

# Surgical interventions for age-related cataract (Review)

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## ABSTRACT

### Background

Cataract is the major cause of global blindness, accounting for 40 to 80% of all blindness in developing countries. The number of people blind from cataract is expected to rise due to the changing age distribution and increasing life expectancy. There is currently no proven intervention to prevent cataract and surgery is the only form of treatment.

### Objectives

The objective of this review is to compare the effects of different surgical interventions for age-related cataract.

### Search strategy

We searched the Cochrane Controlled Trials Register - CENTRAL/CCTR, which contains the Cochrane Eyes and Vision Group trials register (Cochrane Library Issue 3 2001), MEDLINE (1966 to August 2001), EMBASE (1980 to September 2001), the reference lists of identified trials, and we contacted investigators and experts in the field for details of published and unpublished trials.

### Selection criteria

We included randomised controlled trials evaluating surgical treatment for people with age-related cataract.

### Data collection and analysis

Two reviewers independently extracted data and discrepancies were resolved by discussion. Where appropriate, relative risks, odds ratios and weighted mean differences were summarised after assessing heterogeneity between the studies. We used a fixed effect model due to the low number of trials in each comparison.

### Main results

We identified six trials that randomised a total of 7828 people. Phacoemulsification gave a better visual outcome than extracapsular surgery and gave a similar average cost per procedure in one trial conducted in the UK. Extracapsular surgery with posterior chamber lens implant and intracapsular surgery with or without an anterior chamber intraocular lens implant gave acceptable visual outcomes at 12 to 24 months after surgery. In three large trials in south Asia, best-corrected visual acuity of less than 6/60 ranged from 0.5 to 4%. Higher rates of poor outcome were observed in a multicentre study with 19 surgeons compared to a single-centre study with two surgeons.

### Authors' conclusions

This review provides evidence from one randomised controlled trial that phacoemulsification gives a better visual outcome than extracapsular extraction with sutures. However, this trial was conducted in a developed country specialised hospital setting and extrapolation to other settings must be made with caution. This review also found evidence that extracapsular cataract extraction with a posterior chamber lens implant provides better visual outcome than intracapsular extraction with aphakic glasses. This finding is also based on the results of a single trial. The long term effects of posterior capsular opacification need to be assessed in larger populations. The data in the review suggest that intracapsular extraction with an anterior chamber lens implant is an effective alternative to intracapsular extraction with aphakic glasses, with similar safety. Further data from developing regions are needed to compare all aspects of intraocular lens surgery with the three main surgical procedures - intracapsular extraction with an anterior chamber lens, extracapsular surgery with a posterior chamber lens with or without sutures.

## PLAIN LANGUAGE SUMMARY

Surgery to remove a lens with cataract can restore vision and implanting an artificial lens may work better than using glasses

Different surgical techniques can be used to remove a lens that has become cloudy due to cataract. The function of the removed lens can be replaced either by an intraocular lens, aphakic glasses or contact lens. The review found evidence for the safety and effectiveness of all the major techniques for cataract extraction and that use of an intraocular lens improved vision. However, there is a gap in knowledge of cost-effectiveness of the different techniques in developing country settings.

## BACKGROUND

The World Health Organization estimates that there are 45 million people worldwide who are blind. Cataract causes over 40 per cent of all blindness and is thus the most important cause of global blindness (Thylefors 1995). Opacification of the lens occurs as a result of denaturation of lens proteins. This is not thought to be reversible. Some interventions for preventing or delaying the development of cataract are used in some European countries but their effectiveness has not been proven. Surgery is currently the only treatment option once the lens has opacified and vision is decreasing.

The majority of blinding cataract is to be found in developing countries. An increasing number of visually impaired and blind people are gaining access to cataract surgical services due to the development of prevention of blindness programmes in many countries (Kupfer 1994). In India alone over three million cataract surgeries are now performed annually (Gupta 1998). Despite these positive trends the number of people blind due to cataract is increasing because of the changing demographic structure of populations (Minassian 1990; Limburg 1996; Thylefors 1998).

Intracapsular cataract extraction gained popularity in the 1960s and 1970s (Elder 1969) and is still widely used in developing countries. The whole lens with intact capsule is removed from the eye. The function of the removed lens can be replaced either by the insertion of an intraocular lens usually in the anterior chamber, or by the use of aphakic glasses or contact lens. The main advantage of intracapsular cataract extraction is that it is a standardised technique that can be performed by trained surgeons rapidly (three to five minutes) with minimal manipulation of the eye. The secondary problem of opacification of the lens capsule, with the need for further surgical or laser intervention, is avoided because both the lens and capsule are removed.

Extracapsular cataract extraction was re-introduced with the development of microsurgical techniques in the early 1980s. The lens contents are removed leaving the posterior lens capsule intact. A posterior chamber intraocular lens can then be placed in the capsular bag (Duane 1986; Apple 1989). If no intraocular lens is implanted, aphakic glasses or contact lenses must be used. Extracapsular surgery has become the preferred method of extraction

in economically advantaged countries and most surgeons in developing countries are now being trained to use this method.

Further technological development has led to a majority of surgeons in developed countries adopting sutureless extracapsular cataract extraction surgery (Norregaard 1999). This surgery uses either mechanical fragmentation (phacoemulsification) of the lens nucleus (Mehta 1999), or a manual fragmentation technique (Blumenthal 1992; Hennig 1999).

Both suture and sutureless extracapsular cataract extraction leave in place the posterior capsule of the lens. This keeps intact the anatomical barrier between the posterior and anterior segments of the eye. The barrier may reduce the risk of posterior segment complications. The disadvantage of all the extracapsular techniques is that the posterior lens capsule can become cloudy ('after cataract') (Apple 1992) with the need for a primary or secondary capsulotomy by surgery or using a YAG laser. This increases the costs of surgery and incurs the risk of secondary complications (Javitt 1992).

There is now a consensus that all eye surgeons should be trained to implant intraocular lenses. However there continues to be debate as to the role of intracapsular extraction in combination with the use of an anterior chamber lens (Apple 1997a). In addition there is a growing realisation that substantial barriers to surgery still exist, especially in rural areas of developing countries (Snellingen 1998; Fletcher 1999; Vaidyanathan 1999). This complex mix of rapid development of technology, increasing numbers of people blind due to cataract, and barriers to surgery will demand the development of quality information systems, which can monitor outcomes and develop comparative cost models, accessible to both providers and consumers.

## OBJECTIVES

The aim of this review is to examine the effects of the main types of surgery currently used to treat cataract.

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

This review includes randomised controlled trials.

### Types of participants

Participants in the trials were people with age-related cataract.

### Types of intervention

We included the following interventions in this review:

- intracapsular extraction, with or without an anterior chamber intraocular lens implant,
- extracapsular extraction, with or without a posterior chamber intraocular lens implant.

We also considered the different ways in which the lens may be removed in extracapsular extraction. We defined these as:

- techniques requiring the placement of sutures,
- techniques not requiring the placement of sutures with the lens removed after phacoemulsification or manual fragmentation.

### Types of outcome measures

The primary outcome for this review is:

- (1) visual acuity at one year or more after surgery, presented as:
  - (a) the proportion of people with a poor visual outcome after surgery - defined as best corrected vision of less than 6/60 in the operated eye,
  - (b) the proportion of people not achieving good functional vision - defined as functional vision of less than 6/18 in the operated eye. By functional vision, we mean the vision with usual spectacle correction.

Secondary outcomes for this review include:

- (2) complications during surgery including vitreous loss and capsular rupture combined with vitreous loss,
- (3) complications at one year or more after surgery including the proportion of participants with retinal detachment, glaucoma, cystoid macular oedema, corneal decompensation, posterior capsule opacification,
- (4) corneal endothelial cell loss,
- (5) visual function other than visual acuity (visual perception, peripheral vision, sensory adaptation, depth perception),
- (6) quality of life (self-care, mobility, social and mental function),
- (7) costs.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

Trials were identified from the Cochrane Controlled Trials Register - CENTRAL/CCTR (which contains the Cochrane Eyes and Vision Group trials register) on the Cochrane Library, MEDLINE and EMBASE.

The following strategy was used to search CENTRAL Issue 3 2001:

- #1 CATARACT-EXTRACTION\*1:ME
- #2 LENS-IMPLANTATION-INTRAOCULAR\*1:ME
- #3 #1 or #2
- #4 CATARACT near EXTRACT\*
- #5 ((LENS next OPACIT\*) and EXTRACT\*)
- #6 INTRACAPSULAR or EXTRACAPSULAR or PHACO or PHAKO
- #7 ((INTRAOCULAR next LENS\*) near IMPLANT\*)
- #8 SUTURELESS near CATARACT
- #9 #4 or #5 or #6 or #7 or #8
- #10 #3 or #9

The following strategy was used to search MEDLINE on SilverPlatter to August 2001:

- #1 EXPLODE "CATARACT-EXTRACTION"/ all subheadings
- #2 "LENS-IMPLANTATION,-INTRAOCULAR"/ all subheadings
- #3 #1 or #2
- #4 LENS near OPACIT\*
- #5 (CATARACT or #4) near EXTRACT\*
- #6 INTRA?CAPSULAR or EXTRA?CAPSULAR or PHA?O
- #7 INTRA?OCULAR next LENS\*
- #8 #7 near IMPLANT\*
- #9 SUTURELESS near CATARACT
- #10 (#5 or #6 or #8 or #9) in TL,AB
- #11 #3 or #10

To identify randomised controlled trials, this search was combined with the Cochrane Highly Sensitive Search Strategy phases one and two as contained in the Cochrane Reviewers' Handbook (Clarke 2000).

The following strategy was used to search EMBASE on SilverPlatter to September 2001:

- #1 explode "CATARACT-EXTRACTION"/ all subheadings
- #2 "LENS-IMPLANTATION"/ all subheadings
- #3 #1 or #2
- #4 LENS near OPACIT\*
- #5 (CATARACT or #4) near EXTRACT\*
- #6 INTRA?CAPSULAR or EXTRA?CAPSULAR or PHA?O
- #7 INTRA?OCULAR near LENS\*
- #8 #7 near IMPLANT\*

#9 SUTURELESS near CATARACT  
#10 (#5 or #6 or #8 or #9) in TI,AB  
#11 #3 or #10

To identify randomised controlled trials, this search was combined with the following search:

#1 "RANDOMIZED-CONTROLLED-TRIAL"/ all subheadings  
#2 "RANDOMIZATION"/ all subheadings  
#3 "CONTROLLED-STUDY"/ all subheadings  
#4 "MULTICENTER-STUDY"/ all subheadings  
#5 "PHASE-3-CLINICAL-TRIAL"/ all subheadings  
#6 "PHASE-4-CLINICAL-TRIAL"/ all subheadings  
#7 "DOUBLE-BLIND-PROCEDURE"/ all subheadings  
#8 "SINGLE-BLIND-PROCEDURE"/ all subheadings  
#9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8  
#10 RANDOM\* or CROSS?OVER\* or FACTORIAL\* or PLACEBO\* or VOLUNTEER\* in TI,AB  
#11 (SINGL\* or DOUBL\* or TREBL\* or TRIPL\*) near (BLIND\* or MASK\*) in TI,AB  
#12 #9 or #10 or #11  
#13 HUMAN in DER  
#14 (ANIMAL or NONHUMAN) in DER  
#15 #13 and #14  
#16 #14 not #15  
#17 #12 not #16

We searched the reference lists of identified included studies. We contacted study authors and other experts in the field to identify unpublished studies or studies sent for publication or in press. There were no language restrictions in the searches for trials.

## METHODS OF THE REVIEW

### Selection of trials

Two reviewers independently screened the titles and abstracts resulting from the electronic searches. Full copies were obtained of any report referring to definitely or possibly relevant trials. These full copies were assessed according to the definitions in the 'Criteria for considering studies for this review'. Only trials meeting these criteria were assessed for methodological quality.

### Assessment of methodological quality

Trial quality was assessed according to methods set out in section 6 of the Cochrane Handbook (Clarke 2000). Five parameters were considered: allocation concealment, method of allocation to treatment, documentation of exclusions, completeness of follow-up, methods of documentation of complications. Each parameter of trial quality was graded: A - low risk of bias; B - moderate risk of bias; C - high risk of bias. Two reviewers independently assessed the trial quality and disagreement was resolved by discussion. Reviewers were not masked to the report authors and trial results during the assessment.

### Data collection

Data were extracted using a form developed by the Cochrane Eyes and Vision Group. Two reviewers extracted data and compared the results for differences. Discrepancies were resolved by discussion.

### Data synthesis

Data from studies collecting comparable outcome measures with similar follow-up times were analysed using either the relative risk, odds ratio or weighted mean difference. Where it was appropriate to pool results we used a fixed effect model because of the low number of trials in each comparison. We assessed heterogeneity between trial results using a chi-square test. If the studies showed quite different results we did not combine them, even though the test for heterogeneity was not significant, as we felt that it would have low power in these situations.

### Sensitivity analysis

We planned to conduct sensitivity analyses to assess the effect of study quality on effect size. Currently not enough trials are included to conduct any sensitivity analyses.

## DESCRIPTION OF STUDIES

### Finding the trials

The electronic searches found a total of 2824 reports. We obtained the full copy of nine reports of trials that appeared to meet our inclusion criteria. We excluded three of these (Alpar 1984; De Laage 1988; Quentin 1993) (see the Characteristics of excluded studies table) and included six (LAHAN; Minassian 2001; MIOLS; OCTET; SACMS; Vogel 1993).

A summary of the included studies is presented below. Further details can be found in the Characteristics of included studies table.

### Types of participants and settings

The six included trials can be divided into two groups. Three smaller trials were conducted in Europe (Minassian 2001; OCTET; Vogel 1993). Three larger trials have been done in the Indian sub-continent (LAHAN; MIOLS; SACMS). The majority of trials recruited participants aged 40 years and above, with the exception of OCTET and Vogel 1993 where participants were aged over 55 years.

### Types of interventions

Two studies compared intracapsular extraction with aphakic glasses to intracapsular extraction with an anterior chamber lens (LAHAN; SACMS). One study compared intracapsular extraction with aphakic glasses to extracapsular extraction with a posterior chamber lens (MIOLS). Phacoemulsification has been compared with extracapsular cataract surgery in one trial (Minassian 2001).

Two studies used lens types that are no longer in use either because of unacceptable complications or because the lens has been

replaced by an improved model (OCTET; Vogel 1993). Data for these studies are presented separately.

#### Follow-up

All trials had follow-up of at least one year. The longest period of follow-up was five years (LAHAN).

#### Outcomes

Distance visual acuity was measured in all trials using either Snellen acuity or LogMAR scale with the EDTRS chart. Clinical complications were usually presented. Endothelial cell loss was assessed in two studies (OCTET; SACMS).

## METHODOLOGICAL QUALITY

#### Method and concealment of allocation to treatment

Four trials used computer-generated lists of treatment allocation delivered in sequentially numbered, sealed opaque envelopes (LAHAN; Minassian 2001; MIOLS; SACMS). For the other trials, the method of treatment assignment was unclear, although they stated that the groups were randomly allocated (OCTET; Vogel 1993).

#### Documentation of exclusions

There were no exclusions after treatment allocation in three trials (LAHAN; MIOLS; OCTET). In one trial, eight people (four in each group) did not receive surgery after treatment allocation (SACMS). In the phacoemulsification trial five people in the phacoemulsification group were withdrawn after randomisation compared to 13 in the extracapsular group (Minassian 2001). Exclusions were not clearly documented in the other trial (Vogel 1993).

#### Completeness of follow-up one year after surgery

Follow-up rates were good. In LAHAN 91% of the cohort were followed up at one year after surgery with equal follow-up in the two treatment groups. In MIOLS 87% of the group receiving an intraocular lens and 82% of the group receiving aphakic spectacles were followed up. In SACMS 84% were followed up in both groups. In OCTET four out of 327 people randomised died by one year leaving a follow-up rate of 99%. In Minassian 2001 89% of the phacoemulsification group were followed up at one year compared to 86% of the extracapsular group. In general trials did not report whether people who were lost to follow-up differed from those who remained in the trial.

#### Masking of outcome assessment

In trials where an intraocular lens was compared to aphakic spectacles, masking of outcome assessment was not possible because of the obvious difference in appearance of participants in either arm. Aphakic spectacles are thick and heavy while those people with an implant may be able to see well without spectacles. It is therefore usually obvious which intervention the participant has had. In the trial of phacoemulsification, participants were masked to study group but the optometrists performing the outcome mea-

surements were able to see differences in incision that meant that they were effectively unmasked (Minassian 2001).

#### Intention-to-treat analysis

Four trials analysed all participants who completed follow-up in the group to which they were randomised (LAHAN; Minassian 2001; MIOLS; SACMS). In the OCTET study it was not clear if this was done. The analysis was complicated by the fact that for a small minority of participants, both eyes were enrolled in the trial.

#### Handling of data for two eyes

In the four most recent trials, only one eye per person was enrolled in the trial, thus avoiding difficulties with the analysis of correlated data for two eyes (LAHAN; Minassian 2001; MIOLS; SACMS). In OCTET 333 eyes from 331 people were enrolled in the trial. Some people were therefore in more than one treatment group. Since it affects only a small number of eyes it is considered unlikely to have a major effect on the results and this complexity was therefore ignored in the analysis.

## RESULTS

We use the following abbreviations in this section:

ECCE - extracapsular cataract extraction

ICCE - intracapsular cataract extraction

AC - anterior chamber

PC - posterior chamber

IOL - intraocular lens

AG - aphakic glasses

#### (1) PHACOEMULSIFICATION WITH PC-IOL VERSUS ECCE WITH PC-IOL

We found one trial that compared these types of surgery (Minassian 2001).

##### (a) visual outcomes

The study report did not present visual outcomes in the way required for this review and are therefore not presented graphically.

Visual acuity was measured three weeks, six weeks, three months, six months and one year after surgery and presented as the numbers achieving vision of 6/9 or better, unaided or with spectacle correction. People in the phacoemulsification group achieved a better visual outcome during the follow-up period. This was largely due to the fact that the extracapsular group experienced higher levels of astigmatism. One year after surgery, 204/224 (91%) of the phacoemulsification group achieved visual acuity of 6/9 or better with spectacle correction, compared to 184/215 (86%) of the extracapsular group (relative risk (RR) 1.06, 95% confidence interval (CI) 0.99 to 1.14). One year after surgery, 87/224 (39%) of the phacoemulsification group achieved unaided visual acuity of 6/9 or better compared to 42/215 (20%) of the extracapsular group (RR 1.99, 95% CI 1.45 to 2.73).

##### (b) complications during surgery

Complications during surgery were more common in the extracapsular group. In particular, 17 of the extracapsular group had peroperative iris prolapse compared to none of the phacoemulsification group. Capsule rupture and/or vitreous loss were equally common in the two groups with nine cases in the phacoemulsification group compared to eight cases in the extracapsular group.

(c) clinical complications

Corneal decompensation was not reported. There were two retinal detachments, both in the phacoemulsification group, and five cases of macular oedema (two in the phacoemulsification group and three in the extracapsular group). Posterior capsule opacification occurred less commonly in the phacoemulsification group (RR 0.67, 95% CI 0.48 to 0.92).

(d) corneal endothelial cell loss

Corneal endothelial cell loss occurred at a similar rate in the two groups. The mean loss in the phacoemulsification group was 259 per mm<sup>2</sup> compared to 224 per mm<sup>2</sup> in the extracapsular group. (Standard deviation for these results was not presented in the report therefore they are not presented graphically; the authors report that this difference was not significant (P = 0.29)).

(e) costs

The authors found that in the UK setting, the average cost of cataract extraction by phacoemulsification was similar to the average cost of cataract extraction using the standard technique of extracapsular extraction i.e. £332.89 compared to £335.07.

(2) ECCE WITH PC-IOL VERSUS ICCE WITH AG

One trial compared these types of surgery (MIOLS).

(a) visual outcomes

Best-corrected vision less than 6/60 occurred in 0.6% of the ECCE-PCIOL group compared to 1.6% of the ICCE-AG group. People in the ECCE-PCIOL were less likely to experience a poor outcome one year after surgery (RR 0.39, 95% CI 0.18 to 0.84). Functional vision less than 6/18 was recorded in 16% of people receiving IOLs and 15% of people receiving spectacles (RR 1.08, 95% CI 0.91 to 1.28). This analysis includes 155 participants who did not present with personal eye glasses at follow-up.

(b) complications during surgery

Vitreous loss during surgery was reported in 1.7% of participants in the MIOLS. Capsular rupture combined with vitreous loss was observed in 1.7% of the ECCE-PCIOL group in MIOLS.

(c) clinical complications

Posterior capsular opacification occurred in 9% of the ECCE-PCIOL group at one year. There were eight cases of corneal decompensation, four in each group and eight cases of retinal detachment, three in the ECCE-PCIOL group compared to five in the ICCE-AG group. Macular oedema, the diagnosis of which was verified with fluorescein angiography, occurred more frequently in the ICCE-AG group. There were 23/1474 in the ECCE-PCIOL group compared to 59/1401 in the ICCE-AG group (RR 0.37, 95% CI 0.23 to 0.60).

(d) quality of life

The MIOLS study was the only study that examined quality of life. In both study groups participants' responses showed large improvements in visual functioning and quality of life. With improvement in visual acuity from 20/60 to 20/20 there was an increase in visual functioning and quality of life for both procedures with advantage of ECCE with PCIOL over ICCE with AG across all visual categories. The visual functioning and quality of life subscale scores associated with lens implant visual acuity of 20/50 to 20/60 showed consistently the same or slightly better than participants operated without lens implant associated with visual acuity scores of 20/20.

(3) ICCE WITH AC-IOL VERSUS ICCE WITH AG

Two trials compared these interventions (LAHAN; SACMS).

(a) visual outcomes

Best corrected vision less than 6/60 was reported in 2.6% of the ICCE-ACIOL group compared to 2.2% of the ICCE-AG group in the LAHAN study (RR 1.19, 95% CI 0.66 to 2.14). In the SACMS with data up to two years after surgery, 3.9% of the ICCE-ACIOL group compared to 3.6% of the ICCE-AG group had best corrected acuity less than 6/60 one year after surgery (RR 1.06, 95% CI 0.57 to 1.96). The pooled relative risk from these two studies is 1.13, 95% CI 0.74 to 1.72. The whole cohort taking part in the LAHAN trial was invited for re-examination two to five years after surgery; 65% were re-examined. There were 13 new cases of best corrected acuity less than 6/60 occurring after one year follow-up, nine in the ICCE-ACIOL group and four in the ICCE-AG (odds ratio 2.1, 95% CI 0.59 to 9.55). There was no indication that lens-related problems increased over time.

Functional vision less than 6/18 was reported in 55% of the ICCE-ACIOL group compared to 41% of the ICCE-AG group (RR 1.35, 95% CI 1.22 to 1.49) in the LAHAN study. There were similar numbers of people severely visually impaired and blind in both groups at all follow-up times. The exception to this is at one year when there were more people functionally blind in the ICCE-AG. This occurred due to the loss of aphakic glasses. There was a 60% reduced risk of functional blindness in the ICCE-ACIOL group one year after surgery. Significant astigmatism was approximately four times more common in the ICCE-ACIOL group compared to ICCE-AG group. Most participants in both groups had 'against the rule' astigmatism, 446 or 88.8% (95% CI 86.0 to 91.6) and 348 or 83.5% (95% CI 79.9 to 87.1) respectively.

In the SACMS pre-operative assessment was not standardised as two centres used different types of biometry and one centre did not use biometry. In addition, the results were not presented strictly according to the definition of functional vision used in this review. Visual acuity was presented with the entire aphakic group having +10 spectacle correction. This analysis showed that 51% of the ACIOL group had functional vision less than 6/18 compared to 46% of the aphakic group (RR 1.10, 95% CI 0.97 to 1.24). As the outcome is not strictly the same in these two cases, we have



not calculated an overall summary score. In the SACMS a limbal incision was used in 91% of patients. No comparative data are available on degree of astigmatism.

#### (b) complications during surgery

There were similar numbers of perioperative complications in the two groups in SACMS. Vitreous disturbance leading to vitrectomy occurred in 69/616 (11.2%) of the ICCE-ACIOL group compared to 58/613 (9.5%) of the ICCE-AG group. In LAHAN 2.9% of the ICCE-ACIOL group received an anterior vitrectomy compared to 0.4% of the ICCE-AG group.

#### (c) clinical complications

Corneal endothelial cell loss after six week follow-up was 17% in the IOL group and 14.4% in the aphakic group ( $P < 0.05$ ) in the SACMS trial. After six weeks there was no significant difference in the continuing cell loss between eyes having no lens compared to eyes with lens (12 months: IOL 5.3%, AG 4.1%,  $P = 0.06$ ; 24 months: IOL 3.1%, AG 2.9%  $P = 0.71$ ). See Table 01.

The LAHAN and SACMS study reported other complications related only to severe visual impairment. On the whole, these complications occurred infrequently. The power of these studies to detect differences, even when the results are pooled, is therefore low.

**Retinal detachment:** There were few cases of retinal detachment and so the power of these studies to detect a difference was low. At one year after surgery, there were 8/1430 in the ICCE-AG groups and 2/1437 in the ICCE-ACIOL groups (pooled RR 0.29, 95% CI 0.07 to 1.20). However, later follow-up in the LAHAN study found four more cases of retinal detachment in the ICCE-ACIOL group, further evidence for little difference between the two groups in incidence of retinal detachment.

**Glaucoma:** In LAHAN secondary glaucoma as a cause of visual loss was reported more commonly in the ICCE-ACIOL group (five cases) compared to the ICCE-AG group (no cases). Uveitis was also found more commonly in the ACIOL group compared with the aphakic group. SACMS reports the presence of secondary glaucoma at 0.1% with no significant difference between the groups.

**Cystoid macula oedema:** There were two cases of cystoid macular oedema in the ICCE-ACIOL group in LAHAN compared to none in the ICCE-AG group. In the SACMS three cases in the ICCE-ACIOL group compared to two in the ICCE-ACIOL group. The pooled relative risk of having severe visual impairment due to cystoid macula oedema in the ICCE-ACIOL group compared to ICCE-AG group was 2.2 (0.49 to 9.79).

**Corneal endothelial decompensation:** This occurred rarely. In LAHAN there was one case at one year that occurred in the ICCE-AG group. No further cases were identified after one year. In SACMS there was one case in the IOL group.

#### (4) STUDIES OF OLDER LENS TYPES

There were two studies that considered older lens types (OCTET; Vogel 1993). The data for these studies are not presented in the meta-analyses.

#### (a) visual outcomes

Best-corrected vision of less than 6/60 was not reported as an outcome in the OCTET study. In this study, 96% of ICCE without IOL, 84% of ICCE with iris clip lens and 84% of ECCE with iridocapsular lens had best corrected vision better or equal to 6/12 at one year after surgery. In Vogel 1993 the vision outcomes at two years after surgery were presented as medians and mean. There was a non-significant difference between the two study groups. In the ICCE-ACIOL group the mean visual acuity was 0.72 (standard deviation 0.237) compared to 0.74 (standard deviation 0.194) in the ECCE-PCIOL group.

#### (b) complications during surgery

Vitreous loss was reported in 4% of cases in OCTET. Capsular rupture was reported in 2.5% of OCTET cases. The study found a total cell loss of 14.9% 24 months after surgery. There was a significantly higher continuing cell loss with the iridocapsular lens compared to the iris clip lens or no lens implantation. Many of these corneas decompensated two years after surgery.

#### (c) clinical complications

Vogel 1993 reports the presence of secondary glaucoma of 1.2%. Cystoid macula oedema is reported in both studies. Only Vogel 1993 verified the findings with fluorescein angiography. Posterior capsular opacification was reported in the three studies that included an ECCE group and was the most frequent complication relating to visual impairment (all grades of impairment) ranging from 0.5% at one year and 13.5% at four years (in a random subsample) in the MIOLS study to 29.6% in the Vogel 1993 study. (The Vogel 1993 study also reported a 3.1% frequency of toxic lens syndrome).

## DISCUSSION

The different settings in which the trials in this review were done, i.e. industrialised versus developing country setting, must be borne in mind when interpreting the results. In general, high volume surgery, which means simple surgical techniques with high patient throughput, is needed in the Indian sub-continent where cataract is common and resources are limited. Although there is a trend for intracapsular surgery to be supplanted by extracapsular cataract extraction with posterior chamber intraocular lens implantation, the former technique is still being used in up to 40% of total surgeries in some developing countries (Gupta 1998). The three studies conducted in south Asia are therefore relevant to the issue of the prevention of cataract blindness.

Comparison between intracapsular and extracapsular extraction. The MIOLS and Vogel 1993 studies were the only studies that compared two different surgical techniques. These studies showed

that there were no clinically relevant differences in complication frequency for those aspects of surgery that are common in both the procedures, although the power of these studies to detect differences in rare complications was low. For the long term complications however it was found that intracapsular extraction gave a significantly higher frequency of cystoid macular oedema. This complication did not significantly increase the number of participants with severe vision loss (<6/60) compared to the extracapsular group. For these complications there was no significant difference between the study groups. Both studies showed significant increase of posterior capsular opacification in the extracapsular cataract extraction with posterior chamber intraocular lens groups after two years. There is no documentation on long term impact of vision. This will depend on the availability of post-operative facilities for Nd YAG laser posterior capsulotomy.

Comparison between phacoemulsification and extracapsular surgery

Phacoemulsification has been studied in one randomised trial which showed that the technique gave superior clinical and visual results compared to traditional extracapsular surgery. In addition, the costs per procedure were not markedly different between the two techniques. Extrapolation of these results to other parts of the world where cataract surgery is very different must, however, be made with caution.

Comparison of results of the three large studies in south Asia

There were important differences between these trials that need to be highlighted before interpreting the results. MIOLS in Madurai, India compared extracapsular extraction with a posterior chamber lens with intracapsular extraction with aphakic glasses. The study was performed by a few surgeons in one centre of excellence using operating microscopes. The power of the lens required was calculated using biometry before surgery. The LAHAN was conducted in a remote rural eye hospital in the Terai region of Nepal. Intracapsular extraction with an anterior-chamber intraocular lens of a single standard power and dimensions was compared with intracapsular extraction with aphakic glasses. No attempt was made to estimate the power of lens required before surgery. All surgery was done using 4.5 X loupe magnification by two highly trained surgeons. The SACMS study also compared intracapsular extraction with an anterior-chamber lens to intracapsular extraction with aphakic glasses. However, this study was conducted in three centres, in India (Hyderabad), Bangladesh (Chittagong) and western Nepal and 19 surgeons undertook the operations. This study may well be more representative of usual surgical practice and ability, thereby having a greater external validity.

The data in this review suggest that intracapsular extraction with a modern multiflex anterior chamber lens implant has similar safety and effectiveness as intracapsular extraction with aphakic glasses in the developing country setting. In the LAHAN and SACMS studies, the risk of a poor visual outcome (visual acuity less than 6/60) one to two years after surgery did not increase after implan-

tation of an anterior chamber intraocular lens compared to intracapsular extraction without implantation of an intraocular lens. At one year follow-up there were more people functionally blind in the intracapsular extraction with aphakic glasses (control) group due to the loss of aphakic spectacles. There were three cases of corneal decompensation identified 12 to 24 months after surgery in 2867 participants. Two of these cases occurred in the control group i.e. only one case of corneal decompensation occurred in a person with an anterior-chamber intraocular lens. Long term follow-up up to five years after surgery did not show any increased risk of corneal decompensation. In the LAHAN study only, uveitis and secondary glaucoma occurred more frequently in eyes with an anterior chamber lens implant. Relatively high rates of uveitis were also seen in a non-randomised trial conducted in a black African population in southern Africa (Cook 1998).

Higher rates of poor visual outcome were observed in SACMS where many surgeons in three different centres conducted the operations however these were still less than five per cent (visual acuity < 6/60) and there was no increased risk associated with implantation of anterior chamber lenses. In addition, corneal endothelial lens measurements in the SACMS study did not give cause for concern in contrast with previous studies with now outdated anterior chamber lenses (OCTET). Corneal decompensation was commonly seen with the first generations of anterior chamber lenses the first two to five years after implantation. Clinico-pathological data from developed country settings have shown no indication that the new generation of anterior chamber intraocular lenses (Apple 2000) have given rise to a new epidemic of corneal complications. In the United States alone, over 60,000 new generation multiflex anterior chamber lenses were implanted annually up to the end of the last decade.

Use of extracapsular surgery with posterior-chamber lenses in developing country settings

At one year post-operative follow-up extracapsular cataract extraction with posterior chamber lens implantation gave acceptable results with comparable functional visual acuity outcomes to intracapsular extraction with aphakic glasses (MIOLS). Clinically significant posterior capsular opacification, which is a unique complication of extracapsular surgery, was found in 0.5 per cent at one year and 13.5 per cent after four years (random sub-sample).

Quality of life

Substantial improvements in vision-related quality of life were reported by people taking part in the MIOLS study. These improvements were more marked in people receiving an intraocular lens compared to people receiving aphakic glasses.

## AUTHORS' CONCLUSIONS

### Implications for practice

This review provides evidence from one randomised controlled

trial that phacoemulsification gives a better visual outcome than extracapsular extraction with sutures. This trial was conducted in a developed country specialised hospital setting. No comparative clinical data are available to conclude on the safety and cost benefit of the introduction of sutureless surgery (manual phacofragmentation or phacoemulsification) in programmes for the prevention of cataract blindness in the developing country setting.

This review also found evidence that extracapsular cataract extraction with a posterior chamber lens implant provides better visual outcome than intracapsular extraction with aphakic glasses. This finding is also based on the results of a single trial. The data in the review suggest that intracapsular extraction with an anterior chamber lens implant is an effective alternative to intracapsular extraction with aphakic glasses, with similar safety.

In the south Asian setting, good clinical outcomes are seen one to two years after extracapsular surgery with a posterior chamber lens and intracapsular surgery with an anterior chamber lens in environments with high quality patient care. This review does not provide any evidence from controlled trials as to the rates of corneal complications with anterior chamber lenses more than seven or eight years after surgery. However, observational data from developed country settings do not indicate that this is likely to be a problem. Posterior capsular opacification in extracapsular extraction is common - the clinical implications in the developing world have not yet been fully documented.

No comparative data from developing regions outside south Asia are available on the different surgical approaches and no comparative data from any developing region has been published to give a basis for cost benefit analysis comparing the different surgical procedures.

Most young ophthalmologists in developing countries are now learning exclusively extracapsular techniques as this has been adopted as the primary surgery of choice. If intracapsular extraction with anterior chamber lenses is to be included in a cataract management programme it is important that ophthalmologists have received proper training in the techniques.

### **Implications for research**

Further data from developing regions are needed to compare all aspects of intraocular lens surgery with the three main surgical procedures - intracapsular extraction with an anterior chamber lens, extracapsular surgery with a posterior chamber lens with or without sutures.

Clinical data are needed to compare intraoperative and long term outcomes of extracapsular surgery conducted with sutures compared to sutureless surgery (manual phacofragmentation or phacoemulsification) with particular emphasis on the incidence of the most important intraoperative complications (capsular rupture/vitreous loss) and the long term vision threatening complications including the frequency of posterior capsular opacification.

Data on costing of surgical systems and procedures are needed to compare the cost benefit in intervention programmes for cataract blindness.

Techniques in cataract surgery are always changing but they are not usually subjected to trials, rather trial and error. It is difficult for large scale randomised controlled trials (which take many years to execute and require long follow-up for rare but important outcomes) to keep pace with the changing techniques and fashions.

## **POTENTIAL CONFLICT OF INTEREST**

All four reviewers have been involved in the funding, design, execution and analysis of three of the trials included in this review (LAHAN; MIOLS; SACMS).

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\* Indicates the major publication for the study

**T A B L E S****Characteristics of included studies**

Study	LAHAN
Methods	Randomised controlled trial; unmasked.
Participants	Number randomised: 2,000. Age: 40-64 years (mean 55 yrs). Country: Terai region, Nepal.
Interventions	ICCE/AG vs ICCE/ACIOL. Follow-up: five years.
Outcomes	Visual acuity; blinding complication rate; causes of severe visual impairment.
Notes	ACIOL: single-piece four-point fixation CILCO Kelman Multiflex III lens (Alcon).
Allocation concealment	A – Adequate

Study	MIOLS
Methods	Randomised controlled trial; unmasked.
Participants	Number randomised: 3,400. Age: 40-70 years (mean 59 yrs). Country: Madurai, south India.
Interventions	ICCE/AG vs ECCE/PCIOL. Follow-up: > one year.
Outcomes	Visual acuity; complications (OCTET grades); quality of life.
Notes	PCIOL: standard three-piece plano convex (Aurolab).
Allocation concealment	A – Adequate

**Characteristics of included studies (Continued)**

<b>Study</b>	<b>Minassian 2001</b>
Methods	Randomised controlled trial; unmasked.
Participants	Number randomised: 500. Age: 40+ (mean 72 years). Country: UK
Interventions	Phacoemulsification vs ECCE. Follow-up: one year.
Outcomes	Visual acuity; astigmatism; capsule rupture/vitreous loss; capsule opacity.
Notes	
Allocation concealment	A – Adequate

<b>Study</b>	<b>OCTET</b>
Methods	Randomised controlled trial; unmasked.
Participants	Number randomised: 331. Age: 55-90 years. Country: UK.
Interventions	ICCE/contact lens vs ICCE/iris supported vs ECCE/iridocapsular lens. Follow-up: four years.
Outcomes	Visual acuity; complications (OCTET grades); corneal endothelial cell loss (corneal endothelial cells were photographed using a non-contact specular microscope, cell density was assessed by grid counting)
Notes	Iris supported lens: 4-loop iris supported Federov lens. Iridocapsular lens: 2-loop Binkhort iridocapsular lens.
Allocation concealment	B – Unclear

<b>Study</b>	<b>SACMS</b>
Methods	Multicentre, randomised controlled trial; unmasked.
Participants	Number randomised: 1,237. Age: 40-75 years (mean 61 yrs). Countries: western Nepal; Chittagong, Bangladesh; Hyderabad, India.
Interventions	ICCE/AG vs ICCE/ACIOL. Follow-up: two years.
Outcomes	Visual acuity; causes of severe visual impairment; corneal endothelial cell loss (corneal endothelial cells were photographed using a non-contact specular microscope, images analysed using a semi-automated technique).
Notes	ACIOL: single-piece four-point fixation CILCO Kelman Multiflex III lens (Alcon).
Allocation concealment	A – Adequate

<b>Study</b>	<b>Vogel 1993</b>
Methods	Randomised controlled trial; unmasked.
Participants	Number randomised: 360. Age: 60-80 years (mean 73 yrs). Country: Germany.
Interventions	ICCE/ACIOL vs ECCE/PCIOL. Follow-up: two years.
Outcomes	Visual acuity; complications.

Notes ACIOL: Choyce Mark IV.  
PCIOL: Ganz PMMA.

Allocation concealment B – Unclear

ICCE - intracapsular extraction  
ECCE - extracapsular extraction  
AG - aphakic glasses  
ACIOL - anterior chamber intraocular lens  
PCIOL - posterior chamber intraocular lens

## Characteristics of excluded studies

Study	Reason for exclusion
Alpar 1984	This was a small study in people with diabetes comparing intracapsular with extracapsular cataract extraction with intraocular lens implantation. Several of the lenses they used are now no longer used. In addition, the trial was of poor quality and did not present the outcomes of interest to our review, such as visual acuity.
De Laage 1988	This study compared intracapsular extraction with an anterior chamber lens in one eye compared with extracapsular extraction and posterior chamber lens in the other. The allocation was not random, no concealment was mentioned and follow-up was only six months.
Jurgens 1997	This study compared different types of viscoelastics. The surgical technique used was not randomised.
Quentin 1993	This study compared intracapsular cataract extraction with anterior chamber intraocular lens (Choyce Mark IX) with extracapsular cataract extraction. Follow-up data included only six months after surgery.

## ADDITIONAL TABLES

**Table 01. Corneal endothelial cell loss in SACMS**

SACMS	IOL - n	IOL - Mean	IOL - SD	AG - n	AG - Mean	AG - SD
6 weeks	577	17.0	13.5	568	14.4	12.2
6 weeks to 12 months	448	5.3	9.9	437	4.1	9.7
12 months to 24 months	429	3.1	9.0	418	2.9	9.3

## ANALYSES

### Comparison 01. PHACOEMULSIFICATION WITH PC-IOL VS EXTRACAPSULAR EXTRACTION WITH PC-IOL

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Best corrected vision less than 6/60			Odds Ratio (Fixed) 95% CI	Totals not selected
02 Functional vision less than 6/18			Odds Ratio (Fixed) 95% CI	Totals not selected
03 Clinical complications			Relative Risk (Fixed) 95% CI	Totals not selected
04 Corneal endothelial cell loss	0	0	Weighted Mean Difference (Fixed) 95% CI	Not estimable



**Comparison 02. EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES**

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Best-corrected vision less than 6/60 one year after surgery			Relative Risk (Fixed) 95% CI	Totals not selected
02 Functional vision less than 6/18 one year after surgery			Relative Risk (Fixed) 95% CI	Totals not selected
03 Clinical complications			Relative Risk (Fixed) 95% CI	Totals not selected
04 Corneal endothelial cell loss	0	0	Weighted Mean Difference (Fixed) 95% CI	Not estimable

**Comparison 03. INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES**

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Best-corrected vision less than 6/60 one year after surgery	2	2866	Relative Risk (Fixed) 95% CI	1.13 [0.74, 1.72]
02 Functional vision less than 6/18 one year after surgery			Relative Risk (Fixed) 95% CI	Subtotals only
03 Clinical complications			Relative Risk (Fixed) 95% CI	Totals not selected
04 Corneal endothelial cell loss 12- 24 months after surgery			Weighted Mean Difference (Fixed) 95% CI	Totals not selected

**INDEX TERMS**

**Medical Subject Headings (MeSH)**

Age Factors; Cataract Extraction [\*methods]; Phacoemulsification; Randomized Controlled Trials

**MeSH check words**

Humans

**COVER SHEET**

<b>Title</b>	Surgical interventions for age-related cataract
<b>Authors</b>	Snellingen T, Evans JR, Ravilla T, Foster A
<b>Contribution of author(s)</b>	TS wrote the protocol, assessed search results and study quality, extracted and entered data and wrote the text of the review. JE assessed search results and study quality, extracted and entered data and edited the text of the review. TR commented on the review. AF commented on the review.
<b>Issue protocol first published</b>	1998/4
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**What's New** Information not supplied by author

**Date new studies sought but none found** Information not supplied by author

**Date new studies found but not yet included/excluded** Information not supplied by author

**Date new studies found and included/excluded** Information not supplied by author

**Date authors' conclusions section amended** Information not supplied by author

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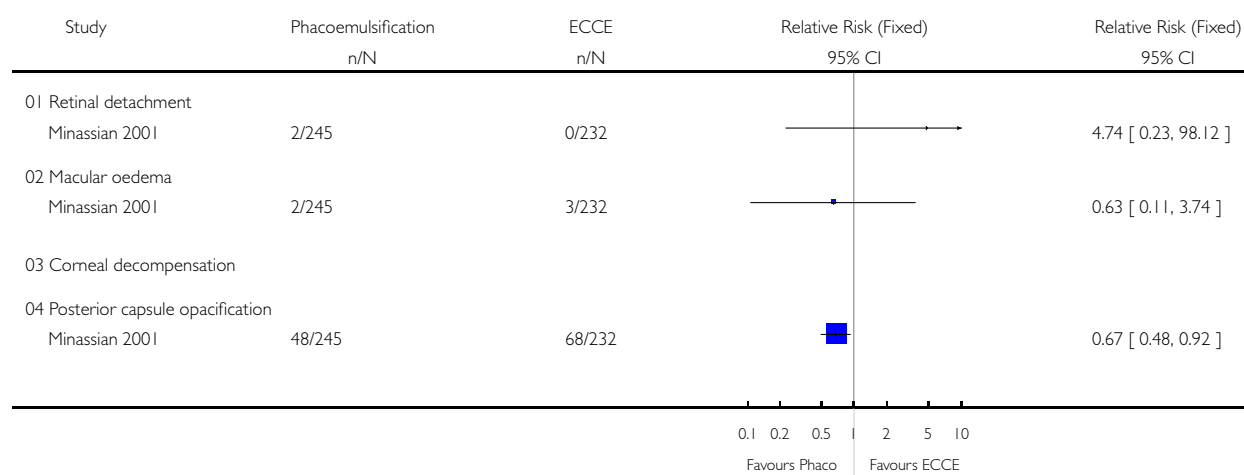
### GRAPHS AND OTHER TABLES

#### Analysis 01.03. Comparison 01 PHACOEMULSIFICATION WITH PC-IOL VS EXTRACAPSULAR EXTRACTION WITH PC-IOL, Outcome 03 Clinical complications

Review: Surgical interventions for age-related cataract

Comparison: 01 PHACOEMULSIFICATION WITH PC-IOL VS EXTRACAPSULAR EXTRACTION WITH PC-IOL

Outcome: 03 Clinical complications

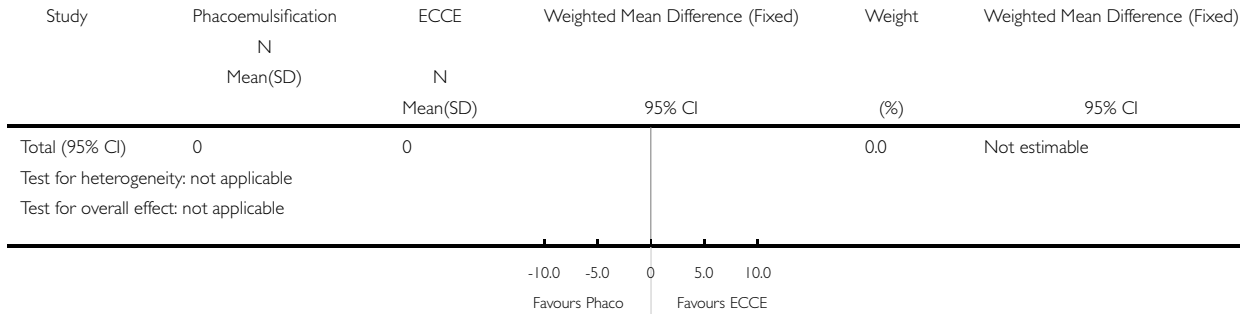


**Analysis 01.04. Comparison 01 PHACOEMULSIFICATION WITH PC-IOL VS EXTRACAPSULAR EXTRACTION WITH PC-IOL, Outcome 04 Corneal endothelial cell loss**

Review: Surgical interventions for age-related cataract

Comparison: 01 PHACOEMULSIFICATION WITH PC-IOL VS EXTRACAPSULAR EXTRACTION WITH PC-IOL

Outcome: 04 Corneal endothelial cell loss

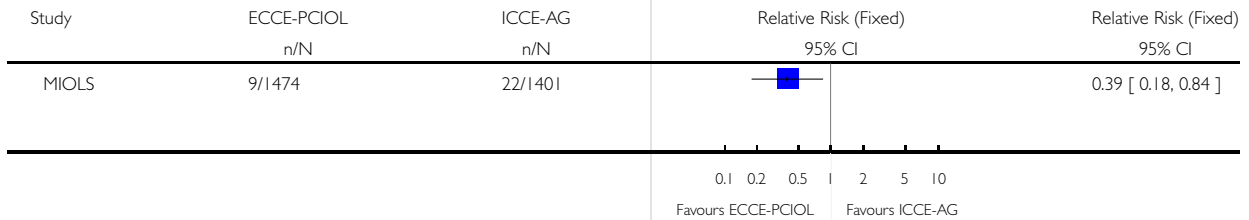


**Analysis 02.01. Comparison 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 01 Best-corrected vision less than 6/60 one year after surgery**

Review: Surgical interventions for age-related cataract

Comparison: 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 01 Best-corrected vision less than 6/60 one year after surgery

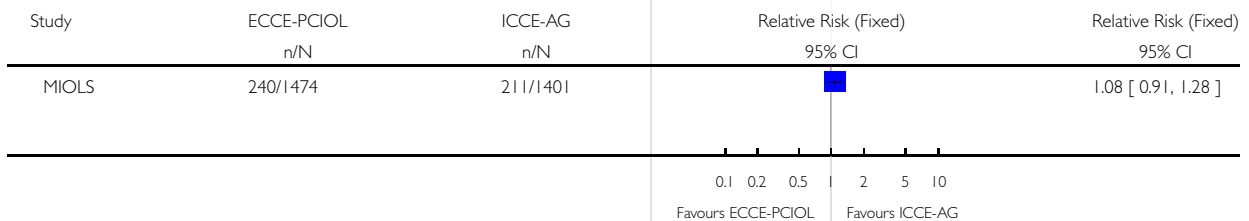


**Analysis 02.02. Comparison 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 02 Functional vision less than 6/18 one year after surgery**

Review: Surgical interventions for age-related cataract

Comparison: 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 02 Functional vision less than 6/18 one year after surgery

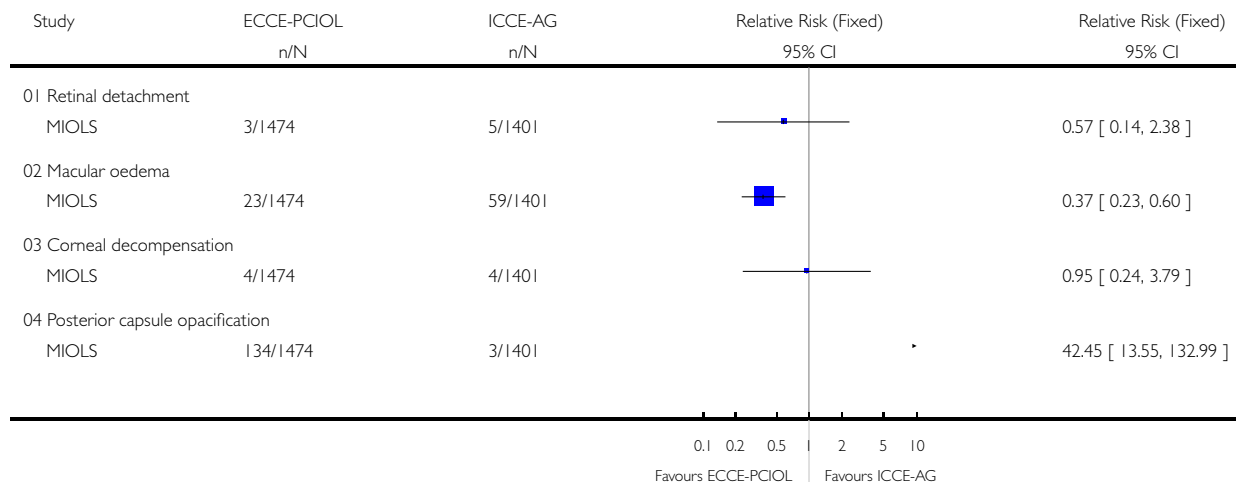


**Analysis 02.03. Comparison 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 03 Clinical complications**

Review: Surgical interventions for age-related cataract

Comparison: 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 03 Clinical complications

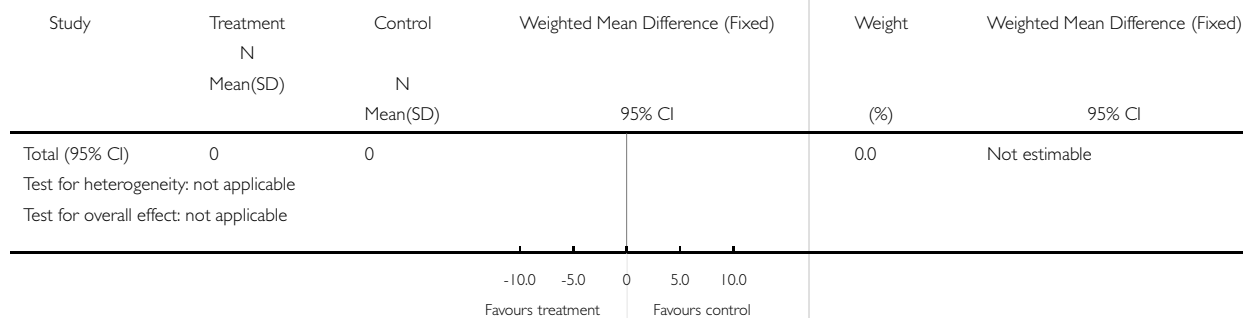


**Analysis 02.04. Comparison 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 04 Corneal endothelial cell loss**

Review: Surgical interventions for age-related cataract

Comparison: 02 EXTRACAPSULAR EXTRACTION WITH PC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 04 Corneal endothelial cell loss

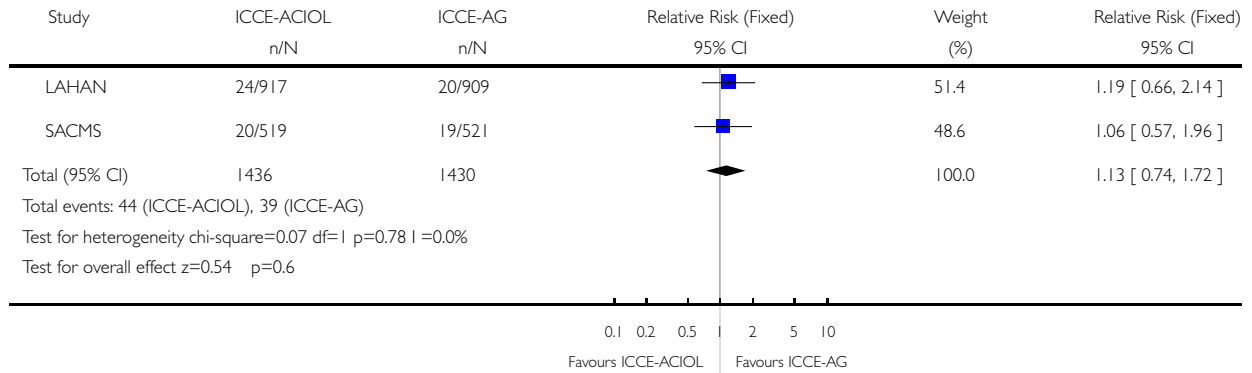


**Analysis 03.01. Comparison 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 01 Best-corrected vision less than 6/60 one year after surgery**

Review: Surgical interventions for age-related cataract

Comparison: 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 01 Best-corrected vision less than 6/60 one year after surgery

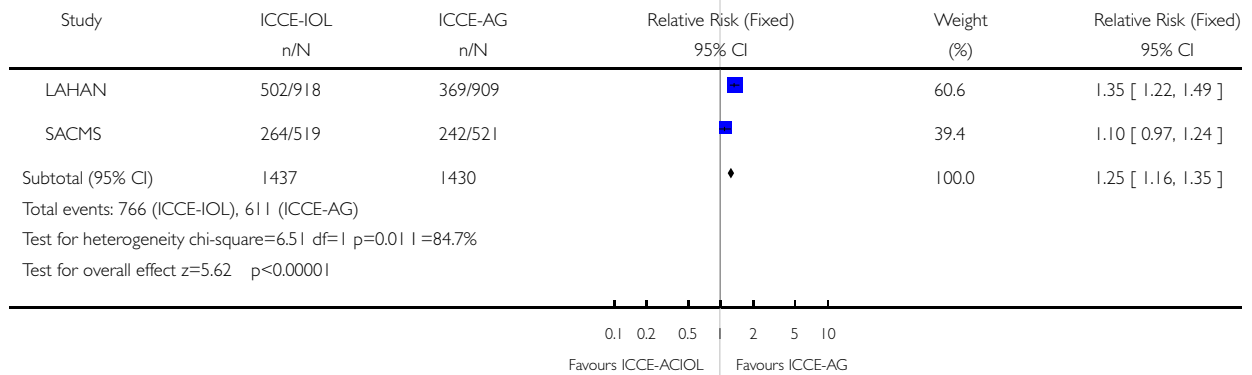


**Analysis 03.02. Comparison 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 02 Functional vision less than 6/18 one year after surgery**

Review: Surgical interventions for age-related cataract

Comparison: 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 02 Functional vision less than 6/18 one year after surgery

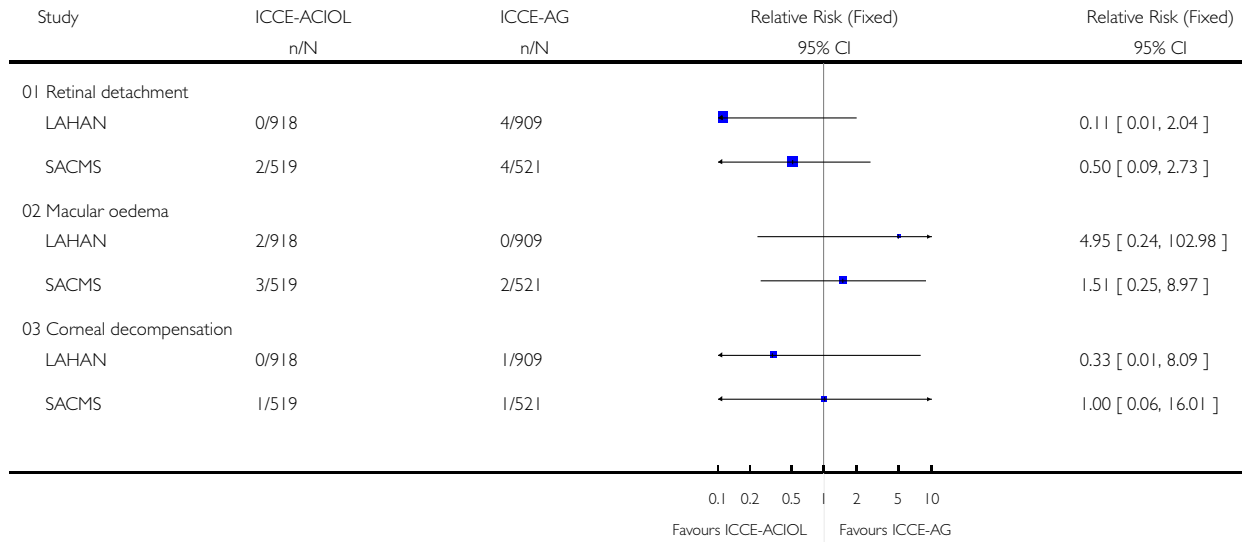


**Analysis 03.03. Comparison 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 03 Clinical complications**

Review: Surgical interventions for age-related cataract

Comparison: 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 03 Clinical complications



**Analysis 03.04. Comparison 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES, Outcome 04 Corneal endothelial cell loss 12- 24 months after surgery**

Review: Surgical interventions for age-related cataract

Comparison: 03 INTRACAPSULAR EXTRACTION WITH AC-IOL VS INTRACAPSULAR EXTRACTION WITH GLASSES

Outcome: 04 Corneal endothelial cell loss 12- 24 months after surgery

