

## EDITORIAL



# Something to SMILE about. Is small incision lenticule extraction (SMILE) ready to become the gold standard in laser refractive surgery? no

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Eye (2024) 38:633–635; <https://doi.org/10.1038/s41433-023-02746-y>

Small Manual Incision Lenticule Extraction (SMILE) is a relatively new surgical procedure that was developed following the introduction of the VisuMax femtosecond laser (Carl Zeiss Meditec, Jena, Germany) in 2008. After Sekundo et al. [1] performed the first SMILE procedures, over 3,500,000 patients have been operated with SMILE. Currently SMILE is approved by the FDA for the treatment of myopia less or equal to  $-10.00$  D with or without astigmatism of a maximum of  $-5.00$  D [2]. SMILE has created a significant interest due to the potential benefits and its advertised safety profile [3]. However, most of these advantages have not been proven over time.

In all modes of refractive surgery high myopia is a known risk factor for post operative regression [4]. Similarly, SMILE does not seem to provide reliable results for the correction of higher myopic corrections. In studies like Hjortdal et al. [5] under-correction was positively correlated with steeper corneal curvatures of more than 7.5 D. Under-correction was initially thought to be the result of non-standardized nomograms that were inappropriate for SMILE. However, adjusted nomograms were eventually introduced without eliminating the incidences of under-correction.

Like under-correction, regression of myopia after refractive correction is also a major issue with SMILE. A number of studies have shown that highly myopic eyes experience significant regression after 1 year post-operatively. For example, Damgaard et al. and Wu et al. [6, 7] reported significant regression of myopia in higher myopic corrections. It appears that although a correction of up to 10 Dioptres of spherical equivalent has a high safety and efficacy profile; some degree of regression is inevitable especially over time.

In contrast and despite facing the same problems as SMILE, LASIK seems to be potentially able to overcome the barrier of high myopic correction. In their study Wallerstein et al. [8] reported good visual outcomes without complications, after appropriately selecting and performing myopic LASIK in patients with very high myopia ( $-10.00$  to  $-13.50$  D). Attributing the outcomes to advances in laser technology Reinstein et al. also reported good results in patients with myopia up to  $-14.25$  D [9].

Regarding dry eye disease after high myopic correction, Wang et al. [10] demonstrated that while SMILE performed better than LASIK in the early follow-up period, this difference did not persist 12 months after surgery.

Reasons for under-correction and regression include complex corneal remodelling, corneal shape, IOP and more recently postoperative epithelial changes [11]. Corneal epithelium after SMILE shows an initial temporary thinning, thought to be the

result of corneal wound healing and dryness. It is then followed by a more long lasting corneal epithelial thickening effect. Any epithelial thickness increase by  $>10$   $\mu\text{m}$  may suggest regression. This is probably a compensatory effect to the change in curvature after tissue subtraction and it seems to be positive correlated with the extent of the refractive correction [6, 12].

SMILE platforms do not incorporate an automatic adjustment for cyclotorsion; hence relying on surgeon-dependant centration of the treatment making the correction of moderate to high levels of myopic astigmatism a lot less standardised compared to LASIK and significantly less accurate. A few studies have reported the outcomes of myopic astigmatism treatment by vector analysis, showing that SMILE presents an acceptable result for the correction of low-to-moderate myopic astigmatism. Despite that, LASIK can be superior to SMILE for the reliable correction of low-to-moderate astigmatism [13, 14].

In higher astigmatism SMILE has a tendency for under-correction. For example, Pederson et al. [15] reported astigmatic under-correction at a level of 11% per dioptre and Ivarsen et al. [16] reported a 13% per dioptre under-correction in low stigmatism and a 16% per dioptre in high astigmatism. Some investigators like Pedersen et al. and Ivarsen et al. [15, 16] have proposed to either modify existing nomograms by 10% of the magnitude of astigmatism correction or to manually compensate for the intraoperative torsional error guided by the preoperative limbal marking [17]. This approach aims to correct astigmatism with a greater degree of predictability and repeatability.

On a different note, SMILE seems to provide acceptable yet inferior results when performed in older patients. Primavera et al. [18] showed that when SMILE is performed in patients over 40 years old, significantly lower efficacy and safety indexes, poorer astigmatic outcomes and under-correction were important issues compared with younger patients.

Since under-correction and regression in higher myopic corrections and astigmatism is considerable in SMILE, retreatment is often needed. While re-treatments in LASIK are more manageable with a simple flap lift and ablation, SMILE retreatment is more complicated. Most common surgical options include surface ablation, cap-to-flap conversion and thin-flap LASIK. Every option offers a safety profile similar to LASIK retreatments, but involve converting to a different strategy and in a way defeating the purpose of performing SMILE in the first place. Also converting to a different method like LASIK comes with its own set of problems as myopic LASIK post SMILE surgery probably necessitates the application of a different nomogram than for LASIK re-treatment post myopic LASIK [19].

While the correction of sphere and astigmatism in refractive surgery is the most significant concern for the treating physician, one should not forget the value of the subtler corneal

**Table 1.** Advantages of LASIK over SMILE.

High and very high myopia → Even more promising results from LASIK
Astigmatism → Superior for low to moderate correction
Retreatment → Easier than SMILE
WG- and WO-LASIK → Better visual outcomes
Visual Recovery → Faster than SMILE
Hyperopia → Not yet available for SMILE


WG wavefront guided, WO wavefront optimised.


irregularities known as Higher Order Aberrations (HOA). HOA like coma, trefoil and tetrafoil can cause a variety of visual symptoms, mainly glare and halos, even in an emmetropic eye. In recent years advances in wavefront aberrometry have offered ophthalmologists the option of two different approaches in refractive surgery with LASIK i.e. Wavefront-Optimized Ablation (WFOA) and Wavefront-Guided Ablation (WFGA) [20]. The aim of WFOA is to induce less HOAs than conventional refractive surgeries, whilst WFGA aims to treat or reduce these pre-operative HOAs. A prospective, randomized study by Chiang et al. [21] performed SMILE in one eye and WFG-LASIK in the contralateral eye. One year later they found that a much higher proportion of WFG-LASIK eyes had an uncorrected distance visual acuity  $\geq 20/20$  at 12 months post-procedure compared with the eyes of the same patient that were treated with SMILE. Likewise, Ye et al. showed superiority of WFG-LASIK vs SMILE in the induction of coma, attributing it to poorer centration in SMILE [22].

As far as visual recovery is concerned, both LASIK and SMILE offer fast results. Yet visual recovery in SMILE seems to be slower than LASIK [23] at least in the earlier post operative days, possible due to the formation interface haze Table 1.

While SMILE has shown promising early to midterm results for the correction of myopia and is FDA approved for the correction of  $\leq -10.00$  D of myopia with or without astigmatism  $\leq -5.00$  D, it is currently not approved for hyperopic correction or mixed astigmatism although a few researchers have shown promising results [24].

Despite the fact that over the past 10 years SMILE has given some positive results, LASIK remains still the more reliable and predictable option for refractive surgery demonstrating excellent results over the past 30 years. Especially in more complicated cases with higher degrees of myopia, astigmatism and HOA, it remains unrivalled.

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## AUTHOR CONTRIBUTIONS

MT Original idea, Data collection, Reference check, Review of the manuscript. IG Data Collection, Reference check, Review of the manuscript. EP Reference check and

Review of the manuscript. SJ Reference check and Review of the manuscript. NZ Reference check and Review of the manuscript.

#### COMPETING INTERESTS

The authors declare no competing interests.

#### ADDITIONAL INFORMATION

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