

Understanding NICE guidance

Information for people who use NHS services

Correcting corneal surface irregularities using phototherapeutic laser surgery

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how laser surgery can be used in the NHS to treat people with corneal surface irregularities. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe corneal surface irregularities or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with corneal surface irregularities provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

The procedure should only be done by ophthalmologists with specific training in corneal surgery, who should also decide which patients should have this procedure.

Other comments from NICE

NICE also received 3 questionnaires from patients treated by the procedure who reported improvements in quality of life including less sensitivity to light and walking with more confidence.

This procedure may not be the only possible treatment for corneal surface irregularities. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Correcting corneal surface irregularities using phototherapeutic laser surgery

The medical name for this procedure is 'phototherapeutic laser keratectomy for corneal surface irregularities'. It is also known as PTK.

The procedure is not described in detail here – please talk to your specialist for a full description.

Irregularities in the surface of the cornea (the clear section at the front of the eye) can be caused by various eye disorders, and may result in symptoms such as loss of ability to see clearly in detail (visual acuity), pain, sensitivity to light, or the sensation that something is in the eye.

Standard treatment includes lubricating or applying medication to the eye surface, or using a special type of contact lens. Surgical procedures to physically correct the cornea are also available.

In this procedure, local anaesthetic eye drops are applied and the outer layer of the cornea is removed. A laser then removes more thin layers from the cornea to leave a smooth surface where new tissue can grow. After surgery, an eye pad and antibiotics are applied to the eye, and sedatives and anti-inflammatory drugs are given.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 8 studies on this procedure.

How well does the procedure work?

In a study of 39 patients (in which 42 eyes were operated on), there was no difference in overall change to vision between patients treated by laser PTK or by diamond burr polishing. In the 14 eyes treated by laser, vision improved in 5 eyes, did not change in 9 and worsened in none. In the 21 eyes treated by diamond burr, vision improved in 3 eyes, did not change in 17 and worsened in 1.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks laser surgery is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

In a study of 211 patients (232 eyes), vision had improved 2 years after the procedure. The patients in the study had different eye disorders but this did not affect the amount vision improved.

In a study of 216 patients (252 eyes), of 103 eyes with recurrent erosion (where the outer layer of the cornea comes away), further recurrent erosion was reported in 9 eyes 1 year after surgery. In the same study, all 29 eyes with band-like keratopathy (calcium deposits in the cornea) were pain free 6 days after the procedure.

In a study of 191 patients (203 eyes), 56 patients with a swollen cornea (bullous keratopathy) had severe symptoms of pain, sensitivity to light and/or watering before surgery, compared with 15 patients 6 months after the procedure. In the same study, 13 patients with a scarred cornea had severe symptoms before the procedure, compared with 4 patients 6 months after surgery.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are to improve vision and the health and comfort of the eye, and to relieve pain.

Risks and possible problems

A cornea transplant was needed following cornea inflammation in 3 out of 232 eyes within 2 years of surgery in the study of 211 patients. Two other patients in separate cases also needed a transplant following cornea deterioration (progressing keratolysis) in the 8 days after the procedure, and corneal scarring in the first 5 months after the procedure.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

In 2 further separate cases, a deformed cornea (progressive kerectasia) was detected 6 months after surgery in 1 patient, and cloudy circles (sterile corneal immune rings) were seen 4 days after the procedure in 1 patient.

In the study of 211 patients, reduced vision was reported in 3 out of 24 patients, iris inflammation occurred in 1 eye, and a corneal ulcer appeared in 1 eye in the period up to 2 years after the procedure.

Mild haze in the cornea was reported in 22 out of 203 eyes treated by the procedure, which cleared up in 12 eyes 6 months after surgery. In the study of 39 patients, there was no difference in corneal haze 7 months after surgery between patients treated by laser (5 out of 15 eyes) and those treated by diamond burr polishing (7 out of 27 eyes).

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems could include cornea infection, and in theory, other problems could include defects in the cornea's outer layer, bulging of the cornea, scarring, or developing astigmatism and blurred vision.

More information about corneal surface irregularities

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'phototherapeutic laser keratectomy for corneal surface irregularities'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG358

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2300 for the standard print version and N2301 for the large print version). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.