



Tempted by promises that you can throw away your glasses or contact lenses? Our investigation could change your mind. By Colin Meek

# Laser eye surgery

**Believe the hype** and you'd have no doubts that laser eye surgery is a safe and easy space-age solution to short or long sight. Boots says its eye surgery clinics use a unique radar eye-tracking system 'developed by NASA' to guide its surgical laser. Ultralase says: 'You too can enjoy freedom from glasses and contact lenses'. Patients are often told they can expect permanent improvements.

The claims are convincing a lot of people – around 100,000 people a year in the UK are now having laser eye surgery. But, as a string of companies gamble millions of pounds on opening networks of clinics all over the UK, patients are gambling with their eyesight.

It's usually claimed that complications caused by laser surgery to correct short or long sight (called refractive surgery) are rare. The Boots website on LASIK surgery – the most common type of laser surgery (see 'Laser options', page 23) – claims 'there are no known long-term side effects or complications'. The Maxivision brochure says that complications from LASIK are 'significantly less than 1 per cent'.

But in this report we uncover evidence to show that these claims are wildly misleading. We show that patients aren't being given all the facts and standards of care are being sacrificed as the market swells.

## Who are the eye surgeons?

One problem is that patients aren't told that complication rates vary widely from one surgeon to another and from clinic to clinic. David Gartry is a consultant ophthalmic surgeon at Moorfields Eye Hospital in London and a spokesman for the Royal College of Ophthalmologists. He's concerned that patients wrongly assume that refractive surgeons are always specialists. 'It's obviously not desirable that clinics can legally employ any doctor to do this work,'

Consultant ophthalmic surgeon at St Thomas' Hospital in London, David O'Brart, agrees. He says it's worrying that, while no surgeon has a 100 per cent success record, anyone with a medical degree can get involved. The Royal College is aware that some clinics have employed keen GPs as eye surgeons. The result, he says, is more eye complications and litigation.

We've found proof that he's right. The Medical Defence Union which provides professional insurance for doctors confirmed to us that it recently told doctors



carrying out any type of refractive surgery that they will have to pay more for their professional indemnity. It said this reflects a growing number of litigation cases. We've also learned that the Medical Protection Society, which plays a similar role, has not only put up its fees for refractive surgeons, it has also asked leading refractive surgeon Dan Reinstein to develop new guidelines to ensure safety standards are met by its members. They were due to be released as we went to press.

Photograph: Dan Duchars

# Laser options: PRK, LASIK and LASEK

Specialists are split on which is best. The use of PRK, the first laser method to hit the high street, has waned as other methods have become more popular. LASEK has fewer complications than PRK. In LASEK the epithelium (top layer of the cornea) is detached. The surface of the cornea is then reshaped using a laser and the epithelium is replaced. Recovery can be uncomfortable and takes about a week.

LASIK was developed in the mid-1990s. A device called a microkeratome cuts a flap about one third of the thickness of the cornea. This flap is left attached to the cornea by a 'hinge'. The bed beneath the flap is then reshaped using the laser and the flap is replaced. Recovery is very rapid, generally over about 12 hours.

Some say there may be more complications with LASIK as it's a more complex procedure. They also say the deep cut may weaken the cornea in the long term, possibly meaning more cases of corneal ectasia. This potentially devastating complication – where corneal weakness causes a bulging of the cornea due to pressure of fluid in the eye ball – may have to be treated with a corneal transplant. It is thought that ectasia is only seen in those who shouldn't have had LASIK – those with abnormal or very thin corneas, for example. It's also widely assumed that ectasia only occurs in fewer than one in 100,000 patients.

However, one follow-up study published in the *Journal of Cataract and Refractive Surgery* in 2001 on the LASIK treatment of 2,873 eyes found that 0.66 per cent developed ectasia – one in every 151. While some of the cases were found among patients who shouldn't have had the treatment in the first place, that wasn't the case for all the patients. The authors concluded that, until patients at risk of ectasia can be better identified, then new and stricter guidelines should be introduced on who can be treated with LASIK surgery.

Dan Reinstein, fellowship-trained specialist refractive surgeon, was an expert advisor to the US Food and Drug Administration on ectasia. His studies show the risk can be cut to just one in 10,000 if corneal thickness is accurately measured before surgery and the flap is cut thinner and more accurately. Other specialists at Moorfields Eye Hospital argue that, in the right hands, LASIK is safe and very effective. So far their results show that to be true. Most specialists reject the view that LASIK weakens the cornea significantly. But given the potential problems and concerns there's a growing interest in LASEK surgery.

Dan Reinstein is one of very few ophthalmologists working in the UK who is a fellowship-trained specialist refractive surgeon. Mr Reinstein is medical director of the London Vision Clinic, assistant professor of clinical ophthalmology at Cornell University in New York and professor of ophthalmology at the University of Paris. He was medical director of a chain of more than 30 laser surgery clinics in the US and Canada.

He told *Health Which?*: 'LASIK is extraordinarily safe in fully trained hands, but even average surgeons can still get it right 90 per cent of the time. There is a marked difference between expert and just experienced surgeons. Expert surgeons are better equipped to avoid complications even if they have not previously seen them. And when these do occur, trained experts will have the knowledge and ability to correct them.'

## What can go wrong?

Complications vary depending on the type of surgery (see 'Laser options', left). LASIK is more popular but it is more invasive than LASEK. Corneal haze (which may affect some patients' vision) is highly unlikely with LASIK, but LASIK is linked with a range of other potential complications – many linked to the cutting, handling or healing of the corneal flap. The flap can be cut too thin, it can 'wrinkle' or become dislodged within weeks after the surgery. The flap can accidentally be cut free from the cornea during the operation or debris can get trapped under the flap. These problems can be corrected but generally require expert management or further surgery.

There is a small chance that LASEK, PRK or LASIK can damage your sight – that is, losing the ability to completely focus the vision with glasses.

Infections are very rare but extremely serious if not managed correctly. In LASIK inflammation under the flap – termed DLK – can also be serious and is more common. Another side effect of LASIK is a temporary increase in dry eye. In rare cases it can be severe and debilitating, although it can be avoided by careful patient screening. One other extremely serious complication is called corneal ectasia (see left).

## How often does it go wrong?

Ophthalmologists measure damage to vision by counting the number of lines a patient is no longer able to read on a vision chart with glasses. They term this a loss of 'best-corrected vision'. When this happens the surgery leaves the patient with decreased sharpness (with or without glasses) compared to before the surgery when using glasses. A loss of two lines or more is considered 'significant.'

While skilled and experienced surgeons can keep the rate of visually significant complications to less than 1 per cent using LASIK there is no agreement about how commonly things go wrong across the industry.

Even so, several clinical studies report LASIK complication rates much higher than 1 per cent. 'If you read the literature from the clinics, then the evidence from peer reviewed journals, sometimes you think you are reading about two different things,' says Mr O'Brart.

For example, studies suggest the incidence of DLK

## Pros and cons

LASIK	LASEK
<b>Pros</b> Little post-operative pain Vision settles within 12 hours	Corneal haze seen in PRK is rare Potentially safer as flap complications of LASIK do not occur
Re-treatment is easy and can be done within three months	Does not weaken the cornea
<b>Cons</b> Several complications related to the corneal flap Evidence LASIK is linked to corneal ectasia although rare Expensive (a. £1,000/eye)	Slow (seven days) and uncomfortable recovery Re-treatment can only be undertaken after six months

### Problems common to both

Glare or starbursts around lights – this can impair night vision.

John Pickering heads the personal injury department of the national firm of solicitors, Irwin Mitchell. He's also a member of the Law Society's clinical negligence panel. He told us his firm is seeing a growing number of enquiries from people who have had poor outcomes from LASIK surgery. 'That's across England,' he told us. 'This may be an early sign that there is a lurking problem. The situation is already recognised to be serious in the US.'

ranges from 0.2 per cent to 3.2 per cent. Flaps can become dislodged in 1.1 to 2 per cent of cases depending on which studies you look at. Moorfields experts say that while most patients will have their sight vastly improved, around 2 to 4 per cent of LASIK patients will have a measurable loss of best-corrected vision. Overall, one study published in the journal *Ophthalmology* in 1999 tracked the outcome of LASIK in more than 1,000 eyes. It found that complications occurred in 5 per cent of cases and 4.8 per cent of patients saw a loss of best-corrected vision. However, this study also found that complication rates improved as the surgeons became more experienced.

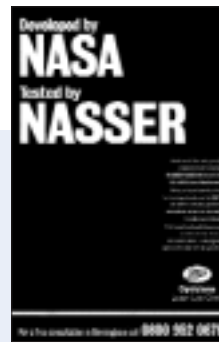
### What is a 'minor' complication?

Another problem in gauging the true level of complications with LASIK is the interpretation of what is 'minor'. Halos, starbursts and glare problems can degrade night vision. 'Ghosting' or double vision has also been reported. 'For some patients these so-called minor symptoms are anything but minor,' Dr Greg Gemoules told us. He is an optometrist based in Texas who specialises in correcting laser surgery complications with hard contact lenses. Patients with these symptoms may have to stop driving, they may find normal functioning in the evening or in dim light impossible and may even lose their jobs.

Rebecca Petris has worked on behalf of people with such complications in the US and the UK. She has experienced months of pain after unsuccessful LASIK surgery and regrets having the treatment. She points out that optometrists and ophthalmologists fail to give serious consideration to the practical impact of so-called 'minor' complications like double vision and starbursting. 'I can't recognise people more than ten feet away, I can no longer drive, but I can read an eye chart,' she told us. Because she can read most of the chart, this sort of problem isn't considered 'significant'.

'Wavefront technology' can correct night vision

Celebrity endorsements and promises of success are attracting thousands to have surgery



problems and other surgery complications by shaping the cornea more accurately. Early research shows it can help. But we've talked to specialists who point out that few Wavefront machines are capable of accurately measuring the optical defects. That may explain why there are conflicting reports about just how effective Wavefront is (see 'Forced to quit job', page 25).

Few studies have looked at the numbers who end up with starbursts and glare following LASIK. But recent research carried out by Melissa Bailey, postdoctoral fellow in vision science at Ohio State University, suggests these complications mean at least a quarter of patients report problems seeing at night, although many were still pleased with their corrected sight.

Rebecca Petris, Dr Gemoules and others are concerned that clinical studies heavily underestimate the number of people with problems following surgery. Statistics are skewed because complications go unreported – this can happen because surgeons may not report complications in patients who go elsewhere for help. Also, studies frequently refer to high success rates but fail to mention the impact of 'minor' problems that can leave patients disabled.

In January last year the results of a major review by the American Academy of Ophthalmology were published. It concluded that while very serious LASIK complications such as ectasia are rare, side effects such as dry eyes, night time starbursts and reduced contrast sensitivity occur 'relatively frequently'.

Our findings on LASIK complications show that Maxivision is wrong when it claims that complications affecting vision are 'significantly less than 1 per cent'.

Boots is also wrong to claim that there are 'no known long-term side effects or complications' of LASIK. Commenting on this claim Dr Gemoules told us: 'Certainly patients have had long-term complications – otherwise I would not be treating them.'

The Advertising Standards Authority has also upheld complaints against misleading ads for LASIK surgery from Boots, Maxivision and Optimax.

### Good and bad practice

There are no certainties with refractive surgery. While most patients are pleased with the results, some doctors are operating on patients not knowing for sure how they will react. As a result there's growing concern that some surgeons and clinics are glossing over the risks. 'People are being told the only realistic risk is under- or over-treatment when that isn't true,' Rebecca Petris told us. She says the verbal promises made by the surgeons often make the informed consent process meaningless.

Dr Gemoules told us: 'Patients literally cannot comprehend what it is like to experience distortions that are omnipresent from which there is no relief,

## Immediate results didn't last

Chris Dyer opted for LASIK as he wanted to ride his motorbike, ski and climb without the hassle of contact lenses. After looking at three clinics he opted for Maxivision in Manchester, paying nearly £1,700.

We planned to use Chris' story as an example of good results. Immediately afterwards he said his vision was 'remarkable'. But while preparing this article Chris' sight became less sharp. He has now been told his sight has deteriorated by about 8 per cent since the operation – although it's better than before. Chris now needs glasses to see things like station departure boards. 'Maxivision went to some length to stress that I may not have perfect vision afterwards,' he says. 'But the fact I still need glasses means LASIK hasn't worked in the way I had hoped.' He may ask for a re-treatment. We'll keep you posted.



Photographs: Robin Beckham, John Trenholm

## Forced to quit job

Jon Whelan is 30 years old. He spent £3,000 on LASIK surgery at Moorfields Eye Hospital in January 2001. Over a year later complications made his sight so bad that he was forced to leave his job in a picture library, he can't drive at night or read in dim light. He told us: 'They kept saying they thought the surgery was a success - I didn't.'

The day after the surgery he had what he describes as an 'even blurring' across his eyes, his peripheral vision was blurred, night vision was terrible and he had lost his awareness of depth. 'I was told I was a higher risk patient, but I was also told that Wavefront treatment could solve potential complications.'

After several follow-up consultations at Moorfields he had Wavefront treatment in January 2002. Although his sight improved during the day it is still bad in the evening and in dim light and he still can't drive at night. He thinks his sight is now worse than before the first surgery. 'The problems affected me in ways I would never have anticipated.' Jon went to Texas to see Dr Greg Gemoules and has been fitted with special hard contact lenses which provide better vision than his 'best corrected' vision before the surgery. However, he now has to rely on the lenses.



or the need to use eye drops every hour, every day.'

However, you may be able to reduce your chances of experiencing a debilitating complication. Mr O'Brart says the surgeons and clinic chains should be able to give patients information detailing complication and success rates so that valid comparisons can be made. Mr Reinstein lists all his complication rates and success statistics on his website and Mr O'Brart's are available in published research.

While clinics are happy to claim that LASIK is safe and has very low complication rates, some clinics in the UK don't make their own rates available. For instance, Boots, Ultralase and Maxivision told us they collect information on the complication rates of their surgeons. But Maxivision says only overall complication rates for their surgeons are available for patients and that's only once they've booked surgery. Ultralase say data is only available to patients on request. Boots said the information isn't publicly available.

Remarkably, Accuvision said they don't monitor complication rates for their individual surgeons. The US Food and Drug Administration says doctors should be willing to discuss their outcomes compared to results reported in studies.

## Check credentials

All the corneal surgeons we spoke to agree that the main problem facing patients is the lack of safeguards on who can carry out refractive surgery. In fact some argue that practically all the significant problems linked to LASIK are down to poor practice. Currently, any doctor employed by a refractive surgery chain can operate after a laser surgery course of just a few days.

But while specialists agree that most doctors can easily do routine surgery, they say it takes years of formal training and then experience to develop expertise to deal with complications. Many eye surgeons simply refer patients on to others or they deal with them in an inappropriate way.

To help protect patients the Royal College of Ophthalmologists is currently reviewing its professional guidelines on refractive surgery. The guidelines, which Mr Gartry helped draft, are due out

soon. He told us that they will state that only doctors with specialist training should practice laser surgery. This means doctors should be on the GMC Specialist Register, they will be an ophthalmologist and will have trained for around eight years. Mr O'Brart says: 'You

need to achieve a high standard before you slice open someone's eye.'

Most surgeons used by the clinic chains we contacted are either on the GMC specialist register or are consultant ophthalmologists. All of those employed by Boots and Accuvision meet that criteria; five out of six in Maxivision and ten out of 13 at Ultralase.

But Mr Reinstein warns patients that being on the specialist register doesn't guarantee that the surgeon is a specialist in laser surgery. 'All it tells you is that the doctor is an ophthalmologist.'

A surgeon can still be on the specialist register and still have no formal training or experience in refractive surgery.

Privately, consultant ophthalmologists in the UK we spoke to concede that only specialist corneal surgeons should perform refractive surgery. Some go further and say only those with formal specialised training should be allowed. However, they admit that the Royal College is unlikely to adopt this in the foreseeable future.

Dan Reinstein argues that until more stringent rules are introduced on who can do the surgery then patients must protect themselves by asking tough questions. He recommends that patients should only use a surgeon who is an ophthalmologist, who can confirm they have had formal, supervised training in refractive surgery of at least several months duration, who have carried out a large number of refractive surgery procedures, who can readily provide exact statistics and show they have a low complication rate and, ideally, manage their own complications.

## Verdict

**Patients shouldn't be taken in by claims about the safety and success rates of laser eye surgery. While most do benefit from laser eye surgery nobody knows the real numbers who have disastrous or disappointing results although we do know litigation is increasing. Complication and success rates vary from clinic to clinic and from surgeon to surgeon.**

**Patients need more honesty about so-called 'minor' complications and the fact that many people who have surgery still need glasses or lenses. We'd like the National Care Standards Commission to ensure all clinics are registered with them. We'd also like all companies to publish their complication rates and results and have these independently audited so that patients can make an informed choice. Until then, patients have no choice but to protect themselves by asking clinics and surgeons very tough questions. □**

Health Which? published by Consumers' Association, 2 Marylebone Road, London NW1 4DF, UK, for further information please call

☎ 0800 252 100 (in the UK), or ☎ +44 1992 822800 from outside the UK.