

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Artificial iris insertion for congenital aniridia

Congenital aniridia is when a person is born with an incomplete or missing iris (the coloured part of the eye). This causes sensitivity to light and sight problems. It may be associated with other eye problems. In this procedure, an artificial iris implant is inserted through a cut in the eye. The aim is to decrease sensitivity to light, improve sight and improve the appearance of the eye.

NICE is looking at artificial iris insertion for congenital aniridia.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 19 December 2019

Target date for publication of guidance: March 2020

1 Draft 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](#).
- 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 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 under 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 A submission from a patient organisation was discussed by the committee.

Committee comments

- 3.5 There is more than 1 device available for this procedure. This includes a flexible implant and a solid one.
- 3.6 The committee was informed that at least 1 of the devices should only be used when the natural lens has been removed.
- 3.7 The committee noted that there was little evidence on the use of the procedure in children.

NICE interventional procedures consultation document, November 2019

Tom Clutton-Brock

Chair, interventional procedures advisory committee

November 2019

ISBN: