

Nerve graft for corneal denervation

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg729

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety of nerve graft for corneal denervation is limited but raises no major safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do nerve graft for corneal denervation should:
- Inform the clinical governance leads in their healthcare organisation.
 - Give people (and their families and carers as appropriate) clear information to support shared decision making, including NICE's information for the public.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:
- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.

- 1.4 Further research should be randomised controlled trials, analysis of registry data or case series.
- 1.5 Patient selection should be done by clinicians experienced in managing the condition.
- 1.6 The procedure should only be done in specialist centres by surgeons with skills and experience in this procedure.

2 The condition, current treatments and procedure

The condition

- 2.1 The cornea is innervated by the ophthalmic branch of the trigeminal nerve. This innervation maintains the health of the cornea. It does this by providing trophic factors to the corneal cells, activating protective blink reflexes, and stimulating tear production.
- 2.2 Damage to the trigeminal nerve can result in a decrease or loss of corneal sensation. The trigeminal nerve can be damaged by various diseases, chemical burns, physical injuries, or by surgery. Loss of innervation to the cornea can result in neurotrophic keratitis (also known as neurotrophic keratopathy). People with neurotrophic keratitis typically have corneal epithelium defects, poor corneal healing, and can develop sight loss. They are also prone to corneal infections.

Current treatments

- 2.3 Current treatment for neurotrophic keratitis aims to stop progression to later stages of the disease and promote regeneration of the epithelium. This can include topical lubricants and artificial tears. Antibiotic tear drops may be needed to prevent infections. Options for severe disease include lateral tarsorrhaphy (using sutures to partially or fully close the eyelids), topical nerve growth factor, topical collagenase inhibitors and amniotic membrane grafting.

The procedure

- 2.4 Nerve graft to restore corneal sensation is done under general anaesthesia. The nerve graft can be either an autograft, when the graft is taken from the person having the procedure, or an allograft, when the graft is a processed nerve from a deceased donor. Several types of grafts have been described in the literature, including the sural nerve, lateral antebrachial cutaneous nerve, great auricular nerve and a nerve from a deceased donor.
- 2.5 The nerve graft is harvested or prepared. At the same time, an incision is made on the contralateral side. This is to access an orbital nerve (the supratrochlear, supraorbital or infraorbital nerve) of the eye that still has normal sensation (the 'donor' nerve). In some people, the ipsilateral supratrochlear, supraorbital or infraorbital nerve, or the ipsilateral great auricular nerve is used as a donor nerve. The nerve graft is attached to the donor nerve and then subcutaneously tunnelled to the perilimbal area of the affected eye. The nerve fascicles can either be placed around the entire limbal circumference and secured to the sclera or are inserted into corneoscleral tunnels. The nerve fascicles are secured with sutures or fibrin glue, or both. The conjunctiva is closed and a temporary lateral tarsorrhaphy may be placed. A patch and topical lubricants may be prescribed after surgery. Over time, new nerve endings grow into the cornea. A corneal transplant may be needed to fully restore sight in people with loss of corneal clarity.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 non-randomised controlled trial, 2 before-and-after studies, 4 case series, and 2 case reports. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the

appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: corneal healing and stabilisation, reduction in use of lubricating eye drops, patient-reported outcomes including quality of life and reduction in corneal complications.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, infection, persistent facial neuropathy, graft nerve disconnect or damage, and donor-site morbidity.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 There were a variety of techniques described in the literature. This guidance only considers indirect corneal neurotisation using an interpositional nerve graft and does not consider direct neurotisation by nerve transfer.
- 3.6 The committee was informed that this procedure can be done with an allograft.
- 3.7 The committee was informed that this procedure may enable people to have a corneal graft if one is indicated.
- 3.8 The committee was informed that the primary purpose of this procedure is to improve healing of the cornea (trophic effect) rather than improving corneal sensation.
- 3.9 The committee was informed that neurotrophic keratitis can be a very disabling condition. Neurotisation is likely to be used only in people whose disease has not responded to other less invasive treatments.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).