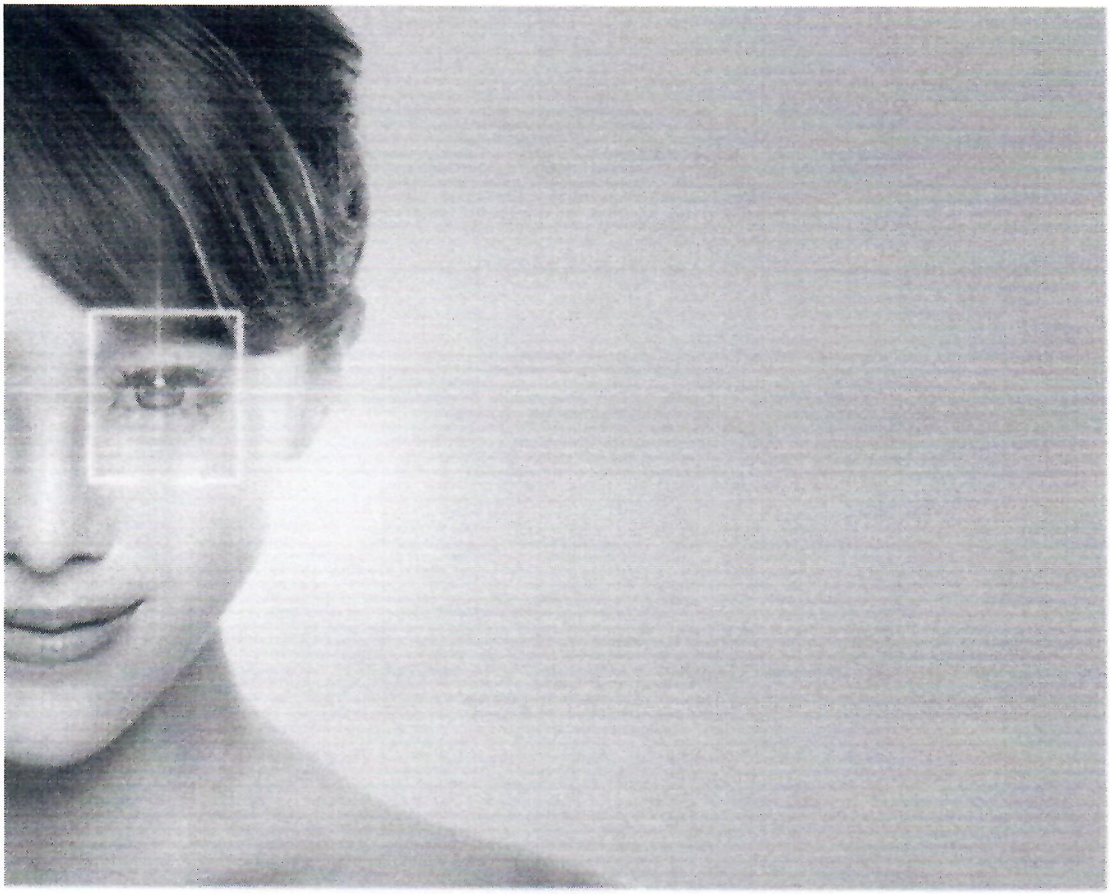
SMILE LASER EYE SURGERY

A consumer's guide



Prof Gerard Sutton & Clinical Assoc Prof Michael Lawless

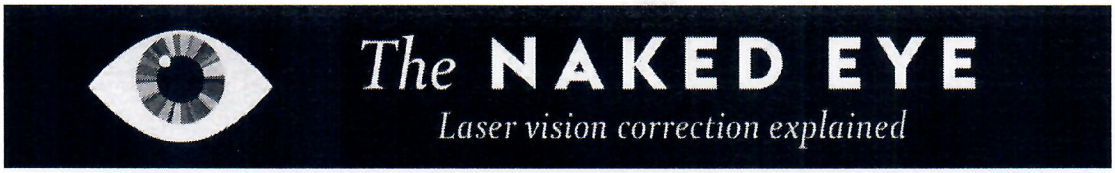


Table of Contents

INTRODUCTION – THE EVOLUTION OF LASER EYE SURGERY 3

PRK 3
LASIK 3
THE INTRODUCTION OF THE ALL-LASER PROCEDURE 4

SMILE – FLAPLESS, KEYHOLE LASER EYE SURGERY 5

WHAT IS SMILE LASER? 5
WHAT ARE THE RESULTS LIKE FOR SMILE LASER EYE SURGERY? 6
IS SMILE LASER SAFE? 6
WHO IS SUITABLE FOR SMILE LASER SURGERY? 6

SMILE LASER VERSUS LASIK AND ASLA 7

PRK / ASLA 7
LASIK 8
SMILE LASER 8
THE OUTCOMES 9
THE TABLE BELOW INDICATES SOME OF THE DIFFERENCES BETWEEN SMILE, LASIK AND ASLA. 9

HOW MUCH DOES SMILE LASER COST? 10

IS SMILE LASER WORTH THE COST? 10
WHAT IF I CAN'T HAVE SMILE LASER WHERE I LIVE? 11

A TYPICAL PATIENT EXPERIENCE 12

SMILE LASER – CASE STUDY 13

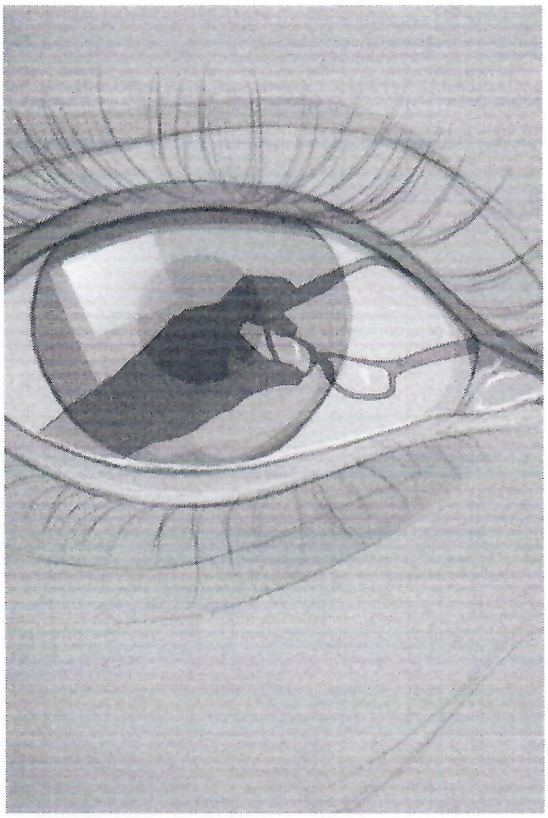
ABOUT THE AUTHORS 16

CLINICAL ASSOCIATE PROFESSOR MICHAEL LAWLESS 16
PROFESSOR GERARD SUTTON 17

Introduction – The Evolution of Laser Eye Surgery

SMILE laser is the latest version of several highly successful laser eye surgery techniques that reshape the cornea – or front surface of your eye – to achieve freedom from glasses. Laser eye surgery has evolved over the past three decades through a range of techniques, culminating in today's procedures, which, in the right hands and for the carefully chosen candidate, are the epitome of modern science – safe, predictable and accurate.

PRK



It all started with PRK, over thirty years ago, when it was discovered that a particular kind of laser called an **excimer** laser, operating at a particular wavelength, could safely reshape corneal tissue. A refinement of this procedure continues to enjoy success today, under the name of ASLA – or Advanced Surface Laser. Although PRK was effective at treating low to moderate levels of short-sightedness and led to good outcomes, it wasn't as successful with higher prescriptions, where it led to a greater incidence of corneal haze and loss of corrected visual acuity. On top of that, it was pretty uncomfortable for the patient during the healing period and that, along with the delay in visual recovery (sometimes several weeks) meant that widespread acceptance of PRK remained elusive.

LASIK

All this changed in 1990 with the invention of LASIK, the most popular laser eye surgery of all time, with millions of successful procedures performed around the world over the past twenty-five years. It involved the creation of a flap of corneal tissue which was folded out of the way so that the laser could access the deeper layers of the cornea and

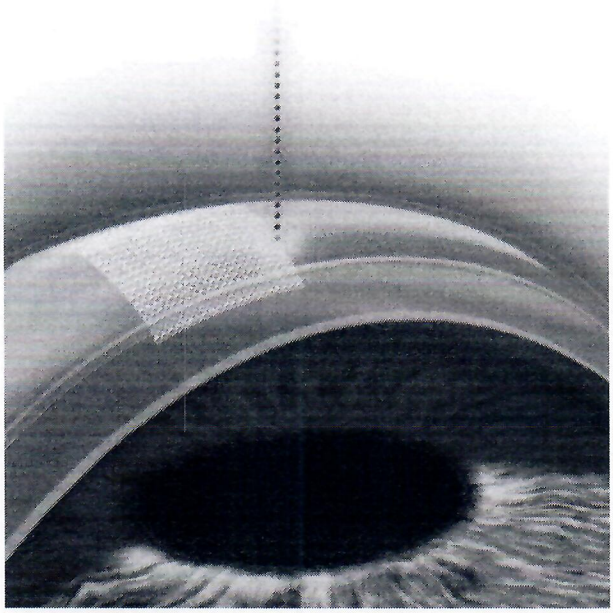
vaporise tissue from there. The LASIK procedure thus bypassed the sensitive surface layers of the eye, resulting in same-day visual recovery and very little discomfort. These qualities made it the 'miracle procedure' it is often claimed to be by happy patients. The first LASIK procedure in Australia was performed in 1995.

The introduction of the all-laser procedure

For nearly ten years, we very successfully performed LASIK eye surgery using a metal blade – called a micro-keratome – to create the thin flap of corneal tissue during the procedure.

In October 2004, the technique changed forever with the introduction to Australia (at our practice) of a new **femtosecond** laser called IntraLase, which used a laser instead of a blade to create the flap during LASIK.

Femtosecond lasers pulse at an incredibly fast rate. Try stretching your mind around this: One femtosecond is to one second what one second is to 31.7 million years... This immense speed allows the laser to separate human tissue at the molecular level so that there is no damage to surrounding tissue. This meant a safer, more accurate and more predictable procedure than ever before and many people who had previously been reluctant to undergo laser eye surgery were happy to hand over their glasses in exchange for everyday clear vision.



Since then there have been minor refinements to the procedure – such as faster operation speeds – but essentially the technique remains the same; flap, zap and put it back. LASIK doesn't suit everyone however. There are some candidates with thinner corneas or drier eyes that just don't suit LASIK and they have been unable to enjoy the benefits of laser eye surgery to date. With the advent of a new version of the procedure called SMILE laser, they may not need to wait any longer.

SMILE – flapless, keyhole laser eye surgery

IntraLase has been around for ten years now and during that time, femtosecond laser technology has also revolutionised lens surgery, for cataract as well as vision correction. The same femtosecond technology has recently been used for a new technique for performing laser vision correction on the cornea.

What is SMILE Laser?

Small incision lenticule extraction – or SMILE – is the latest technique of performing laser vision correction on the cornea. It uses a femtosecond laser to separate a thin lenticule (or lens-shaped disc) of corneal tissue from within the cornea *(Fig. 1).*

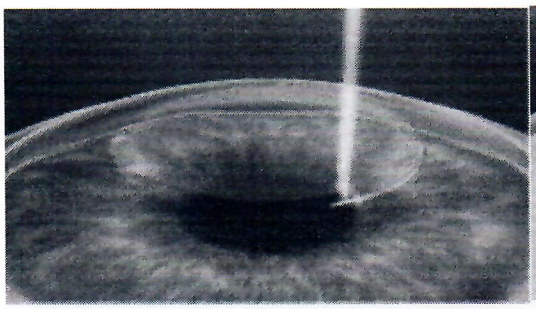


Fig. 1

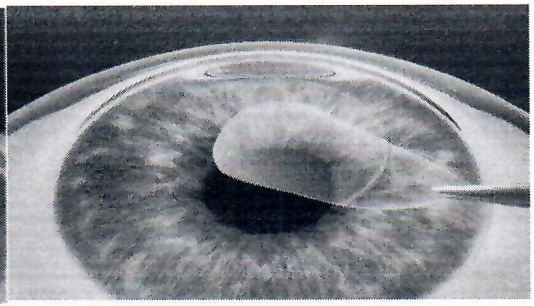


Fig. 2

This disc is then removed through a very small keyhole incision *(Fig. 2)* and the net effect on the corneal shape corrects the patient's short-sightedness (or myopia). There is no corneal flap created and no tissue vaporised. One theoretical advantage of SMILE over LASIK is that it is less disruptive to the corneal surface, with just a small extraction wound instead of a flap. This advantage seems to be borne out in the clinical data that have emerged since the SMILE procedure was introduced.

The good news is that some patients who were previously found unsuitable for LASIK may be suitable for SMILE laser. Particularly for those with dry eyes or thinner corneas, SMILE laser may offer a surgical solution to their vision problems.

Small incision lenticule extraction – or SMILE – is a new way of performing laser vision correction on the cornea. It uses a femtosecond laser to separate a thin lenticule (or disc) of corneal tissue from within the cornea. This disc is then removed through a very small keyhole incision and the net effect on the corneal shape corrects the patient's short-sightedness.

What are the results like for SMILE laser eye surgery?

Many of our SMILE laser patients can see well without glasses within hours of the surgery, although we caution our patients that it can take several days for optimum vision to occur. We are consistently getting results that compare very favourably with our ever popular LASIK procedure in terms of accuracy, safety and vision.

Is SMILE laser safe?

If you are found suitable for a SMILE laser procedure, you can relax in the knowledge that it has an excellent safety profile and all the benefits of a modern all-laser procedure. Well over a hundred thousand SMILE laser procedures have been performed around the world to date, and the data on safety and accuracy are very compelling. SMILE laser offers all the benefits of laser eye surgery with the least possible interference. For certain candidates, such as those with pre-existing dry eyes, or active sportsmen, SMILE laser may be the procedure of choice, and some patients who have been previously found unsuitable for laser eye surgery (for dry eye concerns) may now finally have the opportunity to enjoy life without glasses.

> ***As with all vision correction procedures, SMILE laser carries some risk. In addition, there is no one-size-fits-all procedure and the right procedure for you (if any) an only be determined by an experienced laser eye surgeon.***

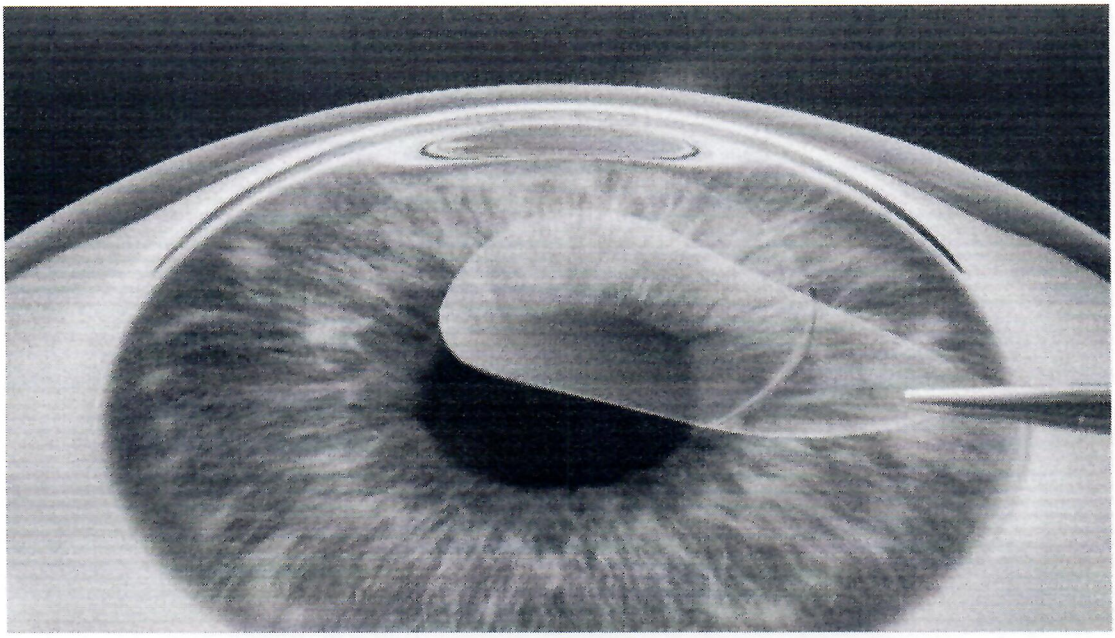
Who is suitable for SMILE laser surgery?

If you are moderately to very short-sighted (-3 to -10 dioptres) including any astigmatism you may have, then SMILE laser could be right for you. It caters for a range of ages from twenty to sixty plus and can even be suitable for people who have previously been advised that they are unsuitable for LASIK due to their dry eye condition. This is because SMILE doesn't create a flap of corneal tissue (as in LASIK) which can aggravate dry eye conditions in some people.

The advantage of SMILE over other corneal procedures revolves around the fact that it is minimally invasive. No flap is created (like in the LASIK procedure) so it really is keyhole surgery, with far less effect on the surface of the eye. SMILE is also a great choice for those involved in high-impact contact sports as there is no corneal flap to possibly dislodge and the strength of the eye's surface is better preserved than with LASIK.

SMILE Laser versus LASIK and ASLA

SMILE laser eye surgery is the latest addition to the array of laser vision correction procedures available that allow you to see clearly with the naked eye. But what makes it different from other corneal procedures like LASIK and PRK?

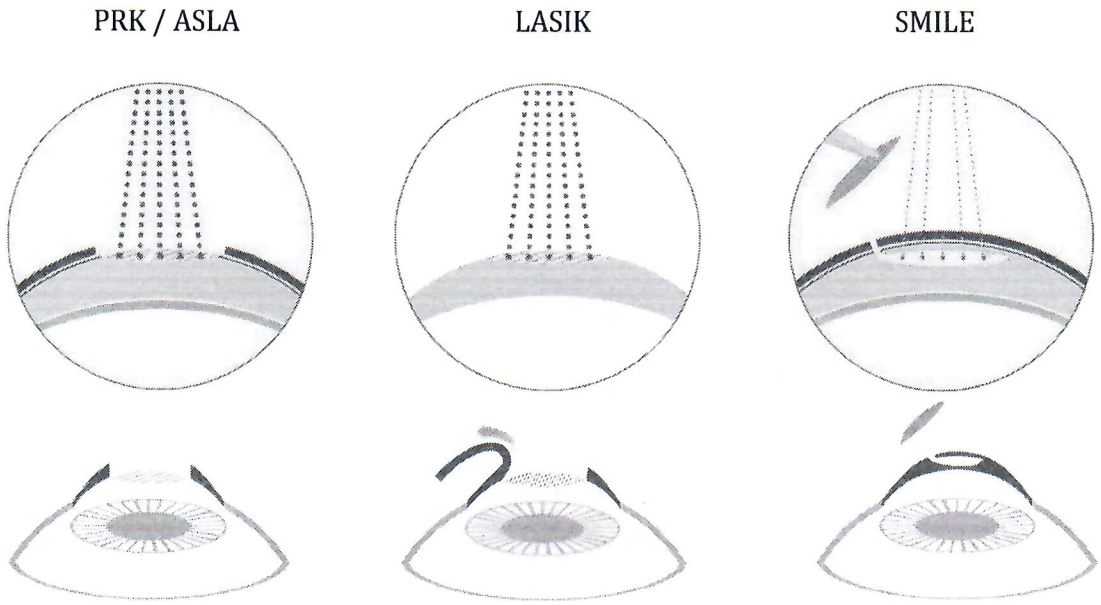


PRK / ASLA

Our practice first introduced laser eye surgery to Australia in 1991 in the form of PRK. PRK has since undergone a number of refinements and is now known as Advanced Surface Laser (or ASLA). As you can see in the diagram below, it involves reshaping the *surface* of the cornea. To do this, a particular kind of laser called an **excimer laser** removes corneal tissue by vaporising it away. The resulting new corneal shape allows clear focus without glasses or contacts.

ASLA continues to be performed around the world and gives fabulous visual outcomes but it has largely been overtaken in the popularity stakes by LASIK. Why? Because ASLA reshapes the top layers of the cornea, it causes discomfort during the initial days of healing and often takes a week or more to achieve functional vision for normal day-to-day activities. In a busy world, nobody likes downtime and certainly not sore eyes, not even for a day or two.

In a busy world, nobody likes downtime and certainly not sore eyes, not even for a day or two.



LASIK

LASIK, in contrast, gives almost instant visual results and little discomfort during healing. As you can see in the diagram, LASIK involves the creation of a superficial flap of corneal tissue using another kind of very fast-pulsing laser called a **femtosecond laser.** The flap is folded back so that the excimer laser can reshape the underlying layers and bypass the superficial layers completely. So, two different lasers are used during the procedure. You usually have little or no downtime with LASIK, apart from the day of the procedure itself. LASIK also gives excellent visual outcomes and covers a wide range of prescriptions from about +4 to -10. However, you need to have adequate corneal thickness to not only correct the error but to create the flap as well, and this makes LASIK unsuitable for some thinner corneas that would be suitable for ASLA or SMILE. Both LASIK and ASLA remove tissue from or near the surface of the cornea and this is now being shown to impact on the overall strength and integrity of the cornea compared to SMILE laser. LASIK also impacts temporarily on the corneal nerve supply and often results in a period of dry eyes. Where this occurs, it usually disappears within a month or two but it is one reason why we don't perform LASIK on patients with chronic dry eye conditions.

SMILE laser

SMILE laser removes corneal tissue in a different way to LASIK and ASLA. An excimer laser is not used at all during this procedure, so gone are many of the hallmarks of traditional laser vision correction. A femtosecond laser is used to define a tiny lens-

shaped disc of tissue from within the cornea and this lenticule is removed through a keyhole (3mm) incision.

Why is it different to the excimer laser? The femtosecond laser is quiet and doesn't create the slight odour that sometimes occurs with the excimer laser. Neither is there any need to change from one laser to another during the procedure.
Recovery from SMILE is slightly slower than for LASIK. But by 2-3 weeks after the procedure the visual results are just as good as for LASIK. In fact, in patients who are very shortsighted, the evidence-based medicine suggests that SMILE patients get even better results.

The Outcomes

Just like LASIK and ASLA, SMILE laser gives excellent visual outcomes and similarly has a very high safety profile. Currently, SMILE laser is only available for moderate to high levels of myopia (or short-sightedness) and astigmatism, from about -3 to -10 dioptres, so it's not for everyone. Clinical evidence continues to emerge that SMILE laser may give better results for patients with higher errors. It is also a more appropriate procedure for patients at risk of dry eye.

The table below indicates some of the differences between SMILE, LASIK and ASLA.

	ASLA	**LASIK**	**SMILE**
Prescription Range	+3 to -8	+4 to -10	-3 to -10
Thinner corneas	Yes	No	Yes
Dry Eye Sufferers	Yes	No	Yes
Visual recovery	1 week +	Same day	2-3 days
Post-op discomfort	Usual	Rare	Rare
Noise/slight odour during procedure	Yes	Yes	No
Excellent outcome	Yes	Yes	Yes

Each of the three procedures still has its role to play. The SMILE technique is a more modern way to perform laser eye surgery and is the procedure of choice for certain groups of patients, especially those with higher errors or drier eyes.

How Much Does SMILE Laser Cost?

This is one of the most frequently asked questions about SMILE laser. We offer SMILE to all suitable candidates at their Vision Eye Institute Chatswood (Sydney) practice. SMILE costs the same as the LASIK procedure – around $3,400 per eye. Quality laser vision correction has hovered at that price for close to a decade now. The cost of laser eye surgery tends to plateau at a certain level, rather than come down over time. This is because there are constantly new refinements to the procedures and ongoing investment in the technology is required to offer patients the safest and most accurate procedure available.

SMILE laser is usually performed on both eyes, bringing the cost for most patients to nearly $7,000, so it's certainly not an impulse buy. The cost includes six months of aftercare as well as any enhancement procedure which may be required within two years. (Our enhancement surgery rate is about 2%).

Is SMILE laser worth the cost?

SMILE laser specifically caters to patients who are moderately to highly myopic (or short-sighted) in the range of about -3 to -10. They tend to wear thicker glasses and often spend a lot of money on their glasses to minimise the weight and thickness of the lenses. These patients also tend to wear contact lenses, often daily disposables, which again cost a significant amount every year. For someone in their twenties or thirties (or even older), the math really do stack up when you compare the cost of laser eye surgery to the cost of high quality glasses and contact lenses over decades of wear. As more clinical data emerges as to the benefits of SMILE laser for certain subgroups of patients, the popularity of SMILE laser continues to rise. The story we hear from our patients is that they are prepared to pay whatever it costs for the most modern laser vision correction procedure available and they are also prepared to travel for it.

For someone in their twenties or thirties (or even older), the math really do stack up when you compare the cost of laser eye surgery to the cost of high quality glasses and contact lenses over decades of wear.

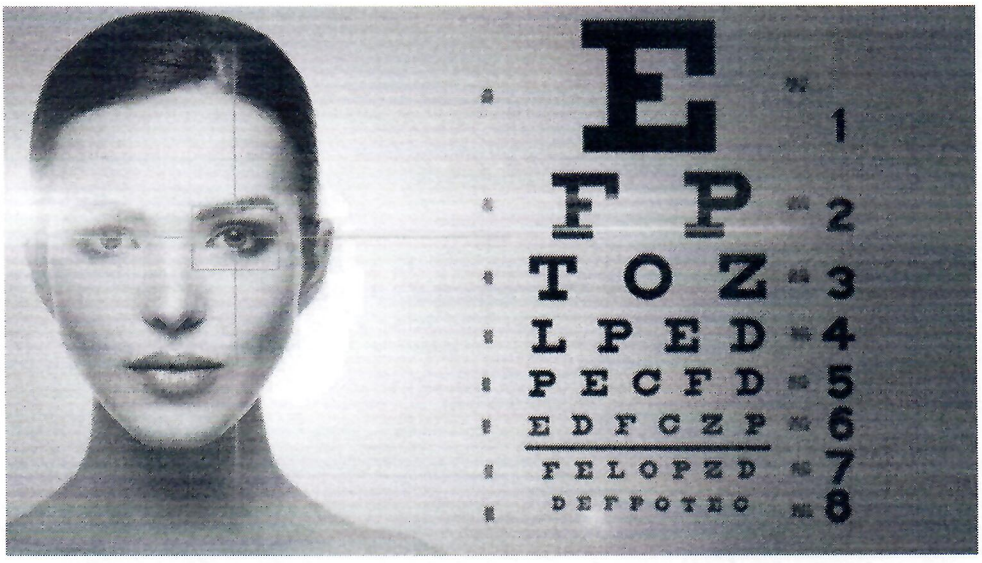
What if I can't have SMILE laser where I live?

Currently, SMILE laser is not widely available, with just a handful of capital cities (Sydney, Canberra, Melbourne and Adelaide) offering it to date. It is expected that the popularity of the procedure will drive availability in a wider range of locations over time. Vision Eye Institute offers SMILE procedures at their Chatswood practice, although the initial consultation and follow-up can also be performed at their Hurstville and Bondi Junction practices.

We have had patient enquiries from Western Australia and even New Zealand about traveling to Sydney to have SMILE laser. These are the lengths to which some people are prepared to go in order to get the best treatment for their eyes.

For a SMILE laser procedure, you need to allow at least one night in Sydney. A typical scenario would be that you would have your consultation one day and your procedure the same day or the next morning, followed by a post-operative visit later that day.

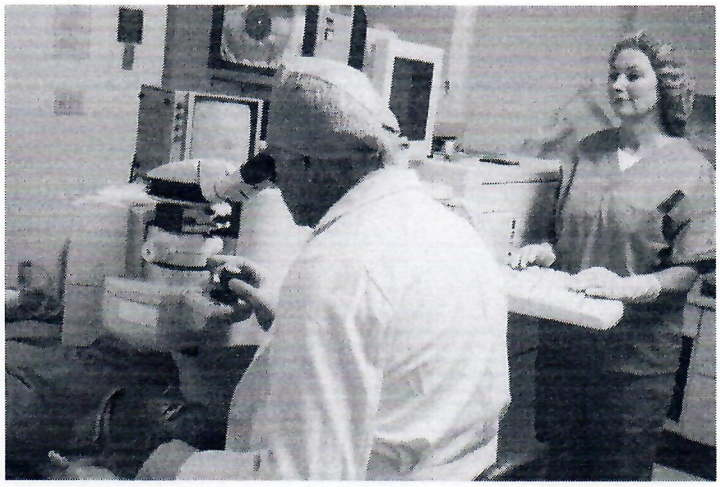
At our practice, we've catered for interstate and even international patients for many years. For a SMILE laser procedure, you need to allow at least one night in Sydney. A typical scenario would be that you would have your consultation one day and your procedure the same day or the next morning, followed by a post-operative visit later that day. The most important thing that we counsel patients traveling for any laser eye surgery procedure is to allow for the possibility that you may not be suitable for SMILE or indeed any laser vision correction procedure. In all the laser eye surgery procedures we perform, we only select patients who we feel will have a successful outcome and benefit from the results for many years to come.



A Typical Patient Experience

It is nearly six months now since we introduced the latest SMILE laser technology to our practice at Vision Eye Institute in Sydney and we have been very impressed with the results. Every now and then a new technology comes along that makes you think, this makes sense, this is a more modern way to reshape the cornea and produce clear vision with the naked eye. But what's it actually like to have a procedure? How long does it take? Does it hurt? What sensations can you expect? Everyone's experience is different and some will mention aspects of the procedure that others are not even aware of. What follows is one patient's account of their SMILE laser procedure:

My wife drove me to Sydney for my SMILE procedure. I was a little nervous but as soon as I arrived at the clinic they gave me a Valium – very welcome! Things didn't seem so scary after that and I tried not to think about it too much. I wasn't sure what I was expecting – you hear all sorts of things going around. I was given a surgical gown and shoe covers and a hair cover and some eye drops.



When it was my turn, I was brought into a special room where the laser was. I lay on the bed and the nurses moved my head around a bit to get it into the right spot. Then they put some more eye drops in and then the laser was lined up above my first eye. I felt slightly uncomfortable as they used something to hold my eye open so I wouldn't blink when the laser was working. Then I felt pressure on my eye – like as if I was pressing on my closed eye with my thumb. I could see some flashing lights. It wasn't long until it stopped and I realized my vision was gone foggy. Then I was rotated out from under the laser and the surgeon gently talked me through the rest of the procedure. My vision still seemed a bit blurry.

Then they did the same on my other eye – this one was a bit more uncomfortable when the laser was working – or maybe it was because I had relaxed a bit now I knew what was involved and was more aware of sensations. I was struck by how quiet the whole thing was. Once the second eye was finished, lots more drops were put in my eyes and then I was led back to the waiting area to recover. I had to wait a while and then later on the surgeon had a look at how much I could read and how my eyes were looking and I was discharged. I had travelled from Newcastle and was allowed to go home now. My wife drove me home and I could already see how much clearer I could see – not perfect yet – they said it would take a few days for the vision to become really clear. My eyes were a bit gritty and sore for the rest of the day but I could already see the number plates of the cars in front of us.

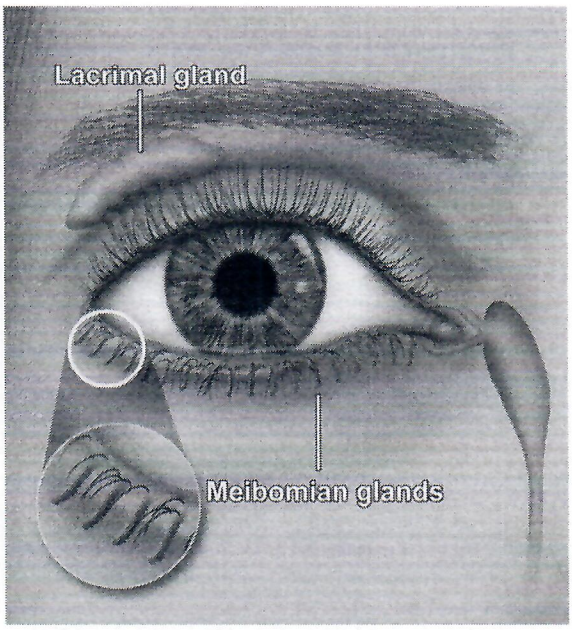
Smile Laser – Case Study

Rachel is 39 when she first comes to see us – about three years ago – to discuss vision correction surgery. She's a busy mother of three young kids and also works part-time as a pharmacist. She has been thinking about laser eye surgery for the past ten years but has been nervous about having it done – especially about any possible pain associated with the surgery or the recovery. Rachel is shortsighted – about –6 in each eye – and wears glasses most of the time. She used to wear contact lenses but has found them increasingly uncomfortable over the past few years. She suffers from a dry eye condition, which means she has to use artificial tears several times a day. She sees a dry eye specialist who has dramatically improved her ocular surface but she has to work hard to stay on top of it.

She has been thinking about laser eye surgery for the past ten years but has been nervous about having it done – especially about any possible pain associated with the surgery or the recovery.

Rachel has the battery of tests we put all our patients through and I can see that she has nice thick corneas, with plenty of tissue available to treat her -6 prescription. But I am reluctant to offer LASIK to Rachel because of her dry eye condition. LASIK involves the creation of a thin flap of corneal tissue, which is folded out of the way while the laser reshapes the underlying tissue. The flap is then replaced and heals very quickly, resulting in almost instant visual recovery and very little discomfort. However, the creation of the flap causes a temporary reduction in the amount of reflex tears secreted into the eyes.

We have a lacrimal gland above each eye that constantly releases watery (aqueous) tears into the eye in response to feedback from the eye's surface. If you cut an onion, for example, the eye's surface is irritated and a lot more reflex tears are released into the eye to flush it out and soothe it. The nerves that stimulate these reflex tears are situated in the surface of the cornea and they are temporarily affected by creating the flap in LASIK. The result is that less reflex tears are produced – especially in the first few weeks after LASIK. This is why all LASIK patients are



given artificial tears to use liberally for the first few weeks after a LASIK procedure.

But for some people, especially if they already have an underlying dry eye condition, the temporary dryness becomes more long term and can really take the good out of having a great result from LASIK. Their eyes may not actually feel any drier – because they have reduced sensation – but their vision can be affected and fluctuate depending on the hydration state of their eyes. In our experience, people with underlying dry eye that persists even when treated, tend to have these lingering issues after LASIK and it is one of the common reasons we would steer clear of LASIK and recommend a surface procedure (ASLA) instead. ASLA gives the same results as LASIK and the procedure itself is quick and painless, but ASLA has a much slower visual recovery and much more discomfort during healing. Until recently, ASLA accounted for about 10% of our corneal vision correction patients, while LASIK accounted for 90%.

In our experience, people with underlying dry eye that persists even when treated, tend to have these lingering issues after LASIK and it is one of the common reasons we would steer clear of LASIK and recommend a surface procedure (ASLA) instead.

I explained to Rachel that LASIK would likely aggravate her dry eye and that ASLA was a much better option for her. But she didn't want to have ASLA. With her busy schedule she just couldn't afford the downtime of a week or two where she may not able to drive or read fine detail at work. She was also terrified of any pain or discomfort – which ASLA would almost certainly cause for a couple of days. (Incidentally, this discomfort is managed with oral medications, topical drops and the use of a contact lens that acts like a bandage, and is rarely an issue for most people).

Rachel decided to stick with glasses for the time being and perhaps return when she was a bit older and have a lens replacement instead.

Then along came SMILE laser... We installed the latest laser vision correction technology in late 2014 and now recommend SMILE laser as one option for all suitable candidates. It reshapes the cornea by defining and separating a disc of tissue within the cornea, which is removed through a keyhole incision. So far it is suitable for prescription ranges from about -3 up to -10 (including any astigmatism). The great thing about SMILE is that the procedure is performed much deeper in the cornea than LASIK – which reshapes the superficial layers directly beneath the microscopic flap. The SMILE laser procedure preserves the corneal nerves intact and this means far less impact on dry eye patients. Studies are now starting to show that SMILE laser may give a better result than LASIK for those with higher errors.

Sure enough, within about a month of the installation of our new SMILE laser (in October 2014), Rachel was back! She had followed the news on our website and noted with interest the advent of the SMILE technique. Her eyes were much the same as before, only this time we could offer her a procedure that wouldn't aggravate her dry eye. She had both eyes treated with the SMILE procedure and within a couple of days (and no discomfort) later, she could see with crisp 20-20 vision - without glasses or contacts. To Rachel it was well worth waiting for; she can do more with her kids and enjoy life to the full without her heavy glasses. And she hardly missed a beat. She had surgery on a Friday and was back at work the following week. Now there's something to SMILE about!

For more case studies on other laser eye surgery procedures, read our book,* The Naked Eye, *available through our website

About the Authors

Clinical Associate Professor Michael Lawless

"People's desire to get out of their glasses is not a recent phenomenon. They have been thinking about alternatives to wearing glasses for hundreds of years. Why? Because, for the majority of people, it feels like a handicap. It is rarely a cosmetic issue. The issue is that if you wear glasses, you are dependent on something that is like a crutch. It is like having hearing loss. You can hear with a hearing aid, but you would prefer not to have the hearing aid." ***Michael Lawless***

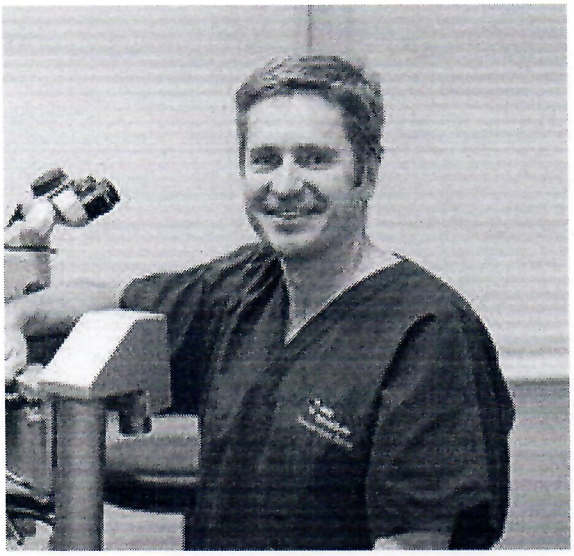
Clinical Associate Professor Michael Lawless is recognised worldwide as an authority in laser eye surgery. He specialises in laser vision correction, laser cataract and corneal transplant surgery.

Michael has performed over 25,000 surgical procedures and has always combined a busy surgical practice with clinical research and innovation. Michael's career highlights include:

- First Australian surgeon to perform laser cataract surgery laser with the femtosecond laser in February 2011
- Performed the first LASIK procedure in Sydney in 1995
- President, International Society of Refractive Surgery, 2001
- Chairman, Department of Ophthalmology, Royal North Shore Hospital and Northern Area Health Service, 2000 – 2006

For an appointment with Michael Lawless, call (02) 9424 9999

Professor Gerard Sutton



"Eye surgery is my passion and vocation. I love helping people to see more clearly..." ***Gerard Sutton***

Gerard Sutton is the Inaugural Professor of Corneal and Refractive Surgery at Sydney University. His appointment to the Chair in 2009 was a reflection of his international reputation as a surgical expert in laser vision correction, laser cataract and corneal transplant surgery. He is first and foremost an ophthalmic surgeon. To date, he has successfully performed around 20,000 surgeries. His chief strength is as an innovator who critically analyses new laser eye surgery technologies in order to provide the best and safest surgical options for his patients.

Gerard has introduced many new surgical techniques to Australia, as well as achieving many milestones in his career. They include:

- First Australian surgeon to complete overseas fellowship training in laser eye surgery
- First Australian surgeon to perform LASIK using the IntraLase femtosecond laser
- First Australian surgeon to perform a corneal transplantation using a femtosecond laser
- Chief Ophthalmologist for Sydney 2000 Olympics
- First Surgeon to perform SMILE laser procedure in Sydney

For an appointment with Gerard Sutton, call (02) 9424 9999