NICE guidance

Laser correction of refractive error following non-refractive ophthalmic surgery

Interventional procedures guidance
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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.

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.

2.3 Efficacy

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.

2.3.1 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 out of 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 out of 87) preoperatively to 70% (61 out of 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 out of 87), 6% (5 out of 85) and 9% (5 out of 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 out of 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 out of 57) of eyes with macular haemorrhages 7 days after LASIK; 7% (4 out of 57) of eyes with epithelial ingrowth; 4% (2 out of 57) of eyes with induced astigmatism; 4% (2 out of 57) of eyes with a free cap; and 25% (14 out of 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

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.