NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of implantation of an opaque intraocular lens for intractable double vision

Double vision (also known as diplopia) is seeing two images of a single object instead of one. In this procedure, the clear lens of one eye is removed and replaced with a non-transparent (opaque) lens. The aim is to block out one of the two images.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in June 2008.

Procedure name

- Implantation of an opaque intraocular lens for intractable double vision

Specialty societies

- Royal College of Ophthalmologists.

Description

Indications and current treatment

Double vision (also known as diplopia) is seeing two images of a single object instead of one. It is most commonly caused by each eye pointing in a different direction and may be caused by a variety of disorders affecting the muscles that move the eyes. This form of binocular double vision will stop if either eye is covered. Some patients, particularly children, may be able to ignore the

image from one eye. However, some people see two separate images of a single object. Other causes of double vision include brain tumours, diabetes, thyroid disease and severe head injury. Occasionally, people may have double vision in only one eye (monocular diplopia), usually caused by a type of cataract; however, this is outside the scope of this overview.

Treatments for binocular double vision include the use of prismatic spectacles, injection of botulinum toxin into the eye muscles, and eye muscle surgery. If these are unsuccessful, it may be necessary to occlude (block) the vision in one eye using a patch worn over one eye or on spectacles, special filters on spectacles or an opaque contact lens. However, these have only temporary results.

What the procedure involves

Implantation of an opaque lens for intractable double vision is done under local or general anaesthesia. It is similar to a conventional cataract operation, but involves the insertion of an opaque intraocular lens (IOL) or an iris claw lens (see below).

The natural lens of one eye is removed using phacoemulsification or extracapsular surgery. With phacoemulsification, a small incision is made in the cornea and an ultrasound probe is used to break the lens into very small pieces, which are removed through the incision. With extracapsular surgery, a longer incision is needed to allow the natural lens nucleus to be removed manually in one piece. An opaque IOL is then inserted through the corneal incision and placed in the capsular bag or sulcus (cleft).

Alternatively, a specially manufactured tinted lens is attached to the iris in the anterior chamber of the eye. The lens has a claw-like mechanism that attaches to the iris tissue by pinching it. Using this lens means that the eye's natural lens can be kept in place.

Efficacy

In a case series of 12 patients, the mean visual function score after an opaque IOL was implanted was 92, 95% confidence interval (CI) 83 to 99 (on a scale of 0 to 100 where 0 is maximum disability and 100 is no disability)[1]. The preoperative score was not measured. The mean postoperative patient satisfaction score was 3.4 (on a scale of 0 to 4 where 0 is unhappy and 4 is very satisfied). One patient had persistent diplopia, which resolved with medical treatment.

A report of two patients stated that the diplopia improved in both patients after they had an opaque IOL implanted. After additional medical treatment, one patient's diplopia completely resolved and the other patient's symptoms improved further[2].

Another report including two patients with intractable diplopia stated that both patients' symptoms improved after opaque IOL implantation[3].

In two case reports both patients' diplopia was resolved after implantation of an opaque IOL[4, 5].

Safety

In the case series of 12 patients, one IOL broke during insertion. An IOL was successfully implanted 6 months later. All patients in the series were described as having an uneventful postoperative recovery[1].

A case series of six patients, including two with intractable diplopia and four with leukocoria (abnormal white hue of the retina on ophthalmoscopy) reported that complications included IOL subluxation (partial dislocation of the lens) and glaucoma, each in one patient with leukocoria[3].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to implantation of an opaque IOL for intractable double vision. Searches were conducted of the following databases, covering the period from their commencement to 03/06/2008: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with intractable double vision.
Intervention/test	Implantation of an opaque IOL.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 22 patients with intractable diplopia from one case series and four case reports[1–5].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in appendix A.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Implantation of accommodating intraocular lenses during cataract surgery. NICE interventional procedures guidance 209 (2007). Available from www.nice.org.uk/IPG209

Technology appraisals

- None

Clinical guidelines

- None

Public health guidance

- None

Table 2 Summary of key efficacy and safety findings on implantation of an opaque intraocular lens for intractable double vision

Abbreviations used: IOL, intraocular lens

Study details	Key efficacy findings	Key safety findings	Comments
Hadid OH (2008)[1] Study type: **case series** Country: UK Study period: 2002–2006 Study population: patients who underwent insertion of an opaque IOL n = **12** Mean age: 43 years ± 16.3 Sex: 42% (5/12) males Inclusion criteria: all patients had constant and persistent diplopia unresponsive to other treatments acceptable to the patient. All patients had tried other occlusive methods before opaque IOL insertion. Median duration of diplopia was 5.5 years. Two patients had early cataract changes in the preoperative assessment and 10 patients had clear lenses. Technique: The lens of the eye with either worse visual acuity or greater restriction of ocular motility was removed. Local anaesthesia was used for seven patients and five patients requested general anaesthesia. Phacoemulsification was used in 10 patients and two patients had extracapsular cataract extraction. IOL placement was in the capsular bag in 10 patients and in the sulcus in two patients. Non-foldable opaque IOL used (Morcher). Mean follow-up: **21 months (range 6–45 months)** Conflict of interest: None declared	Visual function was assessed using the VF-14 questionnaire (patient-reported measure of functional disability related to vision based on 14 everyday activities developed for use in patients with cataracts). Results were reported on a scale from 0 (maximum disability) to 100 (no disability). **Mean postoperative VF-14 score = 92 (95% CI 83 to 99).** Overall satisfaction with visual outcome was scored subjectively by the patient on a scale from 0 (unhappy) to 4 (very satisfied). **Mean patient satisfaction score = 3.4 (range 2–4).** Six patients scored 4 out of 4 and one patient scored 2 out of 4. One patient had persistent diplopia after the operation but it was resolved with topical pilocarpine 1%.	The leading haptic (structure that supports the lens and keeps it in place) of the opaque IOL broke at the haptic-optic junction during insertion in one patient. Another IOL was successfully implanted 6 months later. All patients had an uneventful postoperative recovery.	Retrospective data collection (telephone survey). Preoperative VF-14 scores were not measured.

Abbreviations used: IOL, intraocular lens			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Sandy CJ (2000)[2] Study type: **case reports** Country: UK Study period: not stated Study population: patients with intractable diplopia secondary to paralytic strabismus (squint) n = **2** Age: 53 and 61 years Sex: female One patient failed to tolerate occlusive contact lenses or spectacles. The other patient had tried an opaque contact lens but found it to be unsatisfactory. Inclusion criteria: not stated Technique: phacoemulsification and insertion of a black IOL into the capsular bag. One patient had strabismus surgery at the same time as IOL insertion. The other patient had already had strabismus surgery and treatment with botulinum toxin. Follow-up: **not stated** Conflict of interest: none	Both patients reported improvement in diplopia. One patient had a large pupil and experienced some peripheral diplopia. This resolved with the use of pilocarpine ointment at night. The IOL had moved off-centre slightly. In the second patient, some peripheral vision remained in the treated eye that resulted in occasional diplopia. This was caused by the lens moving off centre slightly. After treatment with pilocarpine drops the patients' symptoms improved further.	No complications were reported.	The authors note that patients need to be informed that reversal of this procedure is not necessarily possible and that the detection of retinal disease is made more difficult by the presence of the opaque IOL.

Abbreviations used: IOL, intraocular lens			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Wong SC (2007)[3] Study type: **case reports** Country: UK Study period: not stated Study population: patients with intractable diplopia (n = 2) or unsightly leukocoria (white pupil, n = 4) n = **6** Mean age: 23.5 years (range 15–39 years) Sex: four males, two females A preoperative trial showed all patients were unable to tolerate an occlusive contact lens. Inclusion criteria: not stated Technique: Black occlusive IOL implantation with or without cataract extraction. Phakic IOL implantation was performed in two patients. Follow-up: **14 months (mean)** Conflict of interest: none stated	All six patients either had symptom relief or satisfactory cosmetic improvement after IOL implantation.	Postoperative complications were seen in two patients. Mild IOL subluxation was reported in one patient, however, it was stated that it did not adversely affect patient satisfaction. One patient who had phakic IOL implantation developed glaucoma.	Reported in a letter to the editor.

Abbreviations used: IOL, intraocular lens			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Landesz M (1997)[4] Study type: **case report** Country: The Netherlands Study period: 1994 Study population: patient with implantation of tinted iris claw lens for persistent diplopia n = **1** Age: 45 years Sex: male Technique: Specially manufactured tinted iris claw IOL was attached to the iris, with the host crystalline lens in place. Follow-up: **14 years** Conflict of interest: none stated	Postoperatively, the crystalline lens remained clear. Slitlamp biomicroscopy showed no inflammation in the anterior chamber and no sign of decompensation of the corneal endothelium (corneal endothelial decompensation resulting from oedema). The patient no longer reported persistent diplopia and he was still able to perceive light and dark through the opaque IOL (no further information was provided). 14 years after IOL implantation, endothelial cell loss was estimated at 18.6% (difference in mean endothelial cell density between eyes). Morphological parameters in terms of variation in cell size and hexagonality did not seem to differ significantly between eyes, indicating sufficient endothelial functioning. (Corneal endothelial cells are essential for maintaining optical clarity of the cornea and are not renewed. Endothelial cell loss can lead to corneal oedema, which reduces visual acuity and can cause pain and discomfort.)	No complications were reported.	Main aim of the study was to evaluate the corneal endothelium, 14 years after IOL implantation.

Abbreviations used: IOL, intraocular lens			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Krieger FT (2006)[5] Study type: **case report** Country: Brazil Study period: not stated in abstract Study population: patient with long-standing strabismus and diplopia n = **1** Age: 65 years Sex: female Diplopia failed to improve following surgery, prism and occlusive spectacles or contact lenses. Technique: Phacoemulsification and opaque IOL implantation Follow-up: **not stated in abstract** Conflict of interest: none stated	Diplopia was successfully neutralised.	No complications were reported.	Non-English language paper. Information from English abstract only.

Validity and generalisability of the studies

- Twenty-two patients treated with opaque IOL implantation for intractable diplopia were identified in the literature. One study also included four patients with leukocoria[3].
- Three studies, including 16 patients with intractable diplopia, were reported from the UK[1–3].
- Four of the five studies reported that patients had unsuccessfully tried other occlusive methods before opaque IOL implantation[1,2, 3, 5].
- One case report used an iris claw IOL, with the natural lens left in place[4]. In three studies, the natural lens was removed in all patients before an opaque IOL was implanted[1,2,5]. In one study, an occlusive IOL was implanted with or without cataract surgery[3].

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Miss G Adams, Mr M Clarke, Mr R Harrad, Mr P Watts (Royal College of Ophthalmologists).

- Three Specialist Advisers considered this procedure to be definitely novel and of uncertain safety and efficacy. One adviser described it as established practice and no longer new.
- There is concern over blocking out a functioning eye. Development of a sight-threatening condition in the other eye would leave the patient with impaired vision.
- The Specialist Advisers stated that the key efficacy outcome was eradication or improvement in symptoms of diplopia without discomfort to the eye. They stated that there were no concerns about the efficacy of the procedure.
- Theoretical adverse events include: failure to recognise pathology (such as a malignant tumour) in the implanted eye because the eye's fundus is obscured by the opaque lens, loss of visual field, dislocation of the opaque lens and raised intraocular pressure. Potential risks associated with routine cataract surgery include intraocular infection and intraocular haemorrhage.
- With an iris claw IOL, there is a theoretical risk of damage to the natural lens of the eye.
- The procedure is difficult to reverse.
- Potential impact on the NHS is minor.

Issues for consideration by IPAC

- None other than those listed above.

References

1. Hadid OH, Wride NK, Griffiths PG et al. (2008) Opaque intraocular lens for intractable diplopia: experience and patients' expectations and satisfaction. British Journal of Ophthalmology 92: 912–5.

2. Sandy CJ, Wilson SB, Page A et al. (2000) Phacoemulsification and opaque intraocular lens implantation for the treatment of intractable diplopia. Ophthalmic Surgery and Lasers 31: 429–31.

3. Wong SC, Islam N, Ficker L (2007) Black occlusive IOLs. Ophthalmology 114: 2365.

4. Landesz M, Worst JG, Van Rij G et al. (1997) Opaque iris claw lens in a phakic eye to correct acquired diplopia. Journal of Cataract and Refractive Surgery 23: 137–8.

5. Krieger FT, Lambert AC, Alves TC et al. (2006) Opaque intraocular lens in intractable diplopia: case report. Arquivos Brasileiros de Oftalmologia 69: 597–600.

Appendix A: Additional papers on **implantation of an opaque intraocular lens for intractable double vision not included in summary table 2**

There were no additional papers identified.

Appendix B: Related NICE guidance for implantation of an opaque intraocular lens for intractable double vision

Guidance	Recommendations
Interventional procedures	**Implantation of accommodating intraocular lenses for cataract. NICE interventional procedures guidance 209 (2007)** 1.1 Current evidence suggests that there are no major safety concerns associated with the implantation of accommodating lenses for cataract. There is evidence of short-term efficacy in correcting visual acuity but there is inadequate evidence that the procedure achieves accommodation. Therefore, the procedure should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake implantation of accommodating lenses should take the following actions. • Ensure that patients understand the uncertainty about the procedure's efficacy, and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG209publicinfo). • Audit and review clinical outcomes of all patients having implantation of accommodating lenses (see section 3.1). 1.3 Publication of long-term efficacy outcomes of the procedure will be useful, particularly on the effects on accommodation. The Institute will review the procedure in due course.

Appendix C: Literature search for implantation of an opaque intraocular lens for intractable double vision

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	05/12/2008	Issue 4, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	05/12/2008	N/A
HTA database (CRD website)	05/12/2008	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	05/12/2008	Issue 4, 2008
MEDLINE (Ovid)	05/12/2008	1950 to November Week 3 2008
MEDLINE In-Process (Ovid)	05/12/2008	December 04, 2008
EMBASE (Ovid)	05/12/2008	1980 to 2008 Week 49
CINAHL (EBSCOhost)	05/12/2008	N/A
Current Contents	05/12/2008	N/A
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	05/12/2008	Issue 4, 2008
Database of Abstracts of Reviews of Effects – DARE (CRD website)	05/12/2008	N/A
HTA database (CRD website)	05/12/2008	N/A
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	05/12/2008	Issue 4, 2008

Websites searched on 03/06/2008:

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) – MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – surgical (ASERNIP-S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites: European Society of Cataract and Refractive Surgeons, American Academy of Ophthalmology, European Society of Ophthalmology
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Diplopia/
2	diplopia$.tw.
3	double vision$.tw.
4	exp strabismus/
5	strabismus$.tw.
6	squint$.tw.
7	((vision$ or visual$ or ocular$) adj3 (misalign$ or defect$ or disorder$ or impairment$)).tw.
8	or/1-7
9	Lenses, Intraocular/
10	Lens Implantation, Intraocular/
11	IOL$.tw.
12	((intraoc$ or intra-oc$ or opaque$ or non transparen$ or non-transparen$) adj3 lens$).tw.
13	or/9-12
14	8 and 13
15	Animals/
16	Humans/
17	15 not (15 and 16)
18	14 not 17
19	200804*.ed.
20	200805*.ed.
21	200806*.ed.
22	200807*.ed.
23	200808*.ed.
24	200809*.ed.
25	200810*.ed.
26	200811*.ed.
27	200812*.ed.
28	or/19-27
29	18 and 28