Treating Hyperopia with SMILE: A clinical study

By Walter Sekundo, MD, PhD

The overall prevalence of hyperopia in the European population is estimated at approximately 35% and is higher among middle to older age adults compared to their younger counterparts.[1] For hyperopes seeking refractive surgery, LASIK is more likely to be considered for younger individuals than a more invasive lens exchange or phakic IOL procedure. Despite advances in techniques and technology, however, efficacy, safety, predictability, and stability outcomes with hyperopic LASIK fall short of those achieved with myopic LASIK.[2]

SMILE has advantages compared with LASIK, including less risk for postoperative dry eye and avoidance of LASIK flap-related complications.[3] While the development of SMILE for hyperopia has faced challenges, modifications in the lenticule profile, optical and transition zone sizes, nomograms, and laser energy settings led to improved outcomes as reported in studies conducted at my center and in Nepal.[4,5]

The promising results achieved with these refinements supported the initiation of an international multicenter registration trial for SMILE to treat hyperopia and hyperopic astigmatism using the VisuMax femtosecond laser (Carl Zeiss Meditec AG; Jena, Germany). The final report from the study, which demonstrates efficacy, safety, and predictability of the procedure, is currently undergoing regulatory review. Hopefully, approval of the hyperopic SMILE is on the near horizon. Meanwhile, engineers at ZEISS Medical Technology guided by customer input were redesigning the company's femtosecond laser. Introduced in September 2021, the new VISUMAX 800 is a significant advance in many ways that include particular benefits for performing hyperopic SMILE* treatments.

SMILE FOR HYPEROPIA during clinical trials:

I was one of eight principal investigators in the hyperopic SMILE study and have the honor of being its coordinating investigator. The final analysis includes data from 374 eyes of 199 patients enrolled at centers in Europe, China, and India.

Eligible patients had up to 6.00 D of hyperopia and 5.00 D of cylinder, a predicted postoperative keratometry ≤51.0 D, and CDVA 20/25 or better in the treated eye(s). The study participants represented a heterogeneous population with respect to age and refractive error. Mean spherical equivalent for the study eyes was +3.20 ± 1.48 D with a range from +0.25 to +6.50 D.

Using fairly low energy (of 25 to 27 nJ and 4.5µm spot/track distance), the VisuMax femtosecond laser was programmed as follows: 8.8 to 8.89 mm diameter cap with a thickness of 120 µm, 25 µm central lenticule thickness, 6.3 mm optical zone, 2 mm transition zone, and a 2 to 4 mm incision for lenticule removal.

The efficacy and safety results were good and equal to or better than those achieved in recent studies of hyperopic LASIK.[6,7] Importantly, serial data from planned follow-up visits showed the refractive and visual outcomes of hyperopic SMILE were stable between 3 and 12 months.

CASE HISTORY

More details of the results from the hyperopic SMILE registration trial are forthcoming. The following case describing one of my patients highlights the efficacy and safety of the procedure.

The patient was my operating room head nurse – a 58-year-old woman who decided she no longer wanted to wear glasses for near vision. She was a low hyperope with minimal astigmatism, and while assisting me during a hyperopia SMILE treatment, she asked me if she could be treated as well. Having assisted during thousands of SMILE cases, she was very familiar with the procedure, and she fulfilled all inclusion criteria. I treated her in 2019, and the procedure was planned to provide micro-monovision with targets determined through testing with Reinstein's PRESBYOND testing protocol.

Parameter	Preop	Postop	Target refraction
OD refraction	+1.25 -0.5@85°	-1.0 -0.75@50°	-1.0 D
OD CDVA/UCVA	1.25/0.8	1.25/0.32	
OS refraction	+0.75 -0.25@5°	-0.5 -0.5@100°	-0.75 D
OS CDVA/UCVA	1.25/0.8	1.0/0.8	
Binocular UNVA		0.8	

Table 1. Preoperative and 12 months postoperative data

As shown in Table 1, the patient's refractive and visual outcomes were excellent, and she achieved her goal for glasses-free vision.

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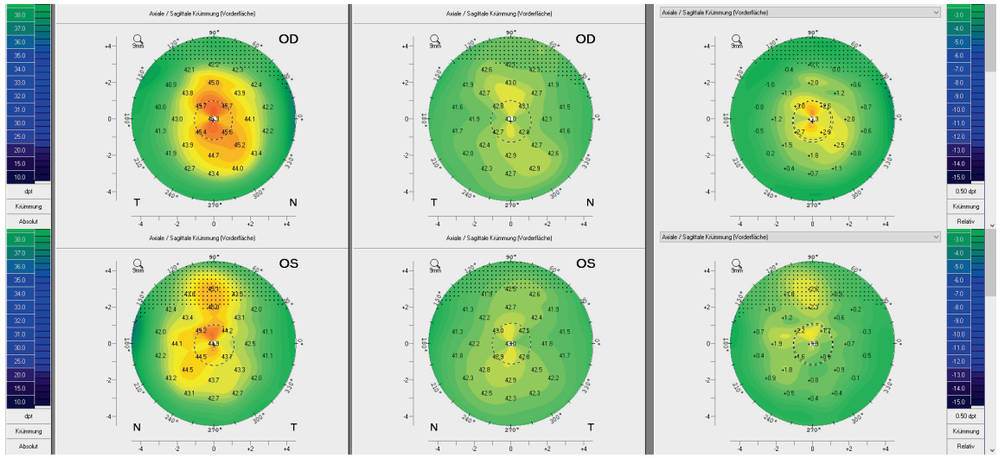

Figure 1. Postoperative (left), preoperative (middle), and differential (right) topography maps for right (OD) and left (OS) eye.

Figure 1 displays the patient's preoperative, postoperative, and differential topography maps that show excellent centration and steepening of the central cornea after the surgery. Furthermore, the patient was extremely happy with her outcome. She reported not needing to wear glasses for distance or near and was somewhat amazed when she found herself capable of threading a 10-0 nylon suture without her glasses. Remarkable to me as well was her ability to assist in the OR without glasses even in the lower light setting of a vitrectomy procedure.

SMILE FOR HYPEROPIA with VISUMAX 800* – overcoming the challenges

While positive results were achieved in the hyperopic SMILE study, the procedure still has some challenges. Accurate centration is important for any refractive surgery procedure and is especially critical for hyperopic treatments. In addition, the technique requires creation of a large lenticule so that use of the M-contact glass is mandatory. However, hyperopes tend to have smaller eyes, and with a laser treatment time of 35 seconds, there is increased potential for suction loss during the procedure. In fact, the rate of suction loss in the multicenter trial was 1.34%. The VISUMAX 800 addresses these issues and brings additional safety.

The possibility for suction loss can be expected to decrease with the VISUMAX 800 because it is 3 times faster than the current VisuMax and completes the SMILE hyperopia protocol in just 12 seconds**. The shorter procedure time reduces stress for the patient and surgeon alike. Moreover, with the new patented computer-assisted centration function (CentraLign®) achieving a perfect centration is no longer an art. It becomes a science. We know that centration of an eye might slightly differ depending on the pupil size (photopic versus scotopic). OcuLign®, a new function featuring in VISUMAX 800 enables cyclotorsion adjustment which is done through digital rotation of the cutting pattern, adding value for astigmatic corrections. And while acquiring images for the cyclotorsion adjustment system, the surgeon can even choose the illumination level in order to define the perfect centration mark.

As other benefits, the VISUMAX 800 femtosecond laser is a mobile device and has a much smaller footprint than the VisuMax. It features two screens – one used for data management and the other that can be used to observe the surgery. The data management screen has a very user-friendly interface, and the heads-up display of the second screen offers better ergonomics for the surgeon and the opportunity for the surgical nurse to visualize the procedure. The VISUMAX 800 is still equipped with an optical infinite resolution microscope. The VISUMAX 800 was also designed for improved workflow efficiency. It is integrated with other devices and software platforms through the DICOM-based FORUM system as central archive. Because data management and treatment planning are centralized, treatment planning can be conveniently done outside the OR using Refractive Workplace (Carl Zeiss Meditec AG)*** and then seamlessly sent to FORUM for transfer to the laser.

CONCLUSION

SMILE for hyperopia and hyperopic astigmatism has become truly feasible. As soon as the procedure receives regulatory approval, it is expected that the hyperopic SMILE module will be released for the VISUMAX 800. This state-of-the art femtosecond laser not only brings benefits that are especially suited to achieve good results with hyperopic SMILE, but its features make it a valuable addition for any surgeon performing corneal laser vision correction procedures.

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* Hyperopic SMILE is currently undergoing regulatory review and is expected to receive the CE mark in 2022.
** The laser time is calculated from the time the footswitch is pressed. If calculated from the time the laser shots are applied, lenticule creation (optical zone of 6.5 mm and smaller) takes less than 10 seconds.
*** CE certification for Refractive Workplace planned in 2022