

Photorefractive (laser) surgery for the correction of refractive errors

This document replaces previous guidance on laser in situ keratomileusis (LASIK) (NICE Interventional Procedure Guidance no. 102).

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 (www.rcophth.ac.uk/docs/publications/RefractiveSurgeryStandardsDec2004.pdf).

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 the Institute.
- 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 2000 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 1800 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.

Interventional Procedure Guidance 164

This guidance is written in the following context

This guidance represents the view of the Institute which 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

at 3–6 months follow-up. Data from eyes treated with LASIK for myopia or astigmatism showed that 77% (7309/9542) were within 0.5 D and 91% (8109/8885) were within 1.0 D of their intended correction at 3–12 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 Sources of evidence.

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% (0–20.5%) of eyes treated with PRK, 0% (0–8.2%) of eyes treated with LASEK and 0.6% (0–3%) 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% (0.0–4.4%) 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 40/10,806 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 0–0.16% 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 0–31% of eyes treated with PRK, 0–25% with LASEK and 0–2% with LASIK). Glare and night vision difficulties were less common after LASIK. For more details, refer to the Sources of evidence.

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.

Andrew Dillon
Chief Executive
March 2006

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG164publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

‘A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error’, April 2005.

Available from: www.nice.org.uk/ip320review

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0937. *Information for the public* can be obtained by quoting reference number N0938.

The distribution list for this guidance is available at www.nice.org.uk/IPG164distributionlist

Published by the National Institute for Health and Clinical Excellence, March 2006; ISBN 1-84629-106-2

© National Institute for Health and Clinical Excellence, March 2006. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the Institute.