Issue date: September 2010

NHS
National Institute for Health and Clinical Excellence

Phototherapeutic laser keratectomy for corneal surface irregularities

1 Guidance

1.1 Current evidence on the safety and efficacy of phototherapeutic laser keratectomy for corneal surface irregularities 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 Symptomatic corneal surface irregularities may result from a range of pathologies including band keratopathy, corneal scarring, nodular degeneration, epithelial basement membrane dystrophy or other dystrophies. Symptoms may include loss of visual acuity, pain, sensitivity to light and foreign body sensation.

2.1.2 Treatment aims to restore a normal regular corneal surface and adherence between the epithelium and Bowman's membrane (a basement membrane that lies between the outer layer of stratified epithelium and the substance of the cornea) with associated improvement in visual acuity and comfort.

2.1.3 Standard treatment includes lubrication of the ocular surface, bandage contact lens placement or topical medication. Surgical procedures may include anterior stromal puncture, mechanical debridement, lamellar keratoplasty or resurfacing keratectomy using a diamond burr. Corneal transplantation may be considered in eyes refractory to treatment.

2.2 Outline of the procedure

2.2.1 The aim of phototherapeutic laser keratectomy for corneal surface irregularities is to create a smooth stromal surface to improve postoperative corneal clarity, decrease existing scarring and facilitate subsequent epithelial adhesion.

2.2.2 Local anaesthetic eye drops are applied and the corneal epithelium is mechanically removed. A laser is used to sequentially ablate uniformly thin layers of corneal tissue, creating a smooth surface which then becomes re-epithelialised. Postoperative management consists of an eye pad, topical antibiotics, sedatives and non-steroidal anti-inflammatory drugs.

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, available at **www.nice.org.uk/IP788overview**

2.3 Efficacy

2.3.1 A non-randomised controlled study of 39 patients (42 eyes) reported no significant difference in overall change in best corrected visual acuity (BCVA) between patients treated by phototherapeutic laser keratectomy and those treated by diamond burr polishing at 7-month follow-up ($p = 0.6$): BCVA improved in 36% (5/14) and 14% (3/21) of eyes, remained unchanged in 64% (9/14) and 81% (17/21) of eyes and worsened in 0% (0/14) and 5% (1/21) of eyes respectively.

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This 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.

This guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by NHS QIS for implementation by NHSScotland.

2.3.2 In a case series of 211 patients (232 eyes) mean BCVA improved by 1.4 lines from baseline at 2-year follow-up ($p < 0.002$). No significant difference was reported in BCVA improvement between subgroups of patients with corneal dystrophy, nodular degeneration, corneal scar, or band keratopathy (absolute figures not stated) ($p = 0.15$).

2.3.3 In a case series of 216 patients (252 eyes), among eyes with recurrent erosion at baseline, further recurrent erosion was reported in 9% (9/103) of eyes at 12-month follow-up.

2.3.4 The case series of 216 patients reported that 100% (29/29) of eyes with band-like keratopathy were pain free by 6-day follow-up.

2.3.5 A case series of 191 patients (203 eyes) reported that significantly fewer patients with bullous keratopathy had severe symptoms of pain, photosensitivity and/or watering at 6-month follow-up ($n = 15$) compared with baseline ($n = 56$) ($p < 0.017$). Similarly, significantly fewer patients with corneal scarring had severe symptoms at 6-month follow-up ($n = 4$) compared with baseline ($n = 13$) ($p < 0.0001$).

2.3.6 The Specialist Advisers listed key efficacy outcomes as visual acuity, ocular surface health, ocular comfort and pain relief.

2.4 Safety

2.4.1 Recurrent keratitis requiring penetrating keratoplasty was reported in 1% (3/232) of eyes at up to 2-year follow-up in the case series of 211 patients.

2.4.2 One occurrence each of progressing keratolysis at 8-day follow-up, circular subepithelial corneal scarring at 5-month follow-up (both requiring penetrating keratoplasty), progressive kerectasia at 6 months (sequelae not reported), and a sterile corneal immune ring at 4-day follow-up, were described in 4 separate case reports.

2.4.3 A loss of BCVA of 2 lines or more was reported in 13% (3/24) of patients at 2-year follow-up in the case series of 211 patients.

2.4.4 Idiopathic iritis and a marginal corneal ulcer developed in 1 eye each at up to 2-year follow-up in the case series of 211 patients.

2.4.5 Mild postoperative haze was reported in 11% (22/203) of eyes in the case series of 191 patients; this resolved in 12 eyes by 6-month follow-up. There was no significant difference in the occurrence of mild haze between patients treated by laser phototherapeutic keratectomy (33% [5/15] of eyes) or by diamond burr polishing (26% [7/27] of eyes) in the non-randomised controlled study of 39 patients at 7-month follow-up ($p = 0.38$).

2.4.6 The Specialist Advisers identified corneal infection as an adverse event reported in the literature. They considered theoretical adverse events to include epithelial defect, corneal ectasia, scarring and induction of astigmatism or refractive error.

2.5 Other comments

2.5.1 The Committee noted that the published evidence comprised a mixture of different indications and outcomes, but nevertheless they considered that the case for safety and efficacy was adequately supported by this evidence and by specialist advice.

2.5.2 NICE received 3 completed questionnaires from patients treated by the procedure. They reported improvements in quality of life including reduced photosensitivity (which had required sunglasses) and the ability to walk with more confidence.

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. See **www.nice.org.uk/guidance/IPG358/publicinfo**

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2299 for this guidance, N2300 for the 'Understanding NICE guidance' or N2301 for the large print version of the 'Understanding NICE guidance'.

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ISBN 978-1-84936-353-2
N2299 1P 5.1k Sep 10