NICE National Institute for Health and Care Excellence

NICE guidance

Insertion of an epiretinal prosthesis for retinitis pigmentosa

HealthTech guidance

Published: 26 June 2015

www.nice.org.uk/guidance/htg372

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 IPG519.

1 Recommendations

More research is needed

1.1 Current evidence on the safety and efficacy of insertion of an epiretinal prosthesis for retinitis pigmentosa is limited in quality and quantity. Therefore, this procedure should only be used in the context of research.

What research is needed

1.2 NICE encourages further research on this technology. Outcomes should include the impact on quality of life and activities of day-to-day living, and durability of implants. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 Retinitis pigmentosa is the encompassing term for a group of degenerative eye conditions that cause progressive loss of retinal photoreceptors. The disease is often inherited. Patients initially experience ring scotoma and night vision problems which, in most cases, slowly progress and lead to the loss of all peripheral vision. Central vision is usually preserved until late stages of the disease, but can be lost earlier with severe disease.

2.2 Conservative treatments are aimed at early identification and treatment of complications such as cataract or macular oedema. Some newer treatments aim to slow the progression of the condition. Surgical treatments are being developed, including subretinal and epiretinal prostheses, as well as optic nerve implants to restore basic sight.

3 The procedure

3.1 Retinitis pigmentosa causes loss of retinal photoreceptors but inner retinal cells (ganglion and bipolar cells) remain intact. Insertion of an epiretinal prosthesis aims to restore perception of light, movement and shapes by surgically implanting an array of electrodes onto the retina. The electrodes emit electrical impulses to stimulate the sensory neurons of surviving retinal cells, which send visual information to the brain.

3.2 An epiretinal prosthesis system has 2 key components: an eye implant and external camera system. The eye implant consists of an episcleral receiver unit and an epiretinal electrode array. The external camera system comprises an eyeglass-mounted video camera and a small patient-worn computer (video processing unit [VPU]).

3.3 Insertion of the eye implant is performed with the patient under general anaesthesia, usually in 1 procedure that may take several hours. The surgeon performs core and peripheral vitrectomies, followed by dissection of any epiretinal membrane in the area where the electrode array will be placed. The electrode array is then inserted through a temporal sclerotomy and secured onto the retina using a retinal tack. It is connected to the receiver unit by a cable that penetrates the sclera in the pars plana.

3.4 After surgery, when the implant is set up and fully functional, the video camera records real-time images and sends them to the VPU. The VPU converts the images into data that are wirelessly transmitted to the episcleral receiver unit. The episcleral receiver unit relays the data to the electrode array, which produces electrical impulses that bypass damaged photoreceptors and stimulate the retina's remaining cells. Visual information is then transmitted by the optic nerve to the brain, creating a visual percept.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 The committee considered evidence from 7 case series that included a total of 129 patients. However, there is likely to have been considerable overlap between studies with patients taking part in more than 1 study.

4.2 In a case series of 30 patients implanted with an epiretinal prosthesis, improvements in visual acuity were reported in 23% (7/30) of patients at follow-up of up to 2.7 years. Visual acuity improved from worse than 2.9 logMAR (logarithm of the minimum angle of resolution) to between 2.9 and 1.6 logMAR (p value not reported).

4.3 In the case series of 30 patients, patients were asked to locate a white square that randomly appeared on a black LCD touchscreen. Significantly better square localisation test results were reported in 96% (27/28) of patients when their prosthesis systems were switched on. No further details were provided.

4.4 In the case series of 30 patients, patients were asked to indicate the path of a white bar that swept across a black LCD touchscreen. Significantly better direction of motion test results were observed in 57% (16/28) of patients when their prosthesis systems were switched on. No further details were provided.

4.5 In the case series of 30 patients, patients were asked to stand in the centre of a room, or offset left of centre by 3 feet, or offset right of centre by 3 feet. They were asked to find a rectangular 'door' 20 feet away and to place their hand on it. The mean success rate was 60% when the prostheses were switched on compared against 5% when the prostheses were switched off, at 24-month follow-up.

4.6 In a case series of 6 patients, the mean percentage of successful grasps of a white cube placed on a black surface was 69% when prostheses were switched on compared against 0% when prostheses were switched off, at 3-year

follow-up. There was no significant difference between the proportion of successful grasps when patients' eyes were 'patched' (both eyes taped closed) or 'unpatched'.

4.7 Specialist advisers listed key efficacy outcomes as improvement in vision (recognition of words or objects, as well as perception of light, movement or direction), performance in spatial or motor tasks and improved quality of life.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 All the adverse events presented to the committee came from a single case series of 30 patients; each affected patient may have experienced more than 1 adverse event.

5.2 Serious retinal complications were reported in 10% (3/30) of patients. A retinal tear was reported in 1 patient (timing not reported and no further details were provided). Rhegmatogenous retinal detachment that needed surgical repair was reported in 1 patient. Tractional retinal detachment was reported in 1 patient at 5-month follow-up: the patient had incurred blunt trauma to the eye with the implant, resulting in proliferative vitreoretinopathy that progressed to retinal detachment. This was repaired by vitrectomy, partial retinectomy and silicone oil.

5.3 Replacement of retinal tacks was needed within the first few days of implantation in 7% (2/30) of patients.

5.4 Conjunctival dehiscence was reported in 10% (3/30) of patients. Neither the timing nor the clinical significance of these dehiscences was described. They were treated by additional sutures with or without placement of additional tissue.

5.5 Conjunctival erosion was reported in 7% (2/30) of patients. Timing of occurrence was not reported.

5.6 Presumed endophthalmitis was reported, within 8 weeks of surgery, in 10% (3/30) of patients. This resolved in all cases with antibiotic treatment.

5.7 Hypotony was reported in 10% (3/30) of patients within 1 year of surgery. All cases of hypotony needed surgical treatment: 2 patients needed intraocular silicone tamponades and 1 patient had the implant removed.

5.8 Severe inflammatory uveitis was reported in 1 patient. Timing of occurrence was

not reported and no further details were provided.

5.9 Intraocular inflammation, hypotony without choroidal detachment, suture irritation and ocular pain were reported in up to 23% (7/30) of patients. All were reported as non-severe events. No exact figures were reported, timing of occurrence was not reported, and no further details were provided.

5.10 Inflammatory conjunctivitis, corneal filaments, epiretinal membrane, high intraocular pressure (controlled by anti-glaucoma medications), epiphora, mild hyphaema, inflammatory uveitis with few keratic precipitates, and mild vitreous haemorrhage were reported in up to 10% (3/30) of patients. All were reported as non-severe events. No exact figures were reported, timing of occurrence was not reported, and no further details were provided.

5.11 A single occurrence was reported of each of the following: limited conjunctival dehiscence, corneal abrasion, mild peripheral corneal vascularisation, cystoid macular oedema, decrease in light perception, dry eye, transient headache, iris vessel engorgement, stable tractional retinal detachment, transient nausea, transient increased nystagmus, scleritis, and transient vertigo. Each occurrence was considered non-severe.

5.12 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not highlight any anecdotal adverse events. They considered that the following were theoretical adverse events: loss of residual existing vision, phthisis bulbi, suprachoroidal haemorrhage, secondary neovascularisation, allergic reaction to the implant, failure of the implant, extrusion of the implant, and complications associated with vitrectomies.

6 Committee comments

6.1 The committee noted that insertion of an epiretinal prosthesis for retinitis pigmentosa is intended for patients with end-stage disease who have no useful sight and no other treatment options. It recognised that even minor improvements in vision may help these patients, but it wanted evidence that any changes in metrics of vision result in improvements in quality of life and activities of daily living. These considerations underpinned the specific recommendations about research in section 1.2.

6.2 The committee recognised that the technology of epiretinal prostheses and related devices is evolving and that further developments may result in substantial changes to outcomes which may influence patient selection in the future.

6.3 The committee noted the importance of careful patient selection, including psychological counselling to ensure that patients have realistic expectations. It also noted the need for continued expert care of patients and their epiretinal prostheses after the procedure.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 519 has been migrated to HealthTech guidance 372. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8176-2

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.