

Treating keratoconus and keratectasia by corneal collagen cross-linking using riboflavin eye drops and UV light

Information for the public

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What has NICE said?

There are 2 different versions of corneal collagen cross-linking: epithelium-off and epithelium-on. Either can be done with other procedures to improve eyesight. NICE made different recommendations for each type of procedure because there was different evidence about their benefits and risks.

- The epithelium-off procedure alone: this procedure is safe enough and works well enough to use in the NHS.
- The epithelium-off procedure combined with other procedures, and all epithelium-on procedures: there is not much good evidence about how well these procedures work or how safe they are. They should only be used if extra care is taken to explain the risks to patients and extra steps are put in place to record and review what happens to

patients who have these procedures.

When health professionals are deciding who should be offered one of these procedures, they should check how thick the patient's cornea is and how likely their disease is to progress.

Only specialists in diseases of the cornea who are trained in using UV light, or trained staff under their supervision, should carry out these procedures.

More research is needed into these procedures, especially the epithelium-on and combination procedures.

Other comments from NICE

NICE said that these procedures might be useful for disabled people with keratoconus or keratectasia who can't wear contact lenses.

What does this mean for me?

Your health professional should fully explain what is involved in having one of these procedures and discuss the possible benefits and risks with you. You should also be told how to find more information about the procedure. All of this should happen before you decide whether you want to have this procedure or not.

If you are offered the epithelium-on procedure or either of the procedures combined with another procedure, your health professional should explain the uncertainty about how well it works and its possible side effects.

Your health professional might ask you if details of your procedure can be used to collect more information about using corneal collagen cross-linking to treat keratoconus. Ask your health professional for more information about this.

The condition

Keratoconus is an eye disease in which the surface of the cornea becomes thinner and begins to bulge into a cone-like shape so eyesight is blurred and distorted. It usually affects children and young adults and can get worse over time. Keratectasia affects the

eye in a similar way, but is caused by medical treatment, for example laser eye surgery.

Glasses, contact lenses or implanting an artificial lens may help but in severe cases surgery may be needed. NICE has looked at corneal collagen cross-linking as another treatment option. Click on to the next page to find out more.

The procedure

The aim of the procedure – which is sometimes known as CXL – is to stop your keratoconus getting any worse by making the cornea stiffer. It isn't clear exactly how it works but it might make the bonds between the collagen fibres (cross-links) in the cornea stronger. It also isn't clear how long the benefits last.

The way the procedure is done varies, but local anaesthetic is used and it usually takes an hour to an hour and a half with no need for a stay in hospital. Riboflavin (vitamin B) eye drops are put on the eye before and during the procedure, during which UV-A light is shone onto the surface of the cornea. It is done on 1 eye at a time and may be repeated.

The difference between the epithelium-on and epithelium-off procedures is that in the epithelium-off procedure, the layer of cells on the surface of the cornea (the epithelium) is removed with a spatula to expose the layer of cornea to be treated and to help the riboflavin eye drops to be absorbed. In the epithelium-on procedure, the layer of cells is not removed but may be thinned using a chemical. It takes longer for the riboflavin eye drops to be absorbed in this form of the procedure.

While the cornea is healing, you will normally be given antibiotics and anti-inflammatory eye drops (to reduce any redness, swelling, heat or pain) and you may be given a bandage contact lens (a type of non-magnifying contact lens that protects the cornea) to use for a few days.

Corneal collagen cross-linking can be done at the same time as procedures to improve eyesight, such as implanting an artificial lens.

Benefits and risks

When NICE looked at the evidence, it found that most of the evidence was on the epithelium-off procedure, and this showed that it worked well enough and was safe

enough to use in the NHS. Because the epithelium-on procedure is a more recent technique, there was not as much good evidence on how safe it is or how well it works. There was also not much good evidence for combining either the epithelium-on or epithelium-off procedure with other procedures.

The studies that NICE looked at involved about 2500 patients in studies of the epithelium-off procedure, about 700 patients in studies of the epithelium-off procedure combined with other procedures, and about 170 patients in studies of the epithelium-on procedure either on its own or combined with other procedures.

Generally, they showed the following benefits:

- Epithelium-off: improved keratoconus, eyesight, and astigmatism (a condition in which the front of the cornea does not curve normally, which can affect eyesight if it is severe).
- Epithelium-off combined with other procedures: clearer eyesight and improved keratoconus.
- Epithelium-on: clearer eyesight and improved keratoconus.
- Epithelium-on combined with other procedures: improved keratoconus and clearer eyesight.

The studies showed that the risks of the procedures included:

- infection
- inflammation (redness, swelling, heat and pain), which in a small number of cases led to scarring or loss of eyesight and the need for a corneal transplant
- scarring
- fluid build-up causing swelling in the eye
- problems with the size, shape and colour of the iris (the coloured part of the eye)
- the cornea breaking down
- the UV light burning the cornea
- ulcers

- clouding of the cornea.

NICE was also told about 1 patient who had a tear in their cornea after the procedure.

If you want to know more about the studies see the [guidance](#). Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Medical terms explained

Collagen

A type of protein that makes up a lot of the connective tissue in the body.

Cornea

The clear covering of the eye – needed for focusing.

Epithelium

The layer of cells covering the outside of the eye.

UV

Ultraviolet light. There are 3 types: UV-A, UV-B and UV-C. UV-A is responsible for skin tanning and the production of vitamin D in the body.

About this information

This NICE HealthTech guidance advises the NHS on the safety of the procedure and how well it works. This information applies to people who use the NHS in England, Wales, Scotland and Northern Ireland.

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