

Laser correction of refractive error following non-refractive ophthalmic surgery

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg385

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laser correction of refractive error following non-refractive ophthalmic surgery is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection and treatment should be carried out only by ophthalmologists who specialise in corneal surgery.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Refractive errors (myopia, hyperopia or astigmatism) can result from non-refractive ophthalmic surgery such as cataract surgery or corneal transplantation.
- 2.1.2 Refractive errors are usually managed by wearing spectacles or contact lenses. In patients for whom spectacles and contact lenses do not adequately correct the refractive error, other options include corneal relieving incisions, intraocular surgery such as cataract extraction with standard or toric intraocular lenses and laser corrective procedures.

2.2 Outline of the procedure

- 2.2.1 Three types of laser correction are considered in this guidance: photorefractive keratectomy (PRK), laser epithelial keratomileusis (LASEK) and laser in situ keratomileusis (LASIK), all performed with the patient under local anaesthesia. If required, they can be performed on both eyes during the same treatment session.
- 2.2.2 PRK involves removal of the corneal epithelium by surgical dissection followed by excimer laser ablation of a calculated amount of the stromal bed of the cornea. LASEK is a modification of PRK in which 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, lifted before laser ablation and then repositioned. Patients may be given pre- or postoperative antibiotics as prophylaxis against infection.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

- 2.3.1 A case series of 62 patients (87 eyes) who had LASIK after non-refractive ophthalmic surgery or refractive surgery reported that mean spherical equivalent refraction (MSER; a negative reading indicates myopia, a positive reading indicates hyperopia) improved from -5.25 D preoperatively to -0.70 D at 1-year follow-up.
- 2.3.2 A case series of 59 patients (85 eyes) who had LASIK after multifocal intraocular lens implantation reported that MSER improved from -0.34 D preoperatively to -0.07 D at 6-month follow-up ($p = 0.004$).
- 2.3.3 A case series of 48 patients (57 eyes) who had LASIK after penetrating keratoplasty (PK) reported that MSER improved from -3.94 D preoperatively to -0.61 D at 2-year follow-up.
- 2.3.4 A case series of 38 patients (46 eyes) who had LASIK after PK reported improvement in preoperative mean spherical refraction in myopic eyes ($n = 40$) and hyperopic eyes ($n = 3$) from -5.16 D to -0.44 D and 5.75 D to 1.67 D respectively, and improvement in mean preoperative cylindrical refraction in eyes with mixed astigmatism ($n = 3$) from -5.50 D to -2.42 D at 5-year follow-up. Overall, at 5-year follow-up, 63% (29/46) had a refractive error within 1.00 D of emmetropia.
- 2.3.5 The case series of 62 patients reported that the proportion of patients' eyes with uncorrected visual acuity of 0.5 or better increased from 5% (4/87) preoperatively to 70% (61/87) at 1-year follow-up.
- 2.3.6 Case series of 62, 59 and 48 patients who had LASIK after non-refractive ophthalmic surgery reported LASIK re-operation in 22% (19/87), 6% (5/85) and 9% (5/57) of eyes because of residual refractive errors, at follow-ups of 12, 6 and 24 months respectively.
- 2.3.7 The Specialist Advisers listed key efficacy outcomes as uncorrected visual acuity, reduced refractive error, maintained best-corrected spectacle vision and improved quality of life.

2.4 Safety

- 2.4.1 The case series of 48 patients reported that 15% (8/52) of eyes had lost ≥ 2 Snellen lines of best-corrected visual acuity at 1-year.
- 2.4.2 A case series of 41 patients (44 eyes) who had PRK after PK reported 3 eyes with grade 2 haze all requiring retreatment.
- 2.4.3 The case series of 59 patients reported 4 eyes with moderate or marked dry eye developing between 3 and 6 months follow-up. All eyes were treated frequently with lubricant. The case series of 48 patients treated with LASIK after PK reported persistent dry eye in 3 eyes at a mean follow-up of 21 months.
- 2.4.4 The case series of 48 patients reported: 4 eyes with epithelial ingrowth (requiring removal) between 1 week and 12 months; 2 eyes that required repeat graft for persistent astigmatism between 1 and 3 years; 3 eyes needing repeat graft for oedema between 8 months and 3 years; and 5 eyes with flap dislocation between 1 day and 1 week (2 required sutures, 1 flap was removed and 1 was repositioned without sutures).
- 2.4.5 A case series of 57 eyes reported: 2% (1/57) of eyes with macular haemorrhages 7 days after LASIK; 7% (4/57) of eyes with epithelial ingrowth; 4% (2/57) of eyes with induced astigmatism; 4% (2/57) of eyes with a free cap; and 25% (14/57) of eyes with night vision problems at a mean follow-up of 9 months.
- 2.4.6 The case series of 38 patients who had LASIK after PK reported endothelial rejection, which was successfully treated in 1 eye.
- 2.4.7 The Specialist Advisers considered theoretical adverse events to include ectasia, recurrent epithelial erosion syndrome, epithelial defects, bleeding from the flap edge, interface haemorrhage, interface debris, flap striae, diffuse lamellar keratitis, corneal scarring, glare, infection and pain after treatment.

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.

3 Further information

- 3.1 For related NICE guidance see our [website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. A large print version is also available.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

2 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

