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# SMILE/SMILE pro laser eye surgery – What have we learned after ten years?

In September, the Vision Eye Institute NSW refractive team celebrated a significant milestone – 10 years of offering Small Incision Lenticule Extraction (SMILE®) and its successor, SMILE pro, to patients with myopia or myopic astigmatism. Our team has performed approximately 8,000 procedures (including around 1,000 SMILE pro), gaining valuable insights along the way.

In 2024, the distribution of laser procedures for Vision Eye Institute Sydney is SMILE 43%, LASIK 39% and ASLA (PRK) 18%. You might be surprised that it's not more heavily skewed towards SMILE – after all, Vision Eye Institute surgeons were among the first in Australia to offer it, worked with engineers from Zeiss to optimise the laser settings (which became the default settings), and continually analyse our data for

benchmarking (both internal and external through research and other publications).

However, these figures simply demonstrate our preference for a patient-centred approach, where the surgical procedure is matched to the individual patient rather than the other way around.

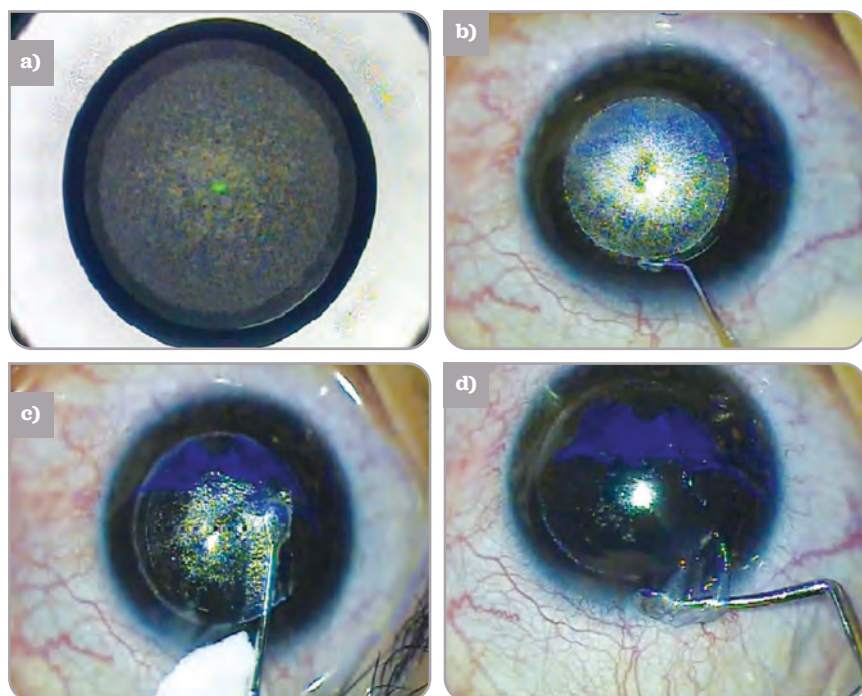
## The evolution of SMILE

Zeiss introduced the VISUMAX 500 Femtosecond Laser in 2011, presenting the new one-laser, one-step SMILE technology.<sup>1</sup> The laser creates an intrastromal lenticule, which is removed manually through a small peripheral incision (**Figure 1**). It offers several potential advantages over LASIK, such as reduced disturbance of the corneal epithelium, nerve plexus and structural integrity.<sup>2,3</sup>

In September 2014, one of Australia's first VISUMAX 500 lasers was installed at the Vision Eye Institute Chatswood Laser Suite (**Figure 2a**). Shortly after, Professor Sutton became the first surgeon in Sydney to perform SMILE.

Fast forward to 2021, and advancing technology demanded the progression to a new femtosecond laser. The Zeiss VISUMAX 800 arrived at Chatswood in January 2022 (**Figure 2b**), with Associate Professor Lawless completing the first SMILE pro 2 months later. Professor Chan presented Vision Eye Institute's first-year SMILE pro results at the Asia Pacific Academy of Ophthalmology Congress in February 2023.

SMILE pro is significantly faster, with lenticule creation taking 10 seconds or less.<sup>4</sup> Continued software developments include advanced features such as OcuLign cyclotorsion for astigmatism (we were selected to be the first centre in the world to have OcuLign, with Associate Professor Lawless first to use this feature in July 2024, followed by Professor Sutton and Professor Chan), hyperopic SMILE and computer-controlled centration, CentraLign.<sup>4</sup> From here on in this article, we use 'SMILE' to refer to both the original and current technology.



**Figure 1.** SMILE procedure.<sup>2</sup> **a)** Docking and laser ablation. **b)** Immediately following the laser ablation. The spatula enters through the side cut. **c)** The spatula is moved across the anterior and posterior lenticule surface. **d)** The lenticule is removed.



**Figure 2.** Installation at Vision Eye Institute Chatswood Laser Suite. **a)** VISUMAX 500 in 2014. **b)** VISUMAX 800 in 2022.

## Real-world patient selection

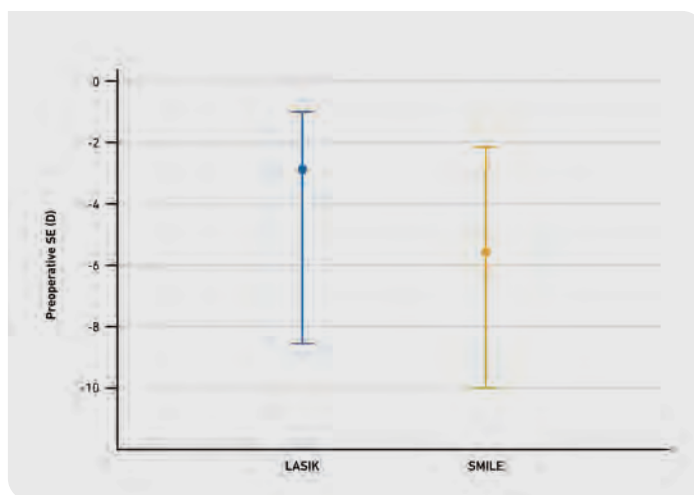
Vision Eye Institute laser eye surgery patients in NSW are more likely to be female (61.7%), with a mean age of 33.9. Nearly three-quarters of corneal refractive patients are aged 40 or less, reflecting the balance between visual demands, patient motivation and surgical inclusion criteria. The percentage of SMILE patients who are female or aged 40 or under is higher again (67.7% and 84.3%, respectively), with a comparable mean age (32.2 years).

### Preoperative refraction

Both LASIK and SMILE are approved for myopes up to -10 dioptres (D) and astigmatism up to -5 D, although these extremes are uncommon in the local Australian population.<sup>2,3</sup> Our surgeons' experience mirrors the published literature, which supports SMILE as more accurate for higher levels of myopia.<sup>2,5</sup>

This is further reflected in the routine patient selection; SMILE is the preferred indication for refractive patients above -5 D (mean spherical equivalent [SE] for LASIK and SMILE are -2.90 vs -5.71 D, respectively). However, matching the patient to the appropriate refractive procedure is reliant on individual patient clinical assessment inclusive of refractive error, corneal thickness and tear film surface, among other parameters. Accordingly, the existing treatment range for both main refractive procedures is variable (-1 to -8.13 D for LASIK vs -2.13 to -10 D for SMILE). This is shown in **Figure 3**. →

**SMILE has been performed on more than 10 million eyes around the world (Zeiss data on file).**



**Figure 3.** Preoperative Spherical Equivalent (SE) LASIK vs SMILE. (Source: Vision Eye Institute Sydney)

Corneal parameters

Although SMILE’s biomechanical advantage should make it an option for patients where borderline corneal parameters may rule out LASIK, there have been reports of postoperative ectasia despite normal baseline tomography.<sup>2,3,5,6</sup> Preoperative corneal pachymetry over 500 microns and a residual stromal bed no less than 250 microns to maintain structural integrity continues to represent the baseline inclusion criteria for SMILE and LASIK;<sup>3,6</sup> however, consideration of topographic and tomographic indices remains paramount.

Patient counselling and referral

Optometrists are crucial in co-managing refractive patients (SMILE included), particularly for pre- and postoperative counselling and monitoring during recovery. The relative and absolute contraindications for corneal refractive surgery help to understand potential suitability in the preoperative assessment (Table 1).

Referrals should include the patient’s refraction. Historical refractive error and/or serial topography are helpful if there is any concern about continued progression.

| RELATIVE CONTRAINDICATIONS                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| LASIK                                                                                                                                                                                                                                                                                                 | SMILE                                                                                                                                                                                                                                                                                           |
| Mild dry eye disease<br>Recurrent corneal erosions<br>History of herpes simplex keratitis or zoster ophthalmicus<br>Atopic disease<br>Autoimmune disorders<br>Thin corneas (dependent on preoperative refraction)<br>Glaucoma<br>Irregular or abnormal corneal topography<br>Pregnancy                | Moderate dry eye disease<br>Recurrent corneal erosions<br>History of herpes simplex keratitis or zoster ophthalmicus<br>Atopic disease<br>Autoimmune disorders<br>Thin corneas (dependent on preoperative refraction)<br>Glaucoma<br>Mild irregular or abnormal corneal topography<br>Pregnancy |
| ABSOLUTE CONTRAINDICATIONS                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                 |
| LASIK                                                                                                                                                                                                                                                                                                 | SMILE                                                                                                                                                                                                                                                                                           |
| Unstable refraction (>0.50 D over previous 12 months)<br>Residual bed thickness $\geq$ 300 microns<br>Keratoconus or abnormal or irregular topography<br>Significant corneal scarring<br>Visually significant cataract<br>Uncontrolled systemic or ocular disease<br>Unrealistic patient expectations | Unstable refraction (>0.50 D over previous 12 months)<br>Keratoconus<br>Mild corneal scarring<br>Visually significant cataract<br>Uncontrolled systemic or ocular disease<br>Unrealistic patient expectations                                                                                   |

Table 1. Relative and absolute contraindications of LASIK and SMILE.<sup>2</sup>

Postoperative recovery

SMILE aftercare is similar to LASIK. Patients should still be monitored for visual recovery, refraction and ocular surface recovery.

Visual recovery

Functional vision returns across the first day, although occasionally, patients may experience a mild delay compared to LASIK for final visual acuity. Ocular surface recovery and irritation settle quickly, and patients can resume activities like swimming and contact sports after one week (2 weeks for LASIK). The target refraction is often achieved around this time.

Almost one-third (29.6%) of our SMILE patients would be considered as high myopes (>-6 D SE), with moderate myopia accounting for over half (55.7%). The mean absolute difference from target between groups was not clinically different (0.15 D, 0.18 D and 0.31 D for low, moderate and high myopia SE, respectively. See Figure 4). Overall, 92.8% of eyes were within +/- 0.5 D of the refractive SE target, highlighting excellent results across the entire spectrum of myopic refractive error treated with SMILE.

Potential complications

Complications such as significant corneal haze, infectious keratitis, epithelial in-growth and diffuse lamellar keratitis may

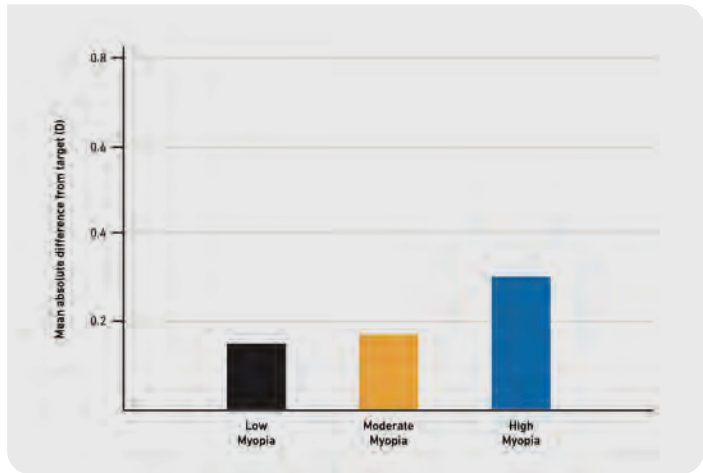


Figure 4. Mean absolute difference from the target after SMILE according to the level of myopia. (Source: Vision Eye Institute Sydney)

manifest over the initial recovery period but remain rare.<sup>2,3,6</sup> Irregular astigmatism and ectasia represent potential medium- to long-term complications and require awareness in the context of visual changes.<sup>2,3,5</sup> ➔

In the literature, enhancement rates vary between 2.7% to 4% for SMILE.<sup>3,5</sup> Our combined enhancement rate across all procedures and refractive error between 2020 and 2024 was 2%, reflecting best practice. Patients with extreme refractive error or mild preoperative corneal irregularity (e.g., mild contact lens distortion) continue to represent a slightly higher risk for undercorrection.<sup>3</sup>

If required, enhancements can be performed using a second SMILE procedure (CIRCLE), thin-flap LASIK or ASLA, albeit consideration of corneal thickness in previously extreme myopes may preclude further intervention.<sup>2,3,5</sup>

## Novel uses for SMILE

In an Australian first, Dr Huynh successfully performed SMILE in a patient with congenital nystagmus.<sup>7</sup> She has also performed SMILE pro Xtra in a small number of patients who meet strict criteria. This involves adding riboflavin within the lenticule cavity to help strengthen the cornea in cases exhibiting suspicious tomographic variables.

Scan the QR code to read more about these novel applications.



## A word on SMILE 'lookalikes'

Refractive lenticule removal procedures similar to SMILE (e.g., SILK, SmartSight, LaLex and CLEAR) have recently emerged. These are laser-dependent variations of SMILE, rather than genuinely new techniques. There is little evidence demonstrating any clinically significant benefit over SMILE, which remains the most established and validated lenticule-extraction technique in the literature.

## Conclusion

SMILE offers unique advantages as the technology continues evolving, but outcomes depend heavily on surgical expertise and patient selection. We encourage co-management of refractive patients with local optometrists.

Optometrists who are interested in co-managing refractive patients and would like to participate in our refractive surgery aftercare program should contact Vision Eye Institute NSW Clinical Relationships Manager Kathryn Rizk (kathryn.rizk@vei.com.au). ●

## About the authors



**Prof Colin Chan** is a renowned refractive surgeon with expertise in SMILE, LASIK, ASLA/PRK, refractive lens exchange and laser cataract surgery. He is an Adjunct Professor (University of Canberra), Clinical Associate Professor (University of Sydney) and Adjunct Associate Professor (Chinese University of Hong Kong). Prof Chan is also Program Director for the Graduate Diploma in Cataract and Refractive Surgery.



**Dr Tess Huynh** is one of Australia's most experienced refractive surgeons, specialising in presbyopia correction, corneal collagen crosslinking for keratoconus and all corneal laser refractive surgery (including SMILE, LASIK and PRK). In an Australian first, Dr Huynh successfully performed SMILE in a patient with congenital nystagmus. She is actively involved in research, teaching and charity work and is often invited to present at conferences in Australia and Asia Pacific.



**A/Prof Michael Lawless** is one of Australia's most experienced eye surgeons, performing over 30,000 surgical procedures. He is a Clinical Associate Professor at Sydney Medical School (University of Sydney) and is recognised worldwide as an authority on laser eye surgery. A/Prof Lawless' refractive expertise encompasses LASIK, ASLA/PRK and SMILE.



**Prof Gerard Sutton** is internationally recognised as an expert in vision correction, cataract surgery and corneal transplantation. Prof Sutton has expertise in laser eye surgery (SMILE, LASIK, ASLA/PRK), refractive lens exchange and implantable lenses. He is a Professor of Ophthalmology at the University of Sydney and established the world's first university course in refractive surgery.

ASLA = advanced surface laser ablation, PRK = photorefractive keratectomy, LASIK = laser in situ keratomileusis, SILK = smooth incision lenticule keratomileusis, LaLEX = laser-assisted lenticular extraction, CLEAR = cornea lenticule extraction for advanced refractive correction. SMILE® is a registered trademark of Carl Zeiss Meditec.

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## Discarded lenticules used to bioengineer corneas

Corneal transplants effectively restore vision, but only 1 in 70 patients can access donor tissue worldwide. By leveraging tissue, such as lenticules discarded following SMILE laser surgery (with patient consent), Professor Gerard Sutton's BIENCO consortium enabled protocols to extract pure collagen and develop a bioengineered full-thickness cornea effectively. This bypasses the need for corneas from deceased donors.

BIENCO has been awarded a \$35 million research grant by the Australian Government to manufacture its bioengineered corneas for global distribution, potentially restoring sight to millions.

Scan the QR code to read more.

\*Project funded by **Future Vision Foundation**, the not-for-profit research charity launched by Vision Eye Institute in 2021.

