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Surgical interventions for bilateral congenital cataract (Review)

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[Intervention Review]

Surgical interventions for bilateral congenital cataract

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ABSTRACT

Background

Congenital cataracts are opacities of the lens in one or both eyes of children that cause a reduction in vision severe enough to require surgery. Cataract is the largest treatable cause of visual loss in childhood. Paediatric cataracts provide different challenges to those in adults. Intense inflammation, amblyopia and posterior capsule opacification can affect results of treatment. Two treatments commonly considered for congenital cataract are lensectomy and lens aspiration.

Objectives

The objective of this review was to assess the effects of surgical treatments for bilateral symmetrical congenital cataracts. Success was measured according to the vision attained and occurrence of adverse events.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochane Library,* which contains the Cochrane Eyes and Vision Group Trials Register (2005, Issue 2), MEDLINE (1966 to June 2005), EMBASE (1980 to June 2005, week 27), LILACS (6 July 2005), the Science Citation Index and the reference list of the included studies. We also contacted trial investigators and experts in the field for details of further studies.

Selection criteria

We included all prospective, randomised controlled trials that compared one type of cataract surgery to another, or to no surgery, in children with bilateral congenital cataracts aged 15 years or younger.

Data collection and analysis

Two authors extracted data. No meta-analysis was performed.

Main results

Four trials met the inclusion criteria. All trials were concerned with reducing the development of visual axis opacification (VAO). This was achieved with techniques that included an anterior vitrectomy or optic capture. Posterior capsulotomy alone was inadequate except in older children.

Authors' conclusions

Evidence exists for the care of children with congenital or developmental bilateral cataracts to reduce the occurrence of visual axis opacification. Further randomised trials are required to inform modern practice about other concerns including the timing of surgery, age for implantation of an intraocular lens and development of long-term complications such as glaucoma and retinal detachment.

PLAIN LANGUAGE SUMMARY

Surgery for cataracts that develop in both eyes at or soon after birth

To have a cataract describes a condition where the normally clear lens inside the eye is cloudy and obscures vision. Cataracts that develop at or soon after birth in both eyes are a major cause of childhood blindness in the world, especially in developing countries. Treatment is indicated if the cataract prevents normal vision. This can be assessed by measuring how much the child can see and looking into the eye at the cataract. The only way to correct the cataract is to surgically remove it. It is generally accepted that early surgery results in a greater chance of good vision. There are two main approaches to surgery: lensectomy and lens aspiration. Lensectomy removes the entire lens and some of the gel which fills the eye (anterior vitrectomy); lens aspiration removes the lens but leaves the posterior lens capsule intact. A significant complication from surgery is re-clouding of the central passage for vision (visual axis opacification (VAO)). All surgical procedures aim to reduce this and the need for further treatment. Removing the cataract leaves the eye without the ability to focus. This must be corrected as soon as possible after surgery using intraocular lenses (IOL), contact lenses or spectacles, or a combination. The aim of the review was to clarify which surgical approach resulted in the best visual improvement. We searched for studies where children with cataract at or soon after birth had been randomised to receive a type of surgical procedure. The primary outcome was the level of vision after surgery. In the four included randomised studies the type of surgical procedure made no real difference to the final vision but there were differences in the number of children who developed VAO. Procedures which appeared to reduce VAO were anterior vitrectomy (removing some of the gel which fills the eye) and optic capture (lodging the lens portion of the IOL into an opening created in the posterior capsule). Three of the four studies used IOLs to correct aphakia, an option increasingly popular but which may not be suitable in regions where careful follow up cannot be guaranteed. While there is evidence for successful surgical treatment of this type of potentially blinding cataract, there is a lack of good evidence regarding aspects of its delivery such as the best timing for surgery and the appropriate method for aftercare.

BACKGROUND

Introduction

Congenital cataracts are opacities of the lens of one or both eyes that are present at birth. They are a major cause of childhood blindness in the world (Taylor 1994). The rate of blindness from congenital cataract is much greater in developing countries probably because better and earlier intervention is possible in industrialised economies (Foster 1997).

Obstruction of a child's vision by cataract prevents normal development of the visual system. This is called amblyopia or lazy eye. The outcome of treatment depends not only on the type of operation used to remove the cataract but also on how soon after birth the cataract is detected and treated and on the postoperative management of visual rehabilitation. It is generally accepted that the earlier the cataract surgery is carried out the greater the likelihood of a good visual result.

This review was concerned with surgery for bilateral congenital cataracts, which have a much greater impact on childhood blindness than unilateral cataracts. Unilateral cataracts are less common but present a difficult and different challenge because they are more likely to be associated with other ocular anomalies (Rahi 2000) and the likelihood of successful amblyopia treatment post-operatively is low (Neumann 1993).

Epidemiology

The reported incidence of congenital cataracts varies depending on both diagnostic criteria and geographical location. The adjusted annual age-specific incidence of new diagnosis of congenital and infantile cataract in the United Kingdom is 2.49/10,000 children (95% confidence interval (CI) 2.10 to 2.87) and at five years is 3.18/10,000 (95% CI 2.76 to 3.59), increasing to 3.46/10,000 by 15 years (95% CI 3.02 to 3.90) (Rahi 2001). While the incidence appears low, it is a significant, under-reported and preventable cause of visual loss in childhood (Rahi 1999) that contributes many more person years of visual impairment than an adult cataract.

Treatment options

Surgery for bilateral congenital cataracts is indicated if the cataracts are preventing normal visual development. Surgery involves removal of the natural lens of the eye, which is made of lens proteins enclosed within a clear membraneous capsule. The cataract is removed by making a hole in the front of the capsule and removing the opaque proteins.

The posterior capsule (back wall of the capsule) is normally left intact in routine adult cataract surgery (extracapsular extraction), which is thought to reduce the risk of certain complications including inflammation, glaucoma and retinal detachment. The posterior capsule is usually breached during or shortly after paediatric cataract surgery because in children the posterior capsule rapidly opacifies thereby obstructing vision again (visual axis opacification (VAO)). However, breaking the posterior capsule may increase the risk of complications. Anterior vitrectomy (removal of the anterior part of the jelly of the eye with a suction/ cutting device) may reduce the incidence of postoperative opacity formation. Also, techniques like optic capture push the intraocular lense (IOL) through the hole made in the posterior capsule (posterior capsulotomy) in the hope of improved IOL position and reduced VAO.

Two treatments commonly considered for congenital cataract are lensectomy and lens aspiration. Lensectomy involves the removal of the entire contents of the lens, central capsule and anterior vitreous (the gel which fills the body of the eye) with a suction cutting device. Lens aspiration removes the cataract but leaves the posterior capsule intact. A posterior capsulotomy (making a hole in the capsule) is often performed because of the high rate of VAO (Vasavada 2004).

Removing the cataract removes a major element of the refractive power of the eye. The resultant refractive error must be corrected as soon as possible after the cataract is removed so that a normal visual stimulus and the potential for normal visual development are restored. Current options for correction of aphakia (absence of a lens in the eye) include intraocular lenses (IOLs), contact lenses, spectacles or a combination of these. If one eye is preferred for vision and the other shows a tendency to become amblyopic, patching of the preferred eye may be required. A more detailed evaluation of this treatment can be found in another published Cochrane systematic review on Interventions for stimulus deprivation amblyopia (Hatt 2006) .

Intraocular lenses are now being used more commonly in paediatric cataract surgery and may either be implanted at the time of the original surgery or planned for some time in the future. Intraocular lens implantation at the time of surgery reduces the power of spectacle or contact lens correction that is required. Controversy exists as to the suitability of very young children for implantation of an IOL that is expected to last a lifetime. There are also different opinions regarding the choice of intraocular lens power for a growing eye. It may be more difficult to replace an IOL than to implant one for the first time in adulthood.

Contact lenses are frequently used after paediatric cataract surgery and are generally worn on a daily basis. The power of the contact lens is changed as required. Contact lenses must be replaced swiftly if lost in order to reduce the risk of amblyopia. Spectacles may be required and these may be very thick. However, for bilateral congenital cataracts they may work well as they are easier and simpler to manage than contact lenses.

Rationale for a systematic review

The aim of this review was to compare different surgical methods for the management of bilateral, visually significant congenital cataracts. The appropriate method may vary depending on geography, population and access to healthcare facilities. Related factors include timing of surgery, maintenance of a clear visual axis, implantation of an IOL and postoperative visual rehabilitation.

OBJECTIVES

The objective of this review was to assess the effects of surgical treatments for bilateral congenital cataracts.

METHODS

Criteria for considering studies for this review

Types of studies

We included prospective, randomised controlled trials.

Types of participants

We included trials in which participants were children, aged 15 years or younger, with bilateral congenital or developmental cataracts. Trials combining unilateral and bilateral cataracts and where the results from the bilateral cases could not be extrapolated were excluded.

Types of interventions

We included any study that compared one type of cataract surgery to another or to no surgery.

Types of outcome measures

Primary outcomes

The primary outcome for this review was visual acuity.

Secondary outcomes

Secondary outcomes for this review included:

- visual axis opacification - any method to assess the type and amount of opacification;
- amblyopia - reduced visual acuity which cannot be improved after optical correction and is not attributable to a structural abnormality;
- glaucoma;
- retinal detachment;
- re-operation rate.

Adverse effects

We included information on any adverse event occurring as a result of surgery.

Follow up

Outcomes could be measured at periods after surgery ranging from a few weeks to several months or years.

Search methods for identification of studies

Electronic searches

We identified studies from the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Group Trials Register), MEDLINE, EMBASE and LILACS. There were no language or date restrictions in the electronic searches.

We used the following strategy to search CENTRAL 2005, Issue 2.
#1 CATARACT
#2 CHILD
#3 INFANT
#4 ADOLESCENT
#5 (#2 or #3 or #4)
#6 (#1 and #5)
#7 ((congenital* or inherit* or paediatr* or pediatr* or child* or adolesc* or juvenile* or minor* or infant*:ti) or (congenital* or inherit* or paediatr* or pediatr* or child* or adolesc* or juvenile* or minor* or infant*:ab))
#8 (cataract* or (lens* near opacit*))
#9 (#7 and #8)
#10 (#6 or #9)
#11 CATARACT EXTRACTION
#12 (lensectomy or phacoemulsif* or phakoemulsif*)
#13 PHACOEMULSIFICATION
#14 ((lens* or cataract*) and (extract* or aspirat* or operat* or remov* or surg* or excis* or implant*))
#15 (#11 or #12 or #13 or #14)
#16 (#10 and #15)

We used the following strategy to search MEDLINE to June 2005.
#1 explode "Cataract-" / all SUBHEADINGS in MIME,MJME
#2 (explode "Cataract-" / all SUBHEADINGS in MIME,MJME) and ((AGE:MEDS = ADOLESCENT) or (AGE:MEDS = CHILD) or (AGE:MEDS = CHILD-PRESCHOOL) or (AGE:MEDS = INFANT) or (AGE:MEDS = INFANT-NEWBORN))
#3 (((cataract* or (lens* near opacit*)) near (congenital* or inherit* or paediatr* or pediatr* or child* or adolesc* or juvenile* or minor* or infant*)) in AB)or(((cataract* or (lens* near opacit*)) near (congenital* or inherit* or paediatr* or pediatr* or child* or adolesc* or juvenile* or minor* or infant*)) in TI)
#4 #2 or #3
#5 explode "Cataract-Extraction" / all SUBHEADINGS in MIME,MJME
#6 ((lensectomy) in AB)or((lensectomy) in TI)
#7 (((lens* or cataract*) near (extract* or aspirat* or operat* or remov* or surg* or excis* or implant*)) in AB)or(((lens* or cataract*) near (extract* or aspirat* or operat* or remov* or surg* or excis* or implant*)) in TI)
#8 explode "Phacoemulsification-" / all SUBHEADINGS in MIME,MJME
#9 ((Pha?oemulsif*) in AB)or((Pha?oemulsif*) in TI)
#10 #5 or #6 or #7 or #8 or #9
#11 #4 and #10

We identified randomised controlled trials by combining this strategy with the Cochrane Highly Sensitive Search Strategy phases one and two as contained in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2005).

We used the following strategy to search EMBASE to June 2005, week 27.
#1 exp CATARACT/
#2 limit 1 to (infant or child or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)
#3 (cataract$ or lens$ near opacit$).mp. and (congenital$ or inherit $ or paediatr$ or pediatr$ or child$ or adolesc$ or juvenile$ or minor$ or infant$).ab,ti.
#4 2 or 3
#5 exp Cataract Extraction/
#6 (lensectomy or phacoemulsif$ or phakoemulsif$).mp.
#7 ((lens$ or cataract$) adj3 (extract$ or aspirat$ or operat$ or remov$ or surg$ or excis$ or implant$)).ab,ti.
#8 5 or 6 or 7
#9 4 and 8

We identified randomised controlled trials by combining the above search with the following search strategy.
#1 Randomized Controlled Trial/
#2 exp Randomization/
#3 Double Blind Procedure/
#4 Single Blind Procedure/
#5 random$.ab,ti.
#6 #1 or #2 or #3 or #4 or #5
#7 (animal or animal experiment).sh.
#8 human.sh.

#9 #7 and #8
#10 #7 not #9
#11 #6 not #10
#12 Clinical Trial/
#13 (clin$ adj3 trial$).ab,ti.
#14 ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask $)).ab,ti.
#15 exp PLACEBO/
#16 placebo$.ab,ti.
#17 random$.ab,ti.
#18 experimental design/
#19 Crossover Procedure/
#20 exp Control Group/
#21 exp LATIN SQUARE DESIGN/
#22 #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21
#23 #22 not #10
#24 #23 not #11
#25 exp Comparative Study/
#26 exp Evaluation/
#27 exp Prospective Study/
#28 (control$ or prospectiv$ or volunteer$).ab,ti.
#29 #25 or #26 or #27 or #28
#30 #29 not #10
#31 #30 not (#11 or #23)
#32 #11 or #24 or #31

We used the following strategy to search LILACS on 6 July 2005.
#1 cataract$ or (lens$ opacit$) [Words]
#2 congenital$ or inherit$ or paediatr$ or pediatr$ or child$ or adolesc$ or juvenile$ or minor$ or infant$ [Words]
#3 (lens$ or cataract$) and (extract$ or aspirat$ or operat$ or remov $ or surg$ or excis$ or implant$)
#4 #1 or #2 or #3

Searching other resources

We contacted paediatric ophthalmologists with an interest in congenital cataracts (Jugnoo Rahi and Arvind Chandna) to ask for details of additional published or unpublished studies.

Data collection and analysis

Finding the trials

Two authors independently screened the titles and abstracts of the 158 new reports found by the updated electronic searches since our initial search in 2001. We excluded 148 reports that did not meet the inclusion criteria and we obtained the full copies of ten reports that were judged to be possibly or definitely relevant.

Six reports were excluded on methodological grounds, on the basis of the published data alone (Bayramlar 2004; Hoyt 1982; Kugelburg 2005; Ram 2003; Saini 2003; Vasavada 2003). Five studies had been excluded previously (Ahmadieh 1999; Basti 1996; Basti 1999; Vasavada 1997; Vasavada 2000) (*See* 'Characteristics of excluded studies'). Four trials met the inclusion criteria and were assessed for methodological quality (Eckstein 1999; Mullner 2003; Raina 2002; Vasavada 2001).

Assessment of methodological quality

Two authors independently assessed trial quality. We were not masked to any study details when assessing trial quality. We assessed the following criteria:

(1) concealment of allocation.
(2) method of randomisation.
(3) completion of follow up.

Each criterion was graded either 'adequate', 'cannot tell' or 'not adequate'.

Data extraction and data entry

Two authors independently abstracted data from the included trials. These were compared and differences were resolved by discussion. Meta-analysis was not possible as each study analysed a different intervention.

RESULTS

Description of studies

Eckstein 1999
Comparison: lensectomy versus lens aspiration with primary capsulotomy for bilateral cataract.
This study involved children aged 3 months to 10 years from the states of Tamil Nadu or Kerala in India. Participants underwent lensectomy in one eye and lens aspiration and primary capsulotomy in the other eye. All eyes were left aphakic and visual rehabilitation was with spectacle correction. The aim was to determine which method produced the best visual acuity with minimum complications. The primary outcome was visual acuity at three years postoperatively.

Mullner 2003
Comparisons:
Group 1: optic capture versus no optic capture (all had anterior vitrectomy);
Group 2: no posterior capsulotomy versus posterior capsulotomy and versus posterior capsulotomy with optic capture (none had vitrectomy).
In this study there were two separate randomised comparisons. All children underwent posterior capsulotomy but were divided before randomisation based on their age. Group 1 were aged 2 to 5.9 years; all underwent anterior vitrectomy before being randomly assigned to either optic capture or no optic capture. Group 2 were aged 6 to 15.5 years; none of these had anterior vitrectomy but they were randomly assigned to either posterior capsulotomy alone or posterior capsulotomy with optic capture or intact posterior capsule. All children had AcrySof intraocular lenses implanted. The aim was to determine which method reduced the incidence of visual axis opacification (VAO) postoperatively. Outcomes were recorded at one day, one week, one, three, six months and then six monthly post operatively. Bilateral and unilateral cases were included.

Raina 2002
Comparison: optic capture versus no optic capture.
Participants were aged from 1.5 to 12 years of age and all had primary posterior capsulotomy without anterior vitrectomy. Thirty-one of the 34 included operations were for children with bilateral cataracts. The purpose was to evaluate the effectiveness of optic capture of the posterior chamber IOL in preventing secondary opacification of the visual axis. Primary outcomes were opacification of the visual axis, visual acuity and complication rate. Mean follow up was 17.5 months, ranging from 8 to 28 months.

Vasavada 2001

Comparison: anterior vitrectomy versus no anterior vitrectomy
All participants in this study had lens aspiration, IOL implant and optic capture; then individual eyes were randomised as to whether or not they would have anterior vitrectomy. All had bilateral cataracts although in some cases only one eye was operated on. Mean age at surgery in this study was 6.9 years (range 5 to 12 years). Randomisation was assigned during surgery. Follow up was at one, three, six months; one, two and three years. There were a variety of data specified as collected at each of these follow-up points but visual acuity was collected separately. High contrast visual acuity was measured using Lea Hyvarinen symbols (not stated whether single or crowded) and contrast sensitivity was assessed using the Cambridge low contrast test.

See 'Characteristics of included studies' for further details of these trials.

Risk of bias in included studies

Eckstein 1999 had clear randomisation procedures with good follow-up data: 56/65 (86%) were reviewed at three years: 8/65 were lost to follow up; 1/65 was excluded as the child only underwent surgery on one eye.
The procedure and the side of the first eye to be operated on were randomly assigned. The other eye was automatically assigned the other operation, rather than randomising it to either procedure. All surgeries were undertaken by a single surgeon. Assessment of outcome acuity was performed by a trained examiner who was blind to treatment allocation; a variety of acuity tests were used and results converted into LogMAR notation for analysis. Complications were recorded on a customised proforma.
To represent real life acuity outcomes, 21 lensectomy eyes and 6 aspiration eyes were presented as if Yag capsulotomy or membranectomy had not been undertaken when it actually had. It is implied that this was achieved by adding 0.3 log units to the acuity score.

In the study by Mullner 2003 individual eyes were randomised but the method of randomisation was unclear. There were a total of 12 children with unilateral cataract included: 10/16 in Group 1; 2/17 in Group 2. There were 50 cataract operations included in the study but the number of eyes in each subgroup was small, ranging from 7 to 15. All operations were performed by the same surgeon.
The primary outcome was VAO (posterior capsule opacification (PCO)); this was graded semi-quantitatively as mild, moderate or severe and analysed by randomised groups. It was impossible to extract data pertaining solely to participants having bilateral surgery from the description of the results.
Visual acuity was not pre-stated as an outcome measure, and although recorded as part of the results, the data were derived from three different acuity measures; minimal pre-operative acuity data were reported. Postoperative acuity data were coarsely categorised into three levels and presented not on the basis of the randomised groups but on the basis of whether the cataract was bilateral or unilateral.
None of the outcomes were described as assessed blind to allocation.

Raina 2002 randomised individual eyes by block randomisation using a random digit table. Allocation was determined after informed consent at the point of enrollment. The eye with worse vision was enrolled before the fellow eye. Both eyes of six children were included in the study. All pre and postoperative examinations were performed by an independent investigator; it was not specified whether outcome was assessed blind to allocation. Visual acuity and fundus examinations were undertaken at each postoperative visit. Visual axis opacification was graded on a detailed four point scale; visual acuity tests were not specified but were reported in Snellen values and decimal units.

Vasavada 2001 was a prospective, randomised controlled trial of children with bilateral cataracts. Randomisation was assigned during surgery by sealed envelopes once it was determined that the posterior capsule was capturable. All children were examined pre and postoperatively and surgery was performed by a single surgeon. One eye randomised to the no-vitrectomy group was excluded from final analysis because of intraoperative reversal of optic capture.
It was not clear whether the reported visual acuity data were collected at the same stage postoperatively for each participant. Although 25 patients are recruited (50 eyes), and in two eyes the IOL was not capturable, only data from 42 eyes were considered in the report. It is suggested that the remaining six eyes were excluded because of inadequate follow up but this was not categorically stated. In the group of participants who contributed data for only one eye, or in whom both eyes were randomised to the same treatment, it appears that preoperative acuity as well as treatment-relevant characteristics were comparable but statistical tests for this were conducted on non-visual acuity parameters only. It remains unclear whether the investigators were masked to the postoperative visual acuity results.

Effects of interventions

The results of the included studies (Eckstein 1999; Mullner 2003; Raina 2002; Vasavada 2001) were summarised according to the pre-stated primary and secondary outcomes of this review.

Primary outcome: postoperative visual acuity
Eckstein 1999
At three years postoperation there was no difference in monocular LogMAR (equivalent) visual acuity between the eyes / procedures. Visual acuity results were grouped as follows:

VA 0 to 0.5 LogMAR (6/6 to 6/19 Snellen)
Aspiration with primary capsulotomy: 26/56 eyes (46.4%).
Lensectomy: 23/56 eyes (41.1%).

VA greater than 0.5 to 1.0 LogMAR (6/19 to 6/60 Snellen)
Aspiration with primary capsulotomy: 23/56 (41.1%).
Lensectomy: 25/56 (44.6%).

The remaining 15 eyes had acuity of worse than 1.0 or 6/60. There was no significant difference between groups.
It is worth noting that 35/65 (54%) patients had nystagmus and 40/65 (62%) had manifest strabismus at presentation. Although both of these conditions would be expected to adversely affect monocular visual acuity this was not adequately addressed in the analysis.

Mullner 2003
Visual acuity was stated as improved in all treated eyes but the lack of quantitative pre-operative acuity data prevented this review from concurring with this.
All eyes with visual acuity less than 20/40 were said to have additional problems such as nystagmus or macular hypoplasia;

this included unilateral cases. Of the bilateral cases, 72% of eyes achieved vision of 20/25 or better. It was not possible to relate visual acuity outcome data with the randomised interventions as analysis was not reported in this way.

Raina 2002
Thirty-one out of 34 included eyes had visual acuity assessed postoperatively. Individual patient data were reported for each group; there were no mean or median calculations. The three unilateral cases were not reported separately so acuity results may include these.
Extracting data from the tables, the number achieving best corrected final visual acuity of 6/6 to 6/12 (inclusive) were as follows:
No optic capture group: 14/18.
Optic capture group: 11/16.
The authors summarised this finding as 'comparable' with no statistically significant difference between groups but actual values were not given. It is important to note, however, that this result is *after* 8/18 eyes in the no optic capture group received a secondary procedure due to 'visually significant' VAO (3/8 cases dropped to less than 6/60). The visual acuity values after the primary procedure were not reported but it is likely they would have shown a significant difference between groups.
Improvement in acuity from pre to postoperation was reported as significant in both groups but statistical or clinical values that would enable verification of this statement were not reported.

Vasavada 2001
High contrast visual acuity was not significantly different between vitrectomy and no-vitrectomy groups; (no group mean visual acuity data were given).
Low contrast sensitivity was significantly better in the vitrectomy group than in the no-vitrectomy group (group mean data were not reported). Visual axis clarity was discussed as being possibly associated with this: it remained clear in all eyes randomised to vitrectomy but in only 6/20 eyes (30%) in the no-vitrectomy group ($P < 0.001$), the remaining 14/20 developing reticular fibrosis of the anterior vitreous face.

Secondary outcomes:
1. Visual axis opacification (VAO)
Eckstein 1999 found visually significant posterior capsule opacification (PCO) occurred in 37/56 (66.1%) of aspiration eyes. All of these eyes required a second procedure to clear the visual axis. There was no posterior opacification in the lensectomy group.
The presence of VAO was the primary outcome measure for the study by Mullner 2003. It was not possible to extract the data on bilateral cases (children aged 6 to 15.5 years) but overall findings showed differences in Group 2: there was no VAO at final follow up in those eyes randomised to posterior capsulotomy without (Group 2a) or with (Group 2b) optic capture but 9/15 (60%) of those allocated to Group 2c, where the posterior capsule was left intact, developed PCO (there was no measure of statistical significance for this finding). Seven out of nine of these were categorised as mild (no further treatment required; 1/9 was moderate, requiring treatment with laser; and 1/9 was severe, requiring further surgery. There was no significant difference in the age or cataract phenotype of those in Group 2c who developed VAO and those who did not. Possible differences in length of follow up were not examined.
Raina 2002 found a significantly higher (statistically) incidence of VAO in the no optic capture group: 8/18 (44.4%) compared to 0/16 in the optic capture group ($P = 0.0011$). The length of follow up was comparable for the two groups: mean 19 months in the no optic capture group; 17.5 in the optic capture group. Age differences between children developing VAO and those not were not examined supposedly due to the relatively small numbers.
The postoperative time scale over which visually significant VAO developed was described: 2/8 eyes by 6 months; 4/8 by 12 months; 2/8 after 12 months.

2. Amblyopia
In Eckstein 1999 5/56 children underwent treatment for amblyopia but no comment was made as to which treatment group they were allocated to or if the amblyopia was associated with pre-existing strabismus. In the study by Mullner 2003 the two cases said to improve with occlusion therapy had unilateral cataracts; it is not clear if additional cases were unsuccessfully treated. Vasavada 2001 recorded that appropriate occlusion was done when necessary but no further details were given.

3. Glaucoma
Eckstein 1999 diagnosed one eye in each group with secondary glaucoma (at three years follow up). No cases were diagnosed in the Vasavada 2001 and Mullner 2003 studies (mean follow up 21 months) or the Raina 2002 study (mean follow up 13 months).

4.Retinal detachment
Eckstein 1999 reported that 2/56 lensectomy eyes developed a retinal detachment while none of the 56 aspiration eyes developed retinal detachment. No retinal detachment was reported in the Vasavada 2001, Mullner 2003 or Raina 2002 studies.

5. Re-operation rate
Re-operation was most often for VAO, which occurred in 37/56 eyes of the lens aspiration group (Eckstein 1999) and 1/56 eyes in the lensectomy group (due to anterior capsule remnant obscuring the visual axis). VAO requiring re-operation occurred at a rate of 1/12 eyes in Group 1a (posterior capsulotomy with anterior vitrectomy but no optic capture) and, 2/15 eyes in Group 2c (IOL with no posterior capsulotomy) in the Mullner report (Mullner 2003). The remaining studies (Raina 2002; Vasavada 2001) reported that no cases required re-operation.

Adverse effects
In the Eckstein 1999 study a backup machine or a technician was required in 12.3% of the lensectomy cases due to instrument failure. The lens aspiration technique did not involve a mechanical device. Three children (5%) died in the first year of the study but it was assumed that the cause of death bore no relation to the cataract surgery or anaesthetic administered for the surgery.
Mullner 2003 report suture granuloma formation with corneal irritation in 35% of Group 1 (2 to 5.9 years) and 23% of Group 2 (6 to 15.5 years); all resolved with topical treatment. The use of absorbable suture material was suggested as a possible remedy.
Posterior synechiae developed in two cases in each group in the Raina 2002 study. There was no reported failure or reversal of optic capture.
Vasavada 2001 found deposits on the IOL in 4/21 (19%) eyes in the vitrectomy group and 6/20 (30%) in the no-vitrectomy group at the last follow up. Synechias developed in 3/21 (14.3%) vitrectomy and 8/20 (40%) no-vitrectomy eyes ($P = 0.06$)

DISCUSSION

Effective surgical intervention is crucial to the successful management of visually significant congenital or early developmental cataracts. The four studies included in this review examined different surgical techniques in an attempt to ascertain which approaches are more likely to maximise long-term visual rehabilitation and minimise complications and the need for further intervention.

It is expected that the most appropriate surgical approach will vary depending on factors such as the age of the patient and the presence of co-existing disease. Maybe it is not so often considered that access to healthcare resources and ophthalmological follow up has a significant impact on this also. This issue is illustrated in the study by Eckstein 1999 conducted in southern India, which found that the standard treatment of lens aspiration was associated with a higher rate of secondary visual axis opacification (VAO) than lensectomy. Although the lensectomy technique is reliant on more sophisticated, mechanised equipment, it is argued that the reduction in visually significant VAO would provide better long-term results in populations where significant numbers are without ready access to specialist follow up for a secondary capsulotomy. For similar reasons Eckstein 1999 is unique among the four included studies for using spectacles rather than IOLs for optical correction. Aphakic spectacles are the preferred method of optical correction in populations where regular follow up is not possible; but this method is being increasingly replaced by contact lenses or IOLs in developed countries. The optical advantages of intra-ocular and contact lens correction are irrefutable but the feasibility of their use in the developing world remains to be established. To our knowledge only one nonrandomised study (Birch 2005) has prospectively assessed visual outcome in children receiving primary IOL implantation and those receiving aphakic contact lens (CL) correction. This study assessed only cases with unilateral cataracts and concluded that IOLs and aphakic CLs supported similar visual acuity development after surgery for a unilateral cataract. The authors also concluded that IOLs may support better visual acuity development when compliance with CL wear is poor or when a cataract is extracted after one year of age.

Knowing whether surgical intervention actually achieves the ultimate aim of satisfactory visual acuity can be difficult as it requires longterm follow up. This is more crucial in studies recruiting very young children not only because accurate acuity testing is not always possible in the very young but because the immaturity of the developing visual system increases the likelihood of amblyopia and other complications. In addition, variables likely to affect visual outcome, such as age at surgery and co-morbidity, need to be recognised and adequately controlled for when interpreting effectiveness. The duration and depth of visual deprivation are also likely to affect visual prognosis but this can often be difficult to determine. The studies included in this review varied in terms of the age of children at surgery, length of follow up, co-morbidity and type of cataract making it impossible to combine or directly compare results. The youngest child included was 1.5 years of age (Raina 2002) and the oldest 15.5 years (Mullner 2003). No eligible studies were recovered that evaluated surgery in the first few postnatal weeks of life and, therefore, issues such as IOL suitability could not be studied in this review. Some nonrandomised study data exists in this area; Lundvall 2002 reported on the long-term outcome of 22 children operated on for bilateral congenital cataract at less than 12 months of age. Better acuity outcomes were achieved in otherwise healthy babies undergoing surgery at less than 8 weeks of age; however, very early surgery was associated with a higher risk of secondary glaucoma. These findings have been corroborated in other recent cohort studies (Casaer 2005; Lambert 2006; Vishwanath 2004).

The Eckstein 1999 study provided the most clearly reported visual acuity data: 41% and 46% of eyes undergoing lensectomy or aspiration respectively achieved between 0.0 to 0.5 LogMAR (6/6 to 6/19) vision with aphakic spectacles. As might be expected the more impressive results were reported in studies using IOLs for optical correction; Raina 2002 reported a high number achieving 6/6 to 6/12 acuity, albeit after some children underwent secondary procedures for VAO. Mullner 2003 also reported good results, 72% of eyes achieving 20/25 (6/7.5) or better. However, concerns regarding study methodology, particular in the Mullner study, mean that the favourable results using primary IOL implantation should be interpreted with some caution.

Although three of the included studies (Eckstein 1999; Mullner 2003; Raina 2002) reported visual acuity data from their patients at final follow up none of them provided adequate methodological information in relation to compliance (to optical correction or amblyopia therapy) or to the standardisation of the acuity testing process. Compliance with optical or patching treatment is essential in order to achieve good acuity, but it is known to be difficult to attain. Attributing a positive or negative effect to the intervention is not possible if it is not known whether or how well the treatment was actually delivered. While there are now ways of objectively measuring compliance (with patching), it must be recognised that the potential benefits of a treatment need to be considered carefully when the treatment is very difficult to deliver. Knowledge of the repeatability of the testing technique and standardisation of the acuity threshold measurements are also crucial for any report of visual acuity outcomes to be reliable (Chen 2006).

In addition, the exact time point postoperatively at which visual acuity (and other outcomes) were recorded was not specified (Mullner 2003; Raina 2002; Vasavada 2001). The reported mean follow up has a significant range indicating that outcomes were recorded at different postoperative time points for different children. This raises the possibility that those with better outcomes also had shorter follow up times. Eckstein 1999 followed up all included children for three years postoperatively making these results more reliable.

Visual axis opacification is a major postoperative complication from cataract surgery in young children (Apple 1992). The principal aim of the studies by Mullner 2003, Vasavada 2001 and Raina 2002 was to compare primary surgical procedures to prevent VAO developing in cases undergoing IOL implantation. In these studies visual axis opacification developed as a result of posterior capsule opacification (PCO) or reticular fibrosis of the anterior vitreous face. Reports of the incidence of PCO in children undergoing IOL implantation vary; Sinskey 1993, detected it in 51% of cases, Apple 1992 in 100% of cases and in Cassidy 2001 all but one eye which did not have a posterior capsulorhexis. Posterior capsule opacification can be assessed directly by fundus examination but the functional impact is only measurable with proper visual assessment.

While the differences between included studies preclude direct comparison of the findings it is useful to comment on the differences in the incidence of PCO within each study. In the study by Eckstein 1999 66.1% of cases undergoing lens aspiration with primary capsulotomy developed PCO. This high incidence led to the conclusion that lensectomy is the preferred procedure, especially

in circumstances where follow-up procedures to check for and treat VAO may be limited. Mullner 2003 found that in children aged 6 to 15.5 years VAO secondary to PCO was more likely to develop if the posterior capsule had been left intact. However, as further intervention was only required in two of nine affected cases this was suggested as acceptable in this age group, where the risk of amblyopia is lower and further treatment is easier to execute. Posterior capsule opacification developed in 44.4% of those cases without optic capture in the Raina 2002 study leading to the conclusion that optic capture helps prevent PCO even in the absence of anterior vitrectomy.
Visual axis opacification caused by reticular fibrosis of the anterior vitreous face developed in 70% of children who did not receive an anterior vitrectomy in the Vasavada 2001 study. No cases developed this complication in the anterior vitrectomy arm. In the absence of complications associated with anterior vitrectomy the authors concluded that this is an appropriate procedure, especially in younger children, to help establish a clear visual axis. It is interesting to note that the high contrast method of acuity testing did not identify impaired visual acuity in those with vitreous fibrosis; there is no comment as to whether those with poorer contrast sensitivity were in anyway symptomatic as a result.

AUTHORS' CONCLUSIONS

Implications for practice

The included studies highlight some of the difficulties in paediatric cataract surgery, particularly the significant postoperative complication of visual axis opacification. It would seem that, in younger children a posterior capsule opening alone is not sufficient to prevent visual axis opacification development but that anterior vitrectomy or optic capture, or both reduce it.
In light of the limited amount of high quality evidence found in this review clear guidance regarding the most suitable surgical technique cannot be provided. The appropriate choice of surgery will depend on available resources, training, equipment and anaesthetic support for small babies. Even allowing for that, it is unclear whether both eyes should be operated on in a single session or in separate but timely sessions (so that refractive outcomes from the first eye inform the second procedure). The use of IOLs is increasing as they reduce the need for contact lenses but much uncertainty remains regarding the choice of lens type, position, material and how to calculate optimal dioptric power.
Frequent and long-term follow up is required whether spectacles, contact lenses or IOLs are used to correct near and distance vision; in addition, treatment for stimulus deprivation amblyopia may need to be undertaken (dealt with in a separate Cochrane review). Achieving adequate follow up is in itself a challenge for the family, especially in poorer countries. However, early surgery (but not too early) in the hands of specialist teams skilled in the care of young children is better than none.

Implications for research

This review has highlighted many gaps in the evidence surrounding the management of bilateral congenital cataracts. In particular, high-level evidence is needed to address:

- the age(s) at which surgery should be undertaken, for maximum benefit and minimum risk;
- when different surgical techniques may be indicated;
- how surgery for the second eye should be managed;
- appropriate age and circumstances for primary IOL implantation and its role in the developing world;
- methods for accurately calculating IOL power;
- the threshold of vision deficit most likely to significantly benefit from surgery;
- at what age(s) and in what situations anterior vitrectomy is indicated;
- risk factors for secondary glaucoma and retinal detachment.

Comparing outcomes is often confounded by the variation in, and unknown validity of methods to measure visual function; standardisation of this and objective monitoring of compliance with treatment would greatly improve the quality of study data and enable more reliable interpretation of outcomes.

ACKNOWLEDGEMENTS

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Eckstein 1999

Methods	The eye to be operated on first and the procedure to be used was randomly assigned. The second eye automatically had the alternative procedure.
Participants	Number enrolled: 130 eyes of 65 children. Age: 3 months to 10 years. Inclusion criteria: 0 to 10 years; resident in Tamil Nadu or Kerala; bilateral symmetrical cataracts both requiring surgery. Exclusion criteria: ill or underweight; pre-existing ocular disease.

Eckstein 1999 *(Continued)*

Interventions	Lensectomy versus lens aspiration and primary capsulotomy.
Outcomes	Visual acuity; complications (iritis, posterior capsule opacification, glaucoma); secondary surgical intervention rates.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Mullner 2003

Methods	Depending on age, randomly assigned to procedure.
Participants	50 eyes of 34 children.
Interventions	Five different procedures aimed at reducing posterior capsule opacity.
Outcomes	Visual acuity; posterior capsule opacification.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Raina 2002

Methods	All had lens aspiration, IOL and posterior capsulorhexis.
Participants	34 eyes; aged 1.5 to 12 years.
Interventions	Optic capture or not.
Outcomes	44% versus no cases of visual axis opacification in the no capture group.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Vasavada 2001

Methods	Lens aspiration and posterior capsulotomy.
Participants	41 eyes of 25 children. All had bilateral cataract. Mean age 6 years (range 5 to 12 years).
Interventions	Anterior vitrectomy versus no anterior vitrectomy.
Outcomes	No difference in high contrast acuity between the groups. Low contrast sensitivity better in vitrectomy group (P = 0.02).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ahmadieh 1999	Bilateral surgery in 14 of 45 eyes. No data are available in the article as to what treatment the bilateral cataracts received and their particular outcomes. Written correspondence attempted.
Basti 1996	No randomisation. Cannot infer results for bilateral cataracts.
Basti 1999	Comparing intra-ocular lens types. All participants had same surgery.
Bayramlar 2004	Not randomised. All were bilateral cataracts. All right eyes had heparin in irrigation fluid while left eyes did not.
Hoyt 1982	No randomisation. Obvious selection and outcome bias.
Kugelburg 2005	Cannot distinguish unilateral from bilateral cases. No visual acuity data.
Ram 2003	Randomisation either insufficient or unclear.
Saini 2003	Randomisation insufficient. The outcome data do not include information on vision improvement and we cannot tell whether the cataracts were bilateral.
Thouvenin 1995	Retrospective study (author correspondence).
Vasavada 1997	No randomisation. Cannot extract data on the two pairs of bilateral cataracts.
Vasavada 2000	Well designed study. Failed or reversed optic capture cases were added to the no capture group. They were not analysed on an intention-to-treat basis.
Vasavada 2003	Well-designed study but the outcome data (duration of lens aspiration in seconds and volume of aspiration fluid used) are not included as a significant outcome.

WHAT'S NEW

Date	Event	Description
6 June 2008	Amended	Converted to new review format.

HISTORY

Review first published: Issue 3, 2001

Date	Event	Description
1 March 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

VL decided the review scope.
VL and SC independently assessed the results of searches and decided on the suitability of studies.
VL and SC jointly wrote the text of the review under the guidance of the Cochrane Eyes and Vision Group.
SH assisted in updating the review and adding detail.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Sightsavers International, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

Cataract [*congenital] [pathology]; Cataract Extraction [adverse effects] [*methods]; Randomized Controlled Trials as Topic; Treatment Outcome; Visual Acuity

MeSH check words

Child; Child, Preschool; Humans; Infant