

Artificial iris insertion for congenital aniridia

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg675

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 and efficacy of artificial iris implant insertion for congenital aniridia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE website.
- 1.2 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.
- 1.3 NICE may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

- 2.1 Congenital aniridia is a rare condition in which the iris has not formed properly, so it is missing or underdeveloped. It affects both eyes. The amount of iris tissue missing varies from person to person. Many people with congenital aniridia also have a part of their retina that is not fully developed, and many have nystagmus.
- 2.2 People with congenital 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 congenital 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 5 sources, which was discussed by the committee. The evidence included 5 case series. It is presented in [table 2b of 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: 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.

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Endorsing organisation

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

Accreditation

