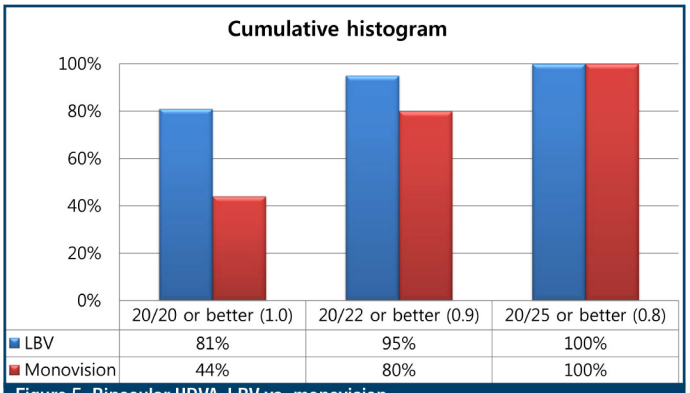

Figure 5. Binocular UDVA, LBV vs. monovision

Source: Beom-Jin Cho, MD

In PRESBYOND LBV, spherical aberration is induced using a proprietary non-linear aspheric ablation profile. The profile modulates the induction of spherical aberration to increase depth of field without affecting contrast sensitivity and quality of vision.

Dr. Cho compared LBV with monovision alone.

In his study, patients 40 to 50 years old with myopic presbyopia and a strong motivation to take off their glasses were included. CDVA in these patients was no worse than 20/25 in either eye.

In the LBV group (n=21), the near eye was targeted to –1.0 to –2.25 D; flaps were made with the VisuMax femtosecond laser, with a thickness of 100 μm and an optical zone of 6.5 mm; the MEL-90 with CRS master programming (Carl Zeiss Meditec) was used to perform LBV.

In the monovision group (n=25), the near add was smaller at –0.85 to –1.25 D because these patients were significantly younger (41.68±1.93 years vs. 47.90±4.72 years in the LBV group). Dr. Cho performed LASIK and LASEK on his monovision patients using the WaveLight EX500 excimer laser (Alcon, Fort Worth, Texas), with or without the VisuMax.

Bearing in mind these differences, Dr. Cho said that monocular visual acuity was comparable between the 2 groups. However, in terms of binocular uncorrected distance visual acuity (UDVA), 81% of patients achieved 20/20 or better with LBV, while only 44% achieved 20/20 or better with monovision (Figure 5).

Meanwhile, in terms of safety, no patients in either group lost any lines of vision, and no patient had to undergo enhancement or retreatment.

In a survey of his LBV patients, Dr. Cho found that patients had high acceptance and tolerance of the procedure. He added that these patients had similar visual acuities to patients in the monovision group despite older age and higher levels of anisometropia.

Accepting the limitations of his study, Dr. Cho hypothesized that LBV has better results than monovision in better matched populations.

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