NICE National Institute for Health and Care Excellence

NICE guidance

Artificial iris insertion for acquired aniridia

HealthTech guidance
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www.nice.org.uk/guidance/htg546

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.

Contents

This guidance replaces IPG674.

1 Recommendations

1.1 Evidence on the safety and efficacy of artificial iris implant insertion for acquired aniridia 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 website.

1.2 Clinicians wishing to do artificial iris implant insertion for acquired aniridia should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear information to support shared decision making, including NICE's information for the public.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

1.3 The procedure should only be done by ophthalmic surgeons with appropriate experience and training.

1.4 Research could include the use of observational data from cohort studies or high-quality case series. Studies should report details of patient selection and the type of implant used. Outcomes should include quality of life and other patient-reported outcomes.

1.5 NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Acquired aniridia means the iris is either missing or incomplete as a result of trauma, surgery or laser treatment.

2.2 People with aniridia may be very light sensitive (photophobic) and report symptoms of glare. They may develop other eye problems such as glaucoma, cataract and corneal opacification. The degree of vision loss varies.

Current treatments

2.3 Treatment includes contact lenses with iris prints and tinted spectacle lenses.

2.4 Surgical implantation of an artificial iris device may be an option for some people with complete or partial acquired aniridia.

The procedure

2.5 There are different devices available, including a solid acrylic ring or segment and a flexible silicone disc, which can be custom-made for each patient. The implant has a defined pupil size, which offers a compromise between day and night vision.

2.6 The artificial iris implant is inserted using local or general anaesthesia. The exact details of the procedure vary according to the type of implant being used.

2.7 Flexible implants are rolled up and inserted through a cut about 3 mm long at the edge of the cornea, into the posterior chamber of the eye. They are then

unfolded and fixed in the eye. If sutures are needed to hold the implant in place, a larger cut may be necessary. The implant insertion can be done on its own or at the time of cataract or lens fixation surgery.

2.8 Solid ring implants are typically inserted during cataract surgery along with an intraocular lens. In some patients, an iris reconstruction lens containing both an artificial iris and a lens is implanted. Depending on the condition of the eye, the lens and iris device may need to be sutured to the sclera.

2.9 The aim of artificial iris implant insertion is to improve visual acuity, reduce photophobia and glare, and improve the eye's appearance.

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 comparative study, 7 case series and 1 case report. It is presented in table 2a of the 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: reduction in symptoms of glare, improvement in visual acuity, quality of life and other patient-reported outcomes.

3.3 The professional experts and the committee considered the key safety outcomes to be: need for explantation, infection, worsening visual acuity, glaucoma and implant displacement.

3.4 One submission from a patient organisation was discussed by the committee.

3.5 Patient commentary was sought but none was received.

Committee comments

3.6 There is more than 1 device available for this procedure, including a flexible implant and a solid implant.

3.7 The committee was informed that at least 1 of the devices should only be used when the natural lens has been removed.

3.8 The committee noted that there was little evidence on the use of the procedure in children.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 674 has been migrated to HealthTech guidance 546. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.