

SMILE FOR CORRECTING MYOPIA WITH ASTIGMATISM

Enhancing the premium refractive procedure with the VISUMAX 800, the new evolution femtosecond laser

By Rainer Wiltfang, MD

I began performing laser vision refractive surgery in 1993. In 2007, I joined the ZEISS scientific advisory board and became involved with the development of Lenticule Extraction technique using femtosecond laser technology to correct myopia with and without astigmatism. The technique became commercially available in 2011 when ZEISS launched its SMILE software to perform lenticule extraction with the VisuMax femtosecond laser (Carl Zeiss Meditec AG; Jena, Germany). Since then, Lenticule Extraction with SMILE has become an established procedure in the refractive surgery community. To date, more than 4 million eyes have been treated with SMILE, and comprehensive data showing positive results have been reported in over 700 peer-reviewed publications. The literature includes long-term outcomes from follow-up to 10 years as well as comparisons with other refractive laser techniques. A recent meta-analysis found the safety, efficacy, and predictability of SMILE for myopia correction were similar to femtosecond laser-LASIK.¹

Considering its outcomes and because of its benefits, SMILE now accounts for nearly 90% of my myopic refractive laser surgeries.

THE NEW VISUMAX 800

Recently, in September, 2021, ZEISS introduced the new VISUMAX 800 femtosecond laser (Figure 1). The developers spent almost 5 years to thoughtfully design the new evolution femtosecond laser - the VISUMAX. The knowledgeable input of corneal refractive surgeons and learnings from 10 years of experience with SMILE were applied to optimize the performance of the new laser. The result is an updated and upgraded system that brings benefits for surgeons, surgical staff, and patients. In a nutshell, the VISUMAX 800 incorporates a faster laser source, which enables the user to cut a complete lenticule in approximately 10 seconds.² The VISUMAX 800 also features computer-assisted centration as well as cyclotorsion adjustment by digital rotation of the cutting pattern.

In addition, the VISUMAX 800 is physically a completely new device. As compared to the former VisuMax, the new laser has a smaller footprint and therefore needs less space in the operating room. The VISUMAX 800 is also mobile and can be relocated according to



Figure 1. ZEISS VISUMAX 800

the needs of the center. Furthermore, all moving parts have been incorporated into the laser itself instead of the patient bed. Therefore, various patient beds can be used with the VISUMAX 800. The VISUMAX 800 is equipped with a slit lamp and two screens. One screen is used for data management before surgery and can also be used by the OR assistant to observe the surgery. While the other screen, provides comprehensive visualization during docking and throughout the surgery and thereby ensures ergonomic comfort for the surgeon.

Additionally, the VISUMAX 800 is fully integrated into the refractive workflow. The femtosecond laser is connected via FORUM with other devices and with software platforms. Data management and treatment planning are now centralized at one place. Treatment planning can be done outside the OR with Refractive Workplace (Carl Zeiss Meditec AG; Jena, Germany) and sent via a click to FORUM and from there to the particular laser.

EARLY CLINICAL EXPERIENCE

In the first 3 months after the VISUMAX 800 was installed at my center, I used it to perform nearly 250 Lenticule Extraction procedures with SMILE pro. Feedback about the intuitive data entry process from the surgical personnel who are responsible for this task has been extremely positive. The speed of the laser was remarkable. Whereas it took almost 30 seconds to cre-

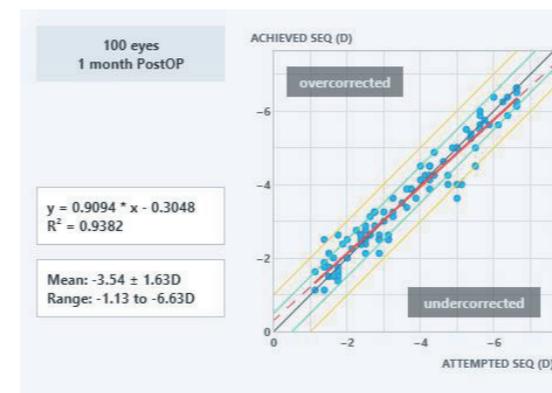


Figure 2. Scattergram showing the attempted versus achieved SEQ.

ate a lenticule using the first generation VisuMax, the cutting procedure with the VISUMAX 800 is done in just 10 seconds.² That means the critical time when the eye is under suction is now significantly shorter.

I was already highly satisfied with the results I was achieving using the former VisuMax. Without any changes made to my existing nomogram, outcomes of patients treated with the VISUMAX 800 have been excellent and as expected with proven SMILE technology.

Our analysis of data from follow-up of 1 month for our first 100 eyes gave us following results: The mean attempted spherical equivalent (SEQ) was -3.54 ± 1.63 D (range -1.13 to -6.63 D) (Figure 2). 89% of the eyes had a refractive outcome within ± 0.5 D of the attempted target and 97% were within ± 1.0 D of the targeted refraction. The postoperative astigmatism magnitude was ≤ 0.50 D in 95.0% of eyes and ≤ 1.00 D in all eyes.

Further analysis of 63 eyes targeted for plano, UDVA³ was $\geq 20/25$ in 90%, $\geq 20/20$ in 78%, and $\geq 20/16$ in 46% of the eyes (Figure 3).

CONCLUSION

The most important factor for achieving success and patient satisfaction when performing laser vision correction surgery is to choose the right procedure for each patient. Because of its outcomes and benefits like flapless technique, Lenticule Extraction with SMILE is my treatment of choice for nearly all patients needing myopic correction with and without astigmatism.



Figure 3. Scattergram showing first month post-op efficacy.

The VisuMax femtosecond laser is the entry card to performing SMILE, and the new VISUMAX 800 raises the experience to a new level that benefits surgeons, the practice, and patients. Performance speed, connectivity advantages for streamlined workflows and computer-assisted functions for centration and cyclotorsion adjustment are not just an improvement for current SMILE surgeons, but also provide a great opportunity for others to begin performing SMILE.

With an eye to the future, the VISUMAX 800 is also capable of accepting software upgrades and is designed for digital integration with a comprehensive armamentarium of surgical tools. Therefore, surgeons who use the VISUMAX 800 will be prepared to be at the forefront in the ever-evolving practice of corneal refractive surgery.

Dr. Rainer Wiltfang is Founder of the SMILE Eyes Group that has centers in Austria and Germany. He is a member of the Zeiss Scientific Advisory Board.



References

- Shen Z, Shi K, Yu Y, et al. 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:e0158176.
- Carl Zeiss Meditec AG. Myopia with optical zone 6.5 mm
- Postoperative UDVA is not measured subjectively (autorefracton (AR) used in about 95%) & Postoperative CDVA is not measured subjectively in all eyes (AR used in about 5%)

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