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Photorefractive (laser) surgery for the correction of refractive errors

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG164

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0937 (full guidance)
- N0938 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on photorefractive (laser) surgery for the correction of refractive errors (see below). It replaces earlier guidance on laser in situ keratomileusis (LASIK) (Interventional Procedure Guidance 102). The information is not a complete description of what is involved in the different procedures – the patient's healthcare team should describe in detail the specific procedure being considered.

NICE has looked at whether laser treatments are safe enough and work well enough for them to be used routinely for the treatment of certain eyesight problems (see below).

To produce this guidance, NICE has:

- looked at the results of studies on the safety of laser treatments and how well they work
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

The aim of laser treatment is to help the type of eyesight problems that usually mean a person has to wear glasses or contact lenses. It involves using a special laser to permanently change the shape of the cornea, which is the clear covering over the front of the eye.

The three main types of laser treatment are photorefractive keratectomy (PRK for short), laser epithelial keratomileusis (LASEK) and laser in situ keratomileusis (LASIK).

In PRK, a small amount of the surface of the cornea is removed and a laser is then used to remove an area of the cornea to change its shape. The amount removed is controlled by a computer, and it depends on how much correction is needed (that is, how bad the person's eyesight is – if someone was strongly short-sighted, for example, they would need to have more of the cornea removed than someone who was mildly short-sighted).

LASEK is a version of PRK. Dilute alcohol is used to loosen the cornea's surface, which is then lifted out of the way. The laser is used to change the shape of the cornea as for PRK. When this is finished, the flap of corneal surface is put back into place. It's kept in place by natural suction.

In LASIK, a cutting instrument called a microkeratome is used to cut a flap in the surface of the cornea. The flap is folded back so that the laser can be used to remove some of the middle section of the cornea. When the laser work is finished, the flap is folded back down into its original position. It's kept in place by natural suction.

How well the procedure works

For this procedure, NICE undertook what is known as a systematic review. This means that evidence from all available sources was looked at, whether it had been published or not. Experts' opinions may also be included in a systematic review.

What the studies said

NICE asked a group of experts to carry out a systematic review of the results from all the studies carried out on laser treatments for eyesight problems.

Seven studies were included in the systematic review. Taking the results of all these studies together, PRK, LASEK and LASIK seemed to be equally effective for the correction of short-sightedness (including short-sightedness caused by an astigmatism).

Information from studies that looked at a total of more than 2000 short-sighted eyes treated with PRK showed that after the procedure 69% were very close to the intended correction – within 0.5 dioptres or D (a dioptre is a unit of measurement of the power of the eye's lens) and 89% were close (within 1.0 D). (Saying 69% is the same as saying 69 people in every 100.)

Information from studies that looked at a total of more than 1800 eyes treated with LASEK for myopia or astigmatism showed that 75% of eyes were within 0.5 D and 92% of eyes were within 1.0 D of the intended correction when they were checked 3 to 6 months after treatment.

Data from eyes treated with LASIK for myopia or astigmatism showed that 77% (7309 out of 9541 eyes) were within 0.5 D and 91% (8109 out of 8885 eyes) were within 1.0 D of the intended correction when they were checked 3 to 12 months after treatment.

One study found that the results with LASEK were better than PRK for long-sighted eyes.

Risks and possible problems with the procedure

What the studies said

Some of the studies compared the person's eyesight in the treated eye with how it had been when the person wore glasses before the treatment. The sight in 0–20% of short-sighted eyes that had PRK was worse after treatment compared with sight with glasses before the procedure. The overall likelihood of this happening was 0.5% (which means it was likely to affect 5 people in 1000). For eyes treated with LASEK, the results for this test were that 0–8% of eyes had worse eyesight. The overall likelihood of it happening was so small that it was said to be zero. With LASIK, the results were 0–3%, and the overall likelihood was said to be 0.6%. People who were very short-sighted were more likely to lose two or more lines in the sight test after treatment than people who were mildly or moderately short-sighted.

Problems with the corneal surface flap affected some people during LASIK and LASEK treatment. In some cases they were changed to the PRK procedure, while other people had their treatment postponed. Epithelial in-growth, when the flap starts to grow into main part of the cornea, happened in some people who had LASIK. In the studies, this happened in 0–4% of eyes.

Ectasia is a serious problem that can follow surgery in which the cornea is made thinner. It can lead to sight loss. Using data from the review, the risk of ectasia following LASIK was estimated to be 0.2% (meaning that 2 people in every 1000 who had LASIK were likely to develop ectasia). However, in the studies, LASIK was carried out on many eyes that weren't suitable for it. If it had been used more selectively, the number of people who developed ectasia might have been lower.

The studies that looked at PRK did not report how many people developed ectasia. And there was very little information about ectasia following LASEK. In one study that followed what happened in 171 eyes treated with LASEK, there were no cases of ectasia.

Infection causing inflammation of the cornea was reported only in the studies that looked at LASIK. It happened in up to 0.16% of eyes. The results show that it happens at about the same level as in people who wear contact lenses, or it might even be rarer following LASIK treatment.

Other problems that affected people included difficulty seeing in dim light, a haze effect, seeing 'halos' of light around things at night, and problems with glare at night. The haze effect happened in some patients regardless of the type of treatment they had: 0–31% of eyes treated with PRK were affected, 0–25% of eyes treated with LASEK were affected, and 0–2% of eyes treated with LASIK were affected. Glare and night vision difficulties were less common after LASIK.

What has NICE decided?

NICE has considered the evidence on laser treatments for eyesight problems. It has recommended that when doctors use these procedures for people with eyesight problems, they should be sure that:

- the treatment is suitable for that particular eye of the person
- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

People should be clear about the benefits and the potential risks of the treatment, which include:

- not having the expected improvement in eyesight after treatment

- the development of new eyesight problems
- infection of the cornea
- problems with the corneal surface flap that's made in the LASIK and LASEK treatments.

These risks should be weighed against the advantages and disadvantages of wearing glasses or contact lenses.

NICE has encouraged people who carry out these procedures to collect information about the effects of the procedures on people's eyesight in the long term. This information will prove useful in the future.

Finally, people who carry out laser surgery on the eye should be trained adequately. The Royal College of Ophthalmologists has produced a set of standards that shows what level of training is expected.

Other comments from NICE

If you have laser treatment to correct an eye problem, it is very important that every time (for the rest of your life) you have an eye check, you tell the person conducting the check that you have had laser treatment. This is so that the equipment used can be adjusted appropriately.

Likewise, having laser treatment can make the measurements made before cataract surgery or to detect glaucoma less accurate. There are ways of getting around this as long as the person taking the measurements is told about the laser treatment.

Laser treatment for eyesight problems is a fast-moving area and new methods of carrying out the treatments are being developed.

It is not always easy to tell whether the person offering this treatment has had proper training. The Royal College of Ophthalmologists is looking into this.

What the decision means for you

You may have been offered laser treatment to correct an eyesight problem. You should understand the benefits and risks of it before you agree to it, and should weigh these up against the advantages and disadvantages of wearing glasses or contact lenses. NICE has considered these procedures because they are relatively new and has decided that laser treatment is safe enough and works well enough for use in the NHS.

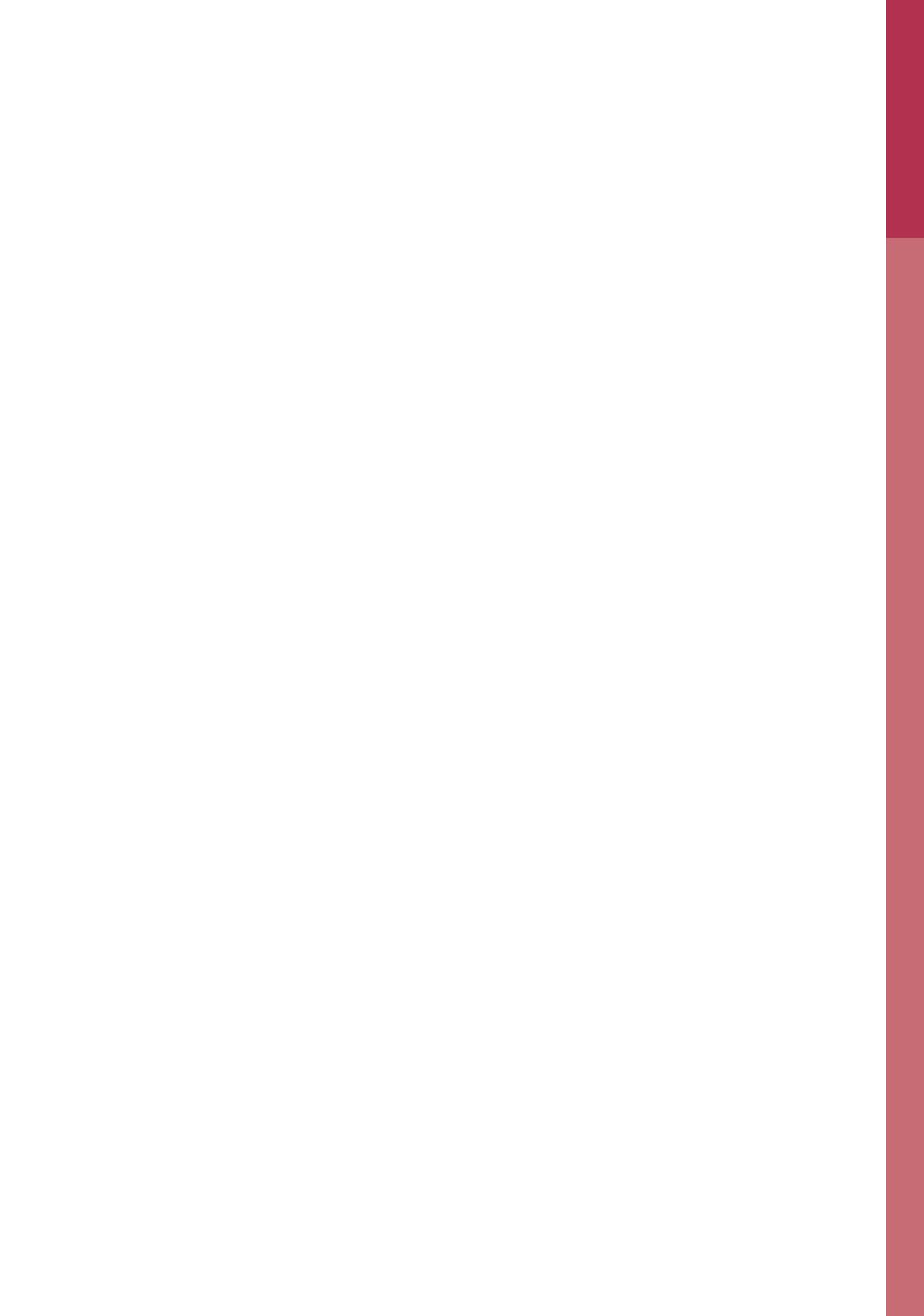
Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on photorefractive (laser) surgery for the correction of refractive errors that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on short-sightedness, long-sightedness and astigmatism on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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