

Success with Zeiss refractive innovations

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SMILE, the ultimate goal of refractive medical services

Feng Jun, MD

Feng Jun, MD, Singapore—who according to session moderator **Detlev R.H. Breyer, MD**, successfully developed the Aier Eye Hospital Group—considers small incision lenticule extraction (SMILE) “the ultimate goal of refractive medical services.”

Dr. Feng has been engaged for 13 years in the management of refractive medical services. This experience has given her a deep understanding of the fact that patient satisfaction is the most important thing for such services to provide. She has a firm conviction in the Mayo spirit, the “best overall management in the world”: *Always insist on the needs of patients, give sincere and unique attention to every patient's health and happiness.*

The question is, how can a clinic or hospital achieve this?

History

Founded in 2002, the Aier Eye Hospital Group currently consists of 174 hospitals covering mainland China, Hong Kong, and the United States. It is the Group's privilege to be the only listed medical institution in China.

Over its 15 years of existence to the time of the Zeiss user meeting, the Group had accomplished 1,500,000 cases, making it the largest ophthalmic institution in China. At the time, the Group had 17 VisuMax laser systems (Zeiss), which were used to perform 58,000 SMILE surgeries—the highest number of SMILE surgeries by a single institution at the time. The Group

had performed the most ICL surgeries in the world, 24,000 cases.

The refractive surgery service had grown into the largest business of the entire Group. At the same time, the Group's management evolved to become more efficient as its patient base grew.

Patient needs

This rapid development wasn't simply about increasing the number of surgeries performed; it was also about enhancing patient experience and, ultimately, satisfaction.

The Group found that most patients were focused on concerns regarding the safety of the operation, the treatment experience, and the information available on the surgery. This is why the Group places extensive efforts on the treatment experience and implementing patient education.

Enter SMILE

Over the previous 4 years predating the user meeting, the Group had achieved rapid growth, due to the introduction of SMILE in 2013. Initially acquiring five VisuMax devices, they would acquire 24 more over those 4 years for a total of 29 devices in 2016. Over the same period, the volume of SMILE surgeries performed by the group grew 57 times, from 640 eyes in 2013 to 36,484 eyes in 2016.

This growth isn't only due to the growing acceptance of SMILE among the Group's surgeons, but also to patients coming to recognize the procedure.

Relentless pursuit

Growth, however, comes from the relentless pursuit of technology and progress. In order to ensure that patients enjoy consistent, optimal results from the procedure, the Group enhanced their technical force through training, teaching, and assessment; communication and expert collaboration; and consistent postoperative follow-up.

On one hand, the Group optimized the training process and established a specialist group. On the other, they organized technical exchange meetings with Zeiss.

In 2017, the Group established the VisuMax Clinical Correlation base at Aier Guangzhou Hospital to further ensure the quality and safety of each medical team so that they can perform SMILE.

The “secret”

Some people ask, how has the Group become so successful with SMILE surgery? The secret, the Group has found, is patient education. Whether a patient understands the value of the SMILE procedure or not is very important.

Over the years, the Group communicated the value of SMILE surgery to patients all over China through patient education activities, providing patients with all the information they need through lectures given by experts.

This strategy gave and continues to give the Group's patients confidence in the procedure, reducing fear and misunderstanding.

The patients' trust and choice are precious, so every member

of the Group's medical teams providing SMILE—the surgeons, the technical and support staff—is careful to make every patient feel good. The Group emphasizes teamwork involving the entire refractive center, including not just the doctors, surgeons, and nurses, but also the technical, service, and even marketing staff.

According to Dr. Feng, reputation can only be won through diligence, full value chain management including ensuring the quality of the techniques and devices used for the procedure and the procedure itself, as well as attentive communication pre- and postoperatively. Every member of the staff is carefully trained and patients feel that the value of SMILE surgery matches the cost.

5 minutes to a lifetime

As their practice grows, members of the Group constantly remind themselves that while SMILE for the surgeon is a 5-minute procedure, it is a lifelong experience for patients. Their patients, in essence, are giving the Group staff their lives.

The procedure is called SMILE not just because the incision resembles a smile, but also because the ultimate goal of the Aier Group, as made possible by the refractive innovation that is SMILE surgery, is to provide patients with a lifelong feeling of satisfaction.

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 fourth symposium of the meeting, moderated by Detlev R.H. Breyer, MD, Duesseldorf, Germany, focused on the practical, practice-related aspects of using Zeiss's innovative refractive technology in the clinic not just to maximize benefit to individual patients, but also to ensure that clinics are able to sustainably provide consistent quality eye care to all patients while allowing practices—encompassing ophthalmologists and all members of their staff—to grow and further expand their services to include a wider range of cases.

ReLEx: SMILE your LASIK troubles away

Detlev R.H. Breyer, MD

As headlines go, saying “SMILE your LASIK troubles away,” admitted **Detlev R.H. Breyer, MD**, Duesseldorf, Germany, is “a little bit provocative.” After all, he said, LASIK is categorically a good procedure, with a proven long-standing overall safety and efficacy track record.

However, he continued, the procedure does risk some complications. At last year’s Zeiss user meeting, Dr. Breyer used the headline as the title of his talk, focusing on the significance of these complications particularly in terms of building and sustaining a refractive surgery practice.

Facts and perspectives

Dr. Breyer detailed the decision making process patients go through when choosing products and services in medicine. He listed four key facts influencing the process.

Fact 1: Word of mouth is #1. This is mainly how refractive surgery practices sell their services to patients.

Fact 2: All refractive patients use the internet. They are very modern, very creative.

Fact 3: Refractive patients love to read blogs. This is an important source for them to learn about the experiences of other patients.

Fact 4: Felt—i.e., perceived—safety is independent of facts. For in-

stance, ophthalmologists know that prolonged contact lens wear does more damage to the cornea than laser vision correction. However, patients simply do not have this perception. They have no idea that contact lens wear causes damage to the cornea comparable to what they mistakenly think results from LASIK; if they did, Dr. Breyer argued, ophthalmic surgeons and clinics should be doing more laser vision correction than current statistics show—it would not make sense that LASIK numbers are not going up.

The problem then is not the reality regarding laser refractive correction, but the perception patients have of this reality.

The internet: Door to perception

Over the last decade, the perception of the safety of laser refractive surgery has been compromised by bad press, with patients who have had bad experiences, bloggers, and media outlets looking for readers and website hits feeding patients’ fears by spreading accounts of alleged complications online—after all, there’s nothing more captivating than fear. This material, unfortunately, is already out there, and the current generation of patients love to get informed on the internet.

In addition, the internet review culture has given patients more defined criteria for evaluating doctors;

they judge their doctors not just in terms of the treatment, but in terms of how well their doctors educate them on their condition, how trustworthy their doctors seem to be, how much time they take to see their patients, and how friendly they are, on top of the general performance of their practice, including waiting times and staff behavior.

Against this onslaught, doctors must have failed to build trust and reassure patients because despite being one of the safest surgical procedures available with modern medicine today, LASIK rates around the world dropped.

Lowering costs: How not to rebuild trust

Trust is built on credibility, but if patients keep seeing pictures of complications online and reading about complaints and complications, then trust is a problem. Despite the factual safety of the procedure, the patients are unable to realize it; they do not feel safe, and in the minds of patients, safety is much more important than cost.

Yet, when LASIK numbers went down around the world, the response of some practices was to lower the cost of the procedure to try to entice patients back into clinics.

According to Dr. Breyer, this only further damaged patients’ trust. Rather than addressing their concerns over safety, informing and educating them about the

potential for complications, in their minds lowering the cost of the procedure constituted an admission of guilt. Practices were admitting, in essence, that the procedure was not worth the original price they put to it.

Thus, rates continued to go down, and practices continued to lower costs—a vicious cycle leading to the failure of practices to rebuild trust, and ultimately the damaged reputation of LASIK.

SMILE to rebuild trust

How can practices rebuild trust? Dr. Breyer thinks turning to SMILE is one answer. There are enough facts, he said, supporting the safety of SMILE and showing favorably comparable results to LASIK published in peer-reviewed journals. Referring to prior talks at the meeting, Dr. Breyer spoke about SMILE’s record of providing high safety with no flap-related complications or restrictions to activity, very few induced higher order aberrations, high refractive stability, little to no intra- and postoperative pain, and less dry eye.

Sharing these facts on their webpages, practices can educate patients on the safety of the procedure.

“Better is the enemy of the good,” Dr. Breyer said, quoting Voltaire. Dr. Breyer, for one, is convinced that SMILE is a little bit better than LASIK.

The MEL 90: Outcomes for the full range of ametropia from high myopia to high hyperopia

Glenn Carp, MD

Looking at all the innovations in refractive surgery today, **Glenn Carp, MD**, London, U.K., said the MEL 90 (Zeiss) represents a great workhorse for refractive surgery practices. While SMILE continues to make leaps and bounds, the excimer laser can still help refractive surgeons with much of their work.

At their practice, Dr. Carp and his colleagues have published the entire range of their treatments using the excimer laser—from just over –14 D of myopia to around +7 D of hyperopia (off-label use).

Focusing on the extreme ends of their range, Dr. Carp went through some approaches to treating high myopia and high hyperopia. This range, he said, illustrates that the platform remains

robust, and with modern profiles practices can similarly expand their range using just the excimer laser, provided there’s enough tissue in the cornea.

LASIK for high myopia

In terms of high myopia, Dr. Carp discussed their published results on 479 eyes treated with an aspherically optimized ablation profile, with flap creation using the

VisuMax femtosecond laser (Zeiss) or the Hansatome microkeratome (Bausch + Lomb, Bridgewater, New Jersey) and 2 years of follow-up.¹

For safety, 16% of the cases were performed as planned two stage procedures. The enhancement rate was 16% for the non-two stage group.

Dr. Carp noted that in these cases, the VisuMax femtosecond

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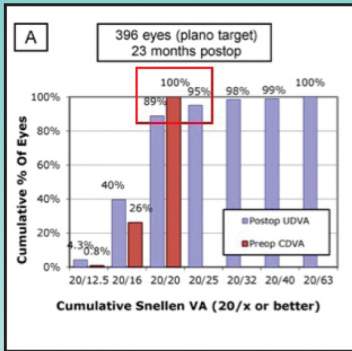


Figure 1. High myopia treatment: Efficacy

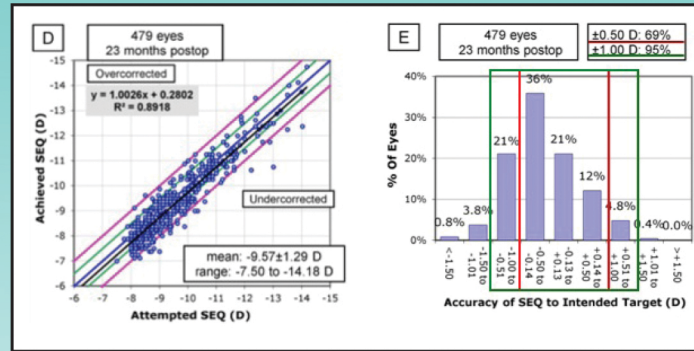


Figure 2. High myopia treatment: Accuracy

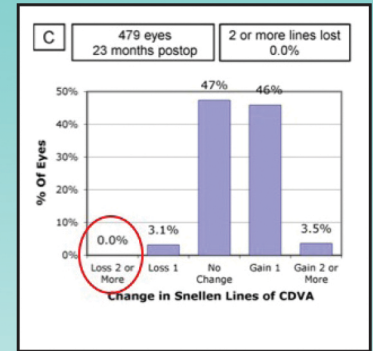


Figure 3. High myopia treatment: Safety by CDVA

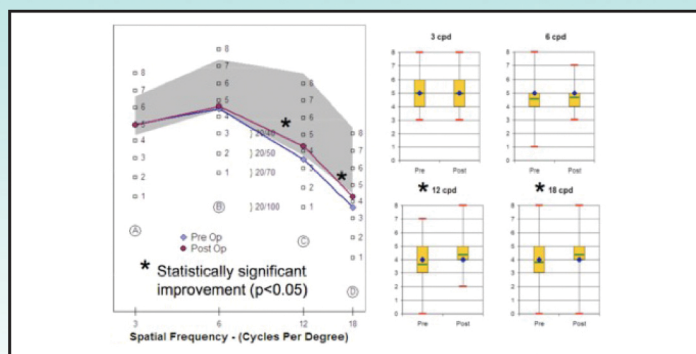


Figure 4. High myopia treatment: Contrast sensitivity

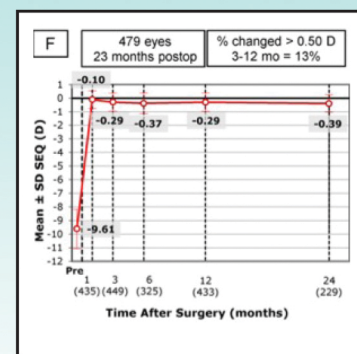


Figure 5. High myopia treatment: Spherical equivalent refraction stability

laser provided an advantage over the microkeratome by improving flap thickness reproducibility, with a standard deviation of only 4.4 μm . Moreover, the femtosecond laser allowed the creation of thinner flaps of around 80 μm , further extending the range of myopia correction possible with LASIK.

In terms of efficacy measured by uncorrected distance visual acuity (UDVA), 95% of eyes were at 20/25 or better, 89% at 20/20 or better, and 40% at 20/16 or better at 23 months of follow-up (Figure 1)—quite impressive, Dr. Carp said, for correction of such high levels of myopia.

In terms of accuracy, 75% were within 0.5 D and 95% within 1 D of targeted spherical equivalent refraction (Figure 2), though these results include enhancements.

In terms of safety, it turns out, Dr. Carp said, it is very safe; no eyes lost two or more lines of corrected distance visual acuity (CDVA), only 3.1% lost one line, 47% were unchanged, and 46% gained one line (Figure 3).

Contrast sensitivity was maintained, with a statistically significant improvement ($p < 0.05$, Figure 4).

Even though you are treating high myopia where you would expect to generate a lot of spherical aberration, this can be controlled using modern aspheric profiles.

Results remained stable up to 2 years, with little change after the first 3 months (Figure 5).

LASIK for high hyperopia

High hyperopic corrections of +4.0 D or more (off-label use) are an altogether different matter. There is a lot more that the surgeon needs to be aware of when treating these cases.

Dr. Carp once again referred to one of their published studies, this one evaluating outcomes of high hyperopic treatments using the Zeiss excimer laser.² In this study, 785 eyes of 644 patients with a mean hyperopia of $+5.19 \pm 0.99$ D (+4.00 to +9.00 D), cylinder of -1.05 ± 0.86 D (0.00 to -5.25 D), and preoperative CDVA of 20/20 or better were followed up for 1 to 2 years.

The cases were divided between two surgeons, Dr. Carp and his co-author **Dan Reinstein, MD**. They used optical zones of 6.50–7.00 mm, preferring the larger optical zones when possible for optimum stability; created 160- μm flaps when using the Hansatome microtome (38%), 90–120- μm flaps when using the VisuMax femtosecond laser (62%); and performed flap and ablation centered as closely as possible on the coaxially sighted corneal light reflex.

Their primary procedure was intentionally undercorrected if either the predicted postop K was more than 50 D or the laser data entry was more than +6.50 D. Patients were offered enhancements if found suitable based on epithelial and residual stromal thickness maps. They also had the option of using topography-guided custom ablations if centration was an issue.

Some treatments were done as planned two stage procedures (20%) to avoid apical syndrome, which occurs when the epithelium becomes too thin at the center

of the cone and begins to break down.

Ks vs. maps

One thing Dr. Carp and his colleagues discovered is that while most surgeons go by keratometry readings, simply avoiding hyperopic treatments for cases with keratometry readings of 50 D or more, epithelial thickness maps are more reliable. They found that there is little correlation between the epithelial thickness in the center, where the cornea gets thinner, and the keratometry readings—a patient can have a flat cornea with a thin epithelium unsuitable for further steepening or a steep cornea with a thick epithelium perfectly capable of undergoing further enhancement.

In addition, the residual stromal thickness will no longer be thinnest at the center in eyes that have undergone myopic treatments, requiring a map to identify the thinnest point. Mapping the epithelium thus allows the surgeon

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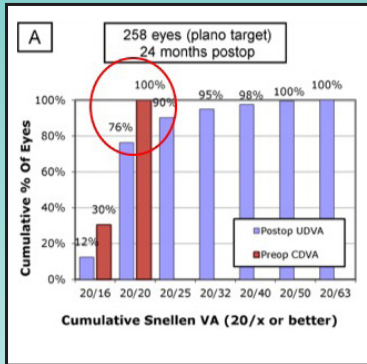


Figure 6. High hyperopia treatment: Monocular efficacy

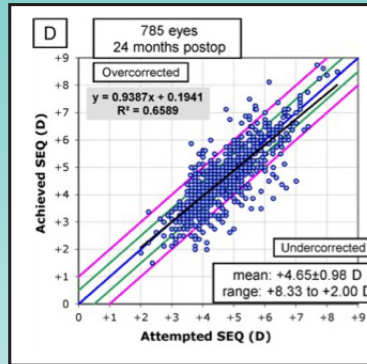


Figure 7. High hyperopia treatment: Accuracy

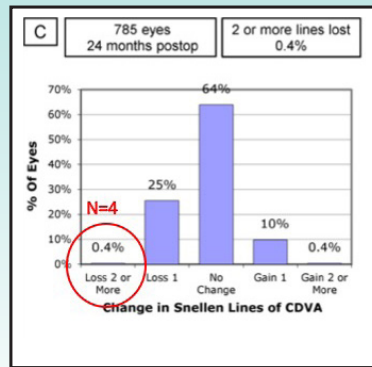
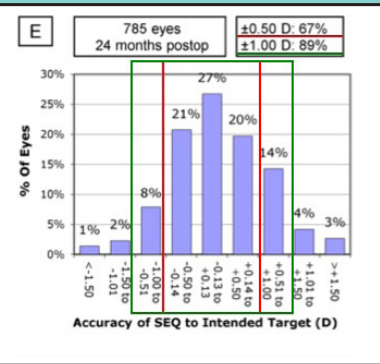


Figure 8. High hyperopia treatment: Safety by CDVA

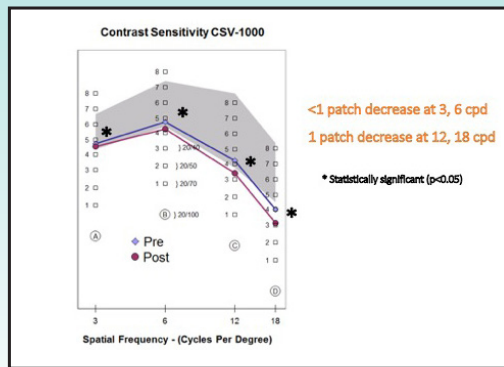


Figure 9. High hyperopia treatment: Contrast sensitivity

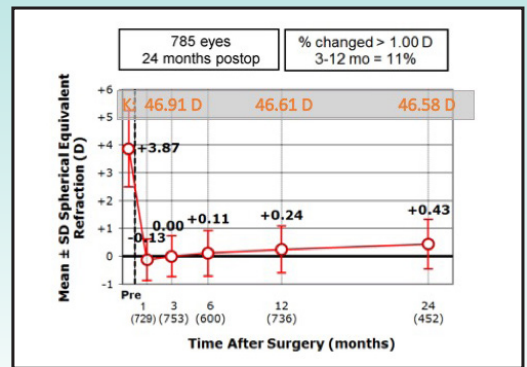


Figure 10. High hyperopia treatment: Stability

to match eyes with the intended ablation profile.

Complications

As expected, patients experienced dry eye after surgery, actively managed on average up to 18 months, with most patients achieving comfort without artificial tears by 6 months.

A significant complication seen in three eyes of two patients was diurnal refractive fluctuation, which remained at 2 years. This is a new rare phenomenon following hyperopic LASIK, diurnal fluctuations in refractive error due to diurnal epithelial thickness profile fluctuations. The patients would wake up in the morning with refractive errors at around +2 D, going back to plano as the day

progressed. In these cases, Dr. Carp said the logical solution would be to flatten the corneas, which are likely too steep to hold the target refraction.

Interestingly, the patients opted not to have their corneas flattened, instead compensating for the fluctuations by wearing glasses in the morning; they were able to function without them the rest of the day.

Hyperopia treatment outcomes

In terms of efficacy, 90% of eyes achieved 20/25 or better and 76% of eyes achieved 20/20 or better UDVA (Figure 6).

In terms of accuracy, 67% of eyes were within 0.5 D and 89% within 1 D of target (Figure 7).

In terms of safety, 0.4% (four eyes) lost two or more lines, 25% lost one line, 64% were unchanged, 10% gained one line, and 0.4% gained two or more lines of CDVA (Figure 8).

There was some non-clinically significant loss in contrast sensitivity (Figure 9).

Most change (11%) happened from 3 to 12 months, with results remaining stable thereafter to 2 years (Figure 10).

Based on their results, Dr. Carp concluded that LASIK using modern ablation profiles and their technique with large optical zones and centering on the coaxially sighted corneal light reflex for hyperopia up to +8.0 D (off-label use) can be performed with good safety, efficacy, and stability up to 2 years.

A small amount of refractive progression of about +0.19 D is seen between 1 and 2 years. Accuracy in their study was similar or better than with intraocular lenses, while avoiding potentially catastrophic complications associated with intraocular surgery.

References

1. Reinstein DZ, et al. Long-term visual and refractive outcomes after LASIK for high myopia and astigmatism from -8.00 to -14.25 D. *J Refract Surg.* 2016;32:290-7.
2. Reinstein DZ, et al. LASIK for the correction of high hyperopic astigmatism with epithelial thickness monitoring. *J Refract Surg.* 2017;33:314-321.