Laser refractive eye surgery

Andrew Bastawrous,¹ Alexander Silvester,² Mark Batterbury¹

¹St Paul's Eye Unit, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Liverpool L7 8XP, UK ²Royal Liverpool and Broadgreen University Hospitals NHS Trust, Liverpool L7 8XP

Correspondence to: A Bastawrous and rew.bastawrous@gmail.com

Cite this as: *BMJ* **2011;342:d2345** doi: 10.1136/bmj.d2345 Early attempts at refractive surgery used partial thickness corneal incisions to alter the curvature of the cornea, with the most popular technique being radial keratotomy. In 1990 the Prospective Evaluation of Radial Keratotomy study found that outcomes were unpredictable and unstable, and this led to the use of ablative laser refractive surgery instead.¹

We review evidence for the efficacy of laser refractive surgery mainly from randomised controlled trials and discuss suitability, contraindications, and potential complications of the procedure to help generalists in answering patients' queries.

Refractive error

Refractive error was recently reviewed in the *BMJ*.² Refraction (measured in dioptres) is the process by which light is focused on the retina. The optical components of the eye are the lens, the length of the eyeball, and the cornea. The cornea provides three quarters of the overall refractive power of the eye.

If the eyeball is too long or the cornea too curved ("steep"), light will focus in front of the retina and result in short sightedness (myopia; fig 1). If the eyeball is too short or the cornea is too flat, light will focus behind the retina and result in long sightedness (hyperopia). Myopia is

SOURCES AND SELECTION CRITERIA

We searched PubMed for articles in English on laser refractive surgery. We also consulted guidelines issued by the Royal College of Ophthalmologists, the American Academy of Ophthalmologists, and the National Institute for Health and Clinical Excellence. We identified systematic reviews and randomised controlled trials as well as informative and relevant level C research. Search terms were "laser assisted in situ keratomileusis", "laser epithelial keratomileusis", "photoreactive keratotomy", "myopia", "hyperopia", "astigmatism", and "laser surgery".

SUMMARY POINTS

Refractive errors are common

Laser eye surgery is an effective alternative to refractive correction with spectacles or contact lenses

Glasses do not cause long term corneal problems, but contact lenses carry a small risk Serious complications of laser eye surgery are rare and can be minimised through patient selection and advances in technology

Less serious complications are common and often under-reported as "side effects" or "symptoms"

Data on long term safety and stability are lacking largely because techniques are still evolving

therefore corrected by placing a concave lens in front of the eye or by surgically flattening the cornea, and hyperopia is corrected by using a convex lens or steepening the cornea. In astigmatism the refractive power of the eye is not the same in all meridians. Astigmatic errors can be partially corrected by flattening or steepening the cornea in the axis where refractive capacity is great or weak, respectively.

Laser treatment ablates (removes) corneal tissue. In myopia the aim is to flatten the centre of the cornea. In hyperopia ablating a mid-peripheral ring of cornea causes the centre to protrude (steepen).

Who is suitable for laser eye surgery and who is not?

Patients over 21 years with myopia (up to about 10 dioptres), hyperopia (up to about 4 dioptres) or moderate astigmatism and a stable spectacle prescription (<0.5 dioptres change after one year) may be suitable for laser refraction surgery.

Box 1 lists the absolute and relative contraindications to laser eye surgery. Patients with intraocular inflammation, keratoconus, or active infection are not suitable for laser refractive surgery. Herpes simplex virus may be reactivated by the laser in patients with previous keratitis caused by the virus and those with active herpes simplex virus may be at risk of corneal perforation.³ Patients with

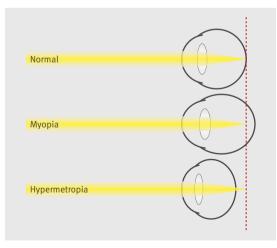


Fig 1 | Diagram depicting emmetropic (normal), myopic, and hypertropic eyes. In myopia, light focuses in front of the retina, usually because of a long axial length, a steep corneal curvature, or a combination of the two. In hypermetropia, the converse is true—light focuses behind the retina, usually because of a short axial length, a flat corneal curvature, or a combination of the two

Box 1 Contraindications to laser eye surgery
Absolute
Unstable refraction
Keratoconus
Active infection
Intraocularinflammation
Uncontrolled glaucoma
Relative (precludes the patient from having surgery in most situations)
Dry eye syndrome
Thin cornea
Blepharitis
Cataract
Glaucoma
History of herpes simplex keratitis
Ocular trauma
Previous ocular surgery

dry eyes should be identified and treated before laser refractive surgery because dry eye syndrome is a common postoperative complication. Laser assisted in situ keratomileusis has been associated with a transient rise in intraocular pressure, so patients with glaucoma are at risk of further nerve damage. Such patients should be offered photorefractive keratectomy as an alternative refractive procedure,⁴ or advised against any type of cosmetic refractive laser surgery. Furthermore, corneal thinning after laser refractive surgery will make intraocular pressure measurements more difficult, which would affect the future management of glaucoma. Patients with pre-existing cataracts should not have refractive laser surgery because progressive cataract can cause refraction to shift. Modern cataract surgery carried out in a good NHS treatment centre has a long track record of predictable unaided vision.

People over the age of 40 are likely to develop presbyopia. Presbyopia is a normal ageing process caused by loss of flexibility of the crystalline lens within the eye. As presbyopia develops so does the need for reading glasses or a reading addition to existing glasses. Laser refractive surgery has no effect on the crystalline lens and the eye's ability to focus at both near and far distances, so it is not recommended for presbyopia. "Monovision" can be attempted in some patients with pre-existing refractive error and presbyopia; in this situation one eye is in focus for near vision and the other is in focus for distance vision.

How should suitability be assessed?

Careful preoperative assessment is necessary to determine whether a patient is suitable for laser refractive surgery, and if so which technique is most appropriate. It is useful to inquire about the patient's expectations, to see whether they are realistic. Take a careful ophthalmic history; in particular ask about previous ocular surgery, history of glaucoma, infection, and dry eyes. Inquire about the patient's occupation and lifestyle to assess the risk of flap injury after laser assisted in situ keratomileusis (for example, during contact sports). Examination should include measurements of visual acuity, refraction, curvature of the cornea (keratometry), corneal thickness (pachymetry), and pupil size. Slit lamp examination of the eye, including intraocular pressure measurement, and dilated funduscopy should be performed. Advise patients not to wear hard contact lenses for four weeks and soft contact lenses for two weeks before assessment.⁵ They may also need to abstain from wearing contact lenses for up to eight weeks before the final measurement and treatment.

It is now routine practice to perform a more detailed test of refraction known as wavefront aberrometry. This can refine and further personalise the laser treatment and can improve visual outcomes.

What do the procedures involve?

In laser assisted in situ keratomileusis a hinged partial thickness corneal flap is cut by a microkeratome or a femtosecond laser; the flap is then folded backwards, the underlying stromal bed is ablated, and the flap is replaced (fig 2). Microkeratome flap creation has excellent predictability in the central area for flap thickness but a greater disparity between the central thickness and peripheral thickness compared with femtosecond laser flap creation.⁶ Specific corneal and eye socket morphologies as well as available technology may lead a surgeon to choose one technique over another.

In photorefractive keratotomy and laser epithelial keratomileusis—both surface laser techniques—the epithelium is removed to expose the corneal stroma, which is then ablated (fig 2). In laser epithelial keratomileusis the epithelium is preserved as a sheet, which is replaced and held in place with a soft contact lens (fig 2). In both situations new epithelium grows back within a week.

The operations are performed as day cases with local anaesthetic eye drops and take 15-20 minutes.

What results can be expected?

Newer technologies allow more accurate measurements of the eye and more precise laser treatment. The healing response is unpredictable, however, so that scarring and refractive error vary and results are impossible to guarantee.

A Cochrane review of photorefractive keratotomy versus laser assisted in situ keratomileusis for myopia in 2005 analysed results from six randomised controlled trials and concluded that final uncorrected visual acuity after laser assisted in situ keratomileusis and photorefractive keratotomy is comparable at 12 months after treatment.⁷ Both techniques were equally effective at achieving a post-treatment refraction within ±1.00 dioptres of target refraction at six and 12 months. Safety was measured as the proportion of eyes that lost two or more lines of best spectacle corrected visual acuity at six months or more after treatment; no difference in this outcome was found between the two treatments. The review found that laser assisted in situ keratomileusis was associated with less postoperative pain and more intraoperative discomfort and that visual recovery is more rapid after this technique than after photorefractive keratotomy.

A more recent meta-analysis compared photorefractive keratotomy with epithelial keratomileusis and found that the efficacy and accuracy outcomes were comparable at one month and 12 months.⁸ It also found no differences in post-procedural discomfort and corneal haze intensity between the two procedures.

A systematic review of the patient reported outcome of satisfaction after laser assisted in situ keratomileusis found that most patients (95.4%) were satisfied with the

Epithelium Stroma Endothelium

results.⁹ Dissatisfaction was associated with postoperative complications, such as dry eye, pain, glare, and halos.

In general, the bigger the refractive error the less accurate the result will be; high astigmatism may not respond well to treatment and cannot always be fully eliminated; and surface laser techniques produce better results for thin corneas.

How well can patients see after surgery?

Chief outcome measures are unaided visual acuity, best corrected visual acuity (with spectacles), and deviation from planned postoperative refraction.

Uncorrected visual acuity has been reported at 6/12 or better (driving standard in the UK approximates to 6/10 with both eyes open) in 46-100% of eyes, depending on the study and degree of myopia (box 2).¹⁰ Higher refractive errors have less predictable results and more undercorrections and overcorrections are seen.¹¹ ¹²

Results for hyperopia are similar to myopia, although visual recovery is slower, with a higher incidence of regression and need for retreatment.

Retreatment is reported after 10% of procedures as a result of initial undertreatment or overtreatment (in high refractive errors intentional undertreatment is common) or regression.¹³ Retreatment is usually performed after three months, once refraction stabilises.

Some loss (for example, one line) of best corrected visual acuity is common but may not be noticed by the patient because the improvement in uncorrected visual acuity can be so profound.

It should be noted that postoperative 6/6 vision may be subjectively different from preoperative 6/6 best corrected visual acuity because of reduced contrast sensitivity, so patients with high visual demands should be cautioned when interpreting data.

What are the possible complications after surgery?

Box 3 lists the potential complications after laser surgery. Patients are routinely prescribed topical antibiotics (usually chloramphenicol) after surgery to reduce the risk of infection. Immediately after the procedure, patients are advised to wear sunglasses (because of mild photophobia) and to arrange for someone to drive them home. Patients should contact the clinic or hospital if they develop loss of

Box 2 | Visual acuity

Visual acuity is a measure of the spatial resolution of the visual processing system. It is measured using a high contrast (black on white) chart at a distance that approximates to infinity; the standard distance is taken as 6 m or 20 ft. This distance is the numerator in the expression of visual acuity (6/X or 20/X). The denominator is the distance at which the optotypes (usually letters but can be symbols or pictures) can be seen with "normal" vision or corrected vision. For example, someone with normal vision, "6/6," should be able to read the top letter of the chart at 60 m, so the denominator would be 60. Hence someone who can see the top letter at only 6 m or closer would have a Snellen visual acuity of 6/60. The terms "20/20" (more common in the United States) and "6/6" (more common in the United Kingdom) vision are the same, with "6/6" being the metric expression.

Fig 2 | (A) Intact cross section of the cornea. (B) Photoreactive keratotomy: epithelium is removed, exposing the corneal stroma, which is then ablated. (C) Laser epithelial keratomileusis: as for photoreactive keratotomy except that the sheet of epithelium is preserved and replaced. (D) Laser assisted in situ keratomileusis: a hinged partial thickness corneal flap is cut by a microkeratome or a femtosecond laser, the flap is folded backwards, and the underlying stromal bed is ablated; the flap is then replaced. (E) Centrally flattened cornea after myopic treatment

Box 3 Complications of laser eye surgery
Serious
Infectious keratitis
Diffuse lamellar keratitis
Flap related complications
Corneal ectasia
Less serious
Dry eyes
Haze
Reduced best corrected visual acuity

vision, increasing redness, or more than mild pain. They are advised not to play contact sports or swim for at least four weeks. Serious complications from refractive surgery are rare but can occur.

Excessive ablation can result in the loss of corneal stability and lead to the serious sight threatening complication of corneal ectasia. A systematic review by the National Institute for Health and Clinical Excellence (NICE) reported a median 0.2% (range 0-0.87%) risk of ectasia after laser assisted in situ keratomileusis; no risk estimates were reported for photorefractive keratotomy.

The risk of infectious keratitis can be reduced by preoperative preparation (lid hygiene and disinfection of skin and eyelids with iodine) and postoperative antibiotics. The incidence of this complication after laser assisted in situ keratomileusis in published studies of more than 1000 cases ranged from 0% to 0.19%.¹⁴ These figures are comparable to the incidence of microbial keratitis in contact lens wearers (daily wear soft contact lenses 1/2000 a year (0.05%), rigid gas permeable lenses 1/3000 a year (0.03%), and overnight wear lenses 1/500 a year (0.2%)).¹⁵

ADDITIONAL EDUCATIONAL RESOURCES

Resources for healthcare professionals

Royal College of Ophthalmologists (www.rcophth.ac.uk/ page.asp?section=368§ionTitle=Excimer±Laser±R efractive±Surgery)—Guidelines on various forms of laser refractive surgery

National Institute for Health and Clinical Excellence (www. nice.org.uk/guidance/IPG164)—Clinical guidelines on photorefractive (laser) surgery for the correction of refractive error

US Food and Drug Administration (www.fda.gov/ MedicalDevices/ProductsandMedicalProcedures/ SurgeryandLifeSupport/LASIK/default.htm)—Advice on laser assisted in situ keratomileusis

International Society of Refractive Surgery (www.aao.org/ isrs/)—Contains patient information leaflets, videos and information for doctors (US based)

Resources for patients

Royal College of Ophthalmologists (www.rcophth.ac.uk/ page.asp?section=368&search)—A patient's guide to excimer laser refractive surgery

Medline Plus (www.nlm.nih.gov/medlineplus/ lasereyesurgery.html)—Information on laser assisted in situ keratomileusis from the US National Library of Medicine

AREAS OF ONGOING RESEARCH

- The use of wavefront aberrometry to improve outcomes
- Femtosecond laser treatment
- Improvements in laser assisted in situ keratomileusis flap creation
- Femtosecond laser intrastromal vision correction: "flapless" refractive laser surgery
- Femtosecond laser assisted refractive cataract surgery
- The treatment of presbyopia with excimer and femtosecond lasers

Long term safety data are lacking largely because the techniques are rapidly evolving, so assumptions have to be made about the safety of the most up to date techniques. In a computer model simulating 30 years of contact lens wear versus laser assisted in situ keratomileusis in which multiple variables were tested, rigid gas permeable lenses were safer than laser treatment in every analysis. The safety of laser assisted in situ keratomileusis exceeded that for daily wear soft lenses only when assumptions were most favourable to laser treatment, whereas the safety of laser treatment always exceeded that for extended wear lenses except when assumptions were least favourable to laser treatment.¹⁶

Complications associated with flap formation in laser assisted in situ keratomileusis include thin, incomplete, and irregular flap creation. The introduction of the femtosecond laser, which is more precise, has reduced these.

Less serious complications are more common. Dry eye syndrome occurs in more than half of patients,¹⁷ is often transient, can be treated with conventional treatment including artificial tears, and improves over weeks to months.¹⁸ Problems with haze, glare, and night vision have been associated with photorefractive keratotomy and are less common after laser assisted in situ keratomileusis.

NICE guidance

NICE issued guidelines on laser surgery for the correction of refractive errors in 2006.¹⁹ The guidelines stated that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious in selected patients; they also acknowledged that laser treatment is a "fast moving area" and that new techniques are emerging. The guidelines made no recommendations about selection, indications, or contraindications, however, but stated that "doctors should be sure that the treatment is suitable for that particular eye of the person." They acknowledged the difficulty that patients have in identifying properly trained practitioners for the procedure; the Royal College of Ophthalmologists responded by outlining standards for laser refractive surgery.²⁰ The college recommended that laser refractive surgeons should hold the Certificate in Laser Refractive Surgery; they must be members of a medical defence organisation or maintain professional indemnity insurance; and they should undertake postoperative evaluation and provide guidance for patients, information on the consent process, and advertising and marketing material on the premises in which the surgery is undertaken.

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4

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Ethics on the London Underground

As I let myself fall into the only vacant seat in the London Underground carriage, I caught sight of something to my left. I closed my eyes to recapture detail. The occupant of the seat to my left had been holding a piece of paper titled with the name of someone I knew, and halfway down was a heading, "Mr X's schooling." Did I really know that Mr X? No, but it was not a usual name, and it was that of a friend of my parents long ago.

A rustle on my left, and I allowed myself to glance in that direction. The page that I had first seen was replaced by a photocopy of what looked like a paper from a journal of psychotherapy or counselling.

What to do? I spend part of my time running personal and professional development groups with junior doctors at Newham University Hospital, and I run similar groups on family therapy courses at the Institute of Psychiatry in south London. I frequently emphasise some of my favourite bits of systems theory, especially how we cannot "not intervene" in a system. Once we have observed, the system is changed and we have become part of it.

The person sitting on my left had transgressed an ethical rule by reading a confidential document in a public place. And I was now part of that system. I, sitting there, was colluding.

What to do? I ruminated. I had to do something—but I was already doing something, and that was colluding. I had to do something different. I stopped ruminating and worked out what to do. I decided to act when the train had departed the station just before the one where I was due to exit. I felt my heart beating fast as my anxiety increased. I was dreading seeming intolerably pompous.

At the planned moment, I turned my whole body, legs and knees included, to face the person. Having gained immediate attention, I spoke as quietly as possible for that person alone to hear. "I must speak to you," I faltered, "I must speak to you." The person looked surprised but attentive and had a pleasant sensitive face. "I knew Mr X," I said. The person looked terribly shocked. "Well, at least, I knew someone called that."

"I'm sorry," the person responded, looking horrified and speaking as quietly as I had.

As the person started to say more, I held up my hand and interrupted: "No, I don't want you to talk. I want you to listen to me. I am a retired psychiatrist, and I was trained as a psychoanalyst [it didn't come out too pompously], and if I'd done what you have done I could have been struck off."

The person stared at me with an appalled expression and said even more quietly, "Thank you" and repeated it.

I said no more as the train slowed down. We stayed looking at each other as it stopped, and I received one last "Thank you."

As I walked down the platform, I realised that I had got out one stop too early, but I did not have time to wait for another train, so I hopped into the next open carriage. Peter Bruggen retired consultant psychiatrist and, once, a psychoanalyst. London

pbruggen@blueyonder.co.uk Cite this as: *BMJ* 2010;340:c2592