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Multifocal versus monofocal intraocular lenses after cataract extraction (Review)

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[Intervention Review]

Multifocal versus monofocal intraocular lenses after cataract extraction

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ABSTRACT

Background

Good unaided distance visual acuity (VA) is now a realistic expectation following cataract surgery and intraocular lens (IOL) implantation. Near vision, however, still requires additional refractive power, usually in the form of reading glasses. Multiple optic (multifocal) IOLs are available which claim to allow good vision at a range of distances. It is unclear whether this benefit outweighs the optical compromises inherent in multifocal IOLs.

Objectives

To assess the visual effects of multifocal IOLs in comparison with the current standard treatment of monofocal lens implantation.

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Trials Register) (2016, Issue 5), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to June 2016), Embase (January 1980 to June 2016), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov), and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 13 June 2016.

Selection criteria

All randomised controlled trials comparing a multifocal IOL of any type with a monofocal IOL as control were included. Both unilateral and bilateral implantation trials were included. We also considered trials comparing multifocal IOLs with "monovision" whereby one eye is corrected for distance vision and one eye corrected for near vision.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. We assessed the 'certainty' of the evidence using GRADE.

Main results

We found 20 eligible trials that enrolled 2230 people with data available on 2061 people (3194 eyes). These trials were conducted in Europe (13), China (three), USA (one), Middle East (one), India (one) and one multicentre study in Europe and the USA. Most of these trials compared multifocal with monofocal lenses; two trials compared multifocal lenses with monovision. There was considerable variety in the make and model of lenses implanted. Overall we considered the trials at risk of performance and detection bias because it was difficult to mask participants and outcome assessors. It was also difficult to assess the role of reporting bias.

There was moderate-certainty evidence that the distance acuity achieved with multifocal lenses was not different to that achieved with monofocal lenses (unaided VA worse than 6/6: pooled RR 0.96, 95% confidence interval (CI) 0.89 to 1.03; eyes = 682; studies = 8). People receiving multifocal lenses may achieve better near vision (RR for unaided near VA worse than J3/J4 was 0.20, 95% CI 0.07 to 0.58; eyes = 782; studies = 8). We judged this to be low-certainty evidence because of risk of bias in the included studies and high heterogeneity (I^2 = 93%) although all included studies favoured multifocal lenses with respect to this outcome.

People receiving multifocal lenses may be less spectacle dependent (RR 0.63, 95% CI 0.55 to 0.73; eyes = 1000; studies = 10). We judged this to be low-certainty evidence because of risk of bias and evidence of publication bias (skewed funnel plot). There was also high heterogeneity (I^2 = 67%) but all studies favoured multifocal lenses. We did not additionally downgrade for this.

Adverse subjective visual phenomena were more prevalent and more troublesome in participants with a multifocal IOL compared with monofocals (RR for glare 1.41, 95% CI 1.03 to 1.93; eyes = 544; studies = 7, low-certainty evidence and RR for haloes 3.58, 95% CI 1.99 to 6.46; eyes = 662; studies = 7; moderate-certainty evidence).

Two studies compared multifocal lenses with monovision. There was no evidence for any important differences in distance VA between the groups (mean difference (MD) 0.02 logMAR, 95% CI -0.02 to 0.06; eyes = 186; studies = 1), unaided intermediate VA (MD 0.07 logMAR, 95% CI 0.04 to 0.10; eyes = 181; studies = 1) and unaided near VA (MD -0.04, 95% CI -0.08 to 0.00; eyes = 186; studies = 1) compared with people receiving monovision. People receiving multifocal lenses were less likely to be spectacle dependent (RR 0.40, 95% CI 0.30 to 0.53; eyes = 262; studies = 2) but more likely to report problems with glare (RR 1.41, 95% CI 1.14 to 1.73; eyes = 187; studies = 1) compared with people receiving monovision. In one study, the investigators noted that more people in the multifocal group underwent IOL exchange in the first year after surgery (6 participants with multifocal vs 0 participants with monovision).

Authors' conclusions

Multifocal IOLs are effective at improving near vision relative to monofocal IOLs although there is uncertainty as to the size of the effect. Whether that improvement outweighs the adverse effects of multifocal IOLs, such as glare and haloes, will vary between people. Motivation to achieve spectacle independence is likely to be the deciding factor.

PLAIN LANGUAGE SUMMARY

Multifocal versus monofocal intraocular lenses for people having cataract surgery

What is the aim of this review?

The aim of this Cochrane Review was to assess the effects of multifocal compared with monofocal intraocular lenses after cataract extraction. Cochrane researchers collected and analysed all relevant studies to answer this question and found 20 studies.

Key messages

The review shows that people who have a multifocal intraocular lens after their cataract is removed may be less likely to need additional spectacles. However, they may experience more visual problems, such as glare or haloes (rings around lights), compared with people who have monofocal lenses.

What was studied in the review?

As people get older, sometimes the lens of the eye becomes cloudy leading to loss of vision. The cloudy lens is known as a 'cataract'. The cataract can be removed and a replacement lens put in its place. Usually the replacement lens has one 'point of focus'. This means that a person's vision after cataract surgery is either good for distance vision (driving, watching television) or good for near vision (reading, sewing) but not good for both. This standard lens is known as a 'monofocal' lens. People who get a monofocal lens will need to use spectacles for either distance or, more usually, for near vision.

To address this problem, new lenses have been developed that provide two or more points of focus. These are known as 'multifocal' lenses. These are designed to reduce the need for spectacles. People with multifocal lenses may have more vision problems such as glare and seeing haloes. Another option is to put a different monofocal lens in each eye: one with a focus for near vision and one with a focus for distance vision. This is known as 'monovision'.

What are the main results of the review?

The Cochrane researchers found 20 relevant studies that were mainly conducted in Europe and North America (15 studies); three studies were conducted in China and one study each in the Middle East and India. Eighteen studies compared multifocal with monofocal lenses and two studies compared multifocal lenses with monovision.

The Cochrane researchers assessed how certain the evidence is for each review finding. They looked for factors that can make the evidence less certain, such as problems with the way the studies were done, very small studies, and inconsistent findings across studies. They also looked for factors that can make the evidence more certain, including very large effects. They graded each finding as very low, low, moderate or high certainty

The review shows that:

• People with multifocal lenses probably have distance vision that is not very different to the distance vision of people who have standard monofocal lenses after cataract extraction (moderate-certainty evidence). However, people with multifocal lenses may have better near vision and may be less likely to need spectacles compared with people with monofocal lenses (low-certainty evidence).

• People who have multifocal lenses may be more likely to experience haloes and glare compared with people who have monofocal lenses (low-certainty evidence).

• People receiving multifocal lenses had similar distance vision and near vision compared with people receiving monovision but reported less spectacle dependence. People with multifocal lenses reported more problems with glare and haloes compared with people with monovision.

How up-to-date is this review?

The Cochrane researchers searched for studies that had been published up to 13 June 2016.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Multifocal compared to monofocal intraocular lenses after cataract extraction

Patient or population: people with cataract
Settings: eye hospital
Intervention: multifocal intraocular lens
Comparison: monofocal intraocular lens

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Monofocal intraocular lens	Multifocal intraocular lens				
Unaided distance visual acuity worse than 6/6 Follow-up: 6 weeks to 18 months	**800 per 1000**	**768 per 1000** (712 to 824)	**RR 0.96** (0.89 to 1.03)	682 (8 studies)	⊕⊕⊕◯ **Moderate**[1]	-
Corrected distance visual acuity worse than 6/6 Follow-up: 6 weeks to 18 months	**See comment**				⊕◯◯◯ **Very low**[1,2,3]	Substantial inconsistency I^2 = 54%. Individual study RR ranged from 0.2 (95% CI 0.03 to 1.56) to 1.50 (0.63 to 3.59)
Unaided near visual acuity worse than J3/J4 Follow-up: 6 weeks to 18 months	**570 per 1000**	**114 per 1000** (40 to 330)	**RR 0.20** (0.07 to 0.58)	782 (8 studies)	⊕⊕◯◯ **Low**[1,3]	Substantial inconsistency I^2 = 93% but all individual study results in direction favouring multifocal IOLs. Individual study RR ranged from 0.02 (0.00 to 0.31) to 0.73 (0.54 to 0.97)

Spectacle dependence Follow-up: 6 weeks to 18 months	**880 per 1000**	**554 per 1000** (484 to 642)	**RR 0.63** (0.55 to 0.73)	1000 (10 studies)	⊕⊕◯◯ **Low**[1,4]	Substantial inconsistency I^2 = 67% but all individual study results favoured multifocal IOLs. Individual study RR ranged from 0.35 (0.21 to 0.57) to 0.79 (0.61 to 1.03)
Participant-reported outcomes: quality of life or visual function	**See comment**	-	-	435 (4 studies)	⊕◯◯◯ **Very low**[1,2,3]	On average most people in both groups achieved high scores on VF-7/VF-14 questionnaires but inconsistent comparative results between the 2 groups
Participant-reported outcomes: glare Follow-up: 6 weeks to 18 months	**180 per 1000**	**254 per 1000** (185 to 347)	**RR 1.41** (1.03 to 1.93)	544 (7 studies)	⊕⊕◯◯ **Low**[1,2]	-
Participant-reported outcomes: haloes Follow-up: 6 weeks to 18 months	**80 per 1000**	**286 per 1000** (159 to 517)	**RR 3.58** **(**1.99 to 6.46)	662 (7 studies)	⊕⊕⊕◯ **Moderate**[1]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **IOL:** intraocular lens; **RR:** risk ratio.

GRADE Working Group grades of evidence
High certainty: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate certainty: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low certainty: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low certainty: We are very uncertain about the estimate.

[1] Downgraded for risk of bias (-1): masking of participants and outcome assessors difficult in these trials; reporting bias unclear.

[2] Downgraded for imprecision (-1): wide confidence intervals.

[3] Downgraded for inconsistency (-1): $I^2 > 50\%$.

[4] Downgraded for publication bias (-1): asymmetric funnel plot.

BACKGROUND

Description of the condition

Cataract, defined as the presence of visually impairing lens opacity in one or both eyes, is present in 30% of people aged 65 years and over in the UK (Desai 1999). Around 400,000 cataract extractions were performed in England in the year 2014 to 2015 (Department of Health 2015).

People with cataract usually present with one or more of the following symptoms: gradual reduction in visual acuity (VA), glare, change in glasses prescription and change in colour appreciation. The diagnosis may be made by the person's general practitioner or optometrist followed by referral to an ophthalmic surgeon for confirmation of the diagnosis and management. Many people with treatable visual impairment from cataract do not access health services (Desai 1999).

Description of the intervention

Cataracts causing only mild symptoms may not need treatment, while changes in glasses prescription due to cataract may simply be managed by the provision of new glasses. Where these options are inadequate the only treatment available is surgical extraction of the cataract. This is routinely accompanied by implantation of an intraocular lens (IOL) to replace the focusing power of the natural lens.

Current techniques of cataract surgery and IOL implantation allow accurate prediction of postoperative refraction. Existing standards of best-corrected postoperative VA (Desai 1993) are being replaced by an expectation of good uncorrected distance acuity. This has been driven partly by the change from cataract surgery using a large (10 mm) incision to small incision (2 mm to 4 mm) phacoemulsification surgery. This change is generally perceived to offer greater predictability of refractive outcomes, a necessary pre-requisite for good VA without the need for glasses. Cochrane systematic reviews comparing surgical approaches have been published (Ang 2012; Riaz 2013; de Silva 2014).

Because standard IOLs have a fixed refractive power the focal length is also fixed (monofocal). This means that most people will require a reading addition to their distance glasses prescription (Javitt 1997). While most people undergoing cataract surgery may be happy to use reading glasses, a proportion are likely to seek good unaided near vision as well as distance vision. The need for reading glasses for near vision is unlikely to be considered an important issue at present in low-income countries where the burden of blindness due to cataract is so high.

How the intervention might work

One approach to improve near VA is to modify the IOL. There are no IOLs currently available that can change shape during accommodation in the manner of the natural crystalline lens. A fixed-shape optic IOL could theoretically provide near vision if attempted accommodation resulted in forward displacement of the IOL. Efforts to design an IOL using this principle have so far been unsuccessful (Legeais 1999).

An IOL can also provide near and distance vision if both powers are present within the optical zone. This has been attempted using diffractive optics or with zones of differing refractive power. Both types of IOL divide light up to focus at two (bifocal) or more (multifocal) points so that the person can focus on objects at more than one distance from them. IOLs of both types are currently commercially available.

Optical evaluation of multifocal IOLs has been performed in detail. Exact figures vary with the IOL tested but essentially a two- to three-fold increase in the depth of field is achieved at the expense of a 50% reduction in the contrast of the retinal image (Holladay 1990; Lang 1993). Clinical evaluation of a multifocal IOL is less clear-cut. Several large studies, including non-randomised comparisons with monofocal IOLs, have indicated that the quality of vision with bifocal and multifocal IOLs is good (Gimbel 1991; Knorz 1993; Lindstrom 1993; Steinert 1999). The key question to be answered is whether the optical trade-off inherent in a multifocal IOL results in better or worse visual function compared to a monofocal IOL. Objective (Desai 1993) and subjective (Desai 1996) improvement in vision following cataract surgery with monofocal IOL implantation is so high that any study lacking a randomised control group as a comparator will be relatively uninformative.

Why it is important to do this review

There is an extensive body of published data on both monofocal and multifocal IOLs describing largely successful outcomes. To draw some conclusions regarding the relative merits of the different IOL types we undertook a systematic review of the best quality data (that from randomised controlled trials).

OBJECTIVES

To assess the visual effects of multifocal IOLs in comparison with the current standard treatment of monofocal lens implantation.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials.

Types of participants

We included trials in which participants were undergoing cataract surgery and IOL implantation in one or both eyes. There were no restrictions on race, gender or ocular comorbidity. We excluded trials that included participants with paediatric cataract (onset prior to age 16 years).

Types of interventions

We included trials in which any type of diffractive or refractive multifocal IOL was compared with monofocal IOL implantation. In the current update 2016 we considered two comparisons. This was a protocol amendment (see Differences between protocol and review for further explanation).

- Multifocal IOLs versus monofocal IOLs.
- Multifocal IOLs versus monovision.

Types of outcome measures

Outcome data were collected at the longest time postoperatively that was available in each study.

We revised the outcomes for the update in 2016 (see Differences between protocol and review).

Primary outcomes

- Distance, intermediate and near VA (unaided and corrected).
    - We used the cut-point of worse than 6/6 for distance VA (20/20, logMAR score > 0) as 6/6 vision is usually considered normal VA. We used the cut-point of worse than J3/J4 (Jaegar cards) or equivalent for near VA.
    - We also considered VA as a continuous variable where it was reported in logMAR units.
- Spectacle dependence as reported by the participant.

Secondary outcomes

- Contrast sensitivity (contrast is the difference between the brightness of an image and its background divided by the total brightness of image plus background. Contrast sensitivity is the inverse of target contrast threshold).
- Participant-reported outcomes including:
    - quality of life or visual function as measured by validated instruments;
    - informal (non-validated) subjective assessment of visual function;
    - participant satisfaction;
    - glare (glare occurs when a light source other than the target image illuminates the retina, resulting in reduced contrast. Scatter of light from the glare source by the optics of an IOL may cause unequal glare between participants);
    - other optical aberrations including halos.
- Resource use and costs.

Adverse effects

- Any other adverse effects or complications as reported in trial reports.

Search methods for identification of studies

Electronic searches

We searched CENTRAL (which contains the Cochrane Eyes and Vision Trials Register) (2016, Issue 5), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to June 2016), Embase (January 1980 to June 2016), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov), and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 13 June 2016.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), Embase (Appendix 3), ISRCTN (Appendix 4), ClinicalTrials.gov (Appendix 5) and the ICTRP (Appendix 6).

Searching other resources

We searched the reference lists of relevant articles and Martin Leyland's personal database of trials. For the first version of the review we contacted investigators of included studies and the manufacturers of multifocal IOL (Acute Care; Spectrum Ophthalmics; Storz Ophthalmics; Bausch & Lomb Surgical Ltd (UK); Alcon Laboratories Ltd; Pharmacia & Upjohn; Rayner Intraocular Lenses Ltd) for details of additional published and unpublished trials. We did not do this for subsequent updates.

Data collection and analysis

Selection of studies

Two review authors working independently examined the titles and abstracts from the electronic searches. We obtained the full paper of any trial that appeared to fit the inclusion criteria. We

assessed full copies according to the definitions in the Criteria for considering studies for this review. We only assessed trials meeting these criteria for risk of bias.

Data extraction and management

For the update 2016, partly because we had revised the outcomes but also because we needed to incorporate more information as a result of the updated methodological expectations of Cochrane Reviews (MECIR 2013), we extracted the data for all trials again using a piloted customised data extraction template in web-based review management software (Covidence 2016). Review author pairs extracted data independently (JE/VK/MZ) and a third review author (SdeS) adjudicated discrepancies as needed. We imported data directly from Covidence into Review Manager 5 (RevMan 2014), which was checked by one review author (JE).

Assessment of risk of bias in included studies

Review author pairs (JE/VK/MZ) independently assessed risk of bias in Covidence using Cochrane's tool for assessing risk of bias (Higgins 2011) and as outlined in Table 1.

Measures of treatment effect

Our measure of treatment effect was the risk ratio (RR) for dichotomous outcomes and mean difference (MD) or standardised mean difference (SMD) for continuous outcomes, with 95% confidence intervals (CI). The use of the MD was a protocol amendment - see Differences between protocol and review. Where possible, we checked for skewness using the method outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

Unit of analysis issues

The intervention could be applied to one or both eyes. We have indicated for each trial whether unilateral or bilateral surgery was done.

For the unilateral trials, the outcome was measured on the operated eye. For the bilateral trials, the outcome could be measured and reported on both eyes, or for the person (i.e. binocular vision). Where available, we have chosen reported binocular vision for the analyses. Where data were reported for both eyes, and appropriate methods of adjustment were not included, we requested further data from the investigators.

For studies with multiple multifocal treatment groups, we combined data for the different groups using the Review Manager 5 calculator (RevMan 2014).

Dealing with missing data

The analyses in this review were available case analyses. This makes the assumption that data were missing at random. We recorded the amount of missing data and reasons for exclusions and attrition, where available and documented this in the 'Risk of bias' table for each study (Characteristics of included studies table, "incomplete outcome data").

Assessment of heterogeneity

We assessed heterogeneity by examining the forest plots to see whether the direction of effect was similar in all studies and whether the CIs for the individual study estimates overlapped. To assess the role of chance we used the Chi^2 test, although this may have low power when there are few studies, or the studies are small. We also considered the I^2 statistic (Higgins 2003). We took an I^2 value of 50% or more to indicate substantial inconsistency in study results.

Assessment of reporting biases

We assessed publication bias when the meta-analysis included 10 or more trials by plotting effect size against standard error.

Data synthesis

Where three or more studies contributed to the analyses, we pooled the data using a random-effects model. If there were fewer than three studies, we used a fixed-effect model. If there was substantial heterogeneity or inconsistency (see Assessment of heterogeneity), we did not report the pooled analyses unless all individual study estimates were in the same direction.

Subgroup analysis and investigation of heterogeneity

We considered two main sources of heterogeneity: type of lens (refractive or diffractive) and whether the surgery was unilateral or bilateral. We compared subgroups using the standard test for interaction implemented in Review Manager 5 (RevMan 2014).

Sensitivity analysis

We performed a sensitivity analysis excluding studies at high risk of bias in one or more domains. This was a protocol amendment (see Differences between protocol and review).

'Summary of findings' table

We prepared a 'Summary of findings' table presenting absolute and RRs with an assessment of the overall quality of the evidence using GRADE (GRADEpro 2014). We included the following outcomes in the table.

- Unaided distance VA worse than 6/6.
- Corrected distance VA worse than 6/6.

- Unaided near VA worse than J3/J4.
- Spectacle dependence.
- Participant-reported outcomes: quality of life or visual function.
- Participant-reported outcomes: glare.
- Participant-reported outcomes: halos.

RESULTS

Description of studies

Results of the search

Original review

The initial electronic searches found 239 titles and abstracts. We obtained the full copies of possibly relevant papers according to the criteria specified (see Search methods for identification of studies). One trial did not include a monofocal control group and was excluded (Walkow 1997). We identified nine papers as meeting the inclusion criteria for this review. On contacting the authors, we identified three as descriptions of the same cohort of participants (Haaskjold 1998a). Interim data were available on 149 participants with five to six months' follow-up (Allen 1996), and a subsequent paper reported corrected distance acuity and contrast sensitivity data only (with no numerical data for contrast sensitivity) on 221 participants (Haaskjold 1998b). An unpublished report from the lens manufacturer described limited data on 190 participants at one year (Pharmacia 1995). The study author was also able to supply additional unpublished results.

Search updates

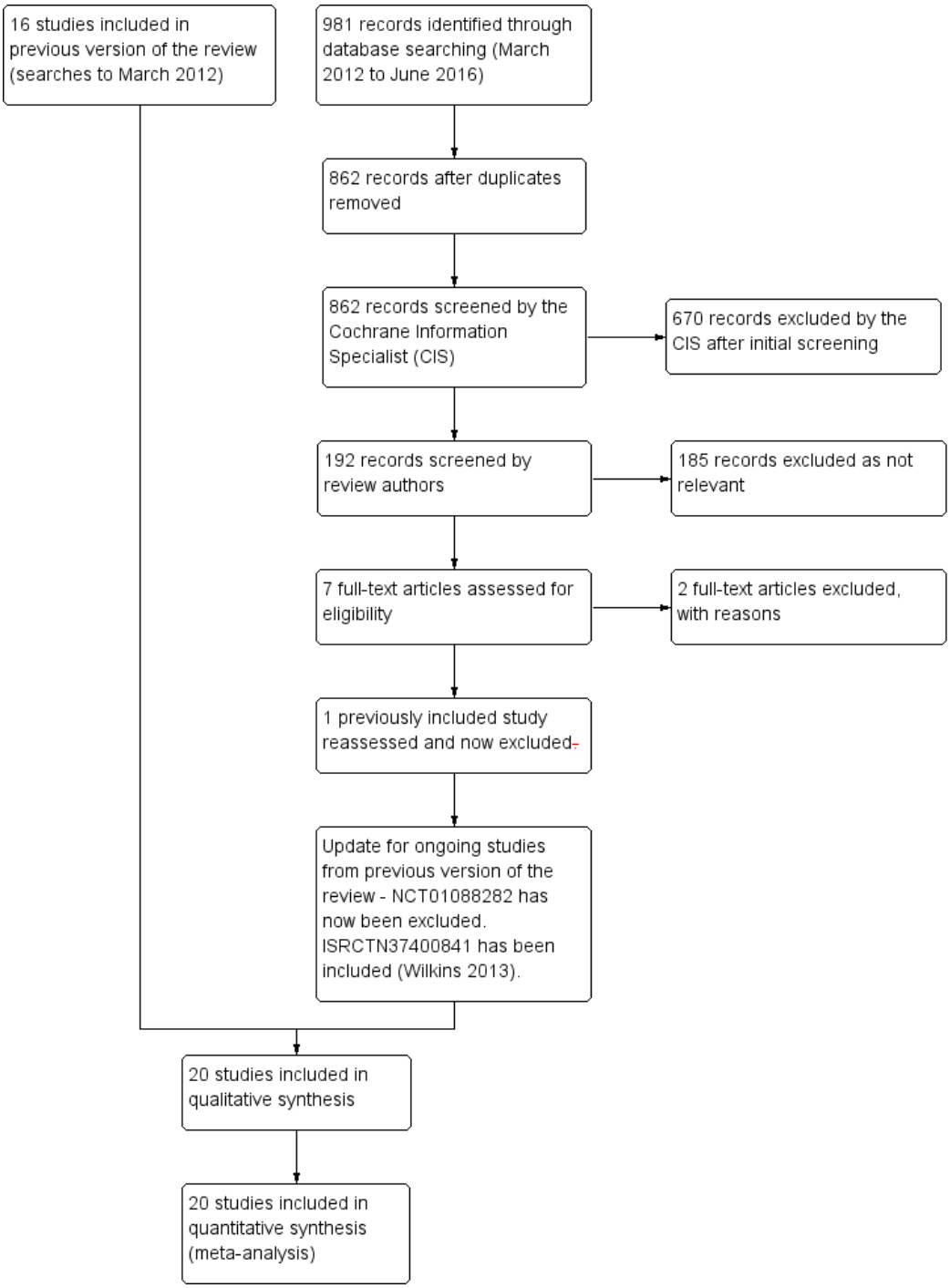
Updated searches in May 2002 identified 32 reports of which two further studies were relevant (Kamlesh 2001; Leyland 2002). An updated in September 2005 found 218 reports of which two further studies were relevant (Nijkamp 2004; Sen 2004). One trial was excluded because it was not randomised (Richter-Mueksch 2002).

An updated search done in March 2012 identified 432 new records. The Trials Search Co-ordinator scanned the search results and removed 308 records which were not relevant to the scope of the review. We assessed the remaining 124 records for potential inclusion. We rejected a further 100 records and obtained the full text of 24 records for further assessment. We included six studies in the review (Cillino 2008; Harman 2008; Palmer 2008; Zhao 2010; Alio 2011a; Jusufovic 2011). We identified two studies that were ongoing in 2012 - one of which has now been included in the review (Wilkins 2013, ISRCTN37400841) and one of which has now been excluded (NCT01088282). We excluded 16 studies (Xu 2007; Maxwell 2008; Ortiz 2008; Allen 2009; Cionni 2009; Hayashi 2009a; Hayashi 2009b; Hayashi 2009c; Hida 2009; Hayashi 2010; Huang 2010; Shah 2010; Alio 2011a; Alio 2011b; Ji 2011; Zhang 2011). See Characteristics of excluded studies table for reasons for exclusion.

To assess the three Chinese studies, we asked Taixiang Wu, who is a Cochrane author and heads the Chinese Clinical Trials Registry, to contact the study authors and ask if the studies were randomised (Xu 2007; Huang 2010; Ji 2011). Taixiang Wu confirmed that none of the three studies randomised participants to interventions. We assessed three studies which had previously been awaiting assessment and excluded them from the review (Liang 2005; Rocha 2005; Souza 2006). See Characteristics of excluded studies table for details of reasons for exclusion.

Update searches ran in June 2016 yielded a further 981 records (Figure 1). After removing 119 duplicates, the Cochrane Information Specialist (CIS) screened the remaining 862 records and removed 670 references which were not relevant to the scope of the review. We screened the remaining 192 references and obtained seven full-text reports for further assessment. We included five reports (Peng 2012; Rasp 2012; Ji 2013; Wilkins 2013; Labiris 2015), and excluded two (Alio 2015; Puell 2015). We checked the status of the ongoing studies published in the previous version of this review and have excluded one study (NCT01088282) and study ISRCTN37400841 has been completed and included (Wilkins 2013). We re-assessed one study which was previously included and have now excluded the study (Alio 2011c).

Figure 1. Study flow diagram.



Included studies

Details of the individual trials are summarised in Table 2; information on the individual trials are included in the Characteristics of included studies table.

Design

There were four multicentre and 16 single-centre studies.

Participants

The total number of people enrolled was 2230. Of these people, 2061 (3194 eyes) were followed up and were included in the analyses. The smallest study randomised 40 people (Kamlesh 2001) and the largest trial randomised 261 people (Javitt 2000). All studies recruited people with age-related cataract with no other apparent ocular morbidity and without excess corneal astigmatism.

Table 3 shows the mean age and sex of people enrolled in these trials. The median mean age was 69 years and median percentage women was 57%.

Interventions

The studies considered different types of multifocal lenses including refractive (10 studies), diffractive (six studies), mixture of refractive and diffractive lenses (three studies) and one study used a multifocal lens with both refractive and diffractive properties (Table 4). Two studies compared the multifocal lens to monovision (Wilkins 2013; Labiris 2015).

The cataract surgery performed in 16 studies was small incision phacoemulsification. Three studies employed extracapsular cataract extraction and one study included both types of surgery. In 12 studies the cataract surgery was bilateral in all or some people (participants had the same type of lens inserted into both eyes).

In cataract surgery, the lens capsule must be breached to gain access to the crystalline lens. A continuous circular tear (capsulorhexis) is preferred to the older 'can-opener' technique using multiple small tears or incisions because the incidence of postoperative IOL decentration is likely to be reduced. Decentration leads to induced astigmatism and a reduction in unaided VA. Most studies used capsulorhexis and four studies used envelope capsulotomy (el Maghraby 1992; Percival 1993; Rossetti 1994; Kamlesh 2001).

Outcomes

Distance VA was measured using either Snellen charts (10 studies), Early Treatment of Diabetic Retinopathy Study charts (ETDRS) (Rossetti 1994; Leyland 2002; Nijkamp 2004; Harman 2008; Peng 2012; Wilkins 2013; Labiris 2015) or Regan contrast acuity charts (Steinert 1992; Javitt 2000). One study did not specify the chart but reported logMAR VA (Rasp 2012).

Jaeger reading cards were most commonly used to measure near VA (seven studies); however, other studies used Sloan near acuity charts (Cillino 2008; Zhao 2010), the De Nederlander Reading chart (Nijkamp 2004), Bailey-Love logMAR word reading acuity chart (Leyland 2002; Harman 2008); Rosenbaum near acuity card (Steinert 1992; Javitt 2000); Snellen chart (Percival 1993; Palmer 2008); and handheld ETDRS near-reading chart (Rossetti 1994; Peng 2012; Wilkins 2013). Labiris 2015 did not state which chart was used but this was likely to be ETDRS.

There was variety in the way that studies reported distance and near acuity. Some trials reported cut-points used in this review (worse than 6/6, worse than J3/J4), some reported acuity as a continuous variable and some reported both.

Contrast sensitivity was measured and reported in many ways. Six studies used the Pelli-Robson chart (Rossetti 1994; Kamlesh 2001; Leyland 2002; Harman 2008; Wilkins 2013; Labiris 2015), four trials used the Vision Contrast Test System (VCTS) chart (Haaskjold 1998a; Sen 2004; Cillino 2008; Zhao 2010), two trials used the Regan Contrast Acuity chart (Steinert 1992; Percival 1993), one trial used the CGT- 1000 contrast sensitivity testing instrument (Ji 2013), and one trial used the Functional Acuity Contrast Test (FACT) chart in the OPTEC 6500 chart (Palmer 2008). Even trials using the same chart did not report the results in the same way - the data were described variously as contrast sensitivity, VA at different contrast levels and difference between high contrast and lower contrast acuity - and it was difficult to pool data for contrast sensitivity. Three studies assessed the extent of glare disability using the Brightness Acuity Tester (Steinert 1992; Leyland 2002; Harman 2008), and most studies elicited information from participants as to the extent of problems with glare or haloes (or both).

Some studies formally addressed visual functioning after surgery using validated instruments such as the VF-7 (Sen 2004; Cillino 2008; Zhao 2010), VF-14 (Nijkamp 2004; Labiris 2015), and TyPE questionnaire (Javitt 2000; Leyland 2002). Eleven studies reported participant-reported satisfaction (Steinert 1992; Percival 1993; Rossetti 1994; Haaskjold 1998a; Kamlesh 2001; Sen 2004; Nijkamp 2004; Cillino 2008; Zhao 2010; Peng 2012; Wilkins 2013).

Follow-up ranged from one month to 18 months.

Data collection and reporting

Near vision and subjective outcomes were poorly assessed and reported. Only five studies reported both unequivocal unaided and corrected logMAR near acuity measures (Javitt 2000; Leyland

2002; Harman 2008; Peng 2012; Rasp 2012). Palmer 2008 reported corrected near vision using Snellen that was converted to logMAR, and near vision with best distance correction. Only five studies used validated instruments for subjective outcomes (Javitt 2000; Leyland 2002; Nijkamp 2004; Sen 2004; Zhao 2010).

Financial support

Two studies had no external funding, eight studies did not give funding details and four studies received some funding from multifocal IOL manufacturers. Seven studies used other sources of funding, namely the Saudi Eye Foundation, Hillingdon Hospital Research and Development Fund, Shanghai Leading Academic Discipline Project, Eye Research Institute Maastricht, Education Department of Liaoning Province grants, a Finnish Government Special Grant and a Finnish Eye Foundation Grant and UK National Institute for Health Research Biomedical Research Centre in Ophthalmology at Moorfields Eye Hospital and UCL Institute of Ophthalmology funding.

Excluded studies

See Characteristics of excluded studies table.

Risk of bias in included studies

See Figure 2 and Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

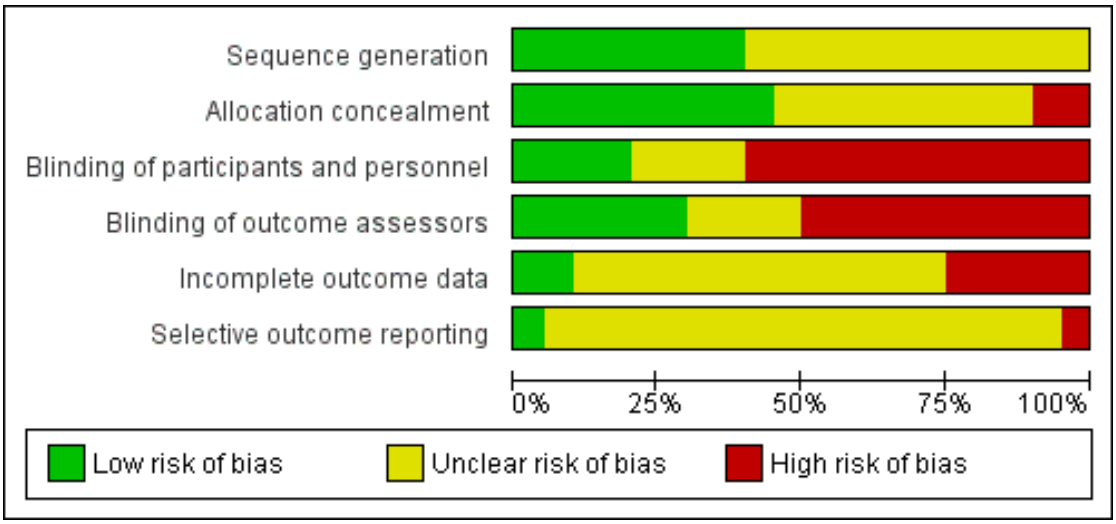
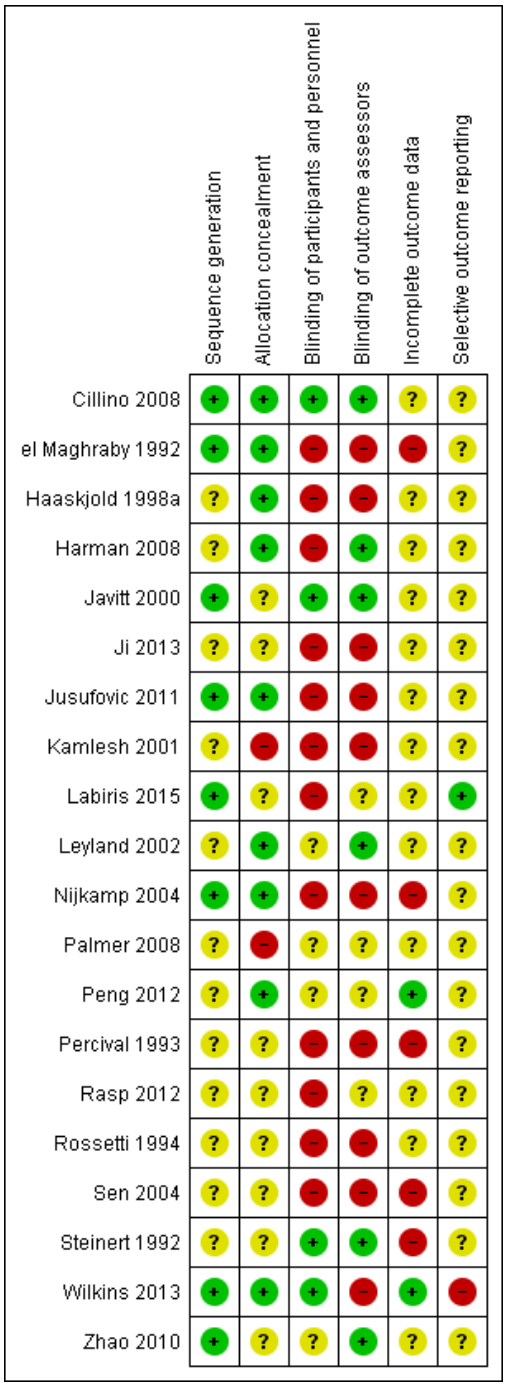


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



We contacted the authors of included papers for further information on their studies. We received replies clarifying various methodological issues for three studies (el Maghraby 1992; Haaskjold 1998a; Javitt 2000).

Allocation

Eight studies described an adequate method for random sequence generation (el Maghraby 1992; Javitt 2000; Nijkamp 2004; Cillino 2008; Zhao 2010; Jusufovic 2011; Wilkins 2013; Labiris 2015). The other studies did not report any information on how the sequence was generated but were described as "randomised".

Seven studies provided a convincing description of allocation concealment (Leyland 2002; Nijkamp 2004; Harman 2008; Cillino 2008; Jusufovic 2011; Peng 2012; Wilkins 2013), and authors for two studies confirmed allocation concealment (el Maghraby 1992; Haaskjold 1998a). Two studies were at high risk of allocation bias because methods of concealment were not clearly reported and there were baseline imbalances (Kamlesh 2001; Palmer 2008).

Masking (performance bias and detection bias)

Four studies described masking of participants (Steinert 1992; Javitt 2000; Cillino 2008; Wilkins 2013). In Harman 2008, the IOL type was disclosed to participants at the three-month visit. All outcomes for this study have therefore been reported for the three-month visit prior to the IOL disclosure, except for spectacle dependence and symptoms of glare/haloes that were only reported at the 18-month visit. Interestingly, following disclosure of multifocal IOL status, participants in this group showed an improvement in near vision and spectacle independence by the 18-month visit.

Several studies mentioned masking but it was not clear how successful it had been. In Leyland 2002, participants were informed that the IOL type implanted would not be revealed to them until completion of the trial but a proportion of participants were reported to be unmasked; in Palmer 2008, participants were not told which lens they would receive but it was unclear whether any of them could have guessed; in Peng 2012, the study was described as a "prospective, randomised, comparative, and observer-masked trial" but there was no information on masking in the study report; in Zhao 2010, participants and medical staff collecting data were masked but there was no information on the staff providing care.

The remaining studies did not mention masking and we have assumed therefore that it was not done. Labiris 2015 did not describe masking and on the clinical trials registry was described as 'open label'.

Three studies that were (possibly) not masked successfully to participants reported masking outcome assessors (Leyland 2002; Harman 2008; Zhao 2010). In general, studies that masked participants and personnel also masked outcome assessors, the exception being Wilkins 2013.

Incomplete outcome data

We judged attrition bias to be low risk in two studies where reasons and numbers of participants who exited the study after intervention and before outcomes were clearly reported and we thought unlikely to affect the outcome (Peng 2012; Wilkins 2013). Five studies were at high risk of attrition bias (Steinert 1992; el Maghraby 1992; Percival 1993; Nijkamp 2004; Sen 2004). This was either due to significant numbers of participants being lost to follow-up without clear indication of which group they had been randomised to, or exclusion of participants after randomisation based on outcome such as high astigmatism. However, most studies did not clearly report follow-up and it was difficult to make a judgement.

Selective reporting

The extent to which selective reporting had occurred for each individual study was unclear because in general we did not have access to study protocols. Of studies registered prospectively on a publicly available database, Labiris 2015 was deemed to have low reporting bias since all outcomes were reported; for Wilkins 2013, there were some differences between the trial registry entry and outcomes reported.

Effects of interventions

See: **Summary of findings for the main comparison** Multifocal compared to monofocal intraocular lenses after cataract extraction

The lenses used in each study are detailed in Table 4 and refractive aims are summarised in Table 5. Five studies compared two (el Maghraby 1992; Leyland 2002), three (Cillino 2008; Palmer 2008), or four (Rasp 2012) different multifocal IOLs with a monofocal control group. The multifocal IOL results within these studies were similar and therefore we have pooled them for this review. Two studies compared multifocal with monovision and are considered separately (Wilkins 2013; Labiris 2015).

Multifocal versus monofocal lenses

Primary outcomes

Distance visual acuity

Eight studies reported the number of participants who did not achieve an unaided VA of 6/6 (n = 682) (Analysis 1.1). These tended to be older studies (Steinert 1992; el Maghraby 1992; Percival 1993; Rossetti 1994; Haaskjold 1998a; Leyland 2002; Sen 2004; Jusufovic 2011). There was little evidence for any important difference between the two groups with a pooled risk ratio (RR) 0.96, 95% confidence interval (CI) 0.89 to 1.03). We judged this to be moderate-certainty evidence, downgrading one level for risk of bias (Summary of findings for the main comparison).

Six studies reported mean unaided logMAR VA (n = 848) (Analysis 1.2). There was substantial inconsistency (I^2 = 74%) but in all studies the mean difference between groups was less than 0.1 logMAR.

Eight studies reported the number of participants that did not achieve a corrected VA of 6/6 (n = 692) (Analysis 1.3). Again these studies were older, all being conducted no later than 2004. There was inconsistency (i^2=54%) possibly reflecting changes over time in lenses used. The individual study estimates ranged from RR 0.20 (95% CI 0.03 to 1.56) (Kamlesh 2001) in favour of multifocal lenses to 1.50 (0.63 to 3.59) (Percival 1993) in favour of monofocal lenses. We judged this to be very low-certainty evidence, downgrading one level for risk of bias, one level for imprecision due to the wide CIs and one level for inconsistency. (Summary of findings for the main comparison).

Six studies reported mean corrected logMAR VA (n = 848) (Analysis 1.4). There was no evidence for any major difference between groups with all studies reporting a mean difference of 0.1 logMAR or less but again with substantial inconsistency (I^2 = 64%).

Intermediate visual acuity

One study reported intermediate VA (Analysis 1.5). Mean unaided logMAR VA was 0.17 (standard deviation (SD) 0.15) in the multifocal group (n = 100) and 0.27 (SD 0.15) in the monofocal group (n = 102). The MD was therefore small at -0.10 logMAR (95% CI -0.14 to -0.06). Mean corrected logMAR intermediate VA was similar at 0.16 (SD 0.11) in the multifocal group and 0.24 (SD 0.11) in the monofocal group, with a small difference between groups (MD -0.08 logMAR, 95% CI -0.11 to -0.05).

Near visual acuity

Eight studies reported unaided near VA of worse than J3/J4 or equivalent (n = 782) (Analysis 1.6). There was significant heterogeneity in the method used for near VA measurement which may affect the accuracy of pooled outcomes. People receiving a multifocal lens were less likely to have poor near vision (RR 0.20, 95% CI 0.07 to 0.58). We judged the evidence to be of low-certainty. We downgraded one level for risk of bias and one level for inconsistency between studies (I^2 = 93%). The RRs ranged from 0.02 (Jusufovic 2011) to 0.73 (Leyland 2002) in the individual studies (Summary of findings for the main comparison).

Five studies reported mean unaided near VA (n = 829) (Analysis 1.7). There was substantial inconsistency between studies (I^2 = 98%) but all studies favoured the multifocal group.

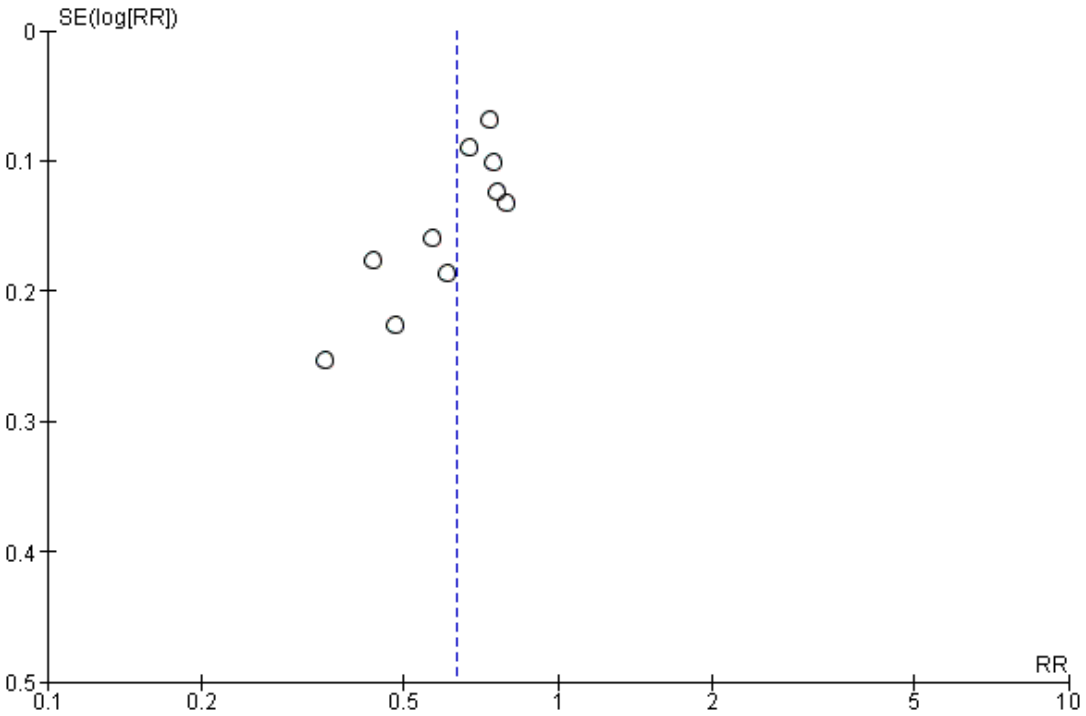
Four studies reported corrected near VA worse than J3/J4 or equivalent (n = 344) (Analysis 1.8). There were better outcomes in the multifocal group (RR 0.32, 95% CI 0.08 to 1.27, I^2 = 18%).

Six studies reported mean corrected near VA (n = 1003) (Analysis 1.9). There was substantial inconsistency (I^2=99%). Four studies reported similar VA in both groups with a mean difference of less than or equal to 0.1 logMAR (Harman 2008; Javitt 2000; Palmer 2008; Rasp 2012). One study documented slightly better corrected near VA in the monofocal group (Leyland 2002) and one study reported substantially better corrected near VA in the multifocal group (Rasp 2012).

Spectacle dependence

Ten studies (n = 1000) reported the outcome of spectacle dependence for distance or near vision (Analysis 1.11). Fewer participants in the multifocal group were spectacle dependent in the multifocal compared with the monofocal group (RR 0.63, 95% CI 0.55 to 0.73). There was substantial heterogeneity between studies (I^2 = 67%) but all studies favoured multifocal IOLs. Since there were data from 10 studies for this outcome, we produced a funnel plot to evaluate publication bias as planned in our protocol. This showed evidence of publication bias with a skewed pattern (Figure 4). We downgraded the evidence for spectacle independence one level for risk of bias and one level for publication bias. We did not additionally downgrade for inconsistency (Summary of findings for the main comparison).

Figure 4. Funnel plot of comparison: 1 Multifocal versus monofocal intraocular lenses, outcome: 1.10 Spectacle dependence (any).



Four studies reported spectacle dependence for distance vision (n = 618) which overall was reduced in the multifocal group (RR 0.71, 95% CI 0.46 to 1.09) (Analysis 1.11). However, there was some inconsistency between studies with two studies showing no overall difference and with the other two studies in favour of the multifocal group (I^2 = 67%).

Six studies reported spectacle dependence for near vision (n = 772) (Analysis 1.11). Fewer participants in the multifocal group required spectacles for near vision (RR 0.53, 95% CI 0.40 to 0.71). Again there was wide variation between studies (I^2 = 85%) but all had better outcomes in the multifocal group.

Secondary outcomes

Contrast sensitivity

Thirteen studies measured contrast sensitivity; however, they used several different methods (see 'Outcomes' of Included studies) and therefore combined analysis of results was difficult. We pooled and analysed data from four trials (n = 288) that used the Pelli-Robson chart (Analysis 1.12). This indicated little evidence of any important difference in contrast sensitivity between groups (MD -0.09, 95% CI -0.26 to 0.08).

The remaining studies reported poorer contrast sensitivity outcomes in the multifocal group. One study reported a small difference in contrast sensitivity in participants with good VA (Haaskjold 1998a); three studies reported contrast sensitivity at a particular spatial frequency (Cillino 2008; Palmer 2008; Zhao 2010), and four studies reported overall poorer contrast sensitivity in the multifocal group (Steinert 1992; Percival 1993; Kamlesh 2001; Ji 2013).

Participant-reported outcomes: visual function and quality of life

Four studies reported results of visual function questionnaires (n = 480) (Analysis 1.13). There was some evidence of more favourable outcomes in the multifocal group, however the size of the effect was small and uncertain due to wide CIs and there was inconsistency between studies such that a pooled result may not be meaningful. (I^2 = 92%).

Only one study assessed vision-related quality of life and found no difference between multifocal or monofocal IOL groups (Analysis 1.14).

Participant-reported outcomes: satisfaction

Six studies reported satisfaction scores (n = 643). The difference between groups was uncertain due to inconsistency between studies (I^2 = 88%) (Analysis 1.15).

Four studies reported the number of participants that reported having 'good' vision or being 'satisfied' with their overall vision (n = 388). There was no evidence of any important differences between groups (RR 0.99, 95% CI 0.92 to 1.06) (Analysis 1.16).

One study assessed participant satisfaction for near vision (n = 80) and found a greater number of participants reporting good outcomes in the multifocal IOL group (RR 1.42, 95% CI 1.13 to 1.78) (Analysis 1.16) (Rossetti 1994). The same study also assessed participant satisfaction for distance vision with a slightly greater level of satisfaction in the monofocal group (RR 0.89, 95% CI 0.72 to 1.10) (Analysis 1.16).

One study assessed visual satisfaction at 12 months using the TyPE questionnaire and found no difference between groups (Analysis 1.17) (Leyland 2002).

Participant-reported outcomes: visual symptoms

Cataract symptom scores

Two studies with 257 participants reported cataract symptom scores (Analysis 1.18). Both studies used the Cataract Symptom Score (CSS) (Steinberg 1994). Nijkamp 2004 reported final value at 3 months, Sen 2004 reported change between surgery and 1 month.

The CSS requires participants to reported whether they are bothered by any of five symptoms: double or distorted vision; seeing glare, halo, or rings around light; blurry vision; colours looking different than they used to in a way that is disturbing; and worsening of vision within the past month. A score was given for each symptom: 0 = "no symptom or not bothered"; 1="a little bothered"; 2 = "somewhat bothered"; and 3 = "very bothered". A total score of 15 was possible ranging from 0 (no symptoms or not bothered by any of the symptoms) to 15 (very bothered by all five symptoms). On average people in the multifocal group had worse symptom scores (MD 1.01 score, 95% CI 0.39 to 1.64; I^2 = 0%).

Glare

Seven studies (n = 544) assessed postoperative glare. More people in the multifocal group reported problems with glare: (RR 1.41, 95% CI 1.03 to 1.93) (Analysis 1.19). We judged this to be low-certainty evidence downgrading one level for risk of bias and one level for imprecision as the lower CI was close to 1 (Summary of findings for the main comparison).

Haloes

Seven studies (n = 662) questioned participants regarding postoperative haloes. More people in the multifocal group reported haloes (RR 3.58, 95% CI 1.99 to 6.46) (Analysis 1.20). We judged this to be moderate-certainty evidence downgrading one level for risk of bias (Summary of findings for the main comparison).

Dysphotopsia

One study reported postoperative dysphotopsia (n = 114). There were more people with dysphotopsia in the multifocal group compared with the monofocal group (RR 1.18, 95% CI 0.76 to 1.82) (Analysis 1.21).

Complications

Complications of surgery can be expected to be similar for multifocal and monofocal IOLs as the lenses are similar in all but the design of the optics and require no modifications to surgical technique. Ten studies reported perioperative and postoperative complications (el Maghraby 1992; Percival 1993; Javitt 2000; Leyland 2002; Sen 2004; Nijkamp 2004; Cillino 2008; Harman 2008; Zhao 2010; Peng 2012). The incidence of complications was low and similar in the multifocal and monofocal groups.

Subgroup analyses

We did two subgroup analyses: refractive lenses versus diffractive lenses (Table 6) and bilateral surgery versus unilateral surgery (Table 7).

These analyses must be interpreted with caution due to the small numbers of studies in each group which means the test for interaction may have low power and the large number of outcomes which may lead to spurious findings.

Comparing diffractive and refractive lenses, there was some indication that the diffractive lenses performed better. Specifically diffractive lenses had better visual function questionnaire scores and better satisfaction scores, and lower spectacle dependence.

The comparison between bilateral and unilateral surgery was difficult to interpret. There were two outcomes that had a significant P value for interaction, corrected distance VA worse than 6/6 and visual function scores, but in both these cases there was only one trial in some of the subgroups so it is difficult to attribute the difference in effect solely to this characteristic.

Sensitivity analysis

We excluded studies at high risk of bias in one or more domain as planned in our protocol (Table 8). There were some differences in outcome but these were not consistent and, due to the relatively high proportion of trials at high risk of bias, it is difficult to interpret these comparisons due to increased imprecision.

Multifocal lenses versus monovision

Two studies compared multifocal lenses with monovision (Wilkins 2013; Labiris 2015).

In Wilkins 2013, the investigators enrolled 212 people who received bilateral sequential cataract surgery either to receive bilateral Tecnis ZM900 diffractive multifocal lenses or Akreos AO monofocal lenses with the powers adjusted to target -1.25 D monovision. The participants were followed up to four months and 187 (88%) were seen at that point.

In Labiris 2015, the investigators enrolled 75 people who received bilateral cataract surgery either to receive bilateral Isert PY60MV refractive multifocal lenses or SN60WF monofocal lenses with the powers adjusted to target -1.25 D monovision. The participants were followed up to six months. Follow-up was unclearly reported but the impression was given that all 75 participants were followed up.

There was no evidence for any important difference in distance VA between the two groups (MD 0.02 logMAR, 95% CI -0.02 to 0.06; n = 186; studies = 1) (Analysis 2.1) (Wilkins 2013). The outcome was similar in Labiris 2015, which reported decimal VA and showed similar distance VA in the two groups.

People receiving multifocal lenses had similar or very slightly worse unaided intermediate VA compared with people receiving monovision (MD 0.07 logMAR, 95% CI 0.04 to 0.10; n = 181; studies = 1) (Analysis 2.1).

People receiving multifocal lenses had similar unaided near VA compared with people receiving monovision (MD -0.04 logMAR, 95% CI -0.08 to -0.00; n = 186; studies = 1) (Analysis 2.1) This was supported by Labiris 2015 which reported decimal VA and showed no significant difference in near VA between the two groups.

People receiving multifocal lenses were less likely to be spectacle dependent compared with people with monovision (RR 0.40, 95% CI 0.30 to 0.53; n = 262; studies = 2; I^2 = 0%) (Analysis 2.2). Only Labiris 2015 reported these separately according to near and distance vision, with people receiving multifocal lenses being less likely to be spectacle dependent for near vision. There was little evidence of any effect on spectacle dependence for distance vision (Analysis 2.2).

Contrast sensitivity was marginally better in the monovision group (MD -0.06, 95% CI -0.10 to -0.02) in Wilkins 2013, but there was little evidence for any difference in Labiris 2015 (I^2 = 67%, data not pooled) (Analysis 2.3).

People receiving multifocal lenses were more likely to report glare compared to people receiving monovision (RR 1.41, 95% CI 1.14 to 1.73; n = 187; studies = 1) (Analysis 2.5). This was supported by data from Labiris 2015, which reported glare and "unwanted shadows" on a 4-point Likert scale. There were higher mean scores in the multifocal group for both glare (MD 0.15, 95% CI -0.00 to 0.30; n = 75; studies = 1) and shadows (MD 0.36, 95% CI 0.07 to 0.65; n = 75; studies = 1).

Wilkins 2013 reported IOL exchange. Quote "In the first postoperative year, 6 patients (5.7%) in the multifocal group underwent IOL exchange (4 had a bilateral and 2 had a unilateral exchange). No patients in the monovision group underwent IOL exchange."

DISCUSSION

Summary of main results

The results are summarised in Summary of findings for the main comparison. Distance VA was similar in the multifocal and monofocal groups but people with multifocal lenses achieved better near vision overall and were less dependent on spectacles. Adverse subjective visual phenomena, particularly haloes, were common and troublesome in people receiving multifocal IOLs.

There was some evidence that contrast sensitivity may be lower in people receiving multifocal IOLs. The differences were smaller than would be expected given the division of light between distance and near focus, which may result from visual processing. Whether the reduction in contrast sensitivity induced by the IOL would be clinically significant would depend on the contrast presented by the visual target and the contrast sensitivity of the person's retina. There were no significant differences between IOLs with respect to objective glare.

Participant satisfaction was not consistently reported between the two lens types. There was some evidence that participants with multifocal lenses experienced improved visual functioning for tasks requiring near vision compared to participants with monofocal lenses.

There was less evidence available for the comparison between multifocal lenses and monovision. The data available suggested similar distance and better near VA in the multifocal and monovision groups. Multifocal lenses were associated with less spectacle dependence but also an increased chance of experiencing glare and haloes compared with monovision.

Overall completeness and applicability of evidence

Ten of the 20 included studies involved participants with surgery on both eyes and two studies had a mixture of both unilateral and bilateral surgery. Unilateral studies allow measurement of unioocular outcomes such as VA but are of limited use when attempting to measure the effect of the multifocal IOLs on quality of life, especially where the fellow eye has good vision. Of the studies that involved unilateral surgery only, Steinert 1992 and Rossetti 1994 reported fellow eye vision as good, Percival 1993 described the fellow eyes as cataractous and Jusufovic 2011 and Zhao 2010 commented that participants had no prior ocular surgery suggesting a phakic status in the other eye. The other studies involving unilateral surgery and the two studies that performed surgery on one or both eyes did not comment on the status of the fellow eye.

We presented results as a combined group of refractive and diffractive IOL studies. Combination of data was valid as both IOL types use the same principle of simultaneous vision once incident light has been split by either the refractive or diffractive optic. Holladay 1990 found very similar optical properties of all multifocal IOLs tested including the Array refractive IOLs and the 3M diffractive IOL used in some of the studies reviewed here (the Pharmacia diffractive IOL is of a similar design to the 3M IOL). We presented separated data, which are likely to become more useful as further studies are published.

Unaided near vision is critical to assessment of multifocal efficacy but was reported in a manner that made comparison between studies difficult. Only eight studies reported unaided near VA worse than J3/J4 or equivalent, and five studies reported mean LogMAR unaided near VA allowing pooled data analysis. Furthermore, only seven studies reported both unaided and corrected near acuity and Palmer 2008 reported corrected near acuity together with unaided near acuity but wearing a distance correction. Reading distances differed in the individual studies and it was unclear in most studies whether the reported print size read had been corrected for reading distance to allow a near acuity to be calculated. A further problem arose because Jaeger cards are not standardised between manufacturers so that J3 from one study cannot be assumed to equal J3 from another (Bailey 1978). Despite these caveats, it is likely that unaided near vision is improved by a multifocal IOL. It is important to remember, however, that monofocal IOL near acuity can be restored using reading glasses.

This review has highlighted the need for a core set of outcome measures in trials comparing multifocal and monofocal lenses. Ideally these outcomes should be based on validated measures, particularly for the more subjective outcome measures.

The optical and visual effects of these IOLs are now well-known, particularly near vision. The search for alternative strategies to achieve spectacle independence, such as monovision and accommodating IOLs, should continue.

Quality of the evidence

We graded the certainty of the evidence as low to moderate for those outcomes for which we could estimate an effect (Summary of findings for the main comparison). In general, we downgraded results for risk of bias because it was difficult to mask participants and outcome assessors in these trials and difficult to assess reporting bias. There was substantial methodological and statistical heterogeneity for some outcomes, in particular for the measurement of corrected distance VA and both unaided and corrected near VA, as well as participant-reported spectacle dependence. There was also some evidence of publication bias with respect to the outcome of spectacle dependence.

Agreements and disagreements with other studies or reviews

One meta-analysis of outcomes of multifocal IOLs that included both randomised controlled trials and studies of other design found slightly better uncorrected distance VA in the monofocal groups but better uncorrected near VA and greater spectacle independence in the multifocal group, the latter being similar to the results from our analysis (Cochener 2011). They also reported better near VA using diffractive (rather than refractive) multifocal IOLs, which is similar to the outcomes we found albeit with small numbers used for analysis. de Vries and colleagues conducted a review including both randomised controlled trials and case series (de Vries 2013). This was a narrative review summarising the outcomes of included studies but did not draw any definitive conclusions regarding outcomes that could be compared with results presented in this systematic Cochrane Review.

AUTHORS' CONCLUSIONS

Implications for practice

Multifocal intraocular lenses may result in better near vision without any adverse effect on distance acuity. Spectacle dependence is less likely with use of these intraocular lenses when compared to the standard practice of monofocal implantation.

Whether the improvement in unaided near vision and increased incidence of spectacle independence are sufficient to outweigh the experience of glare and haloes is a matter for each person to decide. The final choice is likely to depend on a person's motivation to be free of spectacles, guided by realistic expectations as to the likelihood of achieving this aim and understanding of the compromises involved.

Implications for research

This review has highlighted the need for a core set of outcome measures in trials comparing multifocal and monofocal lenses. Standardised outcome reporting for visual acuity is required to be able to pool data and draw robust conclusions. Ideally these outcomes should be based on validated measures, particularly for the more subjective outcomes, and include the views of people who have had cataract surgery.

The search for alternative strategies to achieve spectacle independence, such as monovision, trifocal and accommodating intraocular lenses, should continue.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Cillino 2008

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal 1: Array SA40N, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 16 (32) • *Mean age in years (range)*: 57 • *% female*: 56 • *Ethnic group*: NR Multifocal 2: ReZoom, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 15 (30) • *Mean age in years (range)*: 65 • *% female*: 47 • *Ethnic group*: NR Multifocal 3: Tecnis ZM900, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 16 (32) • *Mean age in years (range)*: 60 • *% female*: 63 • *Ethnic group*: NR Monofocal: AR40, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 15 (30) • *Mean age in years (range)*: 68 • *% female*: 47 • *Ethnic group*: NR **Inclusion criteria:** bilateral juvenile or senile cataract; visually significant (i.e. Snellen VA less than 20/30) in ≥ 1 eye; corneal astigmatism not > 1.0 D; and capability of understanding and signing the informed consent **Exclusion criteria:** aged < 21 years; precataract myopia or hyperopia > 3 D; history of amblyopia; fundus abnormalities that could cause significant vision impairment; previous surgical intraocular procedures; and ocular comorbidities, such as previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal

	opacities, senile miosis or hyporeactive pupil, or alpha-antagonist (tamsulosin) treatment, which might induce floppy iris syndrome. Intraoperative exclusion criteria were iris pupillary trauma; vitreous loss; and inability to place the IOL in the capsular bag **Pretreatment:** there were no significant intergroup differences in age, sex and preoperative SE
Interventions	**Intervention characteristics** Multifocal 1 • *Name of lens*: Array SA40N, AMO • *Type of lens*: refractive • *Target*: emmetropia Multifocal 2 • *Name of lens*: ReZoom, AMO • *Type of lens*: refractive • *Target*: emmetropia Multifocal 3 • *Name of lens*: Tecnis ZM900, AMO • *Type of lens*: diffractive • T*arget*: emmetropia Monofocal • *Name of lens*: AR40, AMO • *Type of lens*: NA • *Target*: emmetropia **Both eyes operated**
Outcomes	**Outcomes:** distance, near and intermediate VA; defocusing curves; contrast sensitivity; participant satisfaction and spectacle independence **Eyes:** outcomes measured by eye, unclear number of eyes reported (we have assumed both eyes reported without adjustment for within-person correlation) **Maximum follow-up:** 12 months
Notes	**Sponsorship source:** NR **Declaration of interest:** "The authors have no proprietary or commercial interest in any materials discussed in this article." **Country:** Italy **Setting:** eye hospital **Date study conducted:** January 2005 to January 2006 **Trial registration ID number:** NR **Author's name:** Salvatore Cillino **Institution:** University of Palermo **Email:** cillino@unipa.it **Address:** Dipartimento di Neuroscienze Cliniche, Sezione di Oftalmologia, Università di Palermo, Italy, Via Liborio Giuffrè, n. 13-90127, Palermo, Italy

Risk of bias

Bias	Authors' judgement	Support for judgement

Cillino 2008 (*Continued*)

Sequence generation	Low risk	Quote: "Randomization used a 1:1:1:1 block randomization scheme generated by SPSS statistical software for Windows (version 14.0, SPSS Inc, Chicago, IL)."
Allocation concealment	Low risk	Quote: "The randomization code was maintained only at the central data facility and was not broken until all data analysis was complete."
Blinding of participants and personnel All outcomes	Low risk	Quote: "The patients and the medical staff who collected functional data and quality-of-life data were masked to the type of lens that each patient received." Judgement comment: not possible to mask the operating surgeon but we judged that this would not have important effect on risk of bias
Blinding of outcome assessors All outcomes	Low risk	Quote: "The patients and the medical staff who collected functional data and quality-of-life data were masked to the type of lens that each patient received." Judgement comment: outcome assessors were masked.
Incomplete outcome data All outcomes	Unclear risk	Quote: "Four patients withdrew after randomization or during the postoperative period. Two patients were excluded from the analysis because of the presence of capsular brosis at 1 week postoperatively." Judgement comment: 91% of participants followed up but some exclusions after randomisation and unclear which group these were in
Selective outcome reporting	Unclear risk	Judgement comment: no protocol or trials registry entry.

el Maghraby 1992

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: 815LE, 3M Vision Care • *Number of people (eyes) randomised*: 39 (39)

	• *Number of people (eyes) excluded after randomisation*: 4 (4) • *Number of people (eyes) lost to follow-up*: 1 (1) • *Number of people (eyes) analysed (at longest time point)*: 28 (28) • *Mean age in years (range)*: 57 (45 to 90) • *% female*: 59 • *Ethnic group*: NR Monofocal: 15LE, 3M Vision Care • *Number of people (eyes) randomised*: 38 (38) • *Number of people (eyes) excluded after randomisation*: 0 (0) • *Number of people (eyes) lost to follow-up*: 2 (2) • *Number of people (eyes) analysed (at longest time point)*: 33 (33) • *Mean age in years (range)*: 56 (45 to 70) • *% female*: 47 • *Ethnic group*: NR **Inclusion criteria:** candidates for cataract extraction by phacoemulsification and IOL to be implanted was within the range of +17:00 to +23:00 D for emmetropia **Exclusion criteria:** evidence or history of uveitis; active progressive corneal disease; history of previous intraocular surgery in the eye to be studies; intraocular pressure > 23 mmHg or on glaucoma medication; diabetic retinopathy; macular degeneration; amblyopia or any other known disease that would decrease postoperative BCVA to worse than 20/40; non age-related cataracts; blind in contralateral eye **Pretreatment:** similar characteristics except for more women (59%) in multifocal compared to monofocal group (47%)
Interventions	**Intervention characteristics** Multifocal: • *Name of lens*: 815LE, 3M Vision Care • *Type of lens*: diffractive • *Target*: emmetropia Monofocal • *Name of lens*: 15LE, 3M Vision Care • *Type of lens*: NA • *Target*: emmetropia **1 eye operated**
Outcomes	**Outcomes:** distance and near VA, refractive error **Eyes:** study eye (1 eye operated per person) **Maximum follow-up:** 2 to 4 months
Notes	**Sponsorship source:** Saudi Eye Foundation **Declaration of interest:** NR **Country:** Saudi Arabia **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Akef El-Magharby **Institution:** El-Maghraby Eye Hospital **Email:** NR **Address:** El-Maghraby Eye Hospital, Jeddah, Saudi Arabia, PO Box 7344, Jeddah 21462,

el Maghraby 1992 (*Continued*)

	Saudi Arabia	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Low risk	Judgement comment: "Randomization schedules were generated using Prodas, a statistical software package."
Allocation concealment	Low risk	Judgement comment: NR but confirmed by author correspondence
Blinding of participants and personnel All outcomes	High risk	Judgement comment: masking NR and lenses different.
Blinding of outcome assessors All outcomes	High risk	Judgement comment: masking NR and lenses different.
Incomplete outcome data All outcomes	High risk	Judgement comment: some exclusions after randomisation 4/39 in multifocal group, 1 of these due to PCO, 1 due to high astigmatism and 2 due to pre-existing maculopathy. Overall follow-up at 2 to 4 months was 28/39 (71%) for multifocal group and 33/38 (87%) for monofocal group
Selective outcome reporting	Unclear risk	Judgement comment: no access to trial registry entry or protocol

Haaskjold 1998a

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** yes
Participants	**Baseline characteristics** Multifocal: 808X, Pharmacia Ophthalmics • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 115 (115) • *Mean age in years*: 67 (maximum age 88) • *% female*: NR • *Ethnic group*: NR Monofocal: 808D, Pharmacia Ophthalmics • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR

	• *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 106 (106) • *Mean age in years*: 67 (maximum age 90) • *% female*: NR • *Ethnic group*: NR **Inclusion criteria:** age-related uncomplicated cataracts, aged ≥ 47 years; preoperative astigmatism < 1.5 D **Exclusion criteria:** eye pathology other than cataract **Pretreatment:** not described
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: 808X, Pharmacia Ophthalmics • *Type of lens*: diffractive, bifocal • *Target*: NR Monofocal • *Name of lens*: 808D, Pharmacia Ophthalmics • *Type of lens*: NA • *Target*: NR **1 eye operated**
Outcomes	**Outcomes:** distance and near VA, contrast sensitivity, participant satisfaction, spectacle independence and adverse effects (halos, glare etc.) **Eyes: s**tudy eye (1 eye operated per person) **Maximum follow-up:** 5 months
Notes	**Sponsorship source:** NR **Declaration of interest:** NR **Country:** Europe (UK, Finland, Germany, Norway, Portugal, Sweden) **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Erling Haaskjold **Institution:** National Hospital, Oslo **Email:** NR **Address:** Sognsvannsveien 20, 0372 Oslo, Norway

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: study was described as "randomised" but no further details given
Allocation concealment	Low risk	Judgement comment: NR but confirmed by author correspondence

Haaskjold 1998a (*Continued*)

Blinding of participants and personnel All outcomes	High risk	Judgement comment: study was described as "open". No information on masking
Blinding of outcome assessors All outcomes	High risk	Judgement comment: study was described as "open" No information on masking
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up not clearly described.
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials register entry

Harman 2008

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: Array SA40N, AMO • *Number of people (eyes) randomised*: 30 (60) • *Number of people (eyes) excluded after randomisation*: 3 (6) • *Number of people (eyes) lost to follow-up*: 3 (6) • *Number of people (eyes) analysed (at longest time point)*: 24 (48) • *Mean age in years*: 73 • *% female*: 50 • *Ethnic group*: Monofocal: Clariflex, AMO • *Number of people (eyes) randomised*: 30 (60) • *Number of people (eyes) excluded after randomisation*: 2 (4) • *Number of people (eyes) lost to follow-up*: 9 (18) • *Number of people (eyes) analysed (at longest time point)*: 19 (38) • *Mean age in years*: 71 • *% female*: 60 • *Ethnic group*: NR **Inclusion criteria:** aged > 21 years; bilateral visually significant cataract; axial length < 25 mm **Exclusion criteria:** mature cataract; anterior segment pathology such as pseudoexfoliation or zonular dialysis; previous ocular surgery and any ocular pathology that might limit the postoperative VA to less than 6/9 (e.g. amblyopia, corneal opacity, macular disease; preoperative corneal astigmatism of > 2 D in either eye **Pretreatment:** baseline comparison of age, gender, logMAR acuity and refractive error. Multifocal group had lower average spherical equivalent and higher average cylinder
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Array SA40N, AMO • *Type of lens*: refractive

	• *Target*: emmetropia Monofocal • *Name of lens*: Clariflex, AMO • *Type of lens*: NA • *Target*: emmetropia **Both eyes operated** There was a third treatment group in this study that was not included in this review (accommodative lenses, 1CU) Quote: "Patients who had >1 D (and <2 D) of corneal astigmatism also underwent limbus-relaxing incisions (LRIs), using the modified Gills nomogram (21) at the time of surgery, aiming for postoperative astigmatism of <1 D." Quote: "Ten patients required LRIs at the time of surgery: 5 from the 1CU group [not included in this review], 3 from the multifocal, and 2 from the monofocal. Of these, only 1 patient from the multifocal group required bilateral LRIs."
Outcomes	Note: participants were asked to practice reading every day without spectacle correction until 3 months **Outcomes:** distance and near VA, refraction, contrast sensitivity, accommodation (defocus, near point), spectacle independence, reading ability and adverse effects (halos, glare, etc.) **Eyes:** both eyes operated, binocular outcomes reported except for refraction and glare disability (right eye only) **Maximum follow-up:** 18 months
Notes	**Sponsorship source:** Hillingdon Hospital Research and Development Fund, Uxbridge, UK **Declaration of interest:** "No author has any conflict of interest with the products investigated." **Country:** UK **Setting:** eye hospital **Date study conducted**: NR **Trial registration ID number:** NR **Author's name:** Fran Harman **Institution:** Ophthalmology Department, Hillingdon Hospital **Email:** harmanfran@hotmail.com **Address:** Ophthalmology Department, Hillingdon Hospital, Pield Heath Road, Uxbridge, Middlesex, UB8 3NN, UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Unclear risk	Judgement comment: participants were randomly allocated to 1 of the 3 types of lenses by sealed envelopes opened on the day of surgery; they received the same IOL in each eye, and the second eye was operated on within 6 weeks of the first. Sequence generation NR

Harman 2008 (*Continued*)

Allocation concealment	Low risk	Judgement comment: participants were randomly allocated to 1 of the 3 types of lenses by sealed envelopes opened on the day of surgery; they received the same IOL in each eye, and the second eye was operated on within 6 weeks of the first
Blinding of participants and personnel All outcomes	High risk	Judgement comment: participants were masked as to the nature of the IOL inserted until the 3-month review, and all were asked to practice reading every day without spectacle correction until this time. Participants were not masked for the 18-month visit
Blinding of outcome assessors All outcomes	Low risk	Judgement comment: all examiners were masked at the 3- and 18-month reviews. A subjective masked assessment was made of PCO in the right eye at the 18-month review, graded as none, mild, moderate or severe
Incomplete outcome data All outcomes	Unclear risk	Quote: "Of the 90 patients entering the trial, 82 completed follow-up at 3 months; withdrawals were all before second-eye surgery (development of subretinal neovascular membranes, n 2; cystoid macular edema, 2; corneal decompensation secondary to undiagnosed Fuchs' endothelial dystrophy, 1; severe local allergic reaction to preoperative tropicamide drops, 1; IOL selection error, 1; anterior capsule tear at time of surgery, 1). Two patients withdrew from the 1CU group and 3 from each of the other groups. There were no cases of a posterior capsule tear or vitreous loss. A further 18 patients were lost to follow-up by 18 months (data from these patients were included in the 3-month results), with 21 patients remaining in the 1CU group, 24 in the multifocal, and 19 in the monofocal. "
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials register entry

Javitt 2000

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** yes
Participants	**Baseline characteristics** Multifocal: Array SA40N, AMO • *Number of people (eyes) randomised*: 134 (268) • *Number of people (eyes) excluded after randomisation*: 7 (14) • *Number of people (eyes) lost to follow-up*: 3 (6) • *Number of people (eyes) analysed (at longest time point)*: 124 (248) • *Mean age in years*: 74 • *% female*: 51 • *Ethnic group*: NR Monofocal: PhacoFlex II SI40NB, AMO • *Number of people (eyes) randomised*: 127 (254) • *Number of people (eyes) excluded after randomisation*: 9 (18) • *Number of people (eyes) lost to follow-up*: 7 (14) • *Number of people (eyes) analysed (at longest time point)*: 111 (222) • *Mean age in years*: 75 • *% female*: 61 • *Ethnic group*: NR **Inclusion criteria:** aged 50 to 85 years with bilateral cataracts; < 1.5 D of keratometric cylinder; 20/30 of better potential VA **Exclusion criteria:** any pre-existing ocular pathology other than cataract **Pretreatment:** no important differences at baseline between both groups
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Array SA40N, AMO • *Type of lens*: zonal-progressive • *Target*: +3.5 D for near Monofocal • *Name of lens*: PhacoFlex II SI40NB, AMO • *Type of lens*: monofocal • *Target*: NR **Both eyes operated**
Outcomes	**Outcomes:** distance and near VA, refraction, spectacle independence, satisfaction, visual function (modified Cataract TyPE questionnaire) and adverse effects (halos, glare, etc.) **Eyes:** both eyes operated, binocular outcomes reported **Maximum follow-up:** 3 to 6 months after second eye surgery
Notes	**Sponsorship source:** Allergan, Inc **Declaration of interest:** "Dr. Javitt and Dr. Steinert are consultants to Allergan, Inc., but do not have a proprietary interest in the company or its products." **Country:** USA **Setting:** eye hospital **Date study conducted:** February 1996 to March 1998 **Trial registration ID number:** NR

	Author's name: Jonathan C Javitt **Institution:** Wilmer Ophthalmological Institute, Johns Hopkins University, Baltimore, MD **Email:** jjavitt@healthdirections.net **Address:** 3 Bethesda Metro Center, Suite 100, Bethesda, MD 20814

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Low risk	Quote: "A block randomization schedule by patient was prepared for each site using SAS software, (SAS Institute, Cary, NC)."
Allocation concealment	Unclear risk	Quote: "Assigned in blocks of two. For each block of two patients, either the rst patient or the second (in random order) received a multifocal lens. The randomization schedule." Quote: "The randomization schedule was drawn up by site before the start of the study, and the assignment of each patient was placed in a sealed container that was not opened until the patient was actually in the operating room. Differences between the ultimate size of the monofocal and multifocal groups resulted from patients withdrawing from study after just one implant, sites stopping ahead of schedule, and chance outcomes." Judgement comment: although efforts make to conceal the allocation a block size of 2 may have been very easy to second guess
Blinding of participants and personnel All outcomes	Low risk	Quote: "The patients, the ophthalmic technicians who collected clinical data, and the interviewers who collected the quality-of-life data were all masked as to the type of lens that each patient received."
Blinding of outcome assessors All outcomes	Low risk	Quote: "The patients, the ophthalmic technicians who collected clinical data, and the interviewers who collected the quality-of-life data were all masked as to the type of lens that each patient received."

Javitt 2000 (*Continued*)

Incomplete outcome data All outcomes	Unclear risk	Judgement comment: slightly lower follow-up in monofocal group (85%) compared to 92% in multifocal group. A higher proportion of monofocal group participants did not undergo second eye surgery because of problems in the first eye 8/127 (6%) compared to 2/134 (1%)
Selective outcome reporting	Unclear risk	Judgement comment: no access to trial protocol and trial not registered

Ji 2013

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: AcrySof ReSTOR, Alcon Laboratories • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 24 (30) • *Mean age in years (range)*: 63 (52 to 71) • *% female*: 58 • *Ethnic group*: NR Monofocal: AcrySof Natural, Alcon Laboratories • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 27 (34) • *Mean age in years (range)*: 63 (55 to 75) • *% female*: 56 • *Ethnic group*: NR **Inclusion criteria:** aged 50 to 75 years; age-associated cataracts. **Exclusion criteria:** corneal astigmatism > 1.5 D; glaucoma; retinal abnormalities; surgical complications **Pretreatment:** NR
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: AcrySof ReSTOR, Alcon Laboratories • *Type of lens*: NR • *Target*: NR Monofocal • *Name of lens*: AcrySof Natural, Alcon Laboratories • *Type of lens*: NA • *Target*: NR

Ji 2013 (*Continued*)

	1 or both eyes operated
Outcomes	**Outcomes:** distance and near VA, contrast sensitivity, refraction, accommodation, aberrometry **Eyes:** probably reported by eye without adjustment for within-person correlation **Maximum follow-up:** 90 days after surgery
Notes	**Sponsorship source:** Shanghai Leading Academic Discipline Project (S30205) **Declaration of interest:** NR **Country:** China **Setting:** eye hospital **Date study conducted:** January 2009 to December 2011 **Trial registration ID number:** NR **Author's name:** Min Luo **Institution:** Shanghai Ninth Hospital **Email:** qiangson@sh163.net **Address:** Department of Ophthalmology, Shanghai Ninth Hospital, Shanghai JiaoTong University School of Medicine, No. 639 ZhiZaoJu Road, Shanghai 200011, P.R. China

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: sequence generation NR.
Allocation concealment	Unclear risk	Judgement comment: allocation concealment NR.
Blinding of participants and personnel All outcomes	High risk	Judgement comment: masking NR so assume not done.
Blinding of outcome assessors All outcomes	High risk	Judgement comment: masking NR so assume not done.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Jusufovic 2011

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no

Participants	**Baseline characteristics** Multifocal: ReZoom NXG1, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 50 (50) • *Mean age in years (range)*: 43 (20 to 57) • *% female*: 46 • *Ethnic group*: NR Monofocal: AcrySof MA60BM, Alcon Laboratories • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 50 (50) • *Mean age in years (range)*: 50 (26 to 64) • *% female*: 42 • *Ethnic group*: NR **Inclusion criteria:** aged 14 to 80 years; astigmatism < 1 D **Exclusion criteria:** chronic inflammatory and degenerative diseases of the posterior eye segment; previous surgery on the eye; high refractive anomalies and systemic diseases, which can cause changes in the eye, which significantly influence on the vision quality outcome after the operation **Pretreatment:** small difference in age
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: ReZoom NXG1, AMO • *Type of lens*: refractive • *Target*: NR Monofocal • *Name of lens*: AcrySof MA60BM, Alcon Laboratories • *Type of lens*: NA • *Target*: NR **1 eye operated**
Outcomes	**Outcomes:** distance and near VA, stereo vision **Eyes:** binocular **Maximum follow-up:** 6 weeks after surgery
Notes	**Sponsorship source:** NR **Declaration of interests:** "The authors declare no competing interests." **Country:** Bosnia and Herzegovina **Setting:** eye hospital **Date study conducted:** February 2006 to January 2007 **Trial registration ID number:** NR **Author's name:** Jasmin Zvornič anin **Institution:** Eye Clinic University Clinical Center Tuzla Tuzla, Bosnia and Herzegovina **Email:** zvornicanin_jasmin@hotmail.com **Address:** Eye Clinic University Clinical Center Tuzla Trnivac bb, 7500 Tuzla, Bosnia

Jusufovic 2011 (*Continued*)

	and Herzegovina

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Low risk	Quote: "Included 50 patients with implanted monofocal IOLs. Randomization was performed as follows: 100 small folded pieces of paper on which "multi" or "mono" was written, are folded and placed in an opaque bag."
Allocation concealment	Low risk	Quote: "The nurse who did not participate in the study picked papers from the bag and divided patients into two groups. Also, surgeon who carried out the operations did not know which group does the patient belong, until the very moment of intraocular lens implantation."
Blinding of participants and personnel All outcomes	High risk	Judgement comment: masking NR.
Blinding of outcome assessors All outcomes	High risk	Judgement comment: masking NR.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Kamlesh 2001

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: Progress 3, Laboratoires Domilens • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 20 (NR) • *Mean age in years*: 56 • *% female*: NR • *Ethnic group*: NR Monofocal: Flex 65, Laboratoires Domilens

	• *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 20 (NR) • *Mean age in years*: 54 • *% female*: NR • *Ethnic group*: NR **Inclusion criteria:** age-related cataract **Exclusion criteria:** known disease likely to interfere with postoperative visual outcome; preoperative astigmatism > 1.50 D; axial length beyond that requiring an estimated IOL power of 18.00 D to 24.00 D for emmetropia; previous eye surgery **Pretreatment:** quite large differences in near vision with 90% of multifocal group having distance-corrected near vision ≥ N9 compared to 10% of the monofocal group. Monofocal group had worse distance VA as well
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Progress 3, Laboratoires Domilens • *Type of lens*: NR • *Target*: + 3.00 D Monofocal • *Name of lens*: Flex 65, Laboratoires Domilens • *Type of lens*: NA • *Target*: emmetropia **1 eye operated**
Outcomes	**Outcomes:** contrast sensitivity, depth of focus, satisfaction, spectacle use and adverse effects (glare, halo, etc.) **Eyes:** unclearly reported, probably by eye as unilateral surgery **Maximum follow-up:** 3 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "The authors do not have any financial interest in any of the products mentioned in this article." **Country:** India **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Dr Subhash Dadeya **Institution:** Guru Nanak Eye Centre, Maulana Asad Medical College **Email:** sdadeya@freedialin.com **Address:** 197 Rouse Ave, New Delhi 110002, India

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Unclear risk	Judgement comment: sequence generation NR.

Kamlesh 2001 (*Continued*)

Allocation concealment	High risk	Judgement comment: allocation concealment NR and considerable baseline imbalance in groups with respect to near vision
Blinding of participants and personnel All outcomes	High risk	Judgement comment: masking NR.
Blinding of outcome assessors All outcomes	High risk	Judgement comment: masking NR.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to trial protocol or registry entry

Labiris 2015

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: Isert PY60MV, Hoya Surgical Optics • *Number of people (eyes) randomised*: 37 (74) • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: NR • *Mean age in years (range)*: 61 (NR) • *% female*: NR • *Ethnic group*: NR Monofocal: SN60WF, Alcon Laboratories • *Number of people (eyes) randomised*: 38 (76) • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: NR • *Mean age in years (range)*: 60 (NR) • *% female*: NR • *Ethnic group*: NR **Inclusion criteria:** age-related cataract with grade 2 nuclear opalescence according to the Lens Opacities Classification System III grading scale **Exclusion criteria:** manifest astigmatism > 1.00 D; reports of headaches or eyestrain (or both) associated with visual activities; positive pathological ocular cover test (near and distance) or the Mallett disparity test (near and distance) (or both) and the double Maddox rod test; endothelial cell count < 1900 cells/mm^2; glaucoma; intraocular pressure-lowering medications; former incisional surgery; former diagnosis of corneal disease; former diagnosis of fundus disease; diabetes; autoimmune or mental diseases **Pretreatment:** no major imbalances in age and grade of cataract

Labiris 2015 (*Continued*)

Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Isert PY60MV, Hoya Surgical Optics • *Type of lens*: refractive • *Target*: +3.00 D of near addition Monofocal • *Name of lens*: SN60WF, Alcon Laboratories • *Type of lens*: NA • *Target*: targeting -0.50 D in the dominant eye and -1.25 D in the non-dominant eye. **Both eyes operated**
Outcomes	**Outcomes:** dysphotopsia, need for spectacles, Visual Function Index-14, binocular uncorrected distance and near VA, contrast sensitivity and stereo acuity **Eyes:** both eyes operated, measurements binocular **Maximum follow-up:** 6 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "No author has a financial or proprietary interest in any material or method mentioned." **Country:** Greece **Setting:** eye hospital **Date study conducted:** January 2013 to July 2013 **Trial registration ID number:** NR **Author's name:** Georgios Labiris **Institution:** Ophthalmology Department, University Hospital of Alexandroupolis **Email:** labiris@usa.net **Address:** Ophthalmology Department, University Hospital of Alexandroupolis, 68100 Dragana, Alexandroupolis, Greece

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Low risk	Quote: "Using a custom computer randomization program, all patients randomly populated 2 study groups according to the cataract extraction technique used: monovision and multifocal IOL."
Allocation concealment	Unclear risk	Judgement comment: not described.
Blinding of participants and personnel All outcomes	High risk	Judgement comment: masking not described. On clinical trials registry entry described as "open label"
Blinding of outcome assessors All outcomes	Unclear risk	Quote: "All preoperative and postoperative assessments were done by the same oph-

Labiris 2015 (*Continued*)

		thalmologist, who had no direct involvement in the study." Judgement comment: unclear if this person was masked or not.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: NR.
Selective outcome reporting	Low risk	Judgement comment: all outcomes on clinical trials registry entry reported

Leyland 2002

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal 1: Array SA40NB, Allergan • *Number of people (eyes) randomised*: 31 (62) • *Number of people (eyes) excluded after randomisation*: 2 (4) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 29 (58) • *Mean age in years*: 75 • *% female*: 53 • *Ethnic group*: NR Multifocal 2: TrueVista 68STUV, Storz • *Number of people (eyes) randomised*: 19 (38) • *Number of people (eyes) excluded after randomisation*: 4 (8) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 15 (30) • *Mean age in years*: 74 • *% female*: 60 • *Ethnic group*: NR Monofocal: PhacoFlex I SI40N, AMO • *Number of people (eyes) randomised*: 19 (38) • *Number of people (eyes) excluded after randomisation*: 3 (6) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 16 (32) • *Mean age in years*: 76 • *% female*: 44 • *Ethnic group*: NR **Inclusion criteria:** aged > 18 years; bilateral visually significant cataracts with extraction indicated; informed consent; ability to understand and complete TyPE questionnaire **Exclusion criteria:** macular or other pathology considered likely to limit postoperative acuity to worse than 6/9 in either eye; corneal astigmatism > 1.5 D in either eye; required IOL power outside range available for multifocal IOL (16 D to 24 D) **Pretreatment:** there were no significant intergroup differences in age, sex, preoperative BCVA and visual satisfaction

Interventions	**Intervention characteristics** Multifocal 1 • *Name of lens*: Array SA40NB, Allergan • *Type of lens*: refractive • *Target*: emmetropia Multifocal 2 • *Name of lens*: TrueVista 68STUV, Storz • *Type of lens*: bifocal • *Target*: emmetropia Monofocal • *Name of lens*: PhacoFlex SI40N, Allergan • *Type of lens*: NA • *Target*: emmetropia **Both eyes operated**
Outcomes	**Outcomes:** distance and near VA, refraction, contrast sensitivity, depth of focus, satisfaction and visual function (TyPE questionnaire including bother from glare/halos) and spectacle use **Eyes:** binocular for acuity outcomes, monocular not adjusted with within-person correlation for refractive outcomes **Maximum follow-up:** 12 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "The authors have no financial interest in any of the products described in this paper." **Country:** UK **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Martin D Leyland **Institution:** Royal Berkshire Hospital **Email:** Martin.Leyland@rbbh-tr.nhs.uk **Address:** London Road, Reading Berks RG1 5AN, UK

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	Low risk	Judgement comment: sealed envelopes opened on the day of surgery
Blinding of participants and personnel All outcomes	Unclear risk	Judgement comment: participants were informed that the IOL type implanted would not be revealed to them until completion of the trial but a proportion of participants were reported to be unmasked

Leyland 2002 (*Continued*)

Blinding of outcome assessors All outcomes	Low risk	Judgement comment: the hospital optometrist and the ophthalmic nurse specialist carrying out these tests were masked as to the nature of the IOL implanted
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up < 80% at 1 year.
Selective outcome reporting	Unclear risk	Judgement comment: no access to protocol or trials registry entry

Nijkamp 2004

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: Array SA40N, AMO • *Number of people (eyes) randomised*: 93 • *Number of people (eyes) excluded after randomisation*: 11 • *Number of people (eyes) lost to follow-up*: 14 • *Number of people (eyes) analysed (at longest time point)*: 68 • *Mean age in years*: 72 • *% female*: 67 • *Ethnic group*: NR Monofocal: PhacoFlex II SI40NB, AMO • *Number of people (eyes) randomised*: 97 • *Number of people (eyes) excluded after randomisation*: 19 • *Number of people (eyes) lost to follow-up*: 9 • *Number of people (eyes) analysed (at longest time point)*: 69 • *Mean age in years*: 72 • *% female*: 64 • *Ethnic group*: NR **Inclusion criteria:** bilateral senile cataract; astigmatism < 1.5 D; spectacle sphere -6.0 to +4.0 D; axial length 19.5 mm to 26 mm; ability to complete questionnaires in Dutch **Exclusion criteria:** professional night driver; mental retardation (diagnosed in the medical file or concluded by contact by telephone); any eye disease other than cataract that might limit postoperative vision **Pretreatment:** slightly more astigmatism in the monofocal group
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Array SA40N, AMO • *Type of lens*: NR • *Target*: emmetropia Monofocal • *Name of lens*: PhacoFlex II SI40NB, AMO

	• *Type of lens*: NA • *Target*: emmetropia **Both eyes operated**
Outcomes	Participants with a postoperative refractive error in SE of > 1.5 D from emmetropia (in at least 1 eye) were excluded from further analyses (monofocal, n = 8; multifocal, n = 3) **Outcomes:** distance and near VA, refraction, contrast sensitivity, depth of focus, satisfaction, visual function and quality of life (including VF-14 and Visual Quality of Life) , Cataract Symptom Score, spectacle dependence **Eyes:** largely unclear how dealt with eyes, measurements monocular **Maximum follow-up:** 3 months after surgery
Notes	**Sponsorship source:** Eye Research Institute Maastricht (Maastricht, The Netherlands) **Declaration of interest:** "None of the authors has a financial or proprietary interest in any product or device mentioned." **Country:** the Netherlands **Setting:** eye hospital **Date study conducted:** August 1999 to January 2001 **Trial registration ID number:** NR **Author's name:** Marjan D Nijkamp **Institution:** Maastricht University **Email:** M.Nijkamp@GVO.unimaas.nl **Address:** Department of Health Education and Health Promotion, Maastricht University, PO Box 616, 6200 MD Maastricht, the Netherlands

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Low risk	Quote: "Block randomization by means of a computerized random number generator was used to keep the number of subjects in the different groups balanced."
Allocation concealment	Low risk	Quote: "After the preoperative assessments, a technical ophthalmic assistant allocated the treatment condition via a sealed envelope that contained a card identifying the lens type. The envelope was opened by a nurse not involved in the study. This was done after biometry and just before surgery, to enable the ophthalmologist to choose the correct lens power."
Blinding of participants and personnel All outcomes	High risk	Quote: "Patients were masked with respect to the type of lens until the first postoperative visit. It was unfeasible to keep patients masked postoperatively, because they were aware of the characteristics of both types of

Nijkamp 2004 (*Continued*)

		IOL from their description in the patient information they received." Quote: "Interviewers and ophthalmologists were unaware of the treatment group of the patient at the preoperative tests. However, because there were perceptible differences between the 2 types of lenses during the slit-lamp examination, masking of interviewers and ophthalmologists was not feasible postoperatively."
Blinding of outcome assessors All outcomes	High risk	Quote: "Interviewers and ophthalmologists were unaware of the treatment group of the patient at the preoperative tests. However, because there were perceptible differences between the 2 types of lenses during the slit-lamp examination, masking of interviewers and ophthalmologists was not feasible postoperatively."
Incomplete outcome data All outcomes	High risk	Judgement comment: rather high loss to follow-up (approximately 30%) potentially linked to outcome although similar loss to follow-up in both groups. Excluded people with high astigmatism after surgery Quote: "Patients with a postoperative refractive error in spherical equivalent (SE) of >1.5 D from emmetropia (in at least one eye) were excluded from further analyses (Fig 1; monofocal, n=8; multifocal, n=3)."
Selective outcome reporting	Unclear risk	Judgement comment: no access to protocol or trials registry entry

Palmer 2008

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal 1: Tecnis ZM900, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 26 (52) • *Mean age in years*: 73 • *% female*: 61 • *Ethnic group*: NR

	Multifocal 2: ReZoom, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 32 (64) • *Mean age in years*: 72 • *% female*: 69 • *Ethnic group*: NR Multifocal 3: TwinSet, Acri.Tec GmbH • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 32 (64) • *Mean age in years*: 74 • *% female*: 67 • *Ethnic group*: NR Monofocal: Tecnis Z9000, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 24 (48) • *Mean age in years*: 75 • *% female*: 53 • *Ethnic group*: NR **Inclusion criteria:** both eyes healthy with no disease except cataract **Exclusion criteria:** professional drivers **Pretreatment:** some differences in gender and SE between groups
Interventions	**Intervention characteristics** Multifocal 1 • *Name of lens*: Tecnis ZM900, AMO • *Type of lens*: diffractive • *Target*: NR Multifocal 2 • *Name of lens*: ReZoom, AMO • *Type of lens*: refractive • *Target*: NR Multifocal 3 • *Name of lens*: TwinSet, Acri.Tec GmbH • *Type of lens*: diffractive • *Target*: NR Monofocal • *Name of lens*: Tecnis Z9000, AMO • *Target*: NR **Both eyes operated**
Outcomes	**Outcomes:** distance and near VA, refraction, contrast sensitivity, visual symptoms, spectacle dependence for near tasks **Eyes:** binocular and monocular, no adjustment for within-person correlation

	Maximum follow-up: 3 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "The authors have no financial interest in the materials presented herein." **Country:** Spain **Setting:** eye hospital **Date study conducted:** June 2004 to March 2005 **Trial registration ID number:** NR **Author's name:** Ana Martinez Palmer **Institution:** University of Barcelona **Email:** 28653amp@comb.es **Address:** Department of Ophthalmology, Hospital Universitario del Mar and Hospital de la Esperanza, Memorial Cristobal Garrigosa, Autonomous University of Barcelona, Barcelona, Spain

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	High risk	Judgement comment: "Sealed envelope method" but not enough detail to be clear what they did and some differences between groups in terms of gender and preoperative SE
Blinding of participants and personnel All outcomes	Unclear risk	Judgement comment: participants were not told which lens they would receive but unclear whether any of them could have guessed. This was not discussed
Blinding of outcome assessors All outcomes	Unclear risk	Quote: "Refraction measurements were performed by a single independent observer who was unaware of the purpose of the study." Judgement comment: this judgement applies to refraction outcomes only
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to trial registry entry or study protocol

Peng 2012

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: AcrySof ReSTOR SN6AD1, Alcon Laboratories • *Number of people (eyes) randomised*: 51 (102) • *Number of people (eyes) excluded after randomisation*: 1 (2) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 50 (100) • *Mean age in years*: 66 • *% female*: 58 • *Ethnic group*: not stated (presume Chinese?) Monofocal: AcrySof IQ SN60WF, Alcon Laboratories • *Number of people (eyes) randomised*: 51 (102) • *Number of people (eyes) excluded after randomisation*: 0 (0) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 51 (102) • *Mean age in years*: 67 • *% female*: 47 • *Ethnic group*: not stated (presume Chinese?) **Inclusion criteria:** bilateral cataract; aged 50 to 75 years; axial length 22.0 mm to 24.0 mm; preoperative corneal astigmatism < 2.0 D; nuclear hardness from grade II to IV based on the Emery-Little classification; corneal endothelium cell count > 2000 cells/mm^2 **Exclusion criteria:** myopia or hyperopia > 3.00 D; history of amblyopia; fundus abnormalities; previous corneal or intraocular surgery; ocular comorbidity (e.g. previous trauma, glaucoma, abnormal iris, chronic uveitis, macular degeneration or retinopathy, neuro-ophthalmic disease). Intraoperative exclusion criteria: iris pupil trauma; vitreous loss; IOL tilt **Pretreatment:** some differences between study groups in pupil size and intraocular straylight
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: AcrySof ReSTOR SN6AD1, Alcon Laboratories • *Type of lens*: diffractive • *Target*: emmetropia Monofocal • *Name of lens*: AcrySof IQ SN60WF, Alcon Laboratories • *Type of lens*: NA • *Target*: emmetropia **Both eyes operated**
Outcomes	**Outcomes:** distance, near and intermediate VA, refraction, contrast sensitivity, defocus curves, aberrations, visual problems, satisfaction, spectacle independence, adverse effects (including PCO, glare, etc.) **Eyes:** binocular acuity, other measures largely unclear, no adjustment for within-person correlation **Maximum follow-up:** 6 months after surgery

Notes	**Sponsorship source:** Education Department of Liaoning Province grants, China (2009R53); and Science and Technology Department of Liaoning Province grants, China (2009225011-3) **Declaration of interest:** "No author has a proprietary or commercial interest in the materials or methods mentioned here." **Country:** China **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Jinsong Zhang **Institution:** Fourth Affiliated Hospital of China Medical University **Email:** cmu.jszhang@gmail.com **Address:** Department of Ophthalmology the Fourth Affiliated Hospital of China Medical University, 11 Xinhua Road, Shenyang, 110005, China

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Unclear risk	Judgement comment: method of randomisation not described. Opaque envelopes were selected
Allocation concealment	Low risk	Quote: "Patients were randomised to each of the IOLs by selecting an unmarked, opaque envelope for each patient from a total of 102 envelopes evolving the type of one of the IOLs. The envelope was opened by a staff not involved in our study."
Blinding of participants and personnel All outcomes	Unclear risk	Quote: "This prospective, randomised, comparative, and observer-masked trial recruited 204 eyes (102 patients)." Judgement comment: it was not clear how the masking was done
Blinding of outcome assessors All outcomes	Unclear risk	Quote: "This prospective, randomised, comparative, and observer-masked trial." Judgement comment: it was not clear how the masking was done
Incomplete outcome data All outcomes	Low risk	Quote: "A total of 101 patients were available at 6 month postoperatively, owing to the presence of posterior capsular opacities in the multifocal IOL group. Therefore, 50 patients (100 eyes) in the multifocal IOL group and 51 patients (102 eyes) in the

Peng 2012 (*Continued*)

		monofocal IOL group were available for analysis." Judgement comment: 100/101 participants followed to 6 months
Selective outcome reporting	Unclear risk	Judgement comment: no protocol or trials registry entry.

Percival 1993

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: MPC25, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 25 (25) • *Mean age in years (range)*: 77 (59 to 89) • *% female*: 58 • *Ethnic group*: NR Monofocal: PC25, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 25 (25) • *Mean age in years (range)*: 78 (60 to 92) • *% female*: 58 • *Ethnic group*: NR **Inclusion criteria:** not specified **Exclusion criteria:** any other ocular pathology **Pretreatment:** 5 participants dropped out of study (due to death, undiagnosed diabetic retinopathy and undiagnosed macular degeneration) and replaced by other randomised participants - unclear which groups these participants were lost from
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: MPC25, AMO • *Type of lens*: refractive • *Target*: SE -0.50 to +0.50 D with cylinder < 1.00 D Monofocal • *Name of lens*: PC25, AMO • *Type of lens*: NA • *Target*: SE -0.30 to -1.30 D with cylinder of 1.00 to 1.75 D **1 eye operated**

Percival 1993 (*Continued*)

Outcomes	**Outcomes:** distance and near VA, refraction, contrast sensitivity, satisfaction, operative and postoperative complications, and adverse effects (including glare, etc.) **Eyes:** 1 eye operated per person **Maximum follow-up:** 4 to 6 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** NR **Country:** UK **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** SPB Percival **Institution:** Scarborough Hospital **Email:** NR **Address:** Department of Ophthalmology, Scarborough Hospital, Scarborough, North Yorkshire, YO12 6QL, UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	Unclear risk	Judgement comment: NR.
Blinding of participants and personnel All outcomes	High risk	Judgement comment: no suggestion of masking in the trial description
Blinding of outcome assessors All outcomes	High risk	Judgement comment: no description of masking.
Incomplete outcome data All outcomes	High risk	Judgement comment: follow-up not clearly reported: 5/30 dropped out and not clear which group they were allocated to
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Rasp 2012

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal 1: AcrySof ReSTOR SN6AD3, Alcon Laboratories • *Number of people (eyes) randomised*: NR

	• *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 28 (56) • *Mean age in years (range)*: 76 (62 to 91) • *% female*: NR • *Ethnic group*: NR Multifocal 2: AT LISA 366D, Carl Zeiss • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 30 (60) • *Mean age in years (range)*: 74 (63 to 89) • *% female*: NR • *Ethnic group*: NR Multifocal 3: ReZoom, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 30 (60) • *Mean age in years (range)*: 79 (66 to 89) • *% female*: NR • *Ethnic group*: NR Multifocal 4: Tecnis ZMA00, AMO • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 29 (58) • *Mean age in years (range)*: 75 (62 to 87) • *% female*: NR • *Ethnic group*: NR Monofocal: Acri.Smart 48S (also known as CT Spheris 209M), Carl Zeiss • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 29 (58) • *Mean age in years (range)*: 76 (63 to 80) • *% female*: NR • *Ethnic group*: NR **Inclusion criteria:** aged > 60 year; and participants seeking bilateral cataract refractive surgery for presbyopia in the presence of significant nuclear sclerosis **Exclusion criteria:** additional ocular disease and illiteracy **Pretreatment:** there were statistically significant between-group differences in sphere, cylinder, corrected distance VA, axial length, anterior chamber depth and IOL power. These differences were the result of the randomisation process and do not represent selection bias
Interventions	**Intervention characteristics** Multifocal 1 • *Name of lens*: AcrySof ReSTOR SN6AD3, Alcon Laboratories • *Type of lens*: refractive/diffractive

	• *Target*: NR Multifocal 2 • *Name of lens*: AT LISA 366D, Carl Zeiss • *Type of lens*: refractive-diffractive bifocal • *Target*: NR Multifocal 3 • *Name of lens*: ReZoom, AMO • *Type of lens*: refractive • *Target*: NR Multifocal 4 • *Name of lens*: Tecnis ZMA00, AMO • *Type of lens*: diffractive • *Target*: NR Monofocal • *Name of lens*: Acri.Smart 48S (also known as CT Spheris 209M), Carl Zeiss • *Type of lens*: NA • *Target*: NR **Both eyes operated**
Outcomes	**Outcomes:** distance VA, refraction, reading ability **Eyes:** monocular, no adjustment for within-person correlation **Maximum follow-up:** 12 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "Drs. Grabner and Dexl were patent owners of the Salzburg Reading Desktechnology (now owned by SRD-Vision, LLC). No other author has a financial or proprietary interest in any material or method mentioned." **Country:** Austria **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Alois K Dexl **Institution:** Paracelsus Medical University **Email:** a.dexl@salk.at **Address:** Paracelsus Medical University, Department of Ophthalmology, Salzburg, Austria

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	Unclear risk	Judgement comment: NR.
Blinding of participants and personnel All outcomes	High risk	Judgement comment: NR.

Rasp 2012 (*Continued*)

Blinding of outcome assessors All outcomes	Unclear risk	Judgement comment: NR.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Rossetti 1994

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: 3M Vision Care multifocal IOL • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 38 (38) • *Mean age in years (range)*: 72 (55 to 84) • *% female*: 61 • *Ethnic group*: NR Monofocal, NR • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 42 (42) • *Mean age in years (range)*: 70 (50 to 90) • *% female*: 57 • *Ethnic group*: NR **Inclusion criteria:** astigmatism ≤ 2.5 D; SE in the fellow eye of no more than 2.5 D; cataract in 1 eye and clear lens or early cataract in the fellow eye that would not require surgery during the study **Exclusion criteria:** astigmatism > 1.5 D; IOL in fellow eye; fundus abnormalities causing significant vision impairment; could not be followed for 1 year **Pretreatment:** no group differences
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: 3M Vision Care multifocal IOL • *Type of lens*: refractive and diffractive • *Target*: emmetropia Monofocal • *Name of lens*: NR • *Type of lens*: NA • *Target*: emmetropia

Rossetti 1994 (*Continued*)

	1 eye operated
Outcomes	**Outcomes:** distance and near VA, contrast sensitivity, satisfaction, spectacle dependence, adverse effects (including glare, halos, etc.) **Eyes:** 1 eye operated per participant **Maximum follow-up:** 12 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** NR **Country:** Italy **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Luca Rossetti **Institution:** University of Milan **Email:** NR **Address:** Department of Ophthalmology, University of Milan, Institute of Biomedical Sciences, S. Paulo Hospital, Milan, Italy

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	Unclear risk	Judgement comment: NR.
Blinding of participants and personnel All outcomes	High risk	Judgement comment: no information on masking.
Blinding of outcome assessors All outcomes	High risk	Judgement comment: no information on masking.
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to trials registry entry or study protocol

Sen 2004

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: Array SA40N, AMO • *Number of people (eyes) randomised*: 40 (NR)

	• *Number of people (eyes) excluded after randomisation*: 5 (NR) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 35 (53) • *Mean age in years (range)*: 69 (48 to 84) • *% female*: 74 • *Ethnic group*: NR Monofocal: PhacoFlex II SI40NB, AMO • *Number of people (eyes) randomised*: 40 (NR) • *Number of people (eyes) excluded after randomisation*: 0 (0) • *Number of people (eyes) lost to follow-up*: 0 (0) • *Number of people (eyes) analysed (at longest time point)*: 40 (67) • *Mean age in years (range)*: 72 (41 to 88) • *% female*: 63 • *Ethnic group*: NR **Inclusion criteria:** both eyes had to be healthy, with no disease except cataract; required to understand the possible benefit of having implantation of a multifocal IOL instead of a monofocal IOL; have potential good vision in both eyes after cataract surgery and IOL implantation **Exclusion criteria:** participants who would likely be more sensitive to glare, halos, and changes in contrast sensitivity; and who did not have realistic expectations of the new technology **Pretreatment:** there were no significant between-group differences in demographics including age, sex, education and profession. VA and the type of cataract were comparable between groups, and no participant in either group had ocular comorbidity in addition to cataract. The VF-7 and CS-5 values were almost identical in the 2 groups preoperatively, and the percentages of those reporting being dissatisfied with their vision (43.1% in multifocal group and 57.6% in monofocal group) or very dissatisfied with their vision (19.6% in multifocal group and 18.2% in monofocal group) were comparable. The proportion of participants with moderate (35.3% in multifocal group and 25.8% in monofocal group) or a great deal (25.5% in multifocal group and 21.2% in monofocal group) of self-reported trouble with vision was also comparable between the 2 groups
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Array SA40N, AMO • *Type of lens*: refractive • *Target*: NR Monofocal • *Name of lens*: PhacoFlex II SI40NB, AMO • *Type of lens*: NA • *Target*: NR **1 or both eyes operated**
Outcomes	**Outcomes:** distance and near VA, refraction, contrast sensitivity, range of accommodation, visual function (VF-7), visual symptoms, satisfaction, adverse effects (glare, halos, etc.) **Eyes:** monocular acuity, no adjustment for within-person correlation **Maximum follow-up:** 1 month after surgery

Notes	**Sponsorship source:** supported by a special government grant for research (TYH 3234), Helsinki University Eye Hospital, and a grant from the Finnish Eye Foundation, Helsinki Finland, and a grant to help in statistical analysis from Allergan Norden **Declaration of interest:** "None of the authors has a financial or proprietary interest in any material or method mentioned." **Country:** Finland **Setting:** eye Hospital **Date study conducted:** February 1998 to August 2002 **Trial registration ID number:** NR **Author's name:** Risto J Uusitalo **Institution:** Helsinki University Eye Hospital **Email:** risto.uusitalo@hus.fi **Address:** Helsinki University Eye Hospital, PO Box 220, 00029 HUS, Helsinki, Finland

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Unclear risk	Judgement comment: NR.
Allocation concealment	Unclear risk	Judgement comment: sealed-envelope method was used but no further details given
Blinding of participants and personnel All outcomes	High risk	Judgement comment: participants and personnel were not blinded
Blinding of outcome assessors All outcomes	High risk	Judgement comment: no blinding was done.
Incomplete outcome data All outcomes	High risk	Judgement comment: 5/40 participants in multifocal group only excluded after randomisation
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Steinert 1992

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** yes
Participants	**Baseline characteristics** Multifocal: Array MPC-25NB, AMO • *Number of people (eyes) randomised*: 40 • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: 8

	• *Number of people (eyes) analysed (at longest time point)*: 32 (32) • *Mean age in years*: 72 • *% female*: 55 • *Ethnic group*: NR Monofocal: PC-26NB, AMO • *Number of people (eyes) randomised*: 40 • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: 10 • *Number of people (eyes) analysed (at longest time point)*: 30 (30) • *Mean age in years*: 71 • *% female*: 78 • *Ethnic group*: NR **Inclusion criteria:** functionally disabling cataracts; potential acuity of ≥ 20/25; preoperative cylinder of ≤ 1.5 D; axial myopia < 26 mm; phakic fellow eye **Exclusion criteria:** non-cataract ocular pathology **Pretreatment:** significant gender difference between both study groups (P = 0.033)
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Array MPC-25NB, AMO • *Type of lens*: refractive • *Target*: NR Monofocal • *Name of lens*: PC-26NB, AMO • *Type of lens*: NA • *Target*: NR **1 eye operated**
Outcomes	**Outcomes:** distance and near, refraction, contrast sensitivity, visual problems (including glare, halos, etc.), satisfaction and spectacle use **Eyes:** Only 1 eye operated **Maximum follow-up:** 3 to 6 months after surgery (mean follow-up approximately 4 months)
Notes	**Sponsorship source:** "Supported in part by Allergan Medical Optics, Irving, California" **Declaration of interest:** "None of the authors has any proprietary or financial interest in the devices used in this study. Dr Steinert is a member of the Allergan Scientific Advisory Committee, for which a stipend is received. Drs Steinert and Oksman are unpaid medical monitors for the multifocal intraocular lens used in this study." **Country:** USA **Setting:** eye hospital **Date study conducted:** NR **Trial registration ID number:** NR **Author's name:** Roger F Steinert **Institution:** Massachusetts Eye and Ear Infirmary and the Harvard Medical School, Boston, MA **Email:** NR **Address:** Center for Eye Research, Ophthalmic Consultants of Boston, 50 Staniford St, Boston, MA 02114, USA

Steinert 1992 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Unclear risk	Judgement comment: randomised block design but no further details
Allocation concealment	Unclear risk	Judgement comment: NR.
Blinding of participants and personnel All outcomes	Low risk	Quote: "The lenses were centrally encoded and labelled such that the patient record did not indicate which IOL was implanted. Both the patient and ophthalmic technical staff performing objective measures were masked regarding the identity of the implant."
Blinding of outcome assessors All outcomes	Low risk	Quote: "The lenses were centrally encoded and labelled such that the patient record did not indicate which IOL was implanted. Both the patient and ophthalmic technical staff performing objective measures were masked regarding the identity of the implant."
Incomplete outcome data All outcomes	High risk	Judgement comment: only 77% followed up and not clear if equal between groups
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

Wilkins 2013

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group **Multicentre:** yes
Participants	**Baseline characteristics** Multifocal: Tecnis ZM900, AMO • *Number of people (eyes) randomised*: 106 (212) • *Number of people (eyes) excluded after randomisation*: 6 (12) • *Number of people (eyes) lost to follow-up*: 6 (12) • *Number of people (eyes) analysed (at longest time point)*: 94 (188) • *Mean age in years (range)*: 67 (NR) • *% female*: 56 • *Ethnic group*: NR Monofocal: Akreos AO, Bausch & Lomb

	• *Number of people (eyes) randomised*: 105 (210) • *Number of people (eyes) excluded after randomisation*: 2 (4) • *Number of people (eyes) lost to follow-up*: 10 (20) • *Number of people (eyes) analysed (at longest time point)*: 93 (186) • *Mean age in years (range)*: 69 (NR) • *% female*: 58 • *Ethnic group*: NR **Inclusion criteria:** bilateral cataract surgery; aged 30 to 90 years; axial length measurable using the Zeiss IOLMaster (Oberkochen, Germany) **Exclusion criteria:** IOL power available to achieve emmetropia with IOL or -1.5 D with the Akreos AO IOL (Bausch & Lomb, Rochester, NY); significant copathology likely to reduce acuity or visual field; keratometric astigmatism likely to be ≥ 1.0 D in either eye after surgery; amblyopia; congenital or traumatic cataracts; poor comprehension of written or spoken English; inability to give informed consent **Pretreatment:** the 2 groups of the study were similar in age (68.7 ± 12.0 years for monovision vs 67.0 ± 11.2 for multifocal) and sex (female 57.5% for monovision vs female 55.7% for multifocal)
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: Tecnis ZM900, AMO • *Type of lens*: diffractive • *Target*: emmetropia Monofocal • *Name of lens*: Akreos AO, Bausch & Lomb • *Type of lens*: monovision • *Target*: emmetropia in distance eye; myopia -1.0 to -1.5 D in the near eye **Both eyes operated**
Outcomes	**Outcomes:** distance, near and intermediate VA, refraction, contrast sensitivity, straylight, aberrations, stereo acuity, visual problems (dysphopsia), satisfaction, spectacle dependence, visual function (VF-14) **Eyes:** binocular acuity or right eye only **Maximum follow-up:** 4 months after surgery
Notes	**Sponsorship source:** "Funded by an unrestricted grant from Abbott Medical Optics and Bausch &Lomb. The funding organizations had no role in the design or conduct of this research. This work was supported in part by the UK National Institute for Health Research Biomedical Research Centre in Ophthalmology at Moorfields Eye Hospital and UCL Institute of Ophthalmology." **Declaration of interest:** "The author(s) have no proprietary or commercial interest in any materials discussed in this article." **Country:** UK **Setting:** eye hospital **Date study conducted:** April 2007 to August 2010 **Trial registration ID number:** ISRCTN37400841 **Author's name:** Mark Wilkins **Institution:** Moorfields Eye Hospital **Email:** mark.wilkins@moorfields.nhs.uk

	Address: Moorfields Eye Hospital, 162 City Road, London, EC1V 2PD, UK

Risk of bias

Bias	Authors' judgement	Support for judgement
Sequence generation	Low risk	Quote: "Randomization was conducted using minimization that incorporated a single factor, hospital site, using Minim, a free minimization program (available at www-users.york.ac.uk/wmb55/guide/ minim.htm, accessed July 22, 2013)."
Allocation concealment	Low risk	Quote: "Access to the procedure was via a medical statistician within the Research and Development department at Moorelds Eye Hospital. The statistician was phoned shortly before surgery after patients had provided written informed consent and been registered into the trial. Sequentially numbered sealed opaque envelopes were available as a backup facility."
Blinding of participants and personnel All outcomes	Low risk	Quote: "The surgeons performing the surgery and staff reviewing the patient at 4 months were not masked to the IOL inserted. However, patients were masked to the lens group."
Blinding of outcome assessors All outcomes	High risk	Judgement comment: the surgeons performing the surgery and staff reviewing the participant at 4 months were not masked to the IOL inserted. However, participants were masked to the lens group
Incomplete outcome data All outcomes	Low risk	Quote: "We planned to conduct the analysis according to the intent-to-treat principal. Primary outcome data were not available on 12% of patients. We compared missing rates between treatment groups and assessed whether missingness was associated with any baseline covariate. We then conducted an available case analysis."
Selective outcome reporting	High risk	Judgement comment: some differences between outcomes on trial register and those reported, e.g. reading speed

Zhao 2010

Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group Surgery in 1 eye only **Multicentre:** no
Participants	**Baseline characteristics** Multifocal: AcrySof ReSTOR SA60D3, Alcon Laboratories • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 72 (72) • *Mean age in years (range)*: 65 (34 to 80) • *% female*: 49 • *Ethnic group*: NR Monofocal: AcrySof SA60AT, Alcon Laboratories • *Number of people (eyes) randomised*: NR • *Number of people (eyes) excluded after randomisation*: NR • *Number of people (eyes) lost to follow-up*: NR • *Number of people (eyes) analysed (at longest time point)*: 89 (72) • *Mean age in years (range)*: 67 (51 to 92) • *% female*: 46 • *Ethnic group*: NR **Inclusion criteria:** corrected distance VA and uncorrected distance VA < 10/25; nuclear hardness from grade II to IV (Emery-Little classification); corneal astigmatism < 1.50 D; corneal endothelium cell count > 2000 cells/mm^2; ability to understand and sign an informed consent form **Exclusion criteria:** aged < 21 years; myopia or hyperopia > 3.00 D; history of amblyopia; fundus abnormalities that could cause significant visual impairment; previous intraocular surgery; ocular comorbidity (e.g. previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal opacity, senile miosis hyporeactive pupil; alpha-antagonist (tamsulosin) treatment because of risk of floppy-iris syndrome; intraoperative iris pupil trauma, vitreous loss and IOL implantation outside the capsular bag **Pretreatment:** no important differences between study groups
Interventions	**Intervention characteristics** Multifocal • *Name of lens*: AcrySof ReSTOR SA60D3, Alcon Laboratories • *Type of lens*: diffractive • *Target*: NR Monofocal • *Name of lens*: AcrySof SA60AT, Alcon Laboratories • *Type of lens*: NA • *Target*: NR **1 eye operated**
Outcomes	**Outcomes:** distance and near VA, contrast sensitivity, defocus curves, aberrations, visual function (VF-7), satisfaction, spectacle independence, adverse effects (including PCO, glare, etc.) **Eyes:** 1 eye per person

Zhao 2010 (*Continued*)

	Maximum follow-up: 6 months after surgery
Notes	**Sponsorship source:** NR **Declaration of interest:** "No author has a financial or proprietary interest in any material or method mentioned." **Country:** China **Setting:** Department of Ophthalmology, Affiliated Hospital of Qingdao University Medical College **Date study conducted:** October 2005 and March 2007 **Trial registration ID number:** NR **Author's name:** Guiqui Zhao **Institution:** Affiliated Hospital of Qingdao University Medical College **Email:** zhaoguiqin-good@126.com **Address:** Department of Ophthalmology, the Affiliated Hospital of Qingdao University Medical College, Qingdao, 266003, China

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Sequence generation	Low risk	Quote: "Immediately preoperatively, the patients were randomised with a coin toss to receive an AcrySof SA60AT single-piece monofocal IOL (monofocal group) or an AcrySof ReSTOR SA60D3 multifocal IOL (multifocal group) (both Alcon, Inc.)."
Allocation concealment	Unclear risk	Judgement comment: not described.
Blinding of participants and personnel All outcomes	Unclear risk	Judgement comment: participants and medical staff collecting data were masked to the IOL. However no description of masking of staff providing care
Blinding of outcome assessors All outcomes	Low risk	Judgement comment: the participants and the medical staff who collected visual function and quality-of-life data were masked to the type of IOL each participant received
Incomplete outcome data All outcomes	Unclear risk	Judgement comment: follow-up NR.
Selective outcome reporting	Unclear risk	Judgement comment: no access to study protocol or trials registry entry

BCVA: best-corrected visual acuity; D: dioptre; IOL: intraocular lens; n: number of participants; NA: not applicable; NR: not reported; PCO: posterior capsule opacification; SE: spherical equivalent; VA: visual acuity.

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

Study	Reason for exclusion
Alio 2011a	Participants not randomly allocated to intervention.
Alio 2011b	Participants not randomly allocated to intervention.
Alio 2011c	Participants not randomly allocated to intervention.
Alio 2015	Participants not randomly allocated to intervention.
Allen 2009	Participants not randomly allocated to intervention.
Cionni 2009	Participants not randomly allocated to intervention.
Hayashi 2009a	Participants not randomly allocated to intervention.
Hayashi 2009b	Participants not randomly allocated to intervention.
Hayashi 2009c	Participants not randomly allocated to intervention.
Hayashi 2010	Participants not randomly allocated to intervention.
Hida 2009	Participants not randomly allocated to intervention.
Huang 2010	Chinese-speaking Cochrane author spoke to trialists and confirmed to us that participants were not randomly allocated to the interventions
Ji 2011	Chinese-speaking Cochrane author spoke to trialists and confirmed to us that participants were not randomly allocated to the interventions
Liang 2005	Chinese-speaking Cochrane author spoke to trialists and confirmed to us that participants were not randomly allocated to the interventions
Maxwell 2008	Participants not randomly allocated to intervention.
NCT01088282	Trial was cancelled and never conducted. Personal communication with author
Ortiz 2008	Participants not randomly allocated to intervention.
Puell 2015	Participants not randomly allocated to intervention.
Richter-Mueksch 2002	Not randomised, case-control study.
Rocha 2005	Participants not randomly allocated to intervention.

(*Continued*)

Shah 2010	Retrospective study.
Souza 2006	Participants not randomly allocated to intervention.
Walkow 1997	Randomised trial comparing diffractive with refractive design multifocal IOLs. Excluded because of the lack of a monofocal control group
Xu 2007	Chinese-speaking Cochrane author spoke to trialists and confirmed to us that participants were not randomly allocated to the interventions
Zhang 2011	Participants not randomly allocated to intervention.

IOL: intraocular lens.

DATA AND ANALYSES

Comparison 1. Multifocal versus monofocal intraocular lenses

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Unaided distance visual acuity (VA) worse than 6/6	8	682	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.89, 1.03]
2 Mean unaided distance VA	6		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Corrected distance VA worse than 6/6	8		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4 Mean corrected distance VA	6		Mean Difference (IV, Random, 95% CI)	Totals not selected
5 Mean intermediate VA	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 Unaided	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 Corrected	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Unaided near VA worse than J3/J4 or equivalent	8	782	Risk Ratio (M-H, Random, 95% CI)	0.20 [0.07, 0.58]
7 Mean unaided near VA	5		Mean Difference (IV, Random, 95% CI)	Totals not selected
8 Corrected near VA worse than J3/J4 or equivalent	4	344	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.08, 1.27]
9 Mean corrected near VA	6		Mean Difference (IV, Random, 95% CI)	Totals not selected
10 Spectacle dependence (any)	10	1000	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.55, 0.73]
11 Spectacle dependence (distance or near)	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
11.1 Distance	4	618	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.46, 1.09]
11.2 Near	6	772	Risk Ratio (M-H, Random, 95% CI)	0.53 [0.40, 0.71]
12 Contrast sensitivity	4	288	Mean Difference (IV, Random, 95% CI)	-0.09 [-0.26, 0.08]
13 Participant-reported outcomes: visual function questionnaires	4		Mean Difference (IV, Random, 95% CI)	Totals not selected
14 Participant-reported outcomes: vision-related quality-of-life questionnaires	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
15 Participant-reported outcomes: satisfaction scores	6		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
16 Participant-reported outcomes: "good" or "satisfied" with vision	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
16.1 Overall	4	344	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.86, 1.08]
16.2 Near vision	1	80	Risk Ratio (M-H, Random, 95% CI)	1.42 [1.13, 1.78]
16.3 Distance vision	1	80	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.72, 1.10]
17 Participant-reported outcomes: other data on satisfaction			Other data	No numeric data
18 Participant-reported outcomes: cataract symptom scores	2	257	Mean Difference (IV, Fixed, 95% CI)	1.01 [0.39, 1.64]
19 Participant-reported outcomes: glare	7	544	Risk Ratio (M-H, Random, 95% CI)	1.41 [1.03, 1.93]
20 Participant-reported outcomes: haloes	7	662	Risk Ratio (M-H, Random, 95% CI)	3.58 [1.99, 6.46]

21 Participant-reported outcomes: dysphotopsia	1	Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 2. Multifocal versus monovision

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Visual acuity (VA)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Mean unaided distance VA	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Mean unaided intermediate VA	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 Mean unaided near VA	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Spectacle dependence	2		Risk Ratio (IV, Fixed, 95% CI)	Subtotals only
2.1 Overall	2	262	Risk Ratio (IV, Fixed, 95% CI)	0.40 [0.30, 0.53]
2.2 Near vision	1	75	Risk Ratio (IV, Fixed, 95% CI)	0.40 [0.22, 0.70]
2.3 Distance vision	1	75	Risk Ratio (IV, Fixed, 95% CI)	1.54 [0.27, 8.70]
3 Contrast sensitivity	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4 Participant-reported outcomes: visual function	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 Overall VF-14 score	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 Near vision VF-14 score	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.3 Distance vision VF-14 score	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Participant-reported outcomes: glare	1		Risk Ratio (IV, Fixed, 95% CI)	Totals not selected
6 Participant-reported outcomes: glare mean score	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7 Participant-reported outcomes: shadows mean score	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

ADDITIONAL TABLES

Table 1. Risk of bias assessment

Domain	Low risk of bias	Unclear risk of bias	High risk of bias
Sequence generation	Computer-generated list, random table, other method of generating random list	Not reported how list was generated. Trial may be described as "randomised" but with no further details	Alternate allocation, date of birth, records (these RCTs were excluded)
Allocation concealment	Central centre (web/telephone access), sealed opaque envelopes	Not reported how allocation administered. Trial may be described as "randomised" but with no further details	Investigator involved in treatment allocation or treatment allocation clearly not masked

Table 1. Risk of bias assessment (*Continued*)

Masking of participants and personnel	Clearly stated that participants and personnel (apart from surgeon) not aware of which lens received	Described as "double blind" with no information on who was masked	No information on masking. As lenses were different, we assumed that in the absence of reporting on this participants and personnel were not masked
Masking of outcome assessors	Clearly stated that outcome assessors were masked.	Described as "double blind" with no information on who was masked	No information on masking. As lenses were different, we assumed that in absence of reporting on this outcome assessors were not masked
Incomplete outcome data	Missing data < 20% (i.e. > 80% follow-up) and equal follow-up in both groups and no obvious reason why loss to follow-up should be related to outcome	Follow-up not reported or missing data > 20% (i.e. follow-up < 80%) but follow-up equal in both groups	Follow-up different in each group or related to outcome (or both)
Selective outcome reporting	All outcomes in protocol or trials registry entry (or both) are reported	No access to protocol or trials registry entry.	Outcomes in protocol or trials registry entry (or both) selectively reported
Other sources of bias	No other source of bias.	Trial stopped early due to poor recruitment. Baseline imbalance but not clear that it is important.	Trial stopped early because of outcome. Important baseline imbalance that might have an effect on the results

RCT: randomised controlled trial.

Table 2. Included studies

Study	Country	Multicentre?	Eyes operated	Number of people randomised	Number of people randomised (assuming same as number analysed when not reported)	Number of people included in the analysis	Number of eyes included in the analysis	For eye outcomes, reporting by eye or person?
Cillino 2008	Italy	No	Both	NR	62	62	124	Eye (no adjustment for within-person correlation)

Table 2. Included studies *(Continued)*

el Maghraby 1992	Saudi Arabia	No	1	77	77	61	61	Eye (unilateral surgery)
Haaskjold 1998a	Europe	Yes	1	NR	221	221	221	Eye (unilateral surgery)
Harman 2008	England	No	Both	60	60	43	86	Person
Javitt 2000	USA, Germany, Austria	Yes	Both	261	261	235	470	Person
Ji 2013	China	No	1 or both	NR	51	51	64	Eye (no adjustment for within-person correlation)
Jusufovic 2011	Bosnia and Herzegovina	No	1	NR	100	100	100	Eye (unilateral surgery)
Kamlesh 2001	India	No	1	NR	40	40	40	Eye (unilateral surgery)
Labiris 2015	Greece	No	Both	75	75	75	150	-
Leyland 2002	England	No	Both	69	69	60	120	Person
Nijkamp 2004	Netherlands	No	Both	190	190	137	274	Unclear
Palmer 2008	Spain	No	Both	NR	114	114	228	Eye (no adjustment for within-person correlation)
Peng 2012	China	No	Both	102	102	101	202	Eye (no adjustment for within-person correlation)
Percival 1993	England	No	1	NR	50	50	50	Eye (unilateral surgery)

Table 2. Included studies *(Continued)*

Rasp 2012	Austria	No	Both	NR	146	146	292	Eye (no adjustment for within-person correlation)
Rossetti 1994	Italy	No	1	NR	80	80	80	Eye (unilateral surgery)
Sen 2004	Finland	No	1 or both	80	80	75	110	Eye (no adjustment for within-person correlation)
Steinert 1992	USA	Yes	1	80	80	62	62	Eye (unilateral surgery)
Wilkins 2013	England	Yes	Both	211	211	187	374	Person
Zhao 2010	China	No	1	NR	161	161	161	Eye (unilateral surgery)
Total					**2230**	**2061**	**3194**	

NR: not reported.

Table 3. Age and sex of participants in included studies

Study	Mean age in years (range)					% female				
	Multifocal 1	Multifocal 2	Multifocal 3	Multifocal 4	Monofocal	Multifocal 1	Multifocal 2	Multifocal 3	Multifocal 4	Monofocal
Cillino 2008	57	65	60	-	68	56	47	63	-	47
el Maghraby 1992	57 (45 to 90)	-	-	-	56 (45 to 70)	59	-	-	-	
Haaskjold 1998a	67 (max 88)	-	-	-	67 (max 90)	-	-	-	-	-

Table 3. Age and sex of participants in included studies (*Continued*)

Harman 2008	73	-	-	-	71	50	-	-	-	60
Javitt 2000	74	-	-	-	75	51	-	-	-	61
Ji 2013	63 (52 to 71)	-	-	-	63 (55 to 75)	58	-	-	-	56
Jusufovic 2011	43 (20 to 57)	-	-	-	50 (26 to 64)	46	-	-	-	42
Kamlesh 2001	56	-	-	-	54	-	-	-	-	-
Labiris 2015	61	-	-	-	60	-	-	-	-	-
Leyland 2002	75	74	NA	-	76	53	60	-	-	44
Nijkamp 2004	72	-	-	-	72	67	-	-	-	64
Palmer 2008	73	72	74	-	75	61	69	67	-	53
Peng 2012	66	NA	NA	-	67	58	-	-	-	47
Percival 1993	77 (59 to 89)	-	-	-	78 (60 to 92)	58	-	-	-	58
Rasp 2012	76 (62 to 91)	74 (63 to 89)	79 (66 to 89)	75 (62 to 87)	76 (63 to 80)	-	-	-	-	-
Rossetti 1994	72 (55 to 84)	-	-	-	70 (50 to 90)	61	-	-	-	57
Sen 2004	69 (48 to 84)	-	-	-	72 (41 to 88)	74	-	-	-	63
Steinert 1992	72	-	-	-	71	55	-	-	-	78
Wilkins 2013	67	-	-	-	69	56	-	-	-	58

Table 3. Age and sex of participants in included studies (*Continued*)

Zhao 2010	65 (34 to 80)	-	-	-	67 (51 to 92)	49	-	-	-	46

max: maximum; NA: not applicable.

Table 4. Lenses used in included studies

Study	Multifocal lens model (manufacturer) type	Monofocal lens name (manufacturer)
Cillino 2008	Array SA40N (AMO) refractive	AR40 (AMO)
	ReZoom (AMO) refractive	
	Tecnis ZM900 (AMO) diffractive	
el Maghraby 1992	815LE (3M Vision Care) diffractive	15LE (3M Vision Care)
Haaskjold 1998a	808X (Pharmacia Ophthalmics) diffractive bifocal	808D (Pharmacia Ophthalmics)
Harman 2008	Array SA40N (AMO) refractive	Clariflex (AMO)
Javitt 2000	Array SA40N (AMO) refractive	PhacoFlex II SI40NB (AMO)
Ji 2013	AcrySof ReSTOR (Alcon Laboratories) diffractive	AcrySof Natural (Alcon Laboratories)
Jusufovic 2011	ReZoom NXG1 (AMO) refractive	AcrySof MA60BM (Alcon Laboratories)
Kamlesh 2001	Progress 3 (Laboratoires Domilens) refractive	Flex 65 (Laboratoires Domilens)

Table 4. Lenses used in included studies (*Continued*)

Labiris 2015	Isert PY60MV (Hoya Surgical Optics)	SN60WF (Alcon Laboratories)
Leyland 2002	Array SA40NB (Allergan) refractive	PhacoFlex I SI40N (Allergan)
	TrueVista 68STUV (Storz) refractive	
Nijkamp 2004	Array SA40N (AMO) refractive	PhacoFlex II SI40NB (AMO)
Palmer 2008	Tecnis ZM900 (AMO) diffractive	Tecnis Z9000 (AMO)
	ReZoom (AMO) refractive	
	TwinSet (Acri.Tec, GmbH) diffractive	
Peng 2012	AcrySof ReSTOR SN6AD1 (Alcon Laboratories) diffractive	AcrySof IQ SN60WF (Alcon Laboratories)
Percival 1993	MPC25 (AMO) refractive	PC25 (AMO)
Rasp 2012	AcrySof ReSTOR SN6AD3 (Alcon Laboratories) diffractive	Acri.Smart 48S (also known as CT Spheris 209M) (Carl Zeiss)
	AT LISA 366D (Carl Zeiss) diffractive	
	ReZoom (AMO) refractive	
	Tecnis ZMA00 (AMO) diffractive	
Rossetti 1994	3M lens “with both refractive and diffractive optics”	Model not reported

Table 4. Lenses used in included studies (*Continued*)

Sen 2004	Array SA40N (AMO) refractive	PhacoFlex II SI40NB (AMO)
Steinert 1992	Array MPC-25NB (AMO) refractive	PC-25NB (AMO)
Wilkins 2013	Tecnis ZM900 (AMO) diffractive	Akreos AO (Bausch & Lomb)
Zhao 2010	AcrySof ReSTOR SA60D3 (Alcon Laboratories) diffractive	AcrySof SA60AT (Alcon Laboratories)

AMO: Advanced Medical Optics.

Table 5. Refractive aims in included studies

Study ID	Refractive aim
Cillino 2008	Emmetropia
el Maghraby 1992	Emmetropia
Haaskjold 1998a	Not stated
Harman 2008	Emmetropia
Javitt 2000	Not stated
Ji 2013	Not stated
Jusufovic 2011	Not stated
Kamlesh 2001	Not stated
Labiris 2015	Multifocal: +3.00 D of near addition; monofocal (monovision): targeting -0.50 D in the dominant eye and -1.25 D in the non-dominant eye
Leyland 2002	Emmetropia
Nijkamp 2004	Within 1 D of emmetropia
Palmer 2008	Between emmetropia and -0.5 D for monofocal emmetropia for multifocal

Table 5. Refractive aims in included studies (*Continued*)

Peng 2012	Emmetropia
Percival 1993	Emmetropia (treatment)/myopic astigmatism (control)
Rasp 2012	Not stated
Rossetti 1994	< 2 D astigmatism
Sen 2004	Not stated
Steinert 1992	Not stated
Wilkins 2013	Multifocal: emmetropia Monofocal (monovision): Emmetropia in distance eye; myopia -1.0 D to -1.5 D in the near eye
Zhao 2010	Not stated

D: dioptre.

Table 6. Subgroup analyses: refractive versus diffractive lenses

Outcome	Effect measure	Analysis model	Studies	Number of eyes	Effect estimate (95% CI)	I^2	Test for interaction (P value)
Unaided distance VA worse than 6/6	**RR**	**Random**	**8**	**682**	**0.96 (0.89,1.03)**	**13.62**	**0.22**
Both refractive and diffractive optics	RR	Random	1	80	1.02 (0.89,1.17)	0.00	-
Refractive	RR	Random	5	392	0.91 (0.83,0.99)	0.00	-
Diffractive	RR	Random	2	210	1.06 (0.87,1.30)	26.32	-
Mean unaided distance VA (logMAR)	**MD**	**Random**	**8**	**924**	**0.01 (-0.02,0.05)**	**69.87**	**0.91**
Refractive	MD	Random	5	414	0.01 (-0.01,0.04)	0.00	-

Table 6. Subgroup analyses: refractive versus diffractive lenses (*Continued*)

Diffractive	MD	Random	3	510	0.02 (-0.05,0.09)	89.72	-
Corrected distance VA worse than 6/6	**RR**	**Random**	**8**	**692**	**1.02 (0.71,1.45)**	**53.97**	**0.24**
Both refractive and diffractive optics	RR	Random	1	80	1.05 (0.65,1.68)	0.00	-
Refractive	RR	Random	5	332	0.84 (0.50,1.41)	46.89	-
Diffractive	RR	Random	2	280	1.44 (0.97,2.13)	0.00	-
Mean corrected distance VA (logMAR)	**MD**	**Random**	**8**	**924**	**0.03 (0.02,0.05)**	**55.65**	**0.92**
Refractive	MD	Random	5	414	0.04 (0.00,0.07)	68.47	-
Diffractive	MD	Random	3	510	0.03 (0.02,0.05)	31.97	-
Mean unaided intermediate VA (logMAR)	No subgroup analysis because only 1 subgroup - diffractive (1 trial)						
Mean corrected intermediate VA (logMAR)	No subgroup analysis because only 1 subgroup - diffractive (1 trial)						
Unaided near VA worse than J3/J4 or equivalent	**RR**	**Random**	**8**	**782**	**0.20 (0.07,0.63)**	**93.38**	**0.88**
Both refractive and diffractive optics	RR	Random	1	80	0.22 (0.09,0.52)	0.00	-

Table 6. Subgroup analyses: refractive versus diffractive lenses (*Continued*)

Refractive	RR	Random	4	442	0.21 (0.03,1.63)	95.35	-
Diffractive	RR	Random	3	260	0.16 (0.07,0.40)	62.77	-
Mean unaided near VA (logMAR)	**MD**	**Random**	**6**	**881**	**-0.20 (-0.37,-0.03)**	**98.28**	**0.13**
Refractive	MD	Random	4	453	-0.11 (-0.19,-0.03)	81.28	-
Diffractive	MD	Random	2	428	-0.39 (-0.74,-0.03)	99.26	-
Corrected near VA worse than J3/J4 or equivalent	**RR**	**Random**	**4**	**344**	**0.32 (0.08,1.27)**	**17.58**	**0.18**
Both refractive and diffractive optics	RR	Random	1	80	0.55 (0.05,5.85)	0.00	-
Refractive	RR	Random	1	59	2.90 (0.12,68.50)	0.00	-
Diffractive	RR	Random	2	205	0.12 (0.02,0.61)	0.00	-
Mean corrected near VA (logMAR)	**MD**	**Random**	**8**	**1079**	**-0.05 (-0.15,0.05)**	**98.11**	**0.29**
Refractive	MD	Random	5	569	0.02 (-0.02,0.06)	83.89	-
Diffractive	MD	Random	3	510	-0.17 (-0.52,0.18)	99.40	-
Contrast sensitivity	**MD**	**Random**	**4**	**288**	**-0.07 (-0.15,0.00)**	**0.00**	**0.60**
Both refractive and	MD	Random	1	80	-0.03 (-0.23,0.17)	0.00	-

Table 6. Subgroup analyses: refractive versus diffractive lenses (*Continued*)

diffractive optics							
Refractive	MD	Random	3	208	-0.09 (-0.20,0.02)	2.89	-
Diffractive	MD	Random	1	0			-
Participant-reported outcomes: visual function questionnaires	**MD**	**Random**	**5**	**495**	**4.43 (-0.79,9.66)**	**90.66**	**0.02**
Refractive	MD	Random	3	303	0.65 (-4.60,5.89)	69.05	-
Diffractive	MD	Random	2	192	8.88 (4.81,12.95)	55.23	-
Participant-reported outcomes: vision-related quality-of-life questionnaires	No subgroup analysis because only 1 subgroup - diffractive (1 trial)						
Participant-reported outcomes: satisfaction scores	**SMD**	**Random**	**7**	**658**	**0.24 (-0.20,0.68)**	**86.02**	**0.00**
Refractive	SMD	Random	4	365	-0.10 (-0.32,0.11)	5.78	-
Diffractive	SMD	Random	3	293	0.83 (0.42,1.23)	57.33	-
Participant-reported outcomes: "good" or "satisfied" with vision	**RR**	**Random**	**4**	**388**	**0.99 (0.92,1.06)**	**0.00**	**0.64**
Both refractive and diffractive op-	RR	Random	1	80	0.87 (0.67,1.14)	0.00	-

Table 6. Subgroup analyses: refractive versus diffractive lenses (*Continued*)

tics							
Refractive	RR	Random	2	159	1.00 (0.91,1.09)	0.00	-
Diffractive	RR	Random	1	149	0.99 (0.87,1.13)	0.00	-
Participant-reported outcomes: cataract symptom scores	No subgroup analysis because only 1 subgroup - refractive (2 trials)						
Participant-reported outcomes: glare	**RR**	**Random**	**8**	**559**	**1.41 (1.03,1.93)**	**0.00**	**0.68**
Both refractive and diffractive optics	RR	Random	1	80	0.97 (0.39,2.41)	0.00	-
Refractive	RR	Random	5	299	1.50 (1.05,2.14)	0.00	-
Diffractive	RR	Random	2	180	1.34 (0.50,3.62)	0.00	-
Participant-reported outcomes: halos	**RR**	**Random**	**8**	**677**	**3.58 (2.06,6.25)**	**19.65**	**1.00**
Both refractive and diffractive optics	RR	Random	1	80	4.86 (2.05,11.56)	0.00	-
Refractive	RR	Random	4	256	4.65 (1.59,13.60)	0.00	-
Diffractive	RR	Random	3	341	4.53 (0.81,25.30)	54.02	-
Participant-reported outcomes: dysphotopsia	**RR**	**Random**	**2**	**138**	**1.13 (0.81,1.60)**	**0.00**	**0.54**

Table 6. Subgroup analyses: refractive versus diffractive lenses (*Continued*)

Refractive	RR	Random	1	56	1.00 (0.59,1.70)	0.00	-
Diffractive	RR	Random	1	82	1.24 (0.79,1.94)	0.00	-
Spectacle dependence	**RR**	**Random**	**11**	**1015**	**0.63 (0.54,0.73)**	**68.19**	**0.04**
Both refractive and diffractive optics	RR	Random	1	80	0.57 (0.41,0.78)	0.00	-
Refractive	RR	Random	6	493	0.74 (0.67,0.80)	0.00	-
Diffractive	RR	Random	4	442	0.43 (0.26,0.71)	82.56	-

CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference; VA: visual acuity.

Table 7. Subgroup analyses: unilateral versus bilateral surgery

Outcome	Effect measure	Analysis model	Studies	Number of eyes	Effect estimate (95% CI)	I^2	Test for interaction (P value)
Unaided distance VA worse than 6/6	**RR**	**Random**	**8**	**682**	**0.96 (0.89,1.03)**	**13.62**	**0.75**
Unilateral	RR	Random	6	502	0.98 (0.88,1.08)	33.14	-
Bilateral	RR	Random	1	60	0.85 (0.25,2.89)	0.00	-
Mixed unilateral/bilateral	RR	Random	1	120	0.92 (0.80,1.05)	100.00	-
Mean unaided distance VA (logMAR)	No subgroup analysis because only 1 subgroup - bilateral (6 trials)						

Table 7. Subgroup analyses: unilateral versus bilateral surgery (*Continued*)

Corrected distance VA worse than 6/6	**RR**	**Random**	**8**	**692**	**1.02 (0.71,1.45)**	**53.97**	**0.00**
Unilateral	RR	Random	6	512	1.24 (0.96,1.62)	0.00	-
Bilateral	RR	Random	1	60	0.73 (0.15,3.60)	0.00	-
Mixed unilateral/bilateral	RR	Random	1	120	0.61 (0.43,0.85)	0.00	-
Mean corrected distance VA (logMAR)	No subgroup analysis because only 1 subgroup - bilateral (6 trials)						
Mean unaided intermediate VA (logMAR)	**MD**	**Fixed**	**1**	**0**	**-**	**-**	**-**
Mean corrected intermediate VA (logMAR)	**MD**	**Fixed**	**1**	**0**	**-**	**-**	**-**
Unaided near VA worse than J3/J4 or equivalent	**RR**	**Random**	**8**	**782**	**0.20 (0.07,0.58)**	**92.77**	**0.89**
Unilateral	RR	Random	5	426	0.20 (0.08,0.51)	73.56	-
Bilateral	RR	Random	2	292	0.27 (0.01,6.63)	97.36	-
Mixed unilateral/bilateral	RR	Random	1	64	0.15 (0.06,0.38)	0.00	-
Mean unaided near VA (logMAR)	No subgroup analysis because only 1 subgroup - bilateral (5 trials)						

Table 7. Subgroup analyses: unilateral versus bilateral surgery (*Continued*)

Corrected near VA worse than J3/J4 or equivalent	No subgroup analysis because only 1 subgroup - unilateral (4 trials)						
Mean corrected near VA (logMAR)	No subgroup analysis because only 1 subgroup - bilateral (6 trials)						
Contrast sensitivity	**MD**	**Random**	**4**	**288**	**-0.09 (-0.26,0.08)**	**0.00**	**0.37**
Unilateral	MD	Random	1	80	-0.03 (-0.23,0.17)	0.00	-
Bilateral	MD	Random	2	88	-0.10 (-0.47,0.27)	0.00	-
Mixed unilateral/bilateral	MD	Random	1	120	-0.40 (-0.87,0.07)	0.00	-
Participant-reported outcomes: visual function questionnaires	**MD**	**Random**	**4**	**480**	**3.09 (-2.77,8.96)**	**92.18**	**0.00**
Unilateral	MD	Random	1	161	7.50 (5.95,9.05)	0.00	-
Bilateral	MD	Random	2	199	3.54 (-5.90,12.97)	88.24	-
Mixed unilateral/bilateral	MD	Random	1	120	-3.60 (-10.19,2.99)	0.00	-
Participant-reported outcomes: vision-related quality-of-life questionnaires	**MD**	**Fixed**	**1**	**0**			
Participant-reported outcomes: satis-	**SMD**	**Random**	**6**	**643**	**0.26 (-0.21,0.73)**	**87.75**	**0.91**

Table 7. Subgroup analyses: unilateral versus bilateral surgery (*Continued*)

faction scores							
Unilateral	SMD	Random	2	223	0.24 (-0.92,1.40)	93.35	-
Bilateral	SMD	Random	3	300	0.31 (-0.55,1.18)	91.45	-
Mixed unilateral/bilateral	SMD	Random	1	120	0.12 (-0.24,0.48)	0.00	-
Participant-reported outcomes: "good" or "satisfied" with vision	**RR**	**Random**	**1**	**0**			
Unilateral	RR	Random	3	269	0.96 (0.85,1.07)	0.00	-
Mixed unilateral/bilateral	RR	Random	1	119	1.00 (0.92,1.10)	0.00	-
Participant-reported outcomes: cataract symptom scores	**MD**	**Fixed**	**2**	**257**	**1.01 (0.39,1.64)**	**0.00**	**0.57**
Bilateral	MD	Fixed	1	137	0.90 (0.16,1.64)	0.00	-
Mixed unilateral/bilateral	MD	Fixed	1	120	1.30 (0.12,2.48)	0.00	-
Participant-reported outcomes: glare	**RR**	**Random**	**7**	**544**	**1.41 (1.03,1.93)**	**0.00**	**0.33**
Unilateral	RR	Random	4	319	1.31 (0.77,2.21)	0.00	-
Bilateral	RR	Random	2	105	2.05 (1.12,3.75)	0.00	-
Mixed unilateral/bilateral	RR	Random	1	120	1.14 (0.67,1.92)	0.00	-

Table 7. Subgroup analyses: unilateral versus bilateral surgery (*Continued*)

Participant-reported outcomes: halos	**RR**	**Random**	**7**	**662**	**3.58 (1.99,6.46)**	**24.75**	**0.69**
Unilateral	RR	Random	5	480	3.50 (1.70,7.19)	36.86	-
Bilateral	RR	Random	1	62	12.33 (0.79, 193.20)	0.00	-
Mixed unilateral/bilateral	RR	Random	1	120	3.79 (0.80,18.03)	0.00	-
Participant-reported outcomes: dysphotopsia	**RR**	**Random**	**1**	**114**	**1.18 (0.76,1.82)**	**0.00**	**1.00**
Spectacle dependence	**RR**	**Random**	**10**	**1000**	**0.63 (0.55,0.73)**	**66.86**	**0.81**
Unilateral	RR	Random	5	499	0.62 (0.51,0.75)	58.74	-
Bilateral	RR	Random	5	501	0.64 (0.51,0.80)	73.16	-

CI: confidence interval; RR: risk ratio; VA: visual acuity.

Table 8. Sensitivity analysis: excluding studies at high risk of bias

Outcome	Effect measure	All trials				Excluding studies at high risk of bias in ≥ 1 domain			
		Number of studies	Number of eyes	Effect estimate (95% CI)	I^2	Number of studies	Number of eyes	Effect estimate (95% CI)	I^2
Unaided distance VA worse than 6/6	RR	8	682	0.96 (0.89,1.03)	13.62	1	60	0.85 (0.25,2.89)	0.00
Mean unaided distance VA (logMAR)	MD	6	848	0.01 (-0.03,0.05)	74.32	2	262	-0.01 (-0.10,0.08)	81.23

Table 8. Sensitivity analysis: excluding studies at high risk of bias (*Continued*)

Corrected distance VA worse than 6/6	RR	8	692	1.02 (0.71,1.45)	53.97	1	60	0.73 (0.15,3.60)	0.00
Mean corrected distance VA (logMAR)	MD	6	848	0.03 (0.01,0.06)	63.79	2	262	0.02 (0.00,0.04)	0.00
Mean unaided intermediate VA (logMAR)	Only 1 study reported this outcome								
Mean corrected intermediate VA (logMAR)	Only 1 study reported this outcome								
Unaided near VA worse than J3/J4 or equivalent	RR	8	782	0.20 (0.07,0.58)	92.77	2	292	0.29 (0.01,8.39)	97.57
Mean unaided near VA (logMAR)	MD	5	829	-0.22 (-0.42,-0.03)	98.41	3	494	-0.26 (-0.58,0.06)	98.94
Corrected near VA worse than J3/J4 or equivalent	All trials were high risk of bias in ≥ 1 domain								
Mean corrected near VA (logMAR)	MD	6	1003	-0.07 (-0.20,0.06)	98.59	3	554	-0.16 (-0.50,0.18)	99.38

Table 8. Sensitivity analysis: excluding studies at high risk of bias (*Continued*)

Contrast sensitivity	MD	4	288	-0.09 (-0.26,0.08)	0.00	1	45	-0.07 (-0.16,0.02)	0.00
Participant-reported outcomes: visual function questionnaires	MD	4	480	3.09 (-2.77,8.96)	92.18	2	223	7.58 (6.08,9.08)	0.00
Participant-reported outcomes: vision-related quality-of-life questionnaires	Only 1 study reported this outcome								
Participant-reported outcomes: satisfaction scores	SMD	6	643	0.26 (-0.21,0.73)	87.75	3	324	0.64 (0.00,1.28)	84.77
Participant-reported outcomes: "good" or "satisfied" with vision	All trials were high risk of bias in ≥ 1 domain								
Participant-reported outcomes: cataract symptom scores	All trials were high risk of bias in ≥ 1 domain								
Participant-reported	RR	7	544	1.41 (1.03,1.93)	0.00	1	62	2.23 (0.30,16.72)	0.00

Table 8. Sensitivity analysis: excluding studies at high risk of bias (*Continued*)

outcomes: glare									
Participant-reported outcomes: halos	RR	7	662	3.58 (1.99,6.46)	24.75	2	223	3.27 (0.64,16.67)	45.56
Participant-reported outcomes: dysphotopsia	Only 1 study reported this outcome								
Spectacle dependence (any)	RR	10	1000	0.63 (0.55,0.73)	66.86	5	619	0.55 (0.41,0.75)	83.77

CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardised mean difference; VA: visual acuity.

FEEDBACK

Savage, November 2004

Summary

The conclusions of the review abstract suggest that multifocals [intraocular lenses (IOL)] improved quality of near vision over the monofocal IOL, however in several studies noted (ie: Javitt & Steinert) the refractive error targeted with monofocal IOLs is not mentioned. It is thus assumed that emmetropia was the goal, rather than monovision. A better question is how do patients with monovision IOL implants function compared to those with the Array [multifocal IOL] ? In my experience, patients prefer monovision! There is no glare or halo, and the quality of vision is sufficient for most to function unaided, including night driving.

Reply

Thank you for your comments.
The studies in this meta-analysis recruited patients into RCTs [randomised controlled trials] comparing a multifocal lens with a monofocal lens. None of the RCTs used monovision as either a control group or intervention group. Whilst this would be an interesting study (glare and haloes may be less in the monofocal monovision group, possibly at the expense of troublesome anisometropia), this scenario is not answered by this analysis.

Contributors

Edward Pringle, review co-author

WHAT'S NEW

Last assessed as up-to-date: 13 June 2016.

Date	Event	Description
26 October 2016	New search has been performed	Issue 12, 2016: Electronic searches were updated and 5 new trials were included (Ji 2013; Labiris 2015; Peng 2012; Rasp 2012; Wilkins 2013) and one previously included study was excluded (Alio 2011c). The review has been updated using current Cochrane methods and an additional comparison, monovision, has been included
26 October 2016	New citation required but conclusions have not changed	Issue 12, 2016: Three new authors have joined the author team: Samantha de Silva, Varo Kirthi and Mohammed Ziaei

HISTORY

Protocol first published: Issue 3, 2000

Review first published: Issue 3, 2001

Date	Event	Description
8 June 2012	New citation required but conclusions have not changed	Three new authors, Daniel Calladine, Jennifer Evans and Sweata Shah, worked on the 2012 update
8 June 2012	New search has been performed	Updated searches yielded six new trials (Alio 2011; Cillino 2008; Harman 2008; Jusufovic 2011; Palmer 2008; Zhao 2010) for inclusion in the review
19 June 2008	Amended	Converted to new review format.
9 July 2006	New citation required and conclusions have changed	Substantive amendment.

CONTRIBUTIONS OF AUTHORS

For the first edition of the review, ML decided the review scope, carried out some electronic database searches, performed additional handsearches, assessed the results of searches, assessed suitability of studies, extracted data, wrote the text and updated the review.

In the 2016 edition of the review, SdeS, JE, VK and MZ screened studies, extracted data and assessed risk of bias. SdeS and JE updated the text. VK and MZ should be considered as joint 3rd authors.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research (NIHR), UK.
- Richard Wormald, Co-ordinating Editor for the Cochrane Eyes and Vision (CEV) acknowledges financial support for his CEV research sessions from the Department of Health through the award made by the NIHR to Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology for a Specialist Biomedical Research Centre for Ophthalmology.
- The NIHR also funds the CEV Editorial Base which includes part of Jennifer Evans's salary.
- The Cochrane Incentive Scheme provided funding for Jennifer Evans to assist with updating this review in 2012.

The views expressed in this publication are those of the authors and not necessarily those of the NIHR, National Health Service or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The original protocol for this review was published in 2000. Since that time there have been substantive changes in recommended Cochrane Review methodology. We have added in specific information on the following methodological issues: unit of analysis, missing data and subgroup analysis.

For the update in 2016, we have collaborated with the National Institute of Care and Health Excellence (NICE) in the UK. NICE are preparing guidelines for cataract management and we agreed to work with them to ensure that the information in this review provided data relevant to the guideline. This mainly affected the comparisons and outcomes.

Types of interventions

We included an additional comparison: multifocal versus monovision. Monovision is a strategy designed to enable people to achieve good distance and near vision by adjusting the powers of the lenses such that one eye is used for distance vision and one for near vision.

Outcomes

We have added in intermediate visual acuity as an outcome.
For the 2016 update, we dropped depth of focus because the data on this were sparse and difficult to interpret because of considerable variability in measurement and reporting.

Risk of bias

We used Cochrane's tool for assessing the risk of bias (replacing the Jadad scale). In the 2012 update of this review, we assessed selective outcome reporting bias by completing an outcome reporting matrix using the ORBIT classification (Kirkham 2010). In the 2016 update, we did not continue with this assessment but assessed selective outcome reporting as part of the risk of bias tool only.

Measures of treatment effect

For dichotomous outcomes, we changed the measure of effect from odds ratio to risk ratio, reflecting changing views as to the relative suitability of the risk ratio/odds ratio as a measure of effect. Although the odds ratio has some statistical advantages, it is not as easily interpreted as the risk ratio and may overestimate the effect of the intervention, particularly when the event occurs commonly within the study population.

In the 2012 update of the review, we pooled visual acuity measured on different scales using the standardised mean difference. The standardised mean difference is difficult to interpret, however, and there is accumulating evidence that different visual acuity charts perform differently at different levels of visual acuity. For these reasons, we have changed our mind about the validity of doing this. As more data were available measured on the logMAR scale we restricted our analyses to studies measuring and reporting visual acuity data on the logMAR scale. We summarised these using the mean difference.

Subgroup analysis

We have added in an additional subgroup analysis comparing unilateral and bilateral surgery.

Sensitivity analysis

Following updated guidance from Cochrane (MECIR 2013), we have added in a sensitivity analysis excluding studies at high risk of bias in one or more domains.

'Summary of findings' table

We prepared a 'Summary of findings' table, including assessing the quality of evidence using GRADE (GRADEpro 2014).

INDEX TERMS

Medical Subject Headings (MeSH)

*Lenses, Intraocular [psychology]; Cataract Extraction [*rehabilitation]; Contrast Sensitivity [physiology]; Patient Satisfaction; Prosthesis Design; Randomized Controlled Trials as Topic; Vision, Ocular [physiology]; Visual Acuity [*physiology]

MeSH check words

Adult; Humans