Multifocal versus monofocal intraocular lenses after cataract extraction (Review)

Calladine D, Evans JR, Shah S, Leyland M

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[Intervention Review]

Multifocal versus monofocal intraocular lenses after cataract extraction

Daniel Calladine[1], Jennifer R Evans[2], Sweata Shah[3], Martin Leyland[4]

[1]Eye Department at West Wing, John Radcliffe Hospital, Oxford, UK. [2]Cochrane Eyes and Vision Group, ICEH, London School of Hygiene & Tropical Medicine, London, UK. [3]Optometry Department, Oxford Eye Hospital, John Radcliffe Hospital, Headington, UK. [4]Royal Berkshire Hospital NHS Trust, Reading, UK

Contact address: Daniel Calladine, Eye Department at West Wing, John Radcliffe Hospital, Oxford, UK. drdancalladine@doctors.org.uk.

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ABSTRACT

Background

Good unaided distance visual acuity 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

The objective of this review was to assess the effects of multifocal IOLs, including effects on visual acuity, subjective visual satisfaction, spectacle dependence, glare and contrast sensitivity, compared to standard monofocal lenses in people undergoing cataract surgery.

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (*The Cochrane Library* 2012, Issue 2), MEDLINE (January 1946 to March 2012), EMBASE (January 1980 to March 2012), the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the 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. The electronic databases were last searched on 6 March 2012. We searched the reference lists of relevant articles and contacted investigators of included studies and manufacturers of multifocal IOLs for information about additional published and unpublished studies.

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.

Data collection and analysis

Two authors collected data and assessed trial quality. Where possible, we pooled data from the individual studies using a random-effects model, otherwise we tabulated data.

Main results

Sixteen completed trials (1608 participants) and two ongoing trials were identified. All included trials compared multifocal and monofocal lenses but 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 patients and outcome assessors. It was also difficult to assess the role of reporting bias. There was moderate quality evidence that similar distance acuity is achieved with both types of lenses (pooled risk ratio (RR) for unaided visual acuity worse than 6/6: 0.98, 95% confidence interval (CI) 0.91 to 1.05). There was also evidence that people with multifocal lenses had better near vision but methodological and statistical heterogeneity meant that we did not calculate a pooled estimate for effect on near vision. Total freedom from use of glasses was achieved more frequently with multifocal than monofocal IOLs. Adverse subjective visual phenomena, particularly haloes, or rings around lights, were more prevalent and more troublesome in participants with the multifocal IOL and there was evidence of reduced contrast sensitivity with the multifocal lenses.

Authors' conclusions

Multifocal IOLs are effective at improving near vision relative to monofocal IOLs. Whether that improvement outweighs the adverse effects of multifocal IOLs will vary between patients. Motivation to achieve spectacle independence is likely to be the deciding factor.

PLAIN LANGUAGE SUMMARY

A comparison of multifocal and monofocal intraocular lens implants used in cataract surgery

As people get older, sometimes the lens of the eye becomes cloudy leading to loss of vision. The cloudy lens or cataract can be removed, and a replacement lens put in its place. In the past, the replacement lens had one 'point of focus', either in the distance or close up ('monofocal' lens). This meant that glasses were needed for focusing at other points, for example, for reading. New lenses have been developed that provide two or more points of focus ('multifocal' lenses). These are designed to avoid the need for glasses. We found 16 trials that randomised over 1600 people to either a multifocal or monofocal lens. People who had multifocal lenses were less likely to need spectacles. They had the same visual acuity for seeing in the distance compared to people who had monofocal lenses but had better visual acuity for near vision. The multifocal lenses had drawbacks: people with these lenses were more likely to see halos around lights and had reduced contrast sensitivity (the ability to distinguish an object against a background which is similar to the object itself). Multifocal lens implants reduce spectacle dependence after cataract surgery but at the expense of clarity. Ultimately it will be up to the individual to decide which type of lens they would prefer.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Multifocal compared to monofocal intraocular lenses after cataract extraction

Patient or population: patients 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)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Monofocal intraocular lens	Multifocal intraocular lens				
Distance visual acuity - less than 6/6 unaided Follow-up: 6 weeks to 18 months	**Moderate-risk population** **750 per 1000**	**735 per 1000** (683 to 787)	**RR 0.98** (0.91 to 1.05)	632 (7 studies)	⊕⊕⊕◯ **moderate**[1]	
Distance visual acuity - less than 6/6 best-corrected Follow-up: 6 weeks to 18 months	**See comment**			691 (8 studies)	**See comment**	Substantial heterogeneity therefore results not pooled: individual study estimates ranged from RR 0.20 (95% CI 0.03 to 1.56) to RR 1.50 (95% CI 0.63 to 3.59) but evenly distributed around the null line (no effect)
Near visual acuity - less than J3/J4 unaided Follow-up: 6 weeks to 18 months	**See comment**			787 (7 studies)	**See comment**	Substantial heterogeneity therefore results not pooled: individual study estimates ranged from RR 0.02 (95% CI 0.00 to

						0.31) to RR 0.87 (95% CI 0.64 to 1.17) but all individual study results in direction favouring multifocal IOLs
Spectacle dependence	**See comment**			1207 (11 studies)	**See comment**	Substantial heterogeneity therefore results not pooled: individual study estimates ranged from RR 0.32 (95% CI 0.24 to 0.45) to RR 0.99 (95% CI 0.90 to 1.08) but all individual study results in direction favouring multifocal IOLs
Glare/haloes Follow-up: 6 weeks to 18 months	**Moderate-risk population**		**RR 1.94** (1.51 to 2.49)	699 (8 studies)	⊕⊕⊕○ **moderate**[1]	
	250 per 1000	**485 per 1000** (377 to 623)				

*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 quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: 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 quality: We are very uncertain about the estimate.

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

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 persons of 65 years and over in the UK (Desai 1999). Around 340,000 cataract extractions were performed in England in the year 2010-11 (Department of Health 2012).

Patients with cataract usually present with one or more of the following symptoms: gradual reduction in visual acuity, glare, change in glasses prescription and change in colour appreciation. The diagnosis may be made by the patient's general practitioner or optometrist followed by referral to an ophthalmic surgeon for confirmation of the diagnosis and management. Many patients 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 visual acuity (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 to 4 mm) phacoemulsification surgery. This change is generally perceived to offer greater predictability of refractive outcomes, a necessary pre-requisite for good visual acuity without the need for glasses. Cochrane systematic reviews comparing surgical approaches have been published (Ang 2012; Riaz 2006).

Because standard IOLs used have a fixed refractive power the focal length is also fixed (monofocal). This means that most patients will require a reading addition to their distance glasses prescription (Javitt 1997). While the majority of 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 developing countries where the burden of blindness due to cataract is so high.

How the intervention might work

One approach to improve near visual acuity is to modify the IOL. There are no IOLs currently available that are able to 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. A detailed explanation of these lenses is beyond the scope of this review. However, both types of IOL divide light up to focus at two (bifocal) or more (multifocal) points so that the patient can focus on objects at more than one distance from them. Intraocular lenses 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. In order 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

The objective of this review was to assess the visual effects of multifocal intraocular lenses in comparison with the current standard treatment of monofocal intraocular 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 intraocular lens 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 intraocular lens was compared with monofocal intraocular lens implantation.

Types of outcome measures

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

Primary outcomes

The primary outcomes for this review were as follows.

(1) Distance visual acuity (unaided and corrected)

- We used the cut-point of less than 6/6 (20/20, logMAR score > 0) as 6/6 vision is usually considered normal visual acuity.
- We also considered visual acuity as a continuous variable.

(2) Near visual acuity (unaided and corrected)

- We used the cut-point of near visual acuity worse than J3/J4 (Jaegar cards) or equivalent.
- We also considered near visual acuity as a continuous variable.

(3) Spectacle dependence

- As reported by the patient.

Secondary outcomes

The secondary outcomes for this review included:

- depth of field (the amount of defocus consistent with retention of useful acuity);
- 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);
- 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 intraocular lens may cause unequal glare between patients);
- validated instruments assessing quality of life or visual function;
- informal (non-validated) subjective assessment of visual function

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) 2012, Issue 2, part of *The Cochrane Library*. www.thecochranelibrary.com (accessed 6 March 2012), MEDLINE (January 1946 to March 2012), EMBASE (January 1980 to March 2012), the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the 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. The electronic databases were last searched on 6 March 2012.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), *m*RCT (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 intraocular lenses (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 the 2012 update.

Data collection and analysis

Selection of studies

Two 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 all full copies according to the definitions in the Criteria for considering studies for this review. We only assessed trials meeting these criteria for methodological quality.

Data extraction and management

Two authors extracted data using a standard form and spreadsheet developed by the Cochrane Eyes and Vision Group (eyes.cochrane.org/resources-review-authors). We compared these

and resolved discrepancies by discussion. In the original review, one author entered data into RevMan 4.1. For the 2006 review update, data were entered directly into RevMan 4.2. For the 2012 update data were cut and pasted into RevMan 5 (RevMan 2011) by one author and checked by another author.

Assessment of risk of bias in included studies

Each author assessed risk of bias independently using The Cochrane Collaboration's tool for assessing the risk of bias as outlined in Chaper 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Discrepancies were resolved by discussion.

Measures of treatment effect

Our measure of treatment effect was the risk ratio for dichotomous outcomes and standardised mean difference (SMD) for continuous outcomes. We used the SMD because distance and near visual acuity were reported on different scales (logMAR or decimal) in different studies. The SMD standardises the results to a uniform scale by expressing the size of the effect (difference in means) in each study relative to the variability observed in that study (Deeks 2011). Where possible, we checked for skewness using the method outlined in the handbook (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 are reported for both eyes, and appropriate methods of adjustment are not included, we requested further data from the investigators.

Dealing with missing data

The analyses in this review are available case analyses. This makes the assumption that data are missing at random. We recorded the amount of missing data and reasons for exclusions and attrition, where available.

Assessment of heterogeneity

We assessed heterogeneity by examining the graphs (forest plots) to see whether the direction of effect was similar in all studies and whether the confidence intervals 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 not many studies, or the studies are small. We also considered the I^2 statistic (Higgins 2003). We took an I^2 statistic value of 50% or more to indicate substantial inconsistency in study results.

Assessment of reporting biases

We planned to assess publication bias when 10 or more trials were included in the meta-analysis by plotting effect size against standard error. One condition of this assessment is that the analysis is not heterogenous. In this version (2012 update) of the review, these two conditions did not apply and we were therefore unable to assess publication bias. We assessed selective outcome reporting bias by completing an outcome reporting matrix using the ORBIT classification (Kirkham 2010).

Data synthesis

Comparisons were made between any multifocal lens versus monofocal intraocular lenses. 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 substantial heterogeneity or inconsistency was present (see Assessment of heterogeneity) we did not report the pooled analyses.

Subgroup analysis and investigation of heterogeneity

We considered two main sources of heterogeneity: type of lens (refractive or diffractive) and whether or not the surgery was unilateral or bilateral. We compared subgroups using the standard test for heterogeneity implemented in Revman 5.1 (RevMan 2011).

Sensitivity analysis

No sensitivity analyses were planned or undertaken.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

The initial electronic searches found 239 titles and abstracts. We obtained the full copies of possibly relevant papers according to the criteria specified above. 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 1998). Interim data were

available on 149 participants with five to six months follow-up (Allen 1996) and a subsequent paper reported best-corrected distance acuity and contrast sensitivity data only (with no numerical data for the latter) on 221 participants (Haaskjold 1998a). 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 a total of 32 reports of which two further studies were relevant (Kamlesh 2001; Leyland 2002). The searches were updated in September 2005 and 218 reports were found 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 in the review. We rejected a further 100 records and obtained the full text of 24 records for further assessment. We included the following six studies in the review: Alio 2011; Cillino 2008; Harman 2008; Jusufovic 2011; Palmer 2008; Zhao 2010. Two ongoing studies (ISRCTN37400841; NCT01088282) have been added to the review and these studies will be assessed when data become available. We excluded the following 16 studies: Alio 2011a; Alio 2011b; Allen 2009; Cionni 2009; Hayashi 2009a; Hayashi 2009b; Hayashi 2009c; Hayashi 2010; Hida 2009; Huang 2010; Ji 2011; Maxwell 2008; Ortiz 2008; Shah 2010; Xu 2007; Zhang 2011. See Characteristics of excluded studies for reasons for exclusion.

In order to assess the three Chinese studies (Huang 2010; Ji 2011; Xu 2007) we asked Taixiang Wu, who is a Cochrane author and also heads the Chinese Clinical Trials Registry, to contact the study authors and ask if the studies were randomised. Taixiang Wu confirmed that after speaking with the authors none of the three studies randomised participants to interventions.

The following three studies which had previously been awaiting assessment have now been assessed and excluded from the review: Liang 2005; Rocha 2005; Souza 2006. See Characteristics of excluded studies for details of reasons for exclusion.

Included studies

The description below refers to the 16 studies included in this review (Table 1). Details of the individual trials are in the table Characteristics of included studies.

Design

There were three multicentre and 13 single-centre studies.

Participants

The smallest study randomised 40 participants while the largest randomised 261 participants. Eight studies included people undergoing bilateral cataract surgery (participants had the same type of lens inserted into both eyes). All studies recruited people with senile cataract with no other apparent ocular morbidity and without excess corneal astigmatism.

Interventions

Nine studies compared refractive with monofocal, four studies compared diffractive with monofocal, two studies used a mixture of refractive and diffractive IOLs and one study used a multifocal lens with both refractive and diffractive properties (Table 2). The cataract surgery performed in 12 studies was small incision phacoemulsification. Three studies employed extracapsular cataract extraction and one study included both types of surgery.

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 visual acuity. The more recent studies used capsulorhexis, except Kamlesh 2001 which used envelope capsulotomy.

Outcomes

Distance visual acuity was measured using Early Treatment of Diabetic Retinopathy Study charts in three studies (Harman 2008; Leyland 2002; Nijkamp 2004), Regan contrast acuity charts in two studies (Javitt 2000; Steinert 1992) and Snellen charts in the remaining studies.

Near visual acuity was measured using Jaeger reading cards in the majority of studies but also Sloan near acuity charts (Cillino 2008; Zhao 2010) and the De Nederlander Reading chart (Nijkamp 2004) was used. There are well-described differences between Jaeger cards from different manufacturers (*see* Discussion for further discussion on this).

There was variety in the way that distance and near acuity was reported. 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 different ways. Four studies used the Pelli-Robson chart (Harman 2008; Kamlesh 2001; Leyland 2002; Rossetti 1994), four trials used the VCTS chart (Cillino 2008; Haaskjold 1998; Sen 2004; Zhao 2010), two trials used the Regan Contrast Acuity chart (Percival 1993; Steinert 1992), one trial used the CST 1800, Vision Science Research Corp (Alio 2011), and one trial the FACT chart in 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, visual acuity at different

contrast levels, and difference between high contrast and lower contrast acuity - and it was difficult to pool data for contrast sensitivity. Similarly, depth of field was reported in a variety of ways, making it difficult to combine the results of studies. Three studies assessed the extent of glare disability using the Brightness Acuity Tester (Harman 2008; Leyland 2002; Steinert 1992) and most studies elicited information from patients as to the extent of problems with glare and/or haloes.

Some studies formally addressed visual functioning after surgery using validated instruments such as the NEI-VFQ (Alio 2011), VF-7 (Cillino 2008; Sen 2004; Zhao 2010), VF-14 (Nijkamp 2004) and TyPE questionnaire (Javitt 2000; Leyland 2002). Patient-reported satisfaction was available for eight studies (Cillino 2008; Haaskjold 1998; Harman 2008; Kamlesh 2001; Palmer 2008; Percival 1993; Rossetti 1994; Zhao 2010).

Follow-up ranged from one month to 18 months.

Data collection and reporting

Near vision and subjective outcomes were poorly assessed and reported. Only Alio 2011, Javitt 2000, Harman 2008 and Leyland 2002 reported both unequivocal unaided and best-corrected logMAR near acuity measures. Palmer 2008 reported best-corrected near vision using Snellen that was converted to logMAR, and near vision with best distance correction. Validated instruments for subjective outcomes were used by only five studies (Javitt 2000; Leyland 2002; Nijkamp 2004; Sen 2004; Zhao 2010)

Financial support

Two studies had no external funding, seven studies did not give funding details and three studies were sponsored by multifocal IOL manufacturers. Four studies used other sources of funding, namely the Spanish Ministry for Health, the Saudi Eye Foundation, the Eye Research Institute Maastricht, a Finnish Government Special Grant (TYH 3234) and a Finnish Eye Foundation Grant.

Excluded studies

See the Characteristics of excluded studies table.

Risk of bias in included studies

See Figure 1 and Figure 2.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

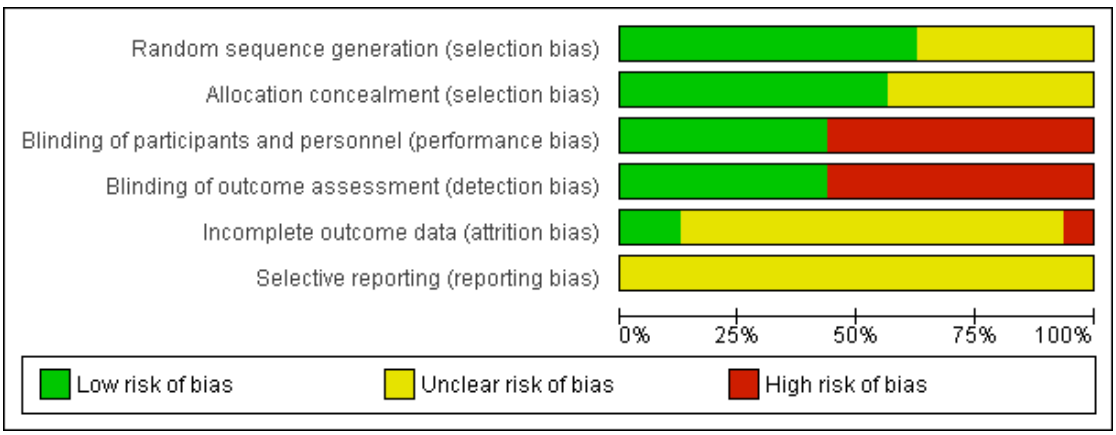
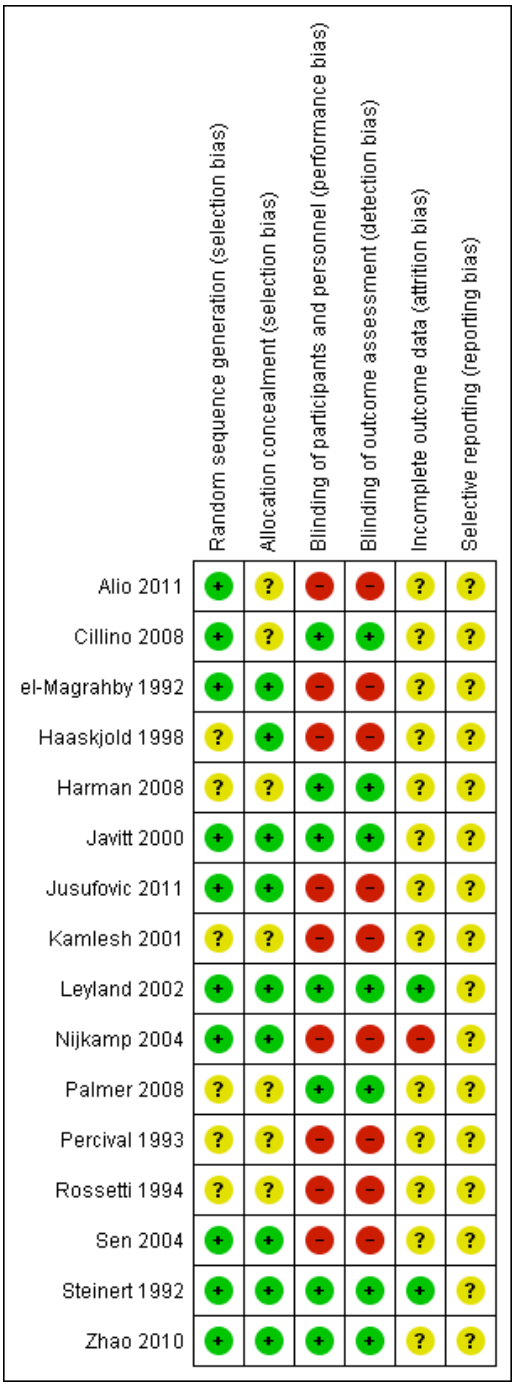


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



We contacted the authors of included papers for further information on their studies. Replies clarifying various methodological issues were received for three studies (el-Magrahby 1992; Haaskjold 1998; Javitt 2000). We will update this review with any additional information received.

Allocation

The technique for random sequence generation was described in all but six studies (Haaskjold 1998; Harman 2008; Kamlesh 2001; Palmer 2008; Percival 1993; Rossetti 1994).

Allocation concealment was reported in seven studies (Javitt 2000; Jusufovic 2011; Leyland 2002; Nijkamp 2004; Sen 2004; Steinert 1992; Zhao 2010) and was confirmed by author correspondence in el-Magrahby 1992 and Haaskjold 1998.

Blinding

Masking of participants was reported in seven studies (Cillino 2008; Harman 2008; Javitt 2000; Leyland 2002; Palmer 2008; Steinert 1992; Zhao 2010). The duration of masking was greater than the measured outcomes in each of these studies except Harman 2008, where 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 symptoms of glare/haloes that were only reported at the 18-month visit. Interestingly, following disclosure of multifocal IOL status, patients in this group showed an improvement in near vision and spectacle independence by the 18-month visit. Only seven studies reported masking of assessors (Cillino 2008; Harman 2008; Javitt 2000; Leyland 2002; Palmer 2008; Steinert 1992; Zhao 2010).

Incomplete outcome data

We judged attrition bias to be of low risk in three studies where reasons for, and numbers of, patients who exited the study after intervention and before outcomes were clearly reported and we thought unlikely to affect the outcome (Leyland 2002; Rossetti 1994; Steinert 1992); in the remaining 13 studies this was unclear.

Selective reporting

The extent to which selective reporting had occurred for each individual study was unclear because we did not have access to study protocols. We completed an outcome reporting matrix (Kirkham 2010) for primary (Table 3) and secondary (Table 4) outcomes using information in the published reports. We judged that selective outcome reporting was not a major concern in these studies..

Effects of interventions

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

A summary of refractive aims and outcomes is given as an additional table (Table 5). Four studies compared either two (Alio 2011; Leyland 2002) or three (Cillino 2008; Palmer 2008) different multifocal intraocular lenses (IOLs) with a monofocal control group. The multifocal IOL results within these studies were similar and therefore we have pooled them for this review.

Primary outcomes

Distance visual acuity

In Percival 1993 the monofocal group was planned to have myopic astigmatism and therefore reduced unaided distance acuity. This study was therefore excluded from this analysis.

Analysis 1.1 compares the proportion of participants achieving visual acuity of 6/6 unaided in multifocal and monofocal lenses in the seven studies that reported this outcome (632 participants). There was no evidence of any difference between the groups (pooled risk ratio (RR) 0.98, 95% confidence interval (CI) 0.91 to 1.05). Ten studies (1015 participants) reported mean distance acuity and again there was no evidence of any difference between the groups (standardised mean difference (SMD) -0.10, 95% CI -0.23 to 0.02) (Analysis 1.2). The findings were consistent (I^2 = 0%) in both analyses. Similar results were seen for best-corrected distance acuity (Analysis 1.3; Analysis 1.4) but more heterogeneity was seen in the study results, with I^2 statistics of 54% and 66% respectively and estimates on both sides of 1 (no effect). This means that the pooled result is not so informative in this case.

Near vision

There was considerable methodological heterogeneity in the way that near vision was measured in the individual trials (see Description of studies). As a consequence of this, there was considerable statistical heterogeneity in the analyses (Analysis 1.5; Analysis 1.6; Analysis 1.7). This means that it is difficult be confident in the size of the overall pooled estimate. In all studies, participants who received a multifocal lens were more likely to achieve good unaided near vision compared to people who received a monofocal lens. The results for corrected near visual acuity were inconsistent, with three studies finding that the multifocal group had better corrected near vision (Alio 2011; Harman 2008; Palmer 2008), one study finding in favour of monofocal lenses (non-significant) (Leyland 2002) and one study finding similar corrected near acuity in both groups (Javitt 2000).

Heterogeneity was particularly evident in the proportion of monofocal control group participants achieving J3. el-Magrahby 1992 found that 17/24 (71%) of their monofocal group could read J3 or better unaided despite a mean spherical error of +0.31 D. In contrast, Haaskjold 1998 found only 9/101 (9%) could read J3 or better (refraction not given). Percival 1993 aimed for a myopic outcome for the control group, which explains the relatively good performance of these participants for near tasks.

Spectacle dependence

In all studies the majority of multifocal IOL participants still used spectacles for some tasks, usually small print. Independence from spectacles was found in 7% (Nijkamp 2004) to 69% (Palmer 2008) of multifocal participants and 0% (Leyland 2002) to 20% (Cillino 2008) of monofocal participants. Steinert 1992 reported figures of 52% and 25% respectively if use of glasses for the fellow eye was counted as spectacle independence. Dependence on spectacles was less likely in the multifocal than the monofocal groups (Analysis 1.9) but an I^2 of 92% means that the size of the overall estimate is uncertain.

Secondary outcomes

Depth of field

Six studies measured depth of field (Analysis 1.10). All described better acuity with minus lens defocus from the distance correction with the multifocal IOL.

Contrast sensitivity

Contrast sensitivity was measured in 12 out of 16 studies. There was considerable variety in the way this was measured (*see* Description of studies), which meant it was difficult to pool study results, with the exception of studies using the Pelli Robson chart (Analysis 1.11, Analysis 1.12). All studies reported lower contrast sensitivity with the multifocal IOL, which is consistent with the expected optical effect of the lens.

Glare

Four studies assessed glare disability using the Brightness Acuity Tester (BAT) (Analysis 1.13). Steinert 1992 reported corrected acuity (Regan lines read) at low, medium and high glare. Acuity fell as glare increased: from 7.67 lines with no glare to 5.67 lines with maximum glare (multifocal, a two line drop) and from 8.19 lines to 6.42 lines (monofocal, 1.57 line drop). The difference between lenses was not statistically significant. Haaskjold 1998 measured the effect of the BAT on contrast sensitivity. However, they reported the mean contrast sensitivity difference between multifocal and monofocal IOLs at three different light levels rather than the change in contrast sensitivity with glare for each IOL. The differences between IOLs were similar across the illumination range and greatest at the medium illumination level, which suggests that glare was not worse with the multifocal IOL. Leyland 2002 found no significant acuity drop with glare with any IOL but reported a significant fall in contrast sensitivity that was similar with all IOLs (-0.38 multifocal versus -0.40 monofocal). Harman 2008 measured glare disability in the right eye only of all patients at three months using the BAT at its highest settings and compared Pelli-Robertson contrast sensitivity letters achieved; this was equally reduced in both the multifocal (27.26) and monofocal IOL groups (27.15).

Patient reported glare and/or haloes

Patients in the multifocal group consistently reported more problems with glare and/or haloes (RR 1.94, 95% CI 1.51 to 2.49, I^2 = 16% (Analysis 1.14). Results for Sen 2004 were excluded from this plot because it was unclear how many patients had glare or haloes, or both symptoms.

The TyPE questionnaire (Javitt 2000) quantifies the degree of bother from 'glare, haloes and rings around lights' as 0 to 4, where 'not at all' scores 0, 'a little bit' scores 1, 'moderately' scores 2, 'quite a bit' scores 3 and 'extremely' scores 4. The mean scores (without glasses on) were 1.57 for the multifocal IOL and 0.43 for the monofocal. Leyland 2002 reports median score for the same outcome as 1 for the multifocal IOL and 0 for the monofocal. Harman 2008 measured the effect on distance visual acuity using the BAT and found there to be no significant differences between groups, but did not state the absolute values.

Visual functioning

A variety of ways of measuring visual function were used in the individual studies (*see* Description of studies). Analysis 1.15 summarises the results. People with multifocal lenses reported better visual function for tasks requiring near vision. Otherwise there was little evidence of any difference in reported visual function between the groups.

Patient-reported satisfaction with vision

Overall patients reported good satisfaction with both types of lenses. There were some inconsistencies. Rossetti 1994 reported that 68% of multifocal participants and 78% of monofocal participants were satisfied or highly satisfied with their surgery, an assessment of overall outcome that favours the monofocal IOL. They also report that 82% of the multifocal group and 67% of the monofocal group thought their vision was good or excellent, another, apparently similar global measure, but this time with the result favouring the multifocal IOL. Using the TyPE instrument Javitt 2000 found a small but statistically significant increase in overall visual satisfaction with the multifocal IOL (8.4/10 with

the multifocal compared to 7.9/10 monofocal) and, as expected, a larger beneficial effect with respect to near vision (7.4/10 and 5.3/10). Leyland 2002, also using the TyPE instrument, found no difference in overall subjective satisfaction between groups (median 8/10 satisfaction).

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. Peroperative and postoperative complications were reported by seven studies (Cillino 2008; el-Magrahby 1992; Harman 2008; Javitt 2000; Leyland 2002; Nijkamp 2004; Percival 1993). The incidence of complications was low and similar in the experimental and control groups.

Subgroup analyses

Subgroup analyses are presented in Appendix 7 and Appendix 8. There was little evidence of any differences in effect according to whether the surgery was bilateral or unilateral (Appendix 7) or whether diffractive or refractive lenses were used (Appendix 8). In three analyses the test for subgroup differences was statistically significant, however in these cases only one trial was in one subgroup and therefore it is difficult to interpret these findings.

DISCUSSION

Summary of main results

The results are summarised in Summary of findings for the main comparison. There was no difference in distance acuity with the two lenses but people with multifocal lenses had better near vision and reported less dependence on spectacles. Adverse subjective visual phenomena, particularly haloes or rings around lights, were more prevalent and more troublesome in participants with the multifocal IOL.

Depth of field was improved with the multifocal IOL compared to the monofocal. Contrast sensitivity was lower in participants implanted with the multifocal IOL. The differences were smaller than would be expected given the division of light between distance and near focus, which may result from post-receptoral 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 patient's retina. No significant differences between IOLs with respect to objective glare were reported.

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

Overall completeness and applicability of evidence

Eight of the 16 included studies involved participants with surgery on both eyes (Alio 2011; Cillino 2008; Harman 2008; Javitt 2000, Leyland 2002; Nijkamp 2004, Palmer 2008, Sen 2004). Sen 2004 had a mixture of both unilateral and bilateral surgery. Unilateral studies allow measurement of uni-ocular outcomes such as visual acuity but are of limited use when attempting to measure the effect of the multifocal intraocular lenses (IOLs) on quality of life, especially where the fellow eye has good vision. Steinert 1992 and Rossetti 1994 reported fellow eye vision as good, Percival 1993 described the fellow eyes as cataractous and Jusufovic 2011 commented that participants had no prior ocular surgery suggesting a phakic status in the other eye, but the multifocal group was of noticeably younger age (years) compared to the monofocal group (mean (standard deviation, SD) multifocal 43 (10), monofocal 50 (10)). Zhao 2010 commented that included participants had not undergone previous ocular surgery suggesting a phakic status of the other eye. el-Magrahby 1992, Haaskjold 1998, Kamlesh 2001 and Sen 2004 did not comment on the status of the fellow eye.

Results are presented as a combined group of refractive and diffractive IOL studies. Combination of data is 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). Separated data are also presented and are likely to become more useful as further studies are published. The Chi^2 test of heterogeneity was significant (indicating that it would be unwise to combine the individual study results) with respect to analysis of mean best-corrected distance vision (P = 0.004) and mean logMAR near vision unaided (P = 0.01). However, these results need to be interpreted with caution as the diffractive group in both cases consisted of only one study (Alio 2011).

Unaided near vision is critical to assessment of multifocal efficacy but was reported in a manner that makes comparison between studies difficult. Reading distances differed in the individual studies and it is not made clear in most studies whether the reported print size read has been corrected for reading distance so as to allow a near acuity to be calculated. Only Alio 2011, Harman 2008, Javitt 2000 and Leyland 2002 explicitly reported both unaided and best-corrected near acuity and Palmer 2008 reported best-corrected near acuity together with unaided near acuity but wearing a distance correction. However, both Alio 2011 and Palmer 2008 did not state the reading distance or whether the logMAR near acuity was corrected for reading distance, which could have

affected their reported results. Alio 2011 reported the greatest improvement in mean (SD) unaided near acuity (0.23 (0.09) versus 0.47 (0.22) logMAR), while Leyland 2002 found no difference (0.44 (0.18) versus 0.43 (0.16) logMAR). A further problem is the use of Jaeger cards. These 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 the use of a multifocal IOL. It is important to remember, however, that monofocal IOL near acuity can be restored by the use of 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 intraocular lenses are now well-known, particularly near vision. The search for alternative strategies to achieve spectacle independence, such as monovision and accommodating intraocular lenses, should continue.

Quality of the evidence

We graded the quality of the evidence as 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 patients 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 best-corrected distance visual acuity and both unaided and best-corrected near visual acuity, as well as patient-reported spectacle dependence.

AUTHORS' CONCLUSIONS

Implications for practice

There is good evidence that the use of multifocal intraocular lenses improves 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 reduction in contrast sensitivity and the experience of haloes is a matter for an individual patient to decide. The final choice for a patient is likely to depend on his or her 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. Ideally these outcomes should be based on validated measures, particularly for the more subjective outcome measures, and include the views of people who have had cataract surgery.

The search for alternative strategies to achieve spectacle independence, such as monovision 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]*

Alio 2011

Methods	Parallel-group randomised controlled trial Number of participants randomised: 53 Number of eyes included in trial: 106
Participants	Country: Spain Average age 62 years Sex: not reported Ethnic group: not reported Inclusion criteria: cataract (Lens Opacity Classification System III: NO1, C1, P1, or more severity) causing a significant reduction in visual quality, older than 45 years and a minimum education level (reading ability) Exclusion criteria: active ocular disease and astigmatism higher than 3.00 dioptres
Interventions	Bilateral surgery, same IOL in both eyes. • Multifocal (19 people): apodised IOL AcrySof ReSTOR SN6AD3 (Alcon Laboratories, Inc.) • Multifocal (21 people): full diffractive IOL Acri.LISA 366D (Carl Zeiss Meditec AG) • Monofocal (13 people): Acri.Smart 48S (Carl Zeiss Meditec AG) Surgical interventions: co-axial microsurgical phacoemulsification, clear corneal incision enlarged to 3.0 mm for IOL insertion. Incision placed on the steeper corneal meridian
Outcomes	Monocular and binocular outcomes reported Distance and near visual acuity, refraction, contrast sensitivity, quality of life, complications Follow-up: 1 day, 1 month and 3 months
Notes	Funding source: Spanish Ministry of Health (part-funded)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	*"Cataract patients who came to Vissum Instituto Oftalmologico de Alicante for consultation were randomised to receive bilateral implantation of 1 of the 3 IOL models using random-number sequence software."* Page 639
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not masked

Alio 2011 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not masked
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Cillino 2008

Methods	Parallel-group randomised controlled trial Number of participants randomised: 62 (68 randomised, 4 withdrew, 2 excluded) Number of eyes included in trial:124
Participants	Country: Italy Average age 62 years, 53% women Ethnic group: not reported Inclusion criteria: bilateral juvenile or senile cataract, visually significant (i.e. Snellen visual acuity 20/30) in at least 1 eye; corneal astigmatism not 1.0 dioptre (D); and capability of understanding and signing the informed consent Exclusion criteria: age less than 21 years; pre-cataract myopia or hyperopia 3 D; history of amblyopia; fundus abnormalities that could cause significant vision impairment; previous surgical intraocular procedures; and ocular co-morbidities, 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
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (16 people, 32 eyes): refractive SA40N • Multifocal (15 people, 30 eyes): ReZoom • Multifocal (16 people, 32 eyes): Tecnis ZM900 • Monofocal (15 people, 30 eyes): AR 40 All lenses made by Advanced Medical Optics, Santa Ana, CA Surgical interventions: bi-axial microsurgical phacoemulsification, clear corneal incision enlarged to 2.75 mm for IOL insertion
Outcomes	Outcomes reported by eye, no adjustment for within-person correlation Distance, near and intermediate visual acuity, contrast sensitivity, visual functioning, patient satisfaction Follow-up: 1 day, 1 week, 1 month, 3 months, 6 months, 12 months
Notes	Funding source: not reported
Risk of bias	

Cillino 2008 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	*"Randomization used a 1:1:1:1 block randomization scheme generated by SPSS statistical software for Windows (version 14.0, SPSS Inc, Chicago, IL)."* Page 1509
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"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. Patients were observed from the initial preoperative examination until 12 months after surgery in the second eye. The randomization code was maintained only at the central data facility and was not broken until all data analysis was complete."* Page 1509
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"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. Patients were observed from the initial preoperative examination until 12 months after surgery in the second eye. The randomization code was maintained only at the central data facility and was not broken until all data analysis was complete."* Page 1509
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4/68 patients withdrew, 2/68 excluded from analysis because of capsular fibrosis. Not stated precisely which group they belonged to but assume randomised 17 in each group it looks like withdrawals/exclusions equally distributed across groups (Table 1, page 1511)
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

el-Magrahby 1992

Methods	Parallel-group randomised controlled trial Number of participants randomised: 77 Number of eyes included in trial: 77
Participants	Country: Saudi Arabia Average age 57 years (range 45 to 90), 53% women Ethnic group: not reported Inclusion criteria: eligible for cataract surgery by phacoemulsification and the IOL to be implanted was in the range +17.00 to +23.00 D for emmetropia Exclusion criteria: evidence or history of uveitis, active progressive corneal disease, previous intraocular surgery, intraocular pressure > 23 mmHg or on glaucoma medication, diabetic retinopathy, macular degeneration, amblyopia or any other ocular condition that would reduce vision to < 20/40, non senile cataracts or blind in contralateral eye
Interventions	Unilateral surgery • Multifocal group (39 people): refractive and diffractive 815LE (3M healthcare) • Monofocal group (38 people): 15LE (3M healthcare) Both IOLs were rigid polymethylmethacrylate (PMMA) Surgical interventions: phacoemulsification via 3 mm scleral tunnel, can-opener capsulotomy, incision enlarged to 6.5 mm for IOL insertion
Outcomes	Distance acuity, near acuity Follow-up: 2 to 4 weeks and 2 to 4 months
Notes	Funding source: Saudi Eye Foundation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"Randomization schedules were generated using Prodas, a statistical software package."* Page 148
Allocation concealment (selection bias)	Low risk	Author correspondence
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and lenses different
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described and lenses different
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4/39 multifocal cases excluded from the analyses, 0/38 monofocal excluded. Reasons for exclusion: maculopathy, posterior subcapsular opacification and high astigmatism

el-Magrahby 1992 (*Continued*)

		Follow-up described in table 2, page 149. 28/35 multifocal and 33/38 monofocal followed up 2 to 4 months
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Haaskjold 1998

Methods	Parallel-group randomised controlled trial Number of participants randomised: 221 Number of eyes included in trial: 221 Multicentre
Participants	Country: England, Finland, Germany, Norway, Portugal, Sweden Average age 67 years, (range ? to 90 years) Sex: not reported in main paper but in interim analysis (Allen 1996) was 51% women Ethnic group: not reported Inclusion criteria: not reported Exclusion criteria: not reported
Interventions	Unilateral surgery • Multifocal (115 people): diffractive bifocal 808X (Pharmacia Ophthalmics) • Monofocal (106 people): monofocal IOL 808D Both IOLs were rigid polymethylmethacrylate (PMMA) Surgical interventions: extracapsular extraction in 49 out of 221 participants, remainder with phacoemulsification (incision type not specified). Capsulotomy type not specified
Outcomes	Distance acuity, near acuity, contrast sensitivity, spectacle use, non-validated questionnaire, adverse phenomena Follow-up: 5 to 6 months
Notes	Funding source: multifocal IOL manufacturer

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Author correspondence
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described and study described as "open"

Haaskjold 1998 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described and study described as "open"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Harman 2008

Methods	Parallel-group randomised controlled trial Number of participants randomised: 60 Number of eyes included in trial: 120 Note: 90 participants in whole trial but 60 in multifocal/monofocal groups
Participants	Country: England Average age 72 years, 55% women Ethnic group: not reported. Inclusion criteria: age over 21 years, bilateral visually significant cataract and 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 visual acuity to 6/9 (e.g. amblyopia, corneal opacity, macular disease), preoperative corneal astigmatism of 2 dioptres (D) in either eye
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (30 people): refractive Array SA40N (AMO) • Monofocal (30 people): Clariflex (AMO) Surgical interventions: phacoemulsification via 2.8 mm clear corneal incision. LRIs performed in 3 multifocal and 2 monofocal
Outcomes	Outcomes measured at person level Binocular distance and near acuity, refraction, contrast sensitivity, glare disability, amplitude of accommodation Follow-up: 3 and 18 months
Notes	Funding source: Hillingdon Hospital Research and Development Fund

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described

Allocation concealment (selection bias)	Unclear risk	*"Patients 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."* Page 994
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"All examiners were masked at the 3- and 18-month reviews. Patients 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."* Page 995 However, data for distance BCVA and UCVA, and NVA extracted at 3 months. Glare data extracted from 18 months
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"All examiners were masked at the 3- and 18-month reviews. Patients 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."* Page 995
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	*"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, 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."* Page 996 However, minimal effect as data extracted at 3 months 82/90 (91%) followed up at 3 months; 64/90 (71%) followed up at 18 months Attrition rate quite high at 18 months and not reported by treatment group

Harman 2008 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Javitt 2000

Methods	Parallel-group randomised controlled trial Number of participants randomised: 245 Multicentre Note: 266 participants enrolled, 261 had first eye surgery and of these 245 (94%) had second eye surgery and were included in the analyses
Participants	Country: USA, Germany, Austria Average age 72 years (range 59 to 87), 56% women Ethnic group: not reported. Inclusion criteria: 50 and 85 years of age with bilateral cataracts, less than 1.50 dioptres (D) of keratometric cylinder, 20/30 or better potential VA, and no indication of existing ocular pathologic characteristics other than cataract Exclusion criteria: not reported
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (127 people): refractive SA40N (Allergan) • Monofocal (118 people): Phacoflex II SI40NB (Allergan) Both IOLs were foldable 3-piece lenses, with polymethylmethacrylate haptics and silicone optics Surgical interventions: phacoemulsification via either scleral tunnel, limbal or clear corneal incision ranging from 3.0 to 4.0 mm wide, continuous circular capsulorhexis
Outcomes	Outcomes measured at person level Spectacle dependence for daily tasks, binocular distance and near acuity, visual functioning and quality of life (modified Cataract TyPE questionnaire) Follow-up: 3 months
Notes	Funding source: multifocal IOL manufacturer

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"A block randomization schedule by patient was prepared for each site using SAS software, (SAS Institute, Cary, NC) with IOL groups assigned in blocks of two. For each block of two patients, either the first patient or the second (in random order) received a multifocal lens."* Page 2041

Allocation concealment (selection bias)	Low risk	*"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".* Page 2041
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"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. Patients were observed from the initial preoperative examination until 3 months after surgery in the second eye.The randomization code was maintained only at the central data facility and was not broken until all data analysis of primary and secondary outcome variables presented in this manuscript was complete."* Page 2041 *"To protect patient safety, those randomly allocated to the multifocal lens group were asked after the first-eye surgery whether they wished to have the same lens type in the second eye, without being told what type that was."* Page 2041
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"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. Patients were observed from the initial preoperative examination until 3 months after surgery in the second eye.The randomization code was maintained only at the central data facility and was not broken until all data analysis of primary and secondary outcome variables presented in this manuscript was complete."* Page 2041 *"To protect patient safety, those randomly allocated to the multifocal lens group were asked after the first-eye surgery whether they wished to have the same lens type in the second eye, without being told what type that was."* Page 2041

Javitt 2000 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	266 enrolled, 5 withdrew as did not meet study entrance criteria, 261 (134 multifocal and 127 monofocal) had first eye surgery, 16 withdrew before second eye surgery (7 multifocal, 9 monofocal), 245 had second eye surgery (included in report) and 235 followed up. 124/134 (93%) multifocal group followed up and 111/127 (87%) of monofocal group followed up
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Jusufovic 2011

Methods	Parallel-group randomised controlled trial Number of participants randomised: 100 Number of eyes included in trial: 100
Participants	Country: Bosnia and Herzegovina Average age 47 years, 44% women Ethnic group: not reported. Inclusion criteria: 14 to 80 years, astigmatism less than 1 D cylinder Exclusion criteria: chronic inflammatory and degenerative diseases of the anterior and posterior eye segment, previous surgery on the eye, high refractive anomalies, systemic diseases that can significantly influence vision quality after surgery
Interventions	Uniltateral surgery • Multifocal (50 people): ReZoom refractive zone-progressive NXG1 (AMO) • Monofocal (50 people): AcrySof MA60BM (Alcon) Surgical interventions: phacoemulsification via 3.0 mm clear corneal incision
Outcomes	Outcomes measured at person level Binocular distance and near vision, stereo vision Follow-up: 6 weeks
Notes	Funding source: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"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. The nurse who did not participate in the study picked papers*

Jusufovic 2011 (*Continued*)

		from the bag and divided patients into two groups." Page 64
Allocation concealment (selection bias)	Low risk	*"Also, surgeon who carried out the operations did not know which group does the patient belong, until the very moment of intraocular lens implantation."* Page 64 Unclear if person enrolling patients was aware?
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Kamlesh 2001

Methods	Parallel-group randomised controlled trial Number of participants randomised: 40 Number of eyes included in trial: 40
Participants	Country: India Average age 55 years Sex: not reported Inclusion criteria: age-related cataract Exclusion criteria: known disease likely to interfere with the postoperative visual function, preoperative astigmatism > 1.50 D, axial length greater than that requiring estimated IOL power of 18.00 D to 24.00 D for emmetropia, previous eye surgery
Interventions	Unilateral surgery - Multifocal (20 people): Progress 3 aspheric (Laboratoires Domilens) - Monofocal (20 people): Flex 65 (Laboratoires Domilens) Surgical intervention: extracapsular extraction, envelope capsulotomy Refractive aim not stated
Outcomes	Distance acuity, near vision and reading addition, contrast sensitivity, depth of focus, subjective quality of vision Follow-up: 1 week, 3 weeks, 6 weeks, 3 months and every 3 months thereafter
Notes	Funding source: not specified

Kamlesh 2001 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Leyland 2002

Methods	Parallel-group randomised controlled trial Number of participants randomised: 50 Number of eyes included in trial: 100
Participants	Country: England Average age 75 years, 50% women Inclusion criteria: > 18 years of age, 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 the range available for multifocal IOL (16 to 24 D)
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (31 people): Array SA40NB (Allergan) • Bifocal (19 people): TrueVista 68STUV (Storz) • Monofocal (19 people): Phacoflex S140N (Allergan) Surgical intervention: phacoemulsification via 2.8 mm clear corneal incision, for insertion of IOL incision enlarged to 3.0 mm for Array SA40NB and Phacoflex s140N, and to 5.5 mm for TrueVista 68STUV, aiming for emmetropia
Outcomes	Outcomes measured at person level Binocular distance acuity, near acuity, contrast sensitivity, glare, depth of field, validated visual functioning and quality of life questionnaire (TyPE)

	Follow-up: 6 weeks and 12 months	
Notes	Funding source: no external funding	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"Patients were randomly allocated to one of the three types of IOL from sealed envelopes opened on the preoperative ward round on the day of surgery"* Page 482 Not clearly stated but judgement is that the allocation was probably random
Allocation concealment (selection bias)	Low risk	*"Patients were randomly allocated to one of the three types of IOL from sealed envelopes opened on the preoperative ward round on the day of surgery"* Page 482
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"Patients were informed that IOL type implanted would not be revealed to them until the completion of the trial"* Page 482 [the observers] *"were masked as to the nature of the IOL implanted"* Page 483
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"Patients were informed that IOL type implanted would not be revealed to them until the completion of the trial"* Page 482 [the observers] *"were masked as to the nature of the IOL implanted"* Page 483
Incomplete outcome data (attrition bias) All outcomes	Low risk	Assessment at 50 weeks: • Monofocal: 15/19 • Multifocal: 25/31 • Bifocal: 14/19 Exclusions after randomisation: • Monofocal: 3/19 (2 died, 1 incorrect IOL) • Multifocal: 2/31 (1 illness, 1 endophthalmitis) • Bifocal: 4/19 (2 illness, 1 AMD, 1 incorrect IOL)
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Nijkamp 2004

Methods	Parallel-group randomised controlled trial Number of participants randomised: 190, reported on 153 Note discrepancy: 190 participants enrolled, 30 excluded after randomisation, a further 23 lost to follow-up
Participants	Country: Austria Average age 72 years, 46% women Ethnic group: not reported Inclusion criteria: bilateral age-related cataract, astigmatism of <= 1.5 D, spectacle sphere power between 6 and 4 D, axial eye length between 19.5 and 26 mm, not professional night driver, ability to complete questionnaires in Dutch and no mental retardation (as diagnosed in the medical file or concluded from contact by telephone) Exclusion criteria: eye disease other than cataract that might limit postoperative vision
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (93 people): Array SA40N (Advanced Medical Optics) • Monofocal group (97 people): PhacoFlex II SI40NB (Advanced Medical Optics) Surgical intervention: phacoemulsification via 3.2 mm posterior limbal incision, sutureless closure, aiming for emmetropia
Outcomes	Unclear if outcomes reported by eye or by person Distance acuity, near acuity Follow-up: 3 months after surgery, reported after first eye and second eye surgery
Notes	Funding source: Eye Research Institute Maastricht

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"Block randomization by means of a computerized random number generator was used to keep the number of subjects in the different groups balanced."* Page 1834
Allocation concealment (selection bias)	Low risk	*"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."* Page 1834/1835
Blinding of participants and personnel (performance bias) All outcomes	High risk	*"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*

Nijkamp 2004 (*Continued*)

		characteristics of both types of IOL from their description in the patient information" Page 1835
Blinding of outcome assessment (detection bias) All outcomes	High risk	"*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. To control the assessments with respect to the amount of attention given to a patient, a time analysis was conducted on both interviews and ophthalmic tests at t1, t2, and t3, which revealed that interviewers and ophthalmologists shared an equal period of time with both patient groups at all time points (P_0.05).*" Page 1835
Incomplete outcome data (attrition bias) All outcomes	High risk	Completed trial: • Monofocal 69/97 • Multifocal 68/93 Excluded people with complications and refractive error (multifocal n = 3 and monofocal n = 8) after randomisation
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Palmer 2008

Methods	Parallel-group randomised controlled trial Number of participants randomised: 114 Number of eyes included in trial: 228
Participants	Country: Spain Average age 73 years, 63% women Ethnic group: not reported Inclusion criteria: both eyes had to be healthy, with no disease except cataract Exclusion criteria: professional drivers
Interventions	Bilateral surgery, same IOL in both eyes • Multifocal (26 people): diffractive Tecnis ZM900 (Advanced Medical Optics) • Multifocal (32 people): refractive ReZoom (Advanced Medical Optics) • Multifocal (32 people): diffractive TwinSet (Acri.Tec, GmbH) • Monofocal (24 people): prolate aspherical Tecnis Z9OOO (Advanced Medical Optics) Surgical interventions: phacoemulsification via 2.75 mm clear corneal incision on steep meridian, coupled incision opposite if pre-operative astigmatism 1.50 to 2.00 D

Palmer 2008 (*Continued*)

Outcomes	Outcomes measured binocularly and monocularly Distance visual acuity, refraction, contrast sensitivity, questionnaire Follow-up: 3 months
Notes	Funding source: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"Patients were informed that the IOL- type implanted would not be revealed to them until the completion of the trial."* Page 258
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"Refraction measurements were performed by a single independent observer who was unaware of the purpose of the study."* Page 258
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Percival 1993

Methods	Parallel-group randomised controlled trial Number of participants randomised: 50 Number of eyes included in trial: 50
Participants	Country: England Average age 77 years, 58% women Ethnic group: not reported Inclusion criteria: scheduled for cataract surgery Exclusion criteria: other ocular pathology
Interventions	Unilateral surgery • Multifocal (25 people): refractive MPC25 (Allergan) • Monofocal (25 people): PC25 (Allergan) The refractive aims were different in the 2 groups: multifocal IOLs were chosen to aim for emmetropia, monofocal IOLs were chosen, and surgical incisions constructed, to aim for myopic astigmatism

Percival 1993 (*Continued*)

	Surgical interventions: extracapsular extraction, can-opener capsulotomy technique
Outcomes	Distance acuity, near acuity, depth of field, contrast sensitivity, spectacle use, non-validated subjective outcome, adverse phenomena Follow-up: 4 to 6 months
Notes	Funding source: not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described, interventions different
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Rossetti 1994

Methods	Parallel-group randomised controlled trial Number of participants randomised: 80 Number of eyes included in trial: 80
Participants	Country: Italy Average age 71 years, 59% women Ethnic group: not reported Inclusion criteria: astigmatism <= 2.5 D, spherical equivalent in the fellow eye of no more than 2.5 D, cataract in one eye, clear lens or very early cataract in fellow eye that would not require surgery during the study Exclusion criteria: > 1.5 D astigmatism, IOL in fellow eye, fundus abnormalities causing significant vision impairment or if they could not be followed for 1 year
Interventions	Unilateral surgery • Multifocal (38 people): diffractive unspecified model (3M healthcare)

Rossetti 1994 (*Continued*)

	• Monofocal (42 people): unspecified (3M healthcare) Both IOLs were rigid polymethylmethacrylate (PMMA) Surgical interventions: extracapsular extraction capsulotomy not specified
Outcomes	Distance acuity, near acuity, contrast sensitivity, spectacle-use, non-validated subjective assessment of visual quality questionnaire, adverse phenomena Follow-up: 3, 6 and 12 months
Notes	Funding source not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Sen 2004

Methods	Parallel-group randomised controlled trial Number of participants randomised: 80 Number of eyes included in trial: 120
Participants	Country: Finland Average age 71 years (range 41 to 88), 68% women Inclusion criteria: patients were "selected from the hospital queue", both eyes had to be healthy, with no disease except cataract, patients needed to understand the possible benefit of having implantation of a multifocal IOL instead of a monofocal IOL and have potential good vision in both eyes after cataract surgery and IOL implantation
Interventions	Some people had bilateral surgery and some people had unilateral surgery. If bilateral surgery, the same lens type was used

Sen 2004 (*Continued*)

	• Multifocal (35 people, 53 eyes): Array SA40N (Advanced Medical Optics) • Monofocal (40 people, 67 eyes): PhacoFlex II SI40NB (Advanced Medical Optics) Surgical interventions: phacoemulsification via 3.0 mm temporal clear corneal incision
Outcomes	Outcomes reported by person and by eye, no adjustment for within-person correlation Distance acuity, near acuity, contrast sensitivity, glare, halos, validated questionnaire Follow-up: 1 month
Notes	Funding source: government grant (TYH 3234), Finnish Eye Foundation Grant and Allergan Norden

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"Patients were randomised to receive a monofocal IOL (SI-40NB, AMO) or multifocal IOL (Array SA40N) using the sealed-envelope method"*. Page 2484
Allocation concealment (selection bias)	Low risk	*"Patients were randomised to receive a monofocal IOL (SI-40NB, AMO) or multifocal IOL (Array SA40N) using the sealed-envelope method"*. Page 2484
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not described
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	5/40 in multifocal group refused to participate after randomisation
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Steinert 1992

Methods	Parallel-group randomised controlled trial Number of participants randomised: 62 Number of eyes included: 62 Multicentre
Participants	Country: USA Average age 72 years, 58% female

Steinert 1992 (*Continued*)

	Ethnic group: not reported
Interventions	Unilateral surgery • Multifocal (32 people): zonal-progressive refractive Array MPC-25NB (Advanced Medical Optics) • Monofocal (30 people) PC25-NB (Advanced Medical Optics) Both IOLs were rigid polymethylmethacrylate (PMMA) Surgical interventions: phacoemulsification, incision type and capsulotomy not specified
Outcomes	Distance acuity, near acuity, depth of field, contrast sensitivity, glare, spectacle use, non-validated subjective assessment of difficulty and limitation with visual tasks questionnaire, adverse phenomena Follow-up: 3 to 6 months
Notes	Funding source: sponsored by multifocal IOL manufacturer

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"To provide balance at each of the 10 sites, a randomized block design was used"*. Page 854
Allocation concealment (selection bias)	Low risk	*"The lenses were centrally encoded labelled such that the patient record did not indicate which IOL was implanted"* Page 854
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"Before giving consent, patients were told that they would not know which lens they had received until 1 year after surgery"*. Page 854 *"Both the patient and the ophthalmic technical staff performing objective measures were masked regarding the identity of the implant."* Page 854
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"Before giving consent, patients were told that they would not know which lens they had received until 1 year after surgery"*. Page 854 *"Both the patient and the ophthalmic technical staff performing objective measures were masked regarding the identity of the implant."* Page 854
Incomplete outcome data (attrition bias) All outcomes	Low risk	Table 1 page 855 shows that mean follow-up was similar in the 2 groups (121 days versus 129 days)

Steinert 1992 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

Zhao 2010

Methods	Parallel-group randomised controlled trial Number of participants randomised: 161 Number of eyes included in trial: 161
Participants	Country: China Average age 66 years (range 34 to 92), 47% women Ethnic group: not reported Inclusion criteria: corrected distance visual acuity worse than 10/25, nuclear hardness from grade II to IV on the Emery-Little classification, corneal astigmatism less than 1. 50 dioptres (D), corneal endothelium cell count greater than 2000 cells/mm^2, ability to understand and sign an informed consent form Exclusion criteria: younger than 21 years, myopia or hyperopia greater than 3.00 D, history of amblyopia, fundus abnormalities that could cause significant vision impairment, previous intraocular surgery, ocular comorbidity (e.g. previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal opacity, senile miosis hyporeactive pupil), or a-antagonist (tamsulosin) treatment. Intraoperative exclusion criteria were iris pupil trauma, vitreous loss and IOL implantation outside the capsular bag
Interventions	Unilateral surgery • Multifocal (n = 72): apodised AcrySof ReSTOR SA60D3 (Alcon) • Monofocal (n = 89): AcrySof SA60AT (Alcon) Surgical intervention: phacoemulsification via either 3.0 mm or 3.2 mm clear corneal incision
Outcomes	Distance and near visual acuity, contrast sensitivity, visual functioning questionnaire (VF-7) Follow-up: 1 week, 1 month, 6 months
Notes	Funding source: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	*"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.)."* Page 283

Zhao 2010 (*Continued*)

Allocation concealment (selection bias)	Low risk	*"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.)."* Page 283
Blinding of participants and personnel (performance bias) All outcomes	Low risk	*"The patients and the medical staff who collected visual function and quality-of-life data were masked to the type of IOL each patient received."* Page 283
Blinding of outcome assessment (detection bias) All outcomes	Low risk	*"The patients and the medical staff who collected visual function and quality-of-life data were masked to the type of IOL each patient received."* Page 283
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	Difficult to ascertain with information available

AMD: age-related macular degeneration
BCVA: best-corrected visual acuity
D: dioptre
ECCE: extracapsular cataract extraction
IOL: intraocular lens
NVA: near visual acuity
Phaco: phacoemulsification
UCVA: uncorrected visual acuity
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
Allen 2009	Participants not randomly allocated to intervention

(*Continued*)

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
Ortiz 2008	Participants not randomly allocated to intervention
Richter-Mueksch 2002	Not randomised, case-control study
Rocha 2005	Participants not randomly allocated to intervention
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

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

ISRCTN37400841

Trial name or title	A prospective randomised controlled trial comparing bilateral multifocal intraocular lens implantation with monovision following cataract surgery
Methods	Prospective randomised controlled trial
Participants	• Patients requiring bilateral cataract surgery with good visual potential and a full visual field in each eye • Age range 30 to 90 years • Biometry indicating IOL power requirement within the range +10 to +30 D for emmetropia (0.00 to -0.50 D spherical equivalent) in both eyes
Interventions	Bilateral intraocular lens implant with either TECNIS ZM000 multifocal or Bausch and Lomb Akreos AO monofocal intraocular lenses
Outcomes	Primary outcome: percentage of patients with total spectacle independence Secondary outcomes: • Visual Function 14-question (VF14) questionnaire • Near visual acuity • Reading speed • Binolcular Logarithm of the Minimum Angle of Resolution (logMAR) acuity • Binocular Pelli Robson contrast sensitivity - photopic and dark adapted • Procyon pupillometry • Forward light scatter - van den Berg forward light scatter test • Wavefront aberrations - Shack Hartmann aberrometry
Starting date	1 February 2007
Contact information	
Notes	http://www.controlled-trials.com/ISRCTN37400841

NCT01088282

Trial name or title	Visual and economic profits of ReSTOR® multifocal intraocular lenses (IOL) on public health patients in Spain
Methods	Randomised controlled trial. Parallel assignment. Not masked
Participants	Men and women aged 50 years and above Inclusion criteria: • Patients of both sexes aged 50 and over, with fully established presbyopia, requiring phacoemulsification + IOL as the surgical technique for the removal of their cataracts • Their capsular bags should be stable, with keratometric astigmatism equal to or lower than 1 dioptre • Biometric calculations should indicate an IOL for emmetropia within the common dioptric range for both lenses, i.e. between +6 to +34 Exclusion criteria: • Previous corneal refractive surgery

NCT01088282 (*Continued*)

	• Maculopathy, amblyopia or other eye conditions that limit visual power • Occupations requiring special driving licenses • Keratometric astigmatism higher than 1 dioptre • Any intraoperative posterior capsular rupture or extracapsular reconversion
Interventions	Difractive multifocal lens (SN6AD1 (Alcon labs, Fotworth, Texas)) compared to monofocal lens (SN60WF (Alcon labs, Fotworth, Texas))
Outcomes	Primary outcome measures: • Visual function quality (VF-14) at 1 and 3 months post-intervention Secondary outcome measures: • Visual acuity with and without correction at 1 and 3 months post-intervention • Expense in glasses at 3 months post-intervention
Starting date	March 2010 to March 2011
Contact information	Josep Torras MD; jtorras@clinic.ub.es
Notes	http://clinicaltrials.gov/show/NCT01088282

IOL: intraocular lens

DATA AND ANALYSES

Comparison 1. Multifocal IOLs versus monofocal IOLs

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Distance visual acuity - less than 6/6 unaided	7	632	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.91, 1.05]
2 Distance visual acuity - mean unaided	10	1015	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.23, 0.02]
3 Distance visual acuity - less than 6/6 best-corrected	8	692	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.71, 1.45]
4 Distance visual acuity - mean best-corrected	9	947	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.17, 0.32]
5 Near visual acuity - less than J3/J4 unaided	7		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
6 Near visual acuity - mean unaided	5		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
7 Near visual acuity - mean best-corrected	5		Std. Mean Difference (IV, Random, 95% CI)	Totals not selected
8 Near vision results not otherwise reported			Other data	No numeric data
9 Spectacle dependence	11	1207	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.48, 0.75]
10 Depth of field			Other data	No numeric data
11 Contrast sensitivity: Pelli Robson chart	4	219	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.15, 0.01]
12 Contrast sensitivity: other charts			Other data	No numeric data
12.1 VCTS chart			Other data	No numeric data
12.2 Regan Contrast Acuity Chart			Other data	No numeric data
12.3 Other charts			Other data	No numeric data
13 Glare disability (Brightness Acuity Tester)			Other data	No numeric data
14 Patient reported glare/haloes	8	699	Risk Ratio (M-H, Random, 95% CI)	1.94 [1.51, 2.49]
15 Visual functioning			Other data	No numeric data
16 Patient-reported satisfaction with vision			Other data	No numeric data

Analysis 1.1. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 1 Distance visual acuity - less than 6/6 unaided.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 1 Distance visual acuity - less than 6/6 unaided

Study or subgroup	Multifocals n/N	Monofocal n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
el-Magrahby 1992	22/28	21/33		4.9 %	1.23 [0.89, 1.70]
Haaskjold 1998	58/79	52/70		13.9 %	0.99 [0.82, 1.20]
Jusufovic 2011 (1)	40/50	44/50		17.1 %	0.91 [0.77, 1.08]
Leyland 2002	7/44	3/16		0.3 %	0.85 [0.25, 2.89]
Rossetti 1994	35/38	38/42		27.8 %	1.02 [0.89, 1.17]
Sen 2004	45/53	62/67		29.1 %	0.92 [0.80, 1.05]
Steinert 1992	26/32	22/30		6.9 %	1.11 [0.84, 1.46]
Total (95% CI)	**324**	**308**		**100.0 %**	**0.98 [0.91, 1.05]**

Total events: 233 (Multifocals), 242 (Monofocal)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 4.90$, df = 6 (P = 0.56); $I^2 = 0.0\%$

Test for overall effect: Z = 0.58 (P = 0.56)

Test for subgroup differences: Not applicable

(1) Follow-up: 6 weeks

Analysis 1.2. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 2 Distance visual acuity - mean unaided.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 2 Distance visual acuity - mean unaided

Study or subgroup	Multifocal N	Mean(SD)	Monofocal N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Alio 2011	80	0.05 (0.09)	26	0.03 (0.06)		8.3 %	0.24 [-0.21, 0.68]
Cillino 2008	47	-0.81 (0.23)	15	-0.79 (0.29)		4.9 %	-0.08 [-0.66, 0.50]
Harman 2008	27	0.05 (0.15)	27	0.08 (0.1)		5.7 %	-0.23 [-0.77, 0.30]
Javitt 2000	123	-7.78 (1.21)	109	-7.66 (1.36)		24.7 %	-0.09 [-0.35, 0.16]
Jusufovic 2011	50	-0.83 (0.131)	50	-0.8 (0.124)		10.6 %	-0.23 [-0.63, 0.16]
Leyland 2002	44	0.08 (0.13)	16	0.05 (0.15)		5.0 %	0.22 [-0.36, 0.79]
Nijkamp 2004	68	0.13 (0.2)	69	0.16 (0.2)		14.6 %	-0.15 [-0.48, 0.19]
Palmer 2008	58	0.16 (0.68)	24	0.13 (0.09)		7.3 %	0.05 [-0.42, 0.53]
Sen 2004	53	-0.66 (0.24)	67	-0.56 (0.23)		12.4 %	-0.42 [-0.79, -0.06]
Steinert 1992	32	-6.33 (1.73)	30	-6.37 (1.93)		6.6 %	0.02 [-0.48, 0.52]
Total (95% CI)	**582**		**433**			**100.0 %**	**-0.10 [-0.23, 0.02]**

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 7.82$, df = 9 (P = 0.55); $I^2 = 0.0\%$

Test for overall effect: Z = 1.58 (P = 0.11)

Test for subgroup differences: Not applicable

Analysis 1.3. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 3 Distance visual acuity - less than 6/6 best-corrected.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 3 Distance visual acuity - less than 6/6 best-corrected

Study or subgroup	Multifocals n/N	Monofocal n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
el-Magrahby 1992	8/27	7/32		10.2 %	1.35 [0.56, 3.25]
Haaskjold 1998	38/115	24/106		19.3 %	1.46 [0.94, 2.26]
Kamlesh 2001	1/20	5/20		2.7 %	0.20 [0.03, 1.56]
Leyland 2002	4/44	2/16		4.2 %	0.73 [0.15, 3.60]
Percival 1993	9/25	6/25		10.3 %	1.50 [0.63, 3.59]
Rossetti 1994	18/38	19/42		18.4 %	1.05 [0.65, 1.68]
Sen 2004	23/53	48/67		21.8 %	0.61 [0.43, 0.85]
Steinert 1992	12/32	9/30		13.1 %	1.25 [0.62, 2.53]
Total (95% CI)	**354**	**338**		**100.0 %**	**1.02 [0.71, 1.45]**

Total events: 113 (Multifocals), 120 (Monofocal)

Heterogeneity: $Tau^2 = 0.12$; $Chi^2 = 15.21$, df = 7 (P = 0.03); $I^2 = 54\%$

Test for overall effect: Z = 0.10 (P = 0.92)

Test for subgroup differences: Not applicable

Analysis 1.4. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 4 Distance visual acuity - mean best-corrected.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

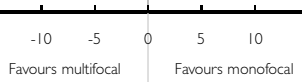
Outcome: 4 Distance visual acuity - mean best-corrected

Study or subgroup	Multifocal N	Mean(SD)	Monofocal N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
Alio 2011	80	0 (0.03)	26	0.02 (0.04)		11.0 %	-0.61 [-1.06, -0.16]
Cillino 2008	47	-0.98 (0.16)	15	-1 (0.1)		8.8 %	0.13 [-0.45, 0.72]
Harman 2008	27	0.02 (0.09)	27	0 (0.1)		9.6 %	0.21 [-0.33, 0.74]
Javitt 2000	123	-8.4 (0.97)	109	-8.46 (0.94)		14.7 %	0.06 [-0.20, 0.32]
Leyland 2002	44	0.05 (0.1)	16	-0.01 (0.11)		8.8 %	0.58 [-0.01, 1.16]
Nijkamp 2004	68	0.02 (0.1)	69	0.03 (0.1)		13.2 %	-0.10 [-0.43, 0.24]
Palmer 2008	90	0.09 (0.07)	24	0.05 (0.05)		10.9 %	0.60 [0.14, 1.06]
Sen 2004	53	-0.87 (0.17)	67	-0.81 (0.19)		12.7 %	-0.33 [-0.69, 0.03]
Steinert 1992	32	-7.67 (1.25)	30	-8.19 (1.49)		10.1 %	0.37 [-0.13, 0.88]
Total (95% CI)	**564**		**383**			**100.0 %**	**0.07 [-0.17, 0.32]**

Heterogeneity: $Tau^2 = 0.09$; $Chi^2 = 23.76$, df = 8 (P = 0.003); $I^2 = 66\%$

Test for overall effect: Z = 0.58 (P = 0.56)

Test for subgroup differences: Not applicable



Analysis 1.5. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 5 Near visual acuity - less than J3/J4 unaided.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 5 Near visual acuity - less than J3/J4 unaided

Study or subgroup	Multifocal n/N	Monofocal n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
el-Magrahby 1992 (1)	3/23	7/24		0.45 [0.13, 1.52]
Haaskjold 1998 (2)	14/116	92/101		0.13 [0.08, 0.22]
Javitt 2000 (3)	4/123	37/109		0.10 [0.04, 0.26]
Jusufovic 2011 (4)	0/50	25/50		0.02 [0.00, 0.31]
Leyland 2002 (5)	31/44	13/16		0.87 [0.64, 1.17]
Percival 1993 (6)	5/25	10/25		0.50 [0.20, 1.25]
Rossetti 1994 (7)	5/38	25/42		0.22 [0.09, 0.52]

(1) Worse than Jaegar J3, reading distance not stated

(2) Worse than Jaegar J3, reading distance 36cm

(3) Worse than Jaegar J3, reading distance 35-46cm

(4) Worse than Jaegar J3, reading distance 40cm

(5) Worse than Jaegar J3, reading distance "patient preference"

(6) Worse than Jaegar J3, reading distance not stated

(7) Worse than Jaegar J4, reading distance 40cm.

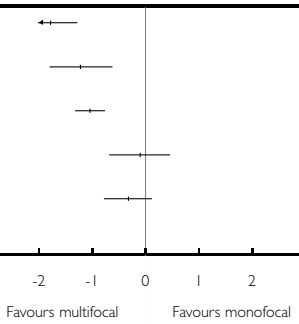
Analysis 1.6. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 6 Near visual acuity - mean unaided.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 6 Near visual acuity - mean unaided

Study or subgroup	Multifocal N	Mean(SD)	Monofocal N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
Alio 2011 (1)	80	0.23 (0.09)	26	0.47 (0.22)		-1.79 [-2.29, -1.28]
Harman 2008 (2)	27	0.55 (0.13)	27	0.73 (0.16)		-1.22 [-1.80, -0.63]
Javitt 2000 (3)	123	0.11 (0.14)	109	0.3 (0.22)		-1.04 [-1.32, -0.77]
Leyland 2002 (4)	44	0.44 (0.18)	16	0.46 (0.16)		-0.11 [-0.69, 0.46]
Palmer 2008 (5)	90	0.02 (0.05)	24	0.04 (0.09)		-0.33 [-0.78, 0.12]



(1) Reading distance: not stated

(2) Reading distance: 40 cm

(3) Reading distance: 35-46 cm

(4) Reading distance: patient preference

(5) Reading distance: not stated

Analysis 1.7. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 7 Near visual acuity - mean best-corrected.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 7 Near visual acuity - mean best-corrected

Study or subgroup	Multifocal N	Mean(SD)	Monofocal N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Std. Mean Difference IV,Random,95% CI
Alio 2011	80	0.18 (0.1)	26	0.24 (0.19)		-0.47 [-0.91, -0.02]
Harman 2008	27	0.39 (0.12)	27	0.5 (0.18)		-0.71 [-1.26, -0.16]
Javitt 2000	123	0 (0.06)	109	0 (0.05)		0.0 [-0.26, 0.26]
Leyland 2002	44	0.33 (0.25)	16	0.2 (0.13)		0.57 [-0.01, 1.15]
Palmer 2008	90	0.02 (0.05)	24	0.04 (0.09)		-0.33 [-0.78, 0.12]

Analysis 1.8. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 8 Near vision results not otherwise reported.

Near vision results not otherwise reported

Study	Outcome	Reading distance	Multifocal	Monofocal
Cillino 2008	Sloan near acuity charts with 100% contrast	35 cm	0.65 (0.25)	0.42 (0.13)
Kamlesh 2001	Worse than N9 with distance correction	Not stated	2/20 (10%)	18/20 (90%)
Nijkamp 2004	Mean (SD) De Nederlander Reading chart: uncorrect Mean (SD) De Nederlander Reading chart: corrected	Not stated	0.8 (0.3) 1.2 (0.2)	0.6 (0.3) 1.1 (0.2)
Sen 2004	Mean (SD) Snellen equivalent near acuity (using Jaeger chart): uncorrected Mean (SD) Snellen equivalent near acuity (using Jaeger chart): distance cor-	Not stated	0.42 (0.15) 0.50 (0.15) 0.71 (0.14)	0.32 (0.18) 0.28 (0.16) 0.72 (0.12)

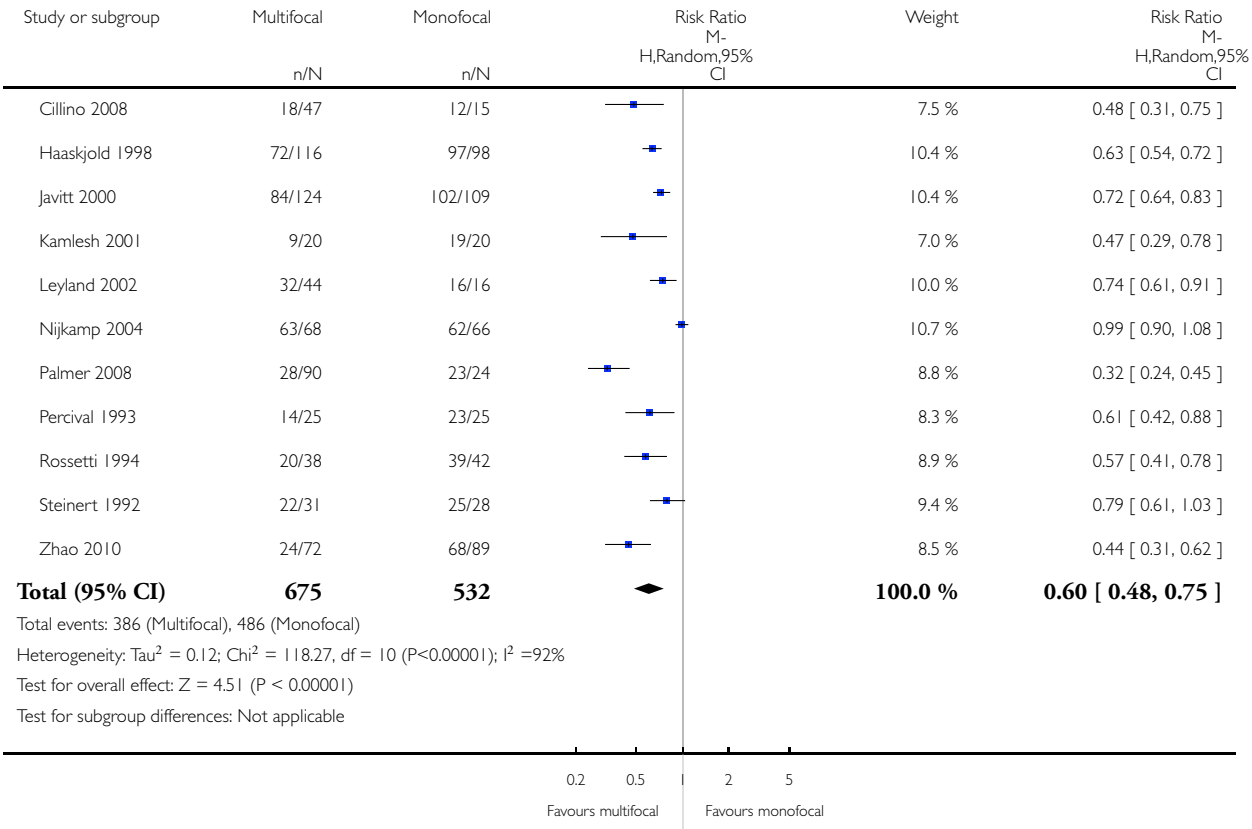
	rected Mean (SD) Snellen equivalent near acuity (using Jaeger chart): near corrected			
Steinert 1992	Mean Jaeger acuity Snellen equivalent (SD)	36 cm	J3+ 20/36 (+/- 2.1 lines)	J7 20/74 (+/-2.6 lines)
Zhao 2010	Sloan near acuity charts with 100% contrast	33 cm	No data	No data

Analysis 1.9. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 9 Spectacle dependence.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 9 Spectacle dependence



Analysis 1.10. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 10 Depth of field.

Depth of field

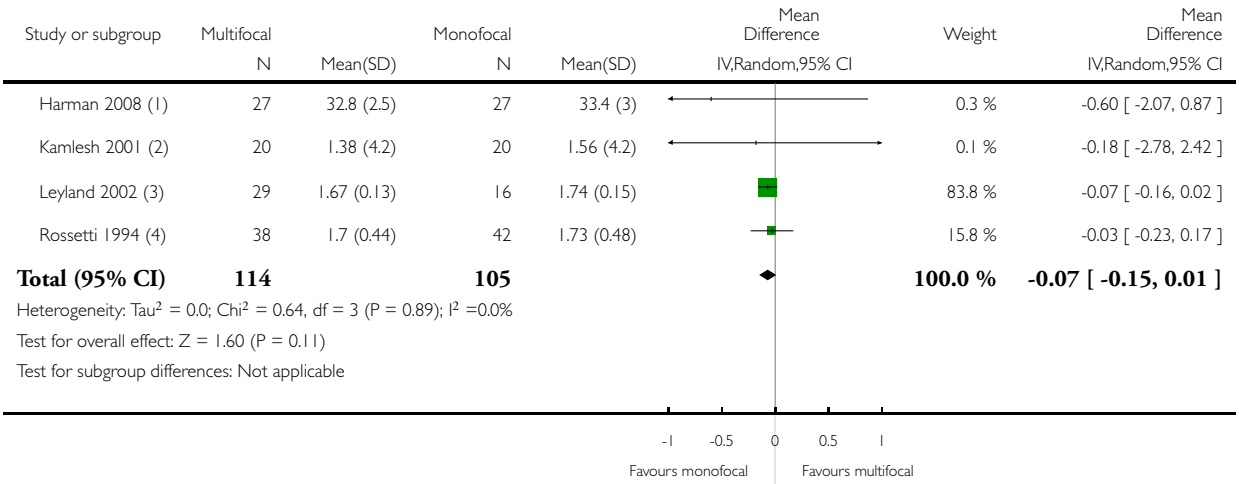
Study	**Method**	**Outcome**	**Multifocal**	**Monofocal**
Cillino 2008	Defocus +2 D through to -5 D from distance Rx	Mean visual acuity (Snellen decimal) with -3 D defocus	> 0.63	< 0.50
Harman 2008	Defocus +3 D through to -5 D	Mean accommodative amplitude (SD) at 3 and 18 months	2.98 (0.91) and 3.38 (1.14)	1.77 (0.53) and 2.15 (0.77)
Kamlesh 2001	Defocus +5 D through to -5 D from distance Rx	Mean dioptres through which acuity >= 6/12	3.1	1.65
Leyland 2002	Defocus +3 D through to -5 D from distance Rx	Mean (SD) dioptres through which acuity >= 6/12	4.88 (1.69)	3.73 (1.03)
Percival 1993	Defocus -1.25 D and -2.5 D from distance Rx	% >= 20/40 with defocus -1.25 D and -2.5 D	76% and 96%	56% and 4%
Steinert 1992	Defocus +6 D through to -6 D from distance Rx	Mean dioptres through which acuity >= 20/50	4.74	2.75

Analysis 1.11. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 11 Contrast sensitivity: Pelli Robson chart.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 11 Contrast sensitivity: Pelli Robson chart



(1) Number of letters read

(2) logMAR score, SD calculated from reported t-value

(3) logMAR score

(4) logMAR score

Analysis 1.12. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 12 Contrast sensitivity: other charts.

Contrast sensitivity: other charts

Study	Method	Outcome	Findings
VCTS chart			
Cillino 2008	VCTS-6500	CS at 5 spatial frequencies at 1 light levels (85 cd/m2)	At 3 cycles/degree, the monofocal IOL and diffractive pupil-independent multifocal IOL groups had better contrast sensitivity than the refractive multifocal IOL groups (P = 0.038, Kruskal-Wallis test) (data reported in graph)
Haaskjold 1998	VCTS chart (6500 for distance, 6000 for near)	Mean of CS at 5 spatial frequencies, at 3 light levels (log units)	In medium light the bifocal group had reduced contrast sensitivity that was still within the normal range at each of the 5 spatial frequencies

Contrast sensitivity: other charts (*Continued*)

			tested. This difference was greatest at the mid-frequencies. The mean difference at distance was greatest at the medium light level but was statistically significant at all 3 light light levels: low light difference 57.9, medium light difference 83.9, high light 78.9. Constrast sensitivity for the near test targets showed a similar slight overall reduction in the bifocal group compared with the monofocal group: mean difference at medium light 74.9. (data reported in graph, Allen 1996)
Sen 2004	VCTS chart	Mean (SD) CS	Cycles per degree: 1.5 multifocal 4.2 (1.3) monofocal 4.5 (1.0), P value 0.09 Cycles per degree: 3 multifocal 4.6 (1.3) monofocal 4.9 (1.1), P value 0.12 Cycles per degree: 6 multifocal 2.6 (1.4) monofocal 3.0 (1.2), P value 0.15 Cycles per degree: 12 multifocal 1.1 (1.3) monofocal 1.1 (1.1), P value 0.52 Cycles per degree: 18 multifocal 0.3 (0.8) monofocal 0.2 (0.6), P value 0.32
Zhao 2010	VCTS-6500	CS at 5 spatial frequencies, 1 light level	At 3 cycles per degree, the monofocal group had statistically significantly better contrast sensitivity than the multifocal group ($P < 0.05$, Kruskal-Wallis test)
Regan Contrast Acuity Chart			
Percival 1993	Regan Contrast Acuity Charts	Acuity at 96%, 50%, 25% and 11% contrast (lines read)	The mean Regan scores were less for the multifocal lenses compare to the monofocal lenses at all contrast levels. The difference was 0.7 lines on the Regan chart at the 96% and 50% contrast levels, 1.2 lines at the 25% level (not significant) and 2.1 lines at the 25% level (not significant) and 2.1 lines at the 11% contrast level

Contrast sensitivity: other charts (*Continued*)

Steinert 1992	Regan Contrast Acuity Charts	Mean Regan lines read (SD)	96% contrast: multifocal 7.67 (1.25) monofocal 8.19 (1.49), P value not reported, not significant 50% contrast: multifocal 6.53 (1.79) monofocal 7.22 (1.82), P value not reported, not significant 25% contrast: multifocal 5.59 (1.90) monofocal 6.20 (1.53), P value not reported, not significant 11% contrast: multifocal 2.59 (2.01) monofocal 4.37 (2.05), P = 0.0024
Other charts			
Alio 2011	CST 1800, Vision Science Research Corp	Mean of CS at 4 spatial frequencies, at 2 light levels (3 and 85 cd/m2)	Contrast sensitivity was significantly better in monofocal IOL group in both photopic and mesopic conditions and at 3, 6, 12 and 18 cycles per degree (data reported in graph)
Palmer 2008	FACT chart in OPTEC 6500 vision tested	CS at 5 spatial frequencies, at 2 light levels (mesopic and scotopic light levels)	Monofocal IOLs had statistically significant better contrast sensitivity compared with the diffractive multifocal IOLs at almost all frequencies and all luminance conditions. Differences between monofocal IOLs and refractive lens were detected only for high frequencies

Analysis 1.13. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 13 Glare disability (Brightness Acuity Tester).

Glare disability (Brightness Acuity Tester)

Study	**Outcome**	**Multifocal**	**Monofocal**	**Comment**
Harman 2008	Visual acuity mean log-MAR (SD) Contrast sensitivity mean log units (SD)	0.06 (0.15) 27.26 (4.1)	0.07 (0.11) 27.15 (6.6)	Visual acuity and contrast sensitivity measured with the BAT at its brightest setting
Leyland 2002	Visual acuity mean log-MAR (SD) Contrast sensitivity mean log units (SD)	-0.02 (0.06) -0.38 (0.25)	-0.02 (0.06) -0.4 (0.36)	"*Glare from the brightness acuity tester had little effect acuity (LogMAR acuity dropped by 0.02 units with the monofocal IOL, 0.01 units with the multifocal IOL,and 0.04 units with the bifocal IOL).*" Page 486

Glare disability (Brightness Acuity Tester) (*Continued*)

Steinert 1992	Visual acuity mean Regan line (SD) at high glare	-5.67 (SD 2.23)	-6.42 (2.43)	Non-significant

Analysis 1.14. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 14 Patient reported glare/haloes.

Review: Multifocal versus monofocal intraocular lenses after cataract extraction

Comparison: 1 Multifocal IOLs versus monofocal IOLs

Outcome: 14 Patient reported glare/haloes

Study or subgroup	Multifocal n/N	Monofocal n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Cillino 2008	25/47	1/15		1.7 %	7.98 [1.18, 54.01]
Haaskjold 1998	21/79	9/70		10.7 %	2.07 [1.01, 4.21]
Harman 2008	18/24	5/19		9.0 %	2.85 [1.30, 6.26]
Kamlesh 2001	12/20	7/20		11.2 %	1.71 [0.85, 3.44]
Palmer 2008	53/90	11/24		21.0 %	1.28 [0.80, 2.05]
Percival 1993	3/25	0/25		0.7 %	7.00 [0.38, 128.87]
Rossetti 1994	29/38	13/42		19.9 %	2.47 [1.52, 4.01]
Zhao 2010	36/72	25/89		25.7 %	1.78 [1.19, 2.67]
Total (95% CI)	**395**	**304**		**100.0 %**	**1.94 [1.51, 2.49]**

Total events: 197 (Multifocal), 71 (Monofocal)

Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 8.37$, df = 7 (P = 0.30); $I^2 = 16\%$

Test for overall effect: Z = 5.17 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 1.15. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 15 Visual functioning.

Visual functioning

Study	Questionnaire	Multifocal	Monofocal	Comment

Visual functioning (*Continued*)

Alio 2011	NEI-VFQ			Multifocal lens groups reported less difficulty reading newspaper and bills (P = 0.04) and performing hobbies that required near vision (P = 0.01). There were no statistically significant differences between multifocal lens and monofocal lens in driving at night although the monofocal group reported fewer problems with driving at night
Cillino 2008	Modified VF-7 questionnaire: mean (SD) score 1 year after surgery	95 (11.6)	87.1 (11.1)	Items inquiring about difficulty in reading small print and doing fine handwork "without glasses" scored significantly better with multifocal than with monofocal IOLs (P < 0.0005, Kruskal-Wallis test), whereas there were no differences in the other items, analysing tasks such as driving at night, television watching and cooking
Nijkamp 2004	VF-14 questionnaire: mean score at 3 months after surgery	89.5 (12.6)	91.9 (8.7)	Not significantly different
Sen 2004	VF-7 questionnaire: score 1 month after surgery			*"Postoperatively, the VF-7 score improved in 88.2% of patients in the multifocal group and 87.9% in the monofocal group and deteriorated in 4.6% and 7.8%, respectively. The mean improvement in the VF-7 score from preoperatively to postoperatively was 19.4 points in the multifocal group and 23.0 points in the monofocal group. There were no statistically significant differences between the groups or when only scores of first-eye cataract surgery were compared (P=0.33)* ". Page 2487
Zhao 2010	Modified VF-7 questionnaire: score (SD) 6 months after surgery	97.3 (3.6)	89.8 (6.3)	"*The mean modified VF-7 score was statistically significantly lower in the monofocal group than in the multifocal group (P=0.002, Kruskal-Wallis test).*" Page 284

Analysis 1.16. Comparison 1 Multifocal IOLs versus monofocal IOLs, Outcome 16 Patient-reported satisfaction with vision.

Patient-reported satisfaction with vision

Study	**Measure**	**Multifocal**	**Monofocal**
Haaskjold 1998	Overall visual satisfaction good	95%	93%
Javitt 2000	Mean overall visual satisfaction 0 to 10 (0 = worst, 10 = best) (TyPE questionnaire)	8.4	7.9
Kamlesh 2001	Percentage rating vision as good	70%	80%

Patient-reported satisfaction with vision (*Continued*)

Leyland 2002	Median overall visual satisfaction 0 to 10 (0 = worst, 10 = best) (TyPE questionnaire)	8	8
Nijkamp 2004	% satisfied with quality of near vision with glasses % satisfied with quality of near vision without glasses	89.7% 61.8%	88.0% 49.2%
Percival 1993	Mean (SD) satisfaction score 1 to 7 (1 = best, 7 = worst)	1.77 (1.36)	1.35 (0.80)
Rossetti 1994	Percentage satisfied or highly satisfied with distance vision/near vision	76.3%/94.7%	85.7%/66.5%
Sen 2004	Number (percentage) satisfied or very satisfied with vision	50/53 (94.3%)	62/67 (92.5%)
Zhao 2010	Mean overall patient satisfaction	4.7 (0.3)	4.3 (0.6)

ADDITIONAL TABLES

Table 1. Characteristics of included studies

Study	Country	Multicentre?	Bilateral/unilateral surgery	Number of people randomised	Average age	Age range	% Women	Number of eyes included	For eye outcomes, reporting by eye or person?	Follow-up
Alio 2011	Spain	No	Bilateral	53	62		Not reported	106	Both	3 months
Cillino 2008	Italy	No	Bilateral	62	62		53	124	Eye	12 months
El-Maghraby 1992	Saudi Arabia	No	Unilateral	77	57	45 to 90	53	77	Eye (unilateral surgery)	2 to 4 months
Haaskjold 1998	Europe	Yes	Unilateral	221	72		56	221	Eye (unilateral surgery)	5 to 6 months

Table 1. Characteristics of included studies (*Continued*)

Harman 2008	England	No	Bilateral	90	72		55	120	Person	3 and 18 months
Javitt 2000	USA, Germany, Austria	Yes	Bilateral	261	72	59 to 87	56	112	Person	3 months
Jusufovic 2011	Bosnia and Herzegovina	No	Unilateral	100	47		44	100	Eye (unilateral surgery)	6 weeks
Kamlesh 2001	India	No	Unilateral	40	55		Not reported	40	Eye (unilateral surgery)	3 months
Leyland 2002	England	No	Bilateral	50	75		50	100	Person	12 months
Nijkamp 2004	Netherlands	No	Bilateral	153	72		46	92	Unclear	3 months after surgery, reported after first eye and second eye surgery
Palmer 2008	Spain	No	Bilateral	114	73		63	126	Both	3 months
Percival 1993	England	No	Unilateral	50	77		58	50	Eye (unilateral surgery)	4 to 6 months
Rossetti 1994	Italy	No	Unilateral	80	71		59	80	Eye (unilateral surgery)	12 months
Sen 2004	Finland	No	Unilateral and bilateral	80	71		68	120	Both	1 month
Steinert 1992	USA	Yes	Unilateral	62	72		58	62	Eye (unilateral surgery)	3 to 6 months

Table 1. Characteristics of included studies (*Continued*)

Zhao 2010	China	No	Unilateral	161	66	34 to 92	47	161	Eye (unilateral surgery)	6 months

Table 2. Lenses used in included studies

Study	Multifocal lens	Monofocal lens
Alio 2011	AcrySof ReSTOR SA60D3 (Alcon) diffractive Acri.LISA 366D (Alcon) diffractive	Acri.Smart 48S (Carl Zeiss)
Cillino 2008	Array SA40N (AMO) refractive ReZoom (AMO) refractive Tecnis ZM900 (AMO) diffractive	AR40 (AMO)
El-Magrahby 1992	815LE (3M) diffractive Tecnis ZM900 (AMO) diffractive	15LE (3M)
Haaskjold 1998	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)
Jusufovic 2011	ReZoom NXG1 (AMO) refractive	AcrySof MA60BM (Alcon)
Kamlesh 2001	Progress 3 (Laboratoires Domilens) refractive	Flex 65 (Laboratoires Domilens)
Leyland 2002	Array SA40N (AMO) refractive TruVista 68STUV (Storz) bifocal	Phacoflex I SI40N (AMO)
Nijkamp 2004	Array SA40N (AMO) refractive	Phacoflex II SI40NB (AMO)
Palmer 2008	Twinset (Acri.Tec, GmbH) diffractive ReZoom (AMO) refractive Tecnis ZM900 (AMO) diffractive	Tecnis Z9000 (AMO) diffractive
Percival 1993	MPC25 (Allergan) refractive	PC25 (Allergan)
Rossetti 1994	3M lens "with both refractive and diffractive optics"	Model not reported
Sen 2004	Array SA40N (AMO) refractive	Phacoflex II SI40NB (AMO)
Steinert 1992	Array MPC-25NB (AMO) refractive	PC-25NB (AMO)
Zhao 2010	AcrySof ReSTOR SA60D3 (Alcon) diffractive	AcrySof SA60AT (Alcon)

AMO: Advanced Medical Optics

Table 3. Outcome reporting matrix: primary outcomes

	Distance visual acuity				Near visual acuity			Spectacle dependence
	Unaided		Best-corrected		Unaided		Best-corrected	
	< 6/6	continuous	< 6/6	continuous	< J3/J4	continuous	continuous	
Alio 2011	F	√	F	√	F	√	√	H
Cillino 2008	F	√	F	√	F	√	√	√
El-Magrahby 1992	√	F	√	F	√	F	F	H
Haaskjold 1998	√	F	√	F	√	F	F	√
Harman 2008	F	√	F	√	F	√	√	H
Javitt 2000	F	√	F	√	√	√	√	√
Jusufovic	√	√	F	F	√	H	H	H
Kamlesh 2001	F	F	√	F	H	H	H	√
Leyland 2002	√	√	√	√	√	√	√	√
Nijkamp 2004	F	√	F	√	F	√	√	√
Palmer 2008	F	√	F	√	F	√	√	√
Percival 1993	√	F	√	F	√	F	F	√
Rossetti 1994	√	F	√	F	√	F	F	√
Sen 2004	√	√	√	√	F	√	√	F

Table 3. Outcome reporting matrix: primary outcomes (*Continued*)

Steinert 1992	√	√	√	√	F	√	√	√
Zhao 2010	C	C	C	C	C	C	C	√

√ reported and included in the review
For codes see Appendix 9

Table 4. Outcome reporting matrix: secondary outcomes

	Depth of field	Contrast sensitivity	Glare	Quality of life/visual function	Subjective assessment of visual function/patient satisfaction
Alio 2011	F	√	F	√	F
Cillino 2008	√	√	√	√	A
El-Magrahby 1992	H	H	H	H	H
Haaskjold 1998	F	√	√	F	√
Harman 2008	√	√	√	H	H
Javitt 2000	H	H	A	C	√
Jusufovic 2011	H	H	H	H	H
Kamlesh 2001	√	√	√	√	√
Leyland 2002	√	√	√	√	√
Nijkamp 2004	H	H	H	√	√
Palmer 2008	H	√	√	H	H
Percival 1993	√	√	√	H	√
Rossetti 1994	H	√	√	H	√
Sen 2004	√	√	√	√	√
Steinert 1992	√	√	√	H	√
Zhao 2010	√	√	√	√	√

√ reported and included in the review

For codes see Appendix 9

Table 5. Refractive outcome

Study ID	Refractive aim	Outcome	Multifocal	Monofocal
Alio 2011	Not stated	Mean spherical equivalent	-0.039	-0.4
Allen 1996	Not stated	No data	No data	No data
Cillino 2008	Emmetropia	Mean spherical equivalent (SD)	0.1 (0.4)	0.1 (0.4)
El-Maghraby 1992	Emmetropia	Mean spherical equivalent (SD)	-0.36 (1.62)	+0.31 (1.01)
Harman 2008	Emmetropia	Mean spherical equivalent (SD)	-0.1 (0.44)	0.26 (0.49)
Javitt 2000	Not stated	Mean spherical equivalent "from -0.27 to -0.36"	No data	No data
Jusufovic 2011	Not stated	No data		
Kamlesh 2001	Not stated	Mean spherical equivalent	-1.4	-1.3
Leyland 2002	Emmetropia	Mean spherical error (SD)	0.01 (0.66)	0.06 (0.66)
Nijkamp 2004	Within 1 D of emmetropia	Percentage cases within 1 D of emmetropia	95.2%	91.1%
Palmer 2008	Between emmetropia and -0.5 D for monofocal emmetropia for multifocal	No data	No data	No data
Percival 1993	Emmetropia (treatment)/ myopic astigmatism (control)	Percentage achieving refractive aim	56%	60%
Rossetti 1994	Less than 2 D astigmatism	Percentage cases < 2 D astigmatism	82%	79%
Sen 2004	Not stated	Percentage cases with 1 D of "target"	84.6%	75.0%
Steinert 1992	Not stated	Mean spherical equivalent (SD)	+0.21 (0.61)	+0.13 (0.92)
Zhao 2010	Not stated	No data	No data	No data

D: dioptre
SD: standard deviation

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Cataract Extraction
#2 MeSH descriptor Pseudophakia
#3 (extract* or aspirat* or operat* or remov* or surg* or excis*) near/3 (cataract*)
#4 pseudophakia
#5 (#1 OR #2 OR #3 OR #4)
#6 MeSH descriptor Lens Implantation, Intraocular
#7 MeSH descriptor Lenses, Intraocular
#8 (intraocular or intra ocular) near/3 (lens*)
#9 (#6 OR #7 OR #8)
#10 multifocal or multi focal or bifocal or bi focal or diffractive or refractive
#11 (#9 AND #10)
#12 (#5 AND #11)

Appendix 2. MEDLINE (OvidSP) search strategy

1. randomised controlled trial.pt.
2. (randomised or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. exp animals/
10. exp humans/
11. 9 not (9 and 10)
12. 8 not 11
13. exp cataract extraction/
14. exp pseudophakia/
15. ((extract$ or aspirat$ or operat$ or remov$ or surg$ or excis$) adj3 cataract$).tw.
16. pseudophakia.tw.
17. or/13-16
18. exp lens implantation intraocular/
19. exp lenses intraocular/
20. ((intraocular or intra ocular) adj3 lens$).tw.
21. or/17-20
22. (multifocal or multi focal or bifocal or bi focal or diffractive or refractive).tw.
23. 21 and 22
24. 17 and 23

25. 12 and 24
The search filter for trials at the beginning of the strategy is from the published paper by Glanville et al (Glanville 2006).

Appendix 3. EMBASE (OvidSP) search strategy

1. exp randomised controlled trial/
2. exp randomization/
3. exp double blind procedure/
4. exp single blind procedure/
5. random$.tw.
6. or/1-5
7. (animal or animal experiment).sh.
8. human.sh.
9. 7 and 8
10. 7 not 9
11. 6 not 10
12. exp clinical trial/
13. (clin$ adj3 trial$).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
15. exp placebo/
16. placebo$.tw.
17. random$.tw.
18. exp experimental design/
19. exp crossover procedure/
20. exp control group/
21. exp latin square design/
22. or/12-21
23. 22 not 10
24. 23 not 11
25. exp comparative study/
26. exp evaluation/
27. exp prospective study/
28. (control$ or prospectiv$ or volunteer$).tw.
29. or/25-28
30. 29 not 10
31. 30 not (11 or 23)
32. 11 or 24 or 31
33. exp cataract extraction/
34. pseudophakia/
35. ((extract$ or aspirat$ or operat$ or remov$ or surg$ or excis$) adj3 cataract$).tw.
36. pseudophakia.tw.
37. or/33-36
38. exp lens implantation/
39. lens implant/
40. ((intraocular or intra ocular) adj3 lens$).tw.
41. or/37-40
42. (multifocal or multi focal or bifocal or bi focal or diffractive or refractive).tw.
43. 41 and 42
44. 37 and 43
45. 32 and 44

Appendix 4. *meta*Register of Controlled Trials search strategy

cataract and multifocal and monofocal

Appendix 5. ClinicalTrials.gov search strategy

Cataract AND Multifocal AND Monofocal

Appendix 6. ICTRP search strategy

Cataract AND Multifocal AND Monofocal

Appendix 7. Subgroup analyses: bilateral and unilateral surgery

Comparing bilateral and unilateral surgery (analyses exclude Sen 2004 because trial reported both bilateral and unilateral surgery)	Multifocal		Monofocal		Effect measure			Test for subgroup differences: P value
	Events	Total	Events	Total	Risk ratio/ SMD	Lower CI	Upper CI	
Distance visual acuity - less than 6/6 unaided								
Bilateral surgery (1 study)	7	44	3	16	0.85	0.25	2.89	
Unilateral surgery (5 studies)	181	227	177	225	1.01	0.92	1.10	0.60
Distance visual acuity - mean unaided								
Bilateral surgery (7 studies)		447		286	-0.04	-0.19	0.11	
Unilateral surgery (2 studies)		82		80	-0.14	-0.44	0.17	0.58

(*Continued*)

Distance visual acuity - less than 6/6 best-corrected								
Bilateral surgery (1 study)	4	44	2	16	0.73	0.15	3.60	
Unilateral surgery (6 studies)	88	259	66	251	1.30	0.96	1.76	0.05
Distance visual acuity - mean best-corrected								
Bilateral surgery (7 studies)		479		286	0.10	-0.18	0.38	
Unilateral surgery (1 study)		32		30	0.37	-0.13	0.88	0.04
Near visual acuity - less than J3/J4 unaided								
Bilateral surgery (2 studies)	35	167	50	125	0.29	0.01	8.39	
Unilateral surgery (5 studies)	27	252	159	242	0.22	0.11	0.47	0.87
Near visual acuity - mean unaided (no subgroup analysis, only bilateral studies)								
Near visual acuity - mean best-corrected (no subgroup analysis, only bilateral studies)								
Glare/haloes								
Bilateral surgery (3 studies)	96	161	17	58	2.32	0.93	5.80	
Unilateral surgery (4 studies)	89	214	47	226	2.06	1.55	2.74	0.81
Spectacle dependence								

(*Continued*)

Bilateral surgery (5 studies)	225	373	215	230	0.18	0.12	0.28	
Unilateral surgery (5 studies)	152	282	252	282	0.15	0.10	0.22	0.50

Appendix 8. Subgroup analyses: refractive and diffractive lenses

Comparing refractive and diffractive lenses (analyses exclude Cillino 2008 because trial included refractive and diffractive lenses)	**Multifocal**		**Monofocal**		**Effect measure**			**Test for subgroup differences: P value**
	Events	**Total**	**Events**	**Total**	**Risk ratio/ SMD**	**Lower CI**	**Upper CI**	
Distance visual acuity - less than 6/6 unaided								
Refractive (4 studies)	118	179	131	163	0.94	0.85	1.03	
Diffractive (3 studies)	115	145	111	145	1.03	0.93	1.14	0.19
Distance visual acuity - mean unaided								
Refractive (8 studies)		397		368	-0.15	-0.30	-0.01	
Diffractive (1 study)		80		26	0.24	-0.21	0.68	0.10
Distance visual acuity - less than 6/6 best-corrected								
Refractive (5 studies)	49	174	70	158	0.84	0.50	1.41	

(*Continued*)

Diffractive (3 studies)	66	182	46	176	1.36	0.95	1.94	0.13
Distance visual acuity - mean best-corrected								
Refractive (7 studies)		347		318	0.07	-0.16	0.30	
Diffractive (1 study)		80		26	-0.67	-1.12	-0.22	0.00
Near visual acuity - less than J3/J4 unaided								
Refractive (4 studies)	40	242	85	200	0.21	0.03	1.63	
Diffractive (3 studies)	22	177	124	167	0.20	0.10	0.37	0.97
Near visual acuity - mean unaided								
Refractive (3 studies)		194		152	-0.81	-1.40	-0.22	
Diffractive (1 study)		80		26	-1.86	-2.37	-1.34	0.01
Near visual acuity - mean best-corrected								
Refractive (3 studies)		194		152	-0.05	-0.64	0.54	
Diffractive (2 studies)		80		26	-0.47	-0.91	-0.02	0.27
Glare/haloes								
Refractive (4 studies)	69	141	37	153	1.94	1.41	2.66	
Diffractive (3 studies)	50	117	22	112	2.33	1.56	3.48	0.48
Spectacle dependence								
Refractive (6 studies)	224	312	247	264	0.22	0.14	0.34	

(*Continued*)

Diffractive (4 studies)	116	226	204	229	0.14	0.09	0.21	0.12

Appendix 9. Outcome reporting: ORBIT classification*

The Outcome Reporting Bias In Trials (ORBIT) study classification system for missing or incomplete outcome reporting in reports of randomised trials as given in Kirkham 2010.

Description		Level of reporting	Risk of bias
Clear that the outcome was measured and analysed			
A	Trial report states that outcome was analysed but only reports that result was not significant (typically stating P > 0.05)	Partial	High risk
B	Trial report states that outcome was analysed but only reports that result was significant (typically stating P < 0.05)	Partial	No risk
C	Trial report states that outcome was analysed but insufficient data were presented for the trial to be included in meta-analysis or to be considered to be fully tabulated	Partial	Low risk
D	Trial report states that outcome was analysed but no results reported	None	High risk
Clear that the outcome was measured			
E	Clear that outcome was measured but not necessarily analysed. Judgement says likely to have been analysed but not reported because of non-significant results	None	High risk
F	Clear that outcome was measured but not necessarily analysed. Judgement says unlikely to have been analysed but not reported because of non-significant results	None	Low risk
Unclear whether the outcome was measured			

(*Continued*)

G	Not mentioned but clinical judgement says likely to have been measured and analysed but not reported on the basis of non-significant results	None	High risk
H	Not mentioned but clinical judgement says unlikely to have been measured at all	None	Low risk
Clear that the outcome was not measured			
I	Clear that outcome was not measured	NA	No risk

FEEDBACK

Savage, November 2004

Summary

The conclusions of the review abstract suggest that multifocals 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? In my experience, patients prefer monovision! There is no glare or halo, and the quality of vision for 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 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: 6 March 2012.

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.

HISTORY

Protocol first published: Issue 3, 2000

Review first published: Issue 3, 2001

Date	Event	Description
19 June 2008	Amended	Converted to new review format.
9 July 2006	New citation required and conclusions have changed	Substantive amendment.

CONTRIBUTIONS OF AUTHORS

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.

EZ decided the review scope, performed handsearches, assessed the results of searches, assessed the suitability of studies and extracted data.

EP updated the review in August 2006 and June 2010.

DC, SS and JE updated the review in July 2012, applied The Cochrane Collaborations' tool for assessing the risk of bias and prepared a 'Summary of findings' table, including assessing the quality of evidence.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute for Health Research, UK.

The Cochrane Incentive Scheme provided funding for Jennifer Evans to assist with updating this review in 2012.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The original protocol for this review was published in 2000. Since that time substantive changes in recommended Cochrane review methodology have taken place. The following is a list of updates to the methods:

- We used The Cochrane Collaboration tool for assessing the risk of bias (replacing the Jadad scale).
- We prepared a 'Summary of findings' table, including assessing the quality of evidence using GRADE (http://www.gradeworkinggroup.org/).
- 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, particular when the event occurs commonly within the study population.
- We added specific information on the following methodological issues: unit of analysis, missing data and subgroup analysis.
- We performed an additional subgroup analysis comparing unilateral and bilateral surgery.

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