

Photorefractive (laser) surgery for the correction of refractive errors

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg164

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG102.

1 Guidance

- 1.1 Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients.
- 1.2 Clinicians undertaking photorefractive (laser) surgery for the correction of refractive errors should ensure that patients understand the benefits and potential risks of the procedure. Risks include failure to achieve the expected improvement in unaided vision, development of new visual disturbances, corneal infection and flap complications. These risks should be weighed against those of wearing spectacles or contact lenses.
- 1.3 Clinicians should audit and review clinical outcomes of all patients who have photorefractive (laser) surgery for the correction of refractive errors. Further research will be useful, and clinicians are encouraged to collect longer-term follow-up data.
- 1.4 Clinicians should have adequate training before performing these procedures. The Royal College of Ophthalmologists has produced standards for laser refractive surgery.

2 The procedure

2.1 Indications

- 2.1.1 Photorefractive (laser) surgery is used to treat refractive errors such as myopia, astigmatism and hyperopia.
- 2.1.2 Refractive errors are usually corrected by wearing spectacles or contact lenses. Surgical treatments have been developed to improve refraction by re-shaping the cornea.

2.2 Outline of the procedure

- 2.2.1 In photorefractive surgery, corneal re-shaping is achieved using excimer laser ablation. Excimer laser techniques include photorefractive keratectomy (PRK), laser epithelial keratomileusis (LASEK) and laser in situ keratomileusis (LASIK).
- 2.2.2 PRK involves the removal of the corneal epithelium by surgical dissection and excimer laser ablation of a calculated amount of the stromal bed of the cornea. LASEK is a modification of PRK; dilute alcohol is used to loosen the corneal epithelium before it is lifted from the treatment zone as a hinged sheet, and then replaced at the end of the procedure. In LASIK, a flap is created with a microkeratome; this is lifted before laser ablation and then repositioned.

2.3 Efficacy

- 2.3.1 A systematic review of the published evidence on these procedures was commissioned by NICE.
- 2.3.2 In seven randomised controlled trials (RCTs) included in the review, there were no significant differences between the three procedures in the proportion of eyes treated for myopia or myopic astigmatism achieving the predicted refractive outcome. Data from more than 2,000 eyes treated with PRK for myopia showed

that a median of 69% of eyes had achieved within 0.5 D of their intended correction, and that 89% had achieved within 1.0 D. Data from case series of more than 1,800 eyes undergoing LASEK for myopia or astigmatism showed that a median of 75% of eyes were within 0.5 D and a median of 92% of eyes were within 1.0 D of their intended correction at 3 to 6 months follow-up. Data from eyes treated with LASIK for myopia or astigmatism showed that 77% (7,309 out of 9,542) were within 0.5 D and 91% (8,109 out of 8,885) were within 1.0 D of their intended correction at 3 to 12 months. One RCT found LASEK to be significantly more accurate than PRK for eyes with hyperopia.

2.3.3 Final uncorrected visual acuity achieved was similar for all three techniques. For more details, refer to the [overview](#).

2.4 Safety

2.4.1 In eyes treated for myopia, loss of two lines of best spectacle-corrected visual acuity was seen in a median of 0.5% (0% to 20.5%) of eyes treated with PRK, 0% (0% to 8.2%) of eyes treated with LASEK and 0.6% (0% to 3%) of eyes treated with LASIK. Patients with high myopia were more likely to lose two or more lines of best spectacle-corrected visual acuity than those with moderate to low myopia.

2.4.2 Flap complications may occur during LASIK and LASEK, requiring conversion to PRK or postponement of ablation (with LASIK), and occasionally there may be loss of best spectacle-corrected visual acuity. Epithelial in-growth was reported in LASIK in a median of 1.3% (0.0% to 4.4%) of eyes.

2.4.3 Ectasia, a condition that can result from corneal thinning, is a serious complication related to refractive surgery that can lead to loss of vision. Data from the review estimated the risk of ectasia following LASIK as a median of 0.2% (range 0 to 0.87%; overall rate of 40 out of 10,806 eyes). However, many of the affected eyes may have been selected inappropriately for LASIK treatment, and with appropriate patient selection the rate might have been lower. Rates of ectasia were not reported following PRK, and very little information was reported about LASEK, with no cases of ectasia described in one case series of 171 eyes.

- 2.4.4 Microbial keratitis was only reported in LASIK studies and occurred in 0% to 0.16% of eyes. This incidence was similar to, or lower than, that reported for contact lens wearers.
- 2.4.5 Other patient-reported problems included visual difficulty in low light conditions, corneal haze, light halos and problems with glare. Significant corneal haze was reported following all three procedures (in 0% to 31% of eyes treated with PRK, 0% to 25% with LASEK and 0% to 2% with LASIK). Glare and night vision difficulties were less common after LASIK. For more details, refer to the [overview](#).

2.5 Other comments

- 2.5.1 These procedures can make it more difficult to measure accurately the intraocular pressure used to detect glaucoma, and the intraocular lens power required for cataract surgery. Techniques are available to address these difficulties, provided it is known that photorefractive surgery has previously been done.
- 2.5.2 It was recognised that this is a rapidly evolving procedure and that new techniques are emerging.
- 2.5.3 The current difficulties for patients in identifying properly trained practitioners for this procedure were noted. A working group of the Royal College of Ophthalmologists is currently devising a set of defined learning outcomes and assessments for all those wishing to undertake laser refractive surgery.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).