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Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia

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[Intervention Review]

Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia

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ABSTRACT

Background

Presbyopia occurs when the lens of the eyes loses its elasticity leading to loss of accommodation. The lens may also progress to develop cataract, affecting visual acuity and contrast sensitivity. One option of care for individuals with presbyopia and cataract is the use of multifocal or extended depth of focus intraocular lens (IOL) after cataract surgery. Although trifocal and bifocal IOLs are designed to restore three and two focal points respectively, trifocal lens may be preferable because it restores near, intermediate, and far vision, and may also provide a greater range of useful vision and allow for greater spectacle independence in individuals with presbyopia.

Objectives

To assess the effectiveness and safety of implantation with trifocal versus bifocal IOLs during cataract surgery among participants with presbyopia.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (2019, Issue 9); Ovid MEDLINE; Embase.com; PubMed; ClinicalTrials.gov; and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP). We did not use any date or language restrictions in the electronic search for trials. We last searched the electronic databases on 26 September 2019. We searched the reference lists of the retrieved articles and the abstracts from the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) for the years 2005 to 2015.

Selection criteria

We included randomized controlled trials that compared trifocal and bifocal IOLs among participants 30 years or older with presbyopia undergoing cataract surgery.

Data collection and analysis

We used standard Cochrane methodology.

Main results

We identified five studies conducted in Europe with a total of 175 participants. All five studies assessed uncorrected distance visual acuity (primary outcome of the review), while some also examined our secondary outcomes including uncorrected near, intermediate, and best-corrected distance visual acuity, as well as contrast sensitivity.

Study characteristics

All participants had bilateral cataracts with no pre-existing ocular pathologies or ocular surgery. Participants' mean age ranged from 58 to 64 years. Only one study reported on gender of participants, and they were mostly women. We assessed all the included studies as being at unclear risk of bias for most domains. Two studies received financial support from manufacturers of lenses evaluated in this review, and at least one author of another study reported receiving payments for delivering lectures with lens manufacturers.

Findings

All studies compared trifocal versus bifocal IOL implantation on visual acuity outcomes measured on a LogMAR scale. At one year, trifocal IOL showed no evidence of effect on uncorrected distance visual acuity (mean difference (MD) 0.00, 95% confidence interval (CI) −0.04 to 0.04; I^2 = 0%; 2 studies, 107 participants; low-certainty evidence) and uncorrected near visual acuity (MD 0.01, 95% CI −0.04 to 0.06; I^2 = 0%; 2 studies, 107 participants; low-certainty evidence). Trifocal IOL implantation may improve uncorrected intermediate visual acuity at one year (MD −0.16, 95% CI −0.22 to −0.10; I^2= 0%; 2 studies, 107 participants; low-certainty evidence), but showed no evidence of effect on best-corrected distance visual acuity at one year (MD 0.00, 95% CI -0.03 to 0.04; I^2= 0%; 2 studies, 107 participants; low-certainty evidence). No study reported on contrast sensitivity or quality of life at one-year follow-up. Data from one study at three months suggest that contrast sensitivity did not differ between groups under photopic conditions, but may be worse in the trifocal group in one of the four frequencies under mesopic conditions (MD −0.19, 95% CI −0.33 to −0.05; 1 study; I^2 = 0%, 25 participants; low-certainty evidence). In two studies, the investigators observed that participants' satisfaction or spectacle independence may be higher in the trifocal group at six months, although another study found no evidence of a difference in participant satisfaction or spectacle independence between groups.

Adverse events

Adverse events reporting varied among studies. Two studies reported information on adverse events at one year. One study reported that participants showed no intraoperative or postoperative complications, while the other study reported that four eyes (11.4%) in the bifocal and three eyes (7.5%) in the trifocal group developed significant posterior capsular opacification requiring YAG capsulotomy. The certainty of the evidence was low.

Authors' conclusions

There is low-certainty of evidence that compared to bifocal IOL, implantation of trifocal IOL may improve uncorrected intermediate visual acuity at one year. However, there is no evidence of a difference between trifocal and bifocal IOL for uncorrected distance visual acuity, uncorrected near visual acuity, and best-corrected visual acuity at one year. Future research should include the comparison of both trifocal IOL and specific bifocal IOLs that correct intermediate visual acuity to evaluate important outcomes such as contrast sensitivity and quality of life.

PLAIN LANGUAGE SUMMARY

Trifocal versus bifocal lenses implantation after cataract surgery

What was the aim of this review?

The aim of this Cochrane Review was to examine whether implantation of a lens that contains three regions that correct for distance, intermediate, and near vision (trifocal) into the eyes during cataract surgery differs from a lens that contains two regions that correct for distance and near vision (bifocal), with regard to effectiveness and safety among participants with cataract.

Key messages

There was low-certainty evidence that people who receive trifocal lens after their cataract surgery may experience improvement in uncorrected intermediate sharpness of vision (visual acuity) at one year compared to those who had received bifocal lens. However, there is no evidence of a difference between trifocal and bifocal intraocular lenses for uncorrected distance visual acuity, uncorrected near visual acuity, and best-corrected distance visual acuity at one year. Their effect on quality of life and the ability to distinguish between fine increments of light and dark (contrast sensitivity) remains uncertain.

What was studied in this review?

Presbyopia is an age-related condition of the lens of the eye that causes a gradual loss of the ability to focus on nearby objects. Further age-related lens changes may lead to loss of clarity of the lens (cataract) causing loss of visual acuity and contrast sensitivity. Lenses with three or two regions (trifocal or bifocal respectively) are a new technology intended to decrease the dependence on eye glasses use after cataract surgery.

What are the main results of this review?

This review included five studies conducted in Europe with a total of 175 participants.

We found that the implantation of trifocal lens at the time of cataract surgery may improve intermediate visual acuity at one year; the certainty of the evidence was low. Comparison of trifocal versus bifocal lens revealed no evidence of a difference with respect to uncorrected distance visual acuity, uncorrected near visual acuity, and best-corrected distance visual acuity at one year; the certainty of the evidence was low. It is uncertain whether trifocal compared to bifocal lens implantation has any effect on quality of life and contrast sensitivity.

How up-to-date is this review?
We searched for studies published up to 26 September 2019.

SUMMARY OF FINDINGS

Summary of findings 1. Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia

Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia

Patient or population: participants (> 30 years) with cataract and presbyopia
Setting: eye clinic
Intervention: trifocal IOL
Comparison: bifocal IOL

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with bifocal IOL	Risk with trifocal IOL				
Mean uncorrected distance visual acuity (LogMAR) - 1 year	The mean uncorrected distance visual acuity (LogMAR) - 1 year was −0.01 to 0.01 LogMar.	MD 0 LogMar (−0.04 to 0.04)	-	107 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	
Mean uncorrected near visual acuity (LogMAR) - 1 year	The mean uncorrected near visual acuity (LogMAR) - 1 year was 0.13 to 0.19 LogMar.	MD 0.01 LogMar (−0.04 to 0.06)	-	107 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	
Mean uncorrected intermediate visual acuity (LogMAR) - 1 year	The mean uncorrected intermediate visual acuity (LogMAR) - 1 year was 0.25 to 0.26 LogMar.	MD −0.16 LogMar (−0.22 to −0.10)	-	107 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	
Mean best-corrected distance acuity (LogMAR) - 1 year	The mean best-corrected distance acuity (LogMAR) - 1 year was −0.03 to −0.01 LogMar.	MD 0 LogMar (−0.03 to 0.04)	-	107 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	
Mean contrast sensitivity - 1 year	See comment	-	-	-	-	No study reported this outcome at 1 year.
Mean quality of life or visual function (measured using Visual Function Index-14 tool) - 1 year	See comment	-	-	-	-	No study reported this outcome at 1 year.
Adverse events - 1 year	See comment	-	-	129 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	1 study reported no intraoperative or postoperative complications; in the other study 4 eyes (11.4%)

				in the bifocal group and 3 eyes (7.5%) in the trifocal group developed significant posterior capsular opacification requiring YAG capsulotomy.

*__The risk in the intervention group__ (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; **LogMAR:** logarithm of the minimum angle of resolution; **MD:** mean difference; **RCT:** randomized controlled trial

GRADE Working Group grades of evidence
High-certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate-certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low-certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low-certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1]Downgraded for risk of bias (one level) as most domains were judged as unclear risk of bias.
[2]Downgraded for imprecision (one level) as evidence was based on a small sample.
[3]Downgraded for inconsistency (one level) as narrative synthesis found that the direction of effect varied across all included studies.

BACKGROUND

Description of the condition

The lens is one of the most important tissues in the human eye. Located in the posterior chamber, it is the second most powerful refractive structure, and contributes 20% to 30% of the total refractive power. It is an elastic and transparent tissue that helps focus images onto the retina. The accommodation process causes the lens to change its anterioposterior length and is associated with convergence and miosis (Glasser 1999). This process allows adequate intermediate and near vision.

The broadly accepted theory of accommodation is the Helmholtz theory, in which accommodation is the result of elastic properties of the human lens and possibly the vitreous that allows the lens to increase its negative power when zonular tension is relieved and vice versa. This movement is performed by the ciliary muscle. This property of the human lens is lost in a progressive manner during aging until the accommodation range is practically none (Glasser 1999; Torricelli 2012).

Accommodation decreases with aging in a process known as presbyopia. In individuals with presbyopia, the ability of the lens to accommodate is insufficient for near vision. This process generally occurs between age 40 and 50 years (Glasser 1999; Papadopoulos 2014) and, if not corrected, has a significant impact on quality of life (Torricelli 2012).

As presbyopia develops and elasticity is lost, the lens may become opaque. The loss of transparency of the lens is called cataract. There are several types of cataracts. The most common type is the senile (age-related) cataract. There are several well-known risk factors for developing this type of vision-impairing lens opacity, including high sodium intake (Bae 2015), some systemic diseases such as diabetes mellitus (Li 2014), high body mass index (WHO 2015), exposure to ultraviolet B radiation, and smoking (Hodge 1995).

According to the World Health Organization, cataract accounts for 51% of worldwide blindness and affects about 20 million people around the world (WHO 2015).

Symptoms associated with this condition are myopia and decrease in contrast sensitivity and visual acuity. Cataract extraction by phacoemulsification followed by capsular bag implantation of an artificial intraocular lens (IOL) is one option of care for individuals with presbyopia and cataract (Carson 2014). Intraocular lens implantation does reduce spectacle dependence compared to aphakia, but many individuals may still need spectacle correction for near vision following cataract surgery.

Description of the intervention

Cataract surgery is performed to extract the cloudy lens material, while preserving some structures such as the capsular bag. An artificial IOL is then placed to restore vision in the eye (Kohnen 2009). The standard practice is usually the implantation of a monofocal IOL, which confers only one focal point on the retina (Carson 2014), typically to provide good distance vision. With a monofocal IOL, a pseudophakic patient thus continues to be presbyopic, and spectacles may still be needed after phacoemulsification surgery to restore vision at other distances. With the advancement of technology and increased expectations of better vision, the goal of cataract surgery is no longer only limited to restoring vision, but management of the refractive component is also important prior, during, and after surgery (Torricelli 2012). Multifocal lenses were therefore designed to give more than one focal point and provide spectacle independence to the patient.

With changes in social and work environments, especially with the use of computers, tablets, smartphones, etc., excellent intermediate distance vision has become more important. New types of IOL design feature a refractive and diffractive component and confer three focal points within the eye. These trifocal IOLs restore near, far, and intermediate vision (Gatinel 2013). Intraocular lenses with this design have been shown to achieve better patient satisfaction (Kretz 2015b).

How the intervention might work

Unlike monofocal IOLs, diffractive IOLs were originally designed using apodization and convolution technologies that cause light to divide, and produce two or more focal points. To restore near, intermediate, and far vision, three focal points may be preferable in an IOL.

Multifocal acrylic IOLs come in several designs. The goal of the first generation of multifocal lens design (bifocal IOL) was to restore two focal points: far and near vision (Voskresenskaya 2010). These bifocal IOLs, known by convention as a multifocal lens, have acceptable visual outcomes and give spectacles independence to many pseudophakic people (Calladine 2012; Torricelli 2012). The latest generation of multifocal IOLs are based on a diffractive/refractive technology design with the main objective of restoring intermediate vision (Papadopoulos 2014).

Different bifocal IOLs have different visual outcomes, mainly because of the different added power placed in the IOL to adjust for different near vision distances. Besides near and distance vision, good intermediate vision is needed to increase patient satisfaction with IOLs (Kretz 2015a; Kretz 2015b). A few trifocal intraocular lenses are available. Excellent visual outcomes and high patient satisfaction scores have been reported with these lenses (Voskresenskaya 2010; Cochener 2012; Lesieur 2012; Torricelli 2012; Sheppard 2013; Vryghem 2013; Law 2014).

However, the most common adverse visual effects in a multifocal IOL are glare, halos, and loss of contrast sensitivity, which result in poor quality of vision during mesopic conditions (Carson 2014). These effects could be related to neuroadaptation when the brain and visual system adapt to the new way of vision. As this process evolves, patients become more comfortable with their new vision, and their perception of side effects decreases (Voskresenskaya 2010).

Why it is important to do this review

It is important to restore visual acuity at all distances in order to treat cataract and presbyopia satisfactorily. Adverse effects such as halos, glare, lowered contrast sensitivity, and dissatisfaction associated with IOLs seem to be inherent with the multifocal designs (bifocal or trifocal IOL). However, other visual and patient-important benefits have been reported for both bifocal and trifocal IOLs (Voskresenskaya 2010; Cochener 2012; Lesieur 2012; Sheppard 2013; Vryghem 2013; Law 2014). Another Cochrane Review comparing multifocal and monofocal intraocular lenses after cataract extraction was published in 2012 (Calladine 2012), but

to our knowledge no high-quality systematic review of evidence for the comparison of trifocal and bifocal IOLs has been published.

OBJECTIVES

To assess the effectiveness and safety of implantation with trifocal versus bifocal IOLs during cataract surgery among participants with presbyopia.

METHODS

Criteria for considering studies for this review

Types of studies

We included only randomized controlled trials (RCTs). We included all eligible trials regardless of their publication status or language of publication.

Types of participants

We included studies in which the participants were 30 years or older with cataract and presbyopia. We documented studies that included participants with other ocular comorbidities, such as pseudoexfoliation syndrome, glaucoma, diabetes mellitus, age-related macular degeneration, retinal disease, optic nerve disease, or amblyopia in the eye undergoing cataract surgery or a history of intraocular surgery, pediatric cataract, or ocular trauma.

Types of interventions

We included studies in which implantation of trifocal IOLs was compared with implantation of bifocal IOLs during cataract surgery.

Types of outcome measures

Primary outcomes

1. Mean uncorrected (without the aid of spectacles or contact lenses) distance visual acuity measured by LogMAR chart at one-year follow-up.

Secondary outcomes

1. Mean uncorrected distance visual acuity measured by LogMAR chart at three-month and six-month follow-up.
2. Mean uncorrected near visual acuity at three-month, six-month, and one-year follow-up.
3. Mean uncorrected intermediate visual acuity at three-month, six-month, and one-year follow-up.
4. Mean best-corrected distance visual acuity at three-month, six-month, and one-year follow-up.
5. Mean contrast sensitivity, measured by the FACT (Functional Acuity Contrast Test) chart (Pesudovs 2004), or by the Pelli-Robson contrast sensitivity test (Mantyjarvi 2001), noted in LogCS at different cycles per grade in spatial frequencies at three-month, six-month, and one-year follow-up.
6. Mean quality of life or visual function evaluated by validated and comparable instruments (e.g. 25-item National Eye Institute Visual Function Questionnaire (NEI-VFQ-25)) noted in numeric scores at three-month, six-month, and one-year follow-up.

Adverse outcomes

1. Visual disturbances such as glare, experienced when a source of light other than the main target image illuminates the retina, and halos, defined as visual disturbances related to the main target image that lower contrast sensitivity; these visual disturbances are only noted by proportions at three months, six months, and one year after surgery.
2. Opacification of the posterior capsule (proliferation of epithelial lens cells in the main visual axis that lowers visual acuity), with or without YAG laser capsulotomy, at three months, six months, and one year after surgery.

We assessed additional adverse effects related to IOLs mentioned in any of the included studies.

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist searched the following electronic databases for RCTs and controlled clinical trials. There were no restrictions on language or year of publication. The electronic databases were last searched on 26 September 2019.

- Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (2019, Issue 9) (Appendix 1).
- MEDLINE Ovid (1946 to 26 September 2019) (Appendix 2).
- Embase.com (1980 to 26 September 2019) (Appendix 3).
- PubMed (1948 to 26 September 2019) (Appendix 4).
- LILACS (Latin American and Caribbean Health Science Information database) (1982 to 26 September 2019) (Appendix 5).
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 26 September 2019) (Appendix 6).
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp; searched 26 September 2019) (Appendix 7).

Searching other resources

We searched the reference lists of retrieved articles and abstracts from the Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) for the years 2005 to 2015 for additional relevant studies that compare outcomes after implantation of trifocal and bifocal IOLs.

Data collection and analysis

Selection of studies

Two review authors independently assessed the titles and abstracts of all records identified by the electronic and manual searches. Each review author reviewed and labeled each record as 'definitely relevant,' 'possibly relevant,' or 'definitely not relevant.' We retrieved the full-text report for all records labeled as 'definitely relevant' or 'possibly relevant.' Two review authors independently assessed each full-text report and classified each as 'include,' 'exclude,' or 'awaiting classification.' Any differences between the two review authors at title, abstract, and full-text screening stage were resolved by discussion. We documented the studies excluded after full-text review and noted their reasons for ineligibility.

Data extraction and management

Two review authors independently extracted data from reports of the included studies using a data collection form developed by Cochrane Eyes and Vision and implemented in Covidence software (Covidence). Two review authors independently checked the data before entering into Review Manager 5 software (Review Manager 2014). We recorded the following characteristics of the included studies: study methods, participants, interventions, and outcomes. Where information about (or outcome data from) included studies was missing or unclear, we contacted the study investigators or organizations involved for additional data, confirmation, or clarification. We collected and used the most detailed numerical data available from the included studies to facilitate analyses. We attempted to obtain data from available reports, investigators, or organizations in preference to less precise methods such as extracting numeric data from graphs. When it was necessary to extract data available only in graphical displays, two review authors independently extracted the data, and resolved any disagreements or discrepancies by discussion or by consulting a third review author.

Assessment of risk of bias in included studies

We used the Cochrane 'Risk of bias' tool as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* to assess the risk of bias for included studies (Higgins 2017). Two review authors independently assessed risk of bias for each included study, grading each 'Risk of bias' domain as low, high, or unclear. We evaluated the following 'Risk of bias' domains: selection bias (sequence generation and allocation concealment before assignment), performance bias (masking of participants and study personnel), detection bias (masking of outcome assessors), attrition bias (loss to follow-up), reporting bias (selective outcome reporting), and other sources of bias. Any disagreements between the review authors were resolved by discussion until consensus was reached or by consulting another review author.

Measures of treatment effect

Continuous outcomes

We had planned to use standardized mean differences (SMDs) and 95% confidence intervals (CIs) calculated for continuous data outcomes in anticipation of the use of different instruments of measurement in different studies. This statistic is used for example when distance and near visual acuity are reported on different scales (LogMAR, decimal, or Snellen fraction) in different studies to permit the analysis of effects on a uniform scale (Deeks 2017). However, because all visual acuity was reported as LogMAR in all studies that contributed data to the meta-analysis, we estimated the overall effects as mean differences (MDs) and 95% CIs. Where possible, we checked for skewness using the methods outlined in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017).

Dichotomous outcomes

When data on adverse outcome such as 'glare,' 'halos,' 'spectacle independence,' 'posterior capsular opacification' (PCO), and 'glistenings' were available, we analyzed them as dichotomous outcomes, and calculated risk ratios (RRs) along with their 95% CIs to estimate effects.

Unit of analysis issues

The participant was the primary unit of analysis whenever only one eye per participant was enrolled in the study. We determined whether the included studies included one or both eyes from each participant and whether study investigators randomized and analyzed data at the participant or eye level. We planned that when both eyes were randomized to the same treatment group (two-eye design) or to different treatment groups (paired-eye design), we would extract the results that had accounted for the correlation and refer to Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* for guidelines regarding considerations of including variants on randomized trials (Higgins 2019). When studies with more than two arms were included (e.g. two or more IOLs), we evaluated each relevant comparison separately, and selected one pair of intervention and comparison that were relevant to the review without double counting them in the analysis (Higgins 2019).

Dealing with missing data

We analyzed outcomes on an intention-to-treat basis. We planned that whenever outcome data were missing, we would contact the study authors, using the best information available to analyze data if no response was received within two weeks. We only analyzed available data, and did not impute missing data for the purposes of this review.

Assessment of heterogeneity

We investigated clinical or methodological heterogeneity among studies by evaluating differences with respect to characteristics of participant populations, interventions, and outcome assessment. We evaluated statistical heterogeneity among outcomes by examining the overlap in confidence intervals of forest plots and by using the Chi^2 and the I^2 statistic, as described in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). We used the I^2 statistic to assess the proportion of total variability explained by heterogeneity among studies. If we observed substantial heterogeneity ($I^2 > 60\%$) or inconsistency among effect sizes estimated from individual studies contributing data to a meta-analysis, we did not report a pooled analysis, instead we provided a narrative summary of the intervention effects estimated from individual studies. However, if all estimates were in the same direction, we performed a meta-analysis despite substantial statistical heterogeneity, and interpreted the findings taking account of the heterogeneity.

Assessment of reporting biases

We assessed selective outcome reporting for each study by comparing the outcomes specified in a protocol or clinical trial registry with the reported results. When protocols or clinical trial registry records were not available, we assessed selective outcome reporting based on the outcomes specified in the methods section of the study reports and on data collected and reported in the study. We intended to use funnel plots to assess small-study effects which could result in publication bias when a sufficient number of trials (more than 10) were included in the review. However, we did not assess publication bias because the number of studies included in the review was less than 10.

Data synthesis

We analyzed data according to the guidelines in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017). If there was no statistical or clinical heterogeneity, or fewer than three trials contributed data to a meta-analysis, we used a fixed-effect model to estimate intervention effects; otherwise we used random-effects models. When we detected substantial statistical heterogeneity ($I^2 > 60\%$), and the direction of treatment effects was not consistent across studies, we did not perform a meta-analysis and instead presented a narrative summary.

Subgroup analysis and investigation of heterogeneity

We had planned to conduct subgroup analysis to investigate the reasons for any clinical or statistical heterogeneity according to outcomes within subgroups of participants defined by such factors as unilateral versus bilateral surgery and optical design in the IOLs. However, we did not conduct these analyses due to insufficient numbers of studies.

Sensitivity analysis

We had planned to conduct sensitivity analysis to examine the impact of excluding studies with high risk of bias, unpublished data, and industry-funded studies to assess the robustness of estimates with respect to these factors. Due to insufficient numbers of included studies and the absence of unpublished studies, we did not perform this analysis. Although we had not planned at the protocol stage to conduct sensitivity analysis based on unit of analysis (participants versus eyes), we had also planned post hoc to conduct additional sensitivity analyses to examine the impact of restricting our analyses to studies for which analysis was performed at the participant level. However, we did not conduct this analysis because only one study analyzed data at the participant level.

Summary of findings and assessment of the certainty of the evidence

We prepared a 'Summary of findings' table according to the methods described in Chapters 11 and 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011a; Schünemann 2011b), and presented the estimated effects of trifocal IOLs versus bifocal IOLs at one-year follow-up. We included the following outcomes.

1. Mean uncorrected distance visual acuity
2. Mean uncorrected near visual acuity
3. Mean uncorrected intermediate visual acuity
4. Mean best-corrected distance visual acuity
5. Mean contrast sensitivity
6. Mean quality of life or visual function scores
7. Adverse events

Using the GRADE approach, two review authors independently judged the certainty of the evidence for each outcome as very low, low, moderate, or high (Langendam 2013). Any differences between the two review authors were resolved by discussion.

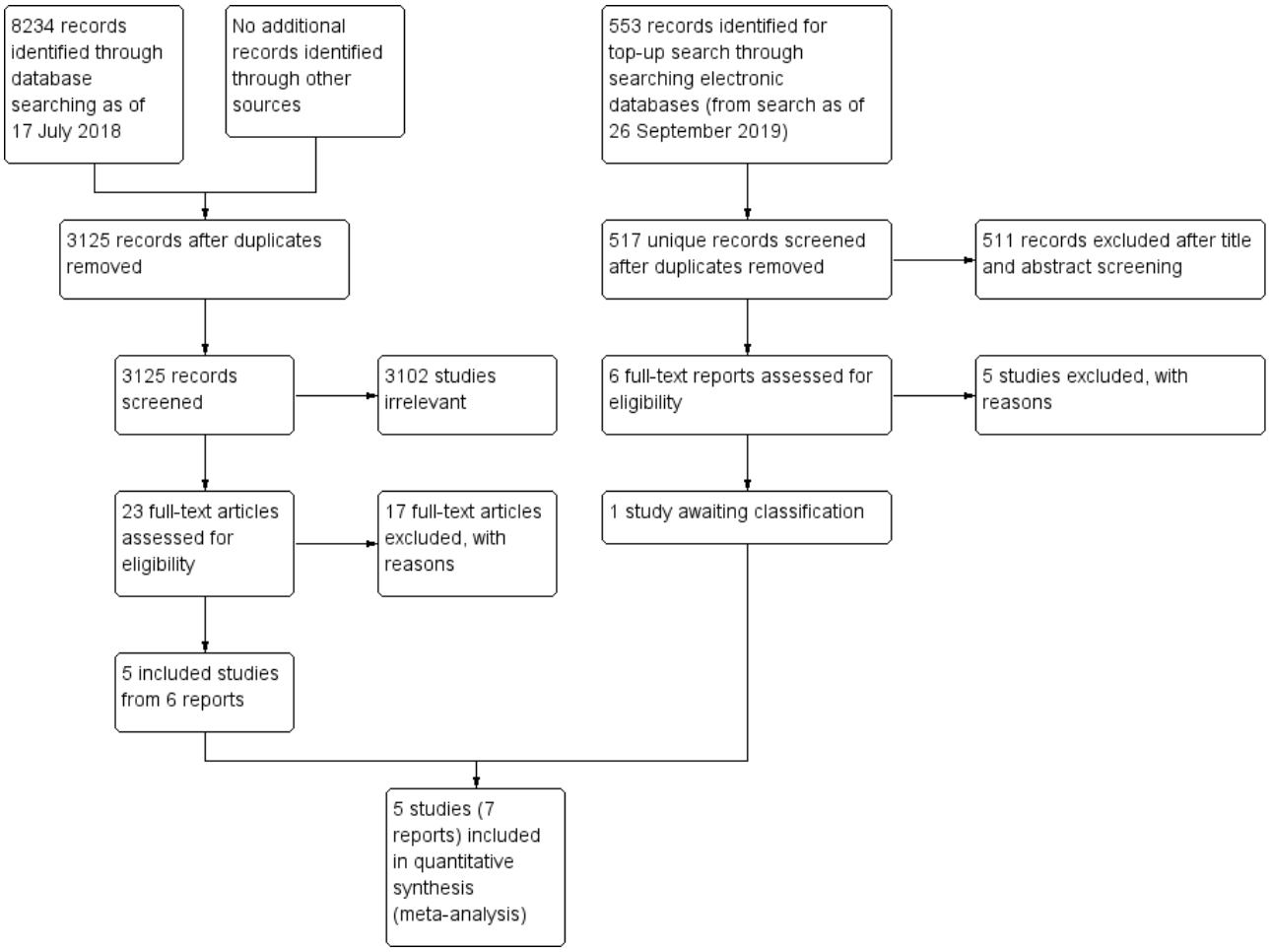
RESULTS

Description of studies

Results of the search

The electronic searches identified a total of 8234 records (Figure 1). After removal of duplicates, we screened 3125 titles and abstracts for eligibility, of which 23 records appeared to be relevant to the scope of the review. We retrieved the full-text articles of these 23 records for further screening. We included six reports of five studies, as there were two records from Kaymak 2017 (see Characteristics of included studies), and excluded 17 reports of 17 studies that did not meet the eligibility criteria (see Characteristics of excluded studies).

Figure 1. Study flow diagram.



We conducted an additional top-up search on 26 September 2019 and identified 553 titles and abstracts, screened 517 after removal of duplicates, and excluded 511 records that did not meet the eligibility criteria. We retrieved six full-text articles for further screening and excluded five records with reasons, listing the remaining record as a study awaiting classification.

Overall, we included 5 studies (6 reports), excluded 22 studies (22 reports), and categorized 1 record (1 full-text) from the top-up search as awaiting classification (Figure 1).

Included studies

Types of studies

We included five studies in the review from six countries in Europe. Two studies were conducted in the Czech Republic (Mojzis 2014; Mojzis 2017), one in France (Cochener 2016), one in the Netherlands (Jonker 2015), and one multicenter study was conducted in Spain, Germany, and France (Kaymak 2017). Further details of the included studies can be found in the Characteristics of included studies table. The included studies were published between 2014 and 2017. Duration of follow-up ranged from three months, in Mojzis 2014, to one year, in Kaymak 2017 and Mojzis 2017. All the included studies randomized both eyes of the same participant to the same intervention. Only one study analyzed data at the participant level (Cochener 2016). The remaining four studies analyzed data at the eyes level, but the investigators did not report whether they accounted for the correlation between eyes in their analysis. Kaymak 2017 was a multi-arm study, and we included only the comparison relevant to this review. We included all five studies in meta-analysis. The authors of two studies reported receiving funding from manufacturers of the lens examined in this review (Jonker 2015; Kaymak 2017). In one study at least one author reported a conflict of interest with manufacturers of the lens examined (Jonker 2015).

Type of participants

The five included studies enrolled a total of 175 participants. The studies varied in size from 27 in the smallest study, Cochener 2016, to 52 participants in the largest study, Kaymak 2017. The mean age of participants ranged from 58 to 64 years. Only one study reported on information on the gender of participants, and participants were predominantly women (Kaymak 2017). Diagnosis of cataract varied among participants, highlighting clinical heterogeneity. All included studies involved participants with bilateral cataracts and no pre-existing ocular pathologies or ocular surgery. Cochener 2016 included participants who started to show clouding of the crystalline lens (Lens Opacities Classification System III classification global score 2 or greater), corneal astigmatism of 1.00 diopter (D) or less. Jonker 2015 and Kaymak 2017 included participants with bilateral cataract with less

than 1.0 D corneal astigmatism in both eyes. The remaining two studies enrolled participants with cataract and presbyopic/pre-presbyopic requiring refractive lenses (Mojzis 2014; Mojzis 2017).

Type of interventions

All five included studies evaluated trifocal versus bifocal IOLs.

Type of outcomes

All five included studies assessed visual acuity measured using a LogMAR chart; two studies assessed contrast sensitivity (Jonker 2015; Mojzis 2017), and three assessed other visual functions such as spectacle independence, Cochener 2016, and reading performance (Jonker 2015; Kaymak 2017). Two studies reported adverse events (Cochener 2016; Mojzis 2017).

Excluded studies

We excluded 22 studies after full-text review. Fourteen of these studies did not address the comparisons of interest and the remaining eight studies were not reports of RCTs (see Characteristics of excluded studies table).

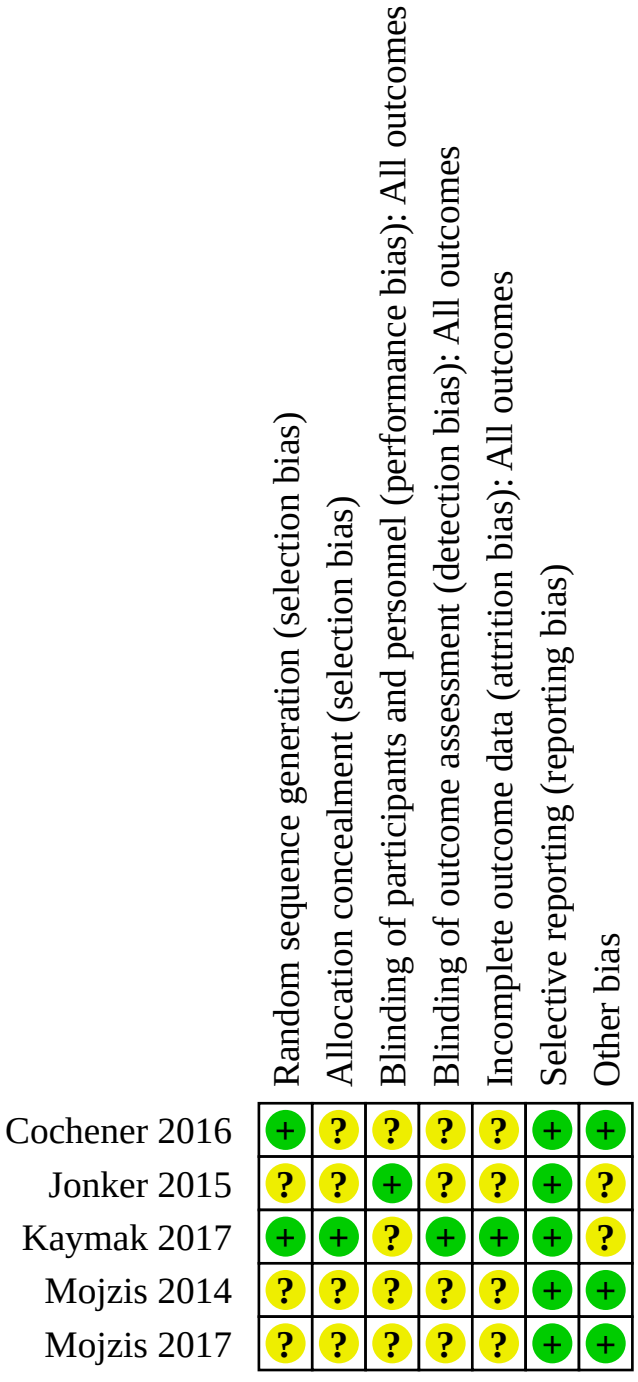
Ongoing studies and studies awaiting classification

We categorized one report from the top-up search as awaiting classification and identified no ongoing studies.

Risk of bias in included studies

Risk of bias assessment for all five studies is summarized in Figure 2.

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



Allocation

Random sequence generation

Randomization sequence was adequately generated in two studies. Participants were assigned to treatment groups using web-based software in Cochener 2016 and by randomization code administered centrally using a vocal server in Kaymak 2017; we judged both studies to be at low risk of bias for this domain. The method of randomization was not reported in three studies (Mojzis 2014; Jonker 2015; Mojzis 2017), therefore they were judged as at unclear risk of bias.

Allocation concealment

We judged one study to be at low risk of bias as the treatment allocation was accomplished centrally (Kaymak 2017). The method of treatment allocation concealment was not reported in the other four studies (Mojzis 2014; Jonker 2015; Cochener 2016; Mojzis 2017), therefore they were judged as at unclear risk of bias.

Blinding

We judged most included studies as at unclear risk of performance and detection bias. Only one study masked both participants and investigators to the IOL implanted, which we judged as at low risk of performance bias (Jonker 2015). We judged the remaining four studies as at unclear risk of bias for various reasons. Mojzis 2014 and Mojzis 2017 masked participants to IOL but did not report masking study personnel. Cochener 2016 and Kaymak 2017 did not report masking participants or study personnel.

The primary outcome of this review was mean uncorrected distance visual acuity at one-year follow-up. Only one study reported that all postoperative outcome assessments were performed by an independent observer who was masked to the intervention (Kaymak 2017); we judged this study to be at low risk of detection bias. The remaining four studies did not report masking outcome assessors and were therefore judged as at unclear risk of detection bias (Mojzis 2014; Jonker 2015; Cochener 2016; Mojzis 2017).

Incomplete outcome data

Kaymak 2017 excluded six eyes, three (9%) of participants from the analysis, because participants withdrew after IOL implantation. As this proportion was small, we judged Kaymak 2017 as at low risk of attrition bias. The remaining four studies did not report attrition information and were therefore judged as at unclear risk of attrition bias (Mojzis 2014; Jonker 2015; Cochener 2016; Mojzis 2017).

Selective reporting

Although all five included studies had no trial registration or published protocol, the authors reported all outcomes specified in the methods section of the study. We therefore judged all five studies as at low risk of reporting bias.

Other potential sources of bias

At least one study investigator in two of the five studies included, had financial relationship with manufacturers of one of the intervention devices. The remaining three studies appeared to be free from other sources of bias.

Effects of interventions

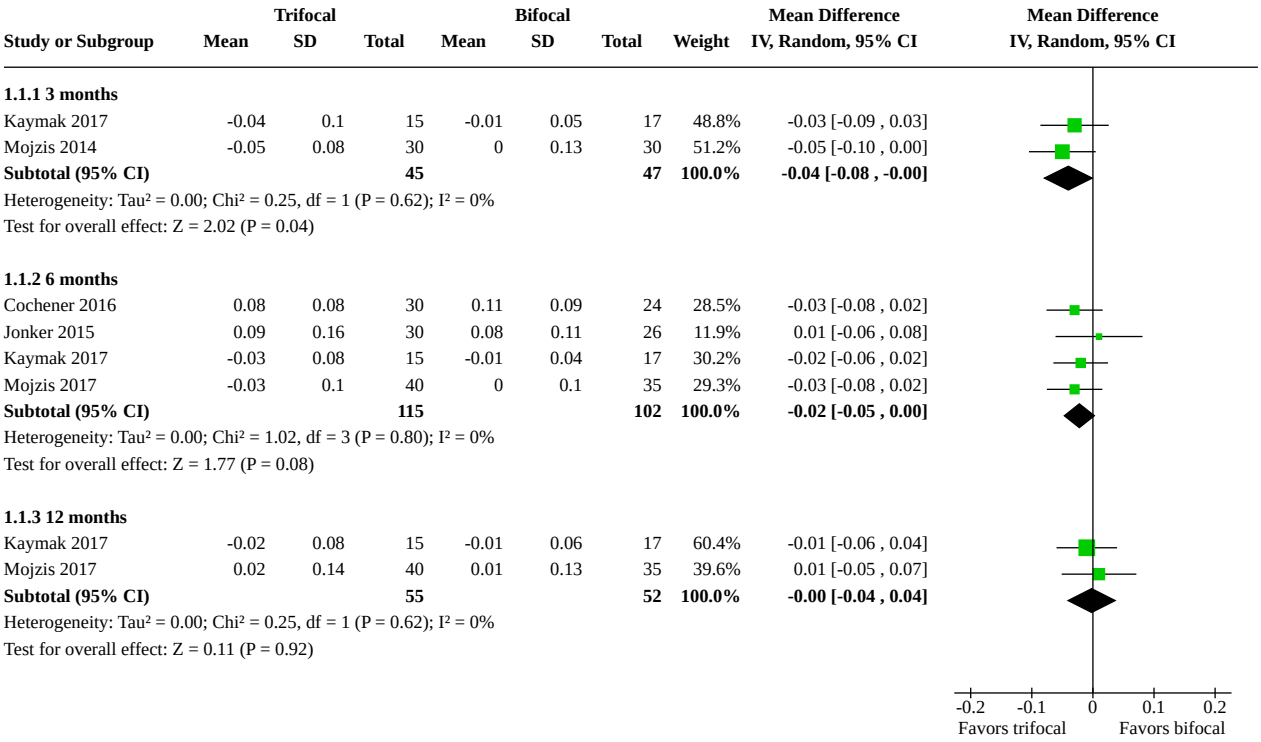
See: **Summary of findings 1** Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia

The only comparison for this review was trifocal compared to bifocal IOL implantation during cataract surgery for visual acuity among presbyopic participants. All five included studies reported data on at least one outcome specified in the review.

Mean uncorrected distance visual acuity

At three months, data were available from only two studies. Participants treated with trifocal IOL implantation probably experienced improvement in uncorrected distance visual acuity (UDVA) more than those treated with bifocal IOL (mean difference (MD) −0.04, 95% confidence interval (CI) −0.08 to −0.00; I^2 = 0%; 2 studies, 92 participants; Analysis 1.1; Figure 3). The certainty of the evidence was moderate, downgraded for risk of bias. The beneficial effect of trifocal IOL for this outcome persisted at six months (MD −0.02, 95% CI −0.05 to 0.00; I^2 = 0%; 4 studies, 217 participants; Analysis 1.1; Figure 3). The certainty of the evidence was moderate, downgraded for risk of bias. However, the observed beneficial effect of trifocal IOL disappeared at one year (MD 0.00, 95% CI −0.04 to 0.04; I^2 = 0%; 2 studies, 107 participants; Analysis 1.1; Figure 3), the primary outcome of our review. The certainty of the evidence was low, downgraded for imprecision and risk of bias.

Figure 3. Forest plot of comparison: 1 Trifocal versus bifocal intraocular lenses after cataract extraction, outcome: 1.1 Mean uncorrected distance visual acuity (LogMAR).

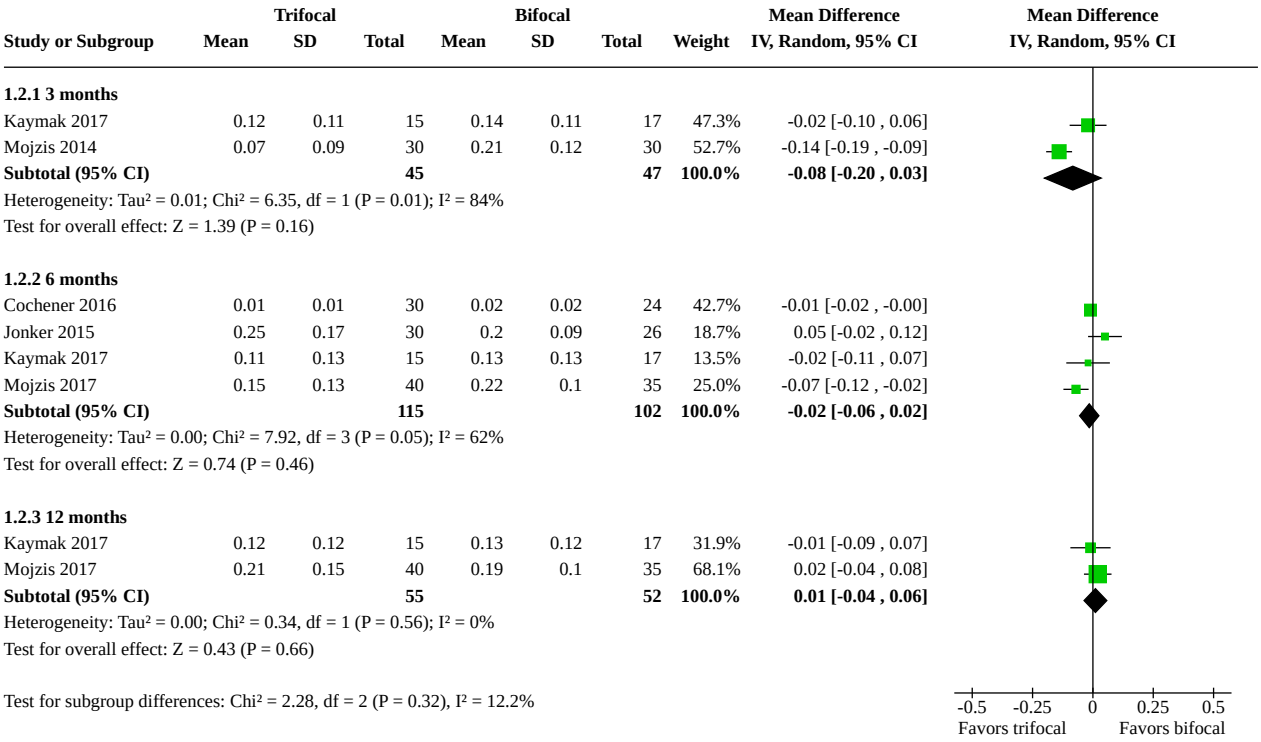


Mean uncorrected near visual acuity

At three months, pooled data from two studies suggested that trifocal IOL implantation had no evidence of an effect on uncorrected near visual acuity (UNVA) compared to bifocal IOL (MD −0.08, 95% CI −0.20 to 0.03; I^2 = 84%; 2 studies, 92 participants; Analysis 1.2; Figure 4). There was considerable statistical heterogeneity, and the certainty of the evidence was very low, downgraded for risk of bias, imprecision, and inconsistency.

We observed similar findings at six months (MD −0.02, 95% CI −0.06 to 0.02; I^2 = 62%; 4 studies, 217 participants; Analysis 1.2; Figure 4) and at one year (MD 0.01, 95% CI −0.04 to 0.06; I^2 = 0%; 2 studies, 107 participants; Analysis 1.2; Figure 4). Estimates at both time points were imprecise. The certainty of the evidence was very low at six months (downgraded for risk of bias, imprecision, and inconsistency) and low at one year (downgraded for imprecision and risk of bias).

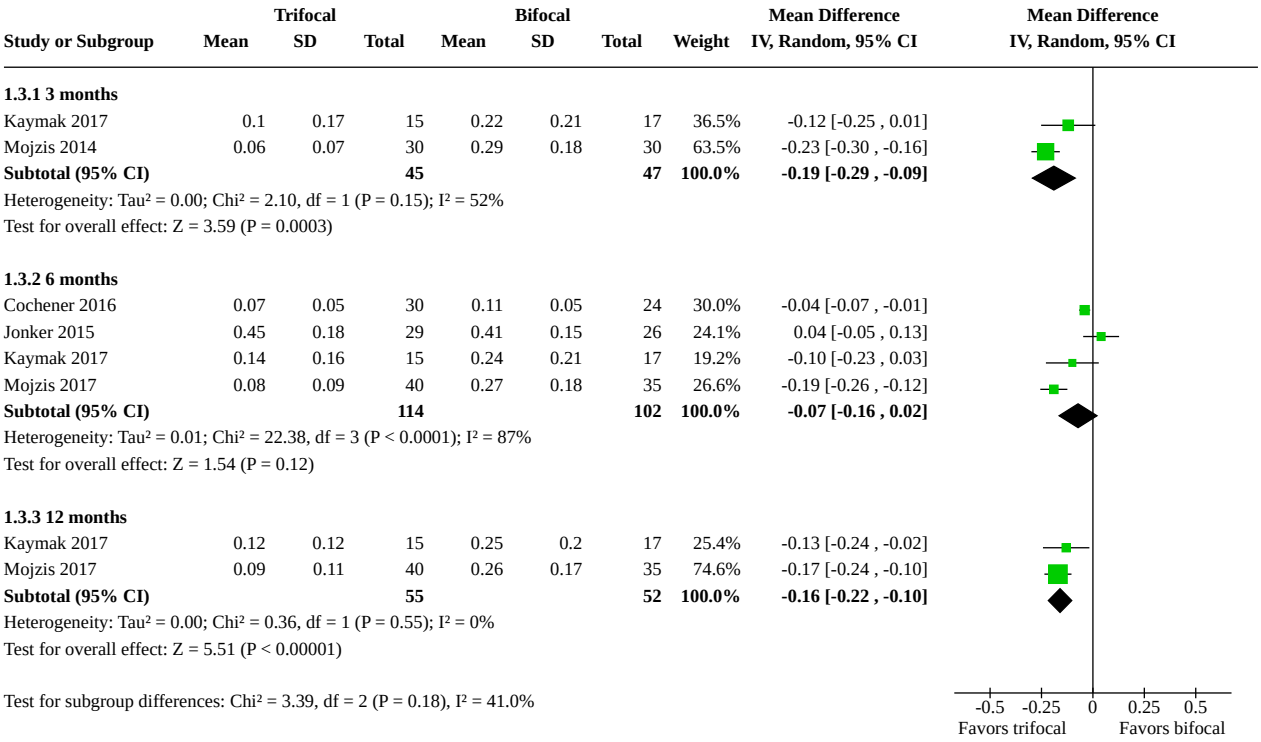
Figure 4. Forest plot of comparison: 1 Trifocal versus bifocal intraocular lenses after cataract extraction, outcome: 1.2 Mean uncorrected near visual acuity (LogMAR).



Mean uncorrected intermediate visual acuity

At three months, data were available for two studies. Participants treated with trifocal IOL implantation may experience more improvement in uncorrected intermediate visual acuity (UIVA) than those treated with bifocal IOL (MD −0.19, 95% CI −0.29 to −0.09; I^2 = 52%; 2 studies, 92 participants; Analysis 1.3; Figure 5). The certainty of the evidence was low, downgraded for risk of bias and imprecision. Although the observed beneficial effect of trifocal IOL implantation disappeared at six months (MD −0.07, 95% CI −0.16 to 0.02; I^2 = 87%; 4 studies, 216 participants; Analysis 1.3; Figure 5), data from two studies suggest that trifocal IOL implantation may improve UIVA more than bifocal IOL at one year (MD −0.16, 95% CI −0.22 to −0.10; I^2 = 0%; 2 studies, 107 participants; Analysis 1.3; Figure 5). The certainty of the evidence was very low at six months (downgraded for risk of bias, imprecision, and inconsistency) and low at one year (downgraded for risk of bias and imprecision).

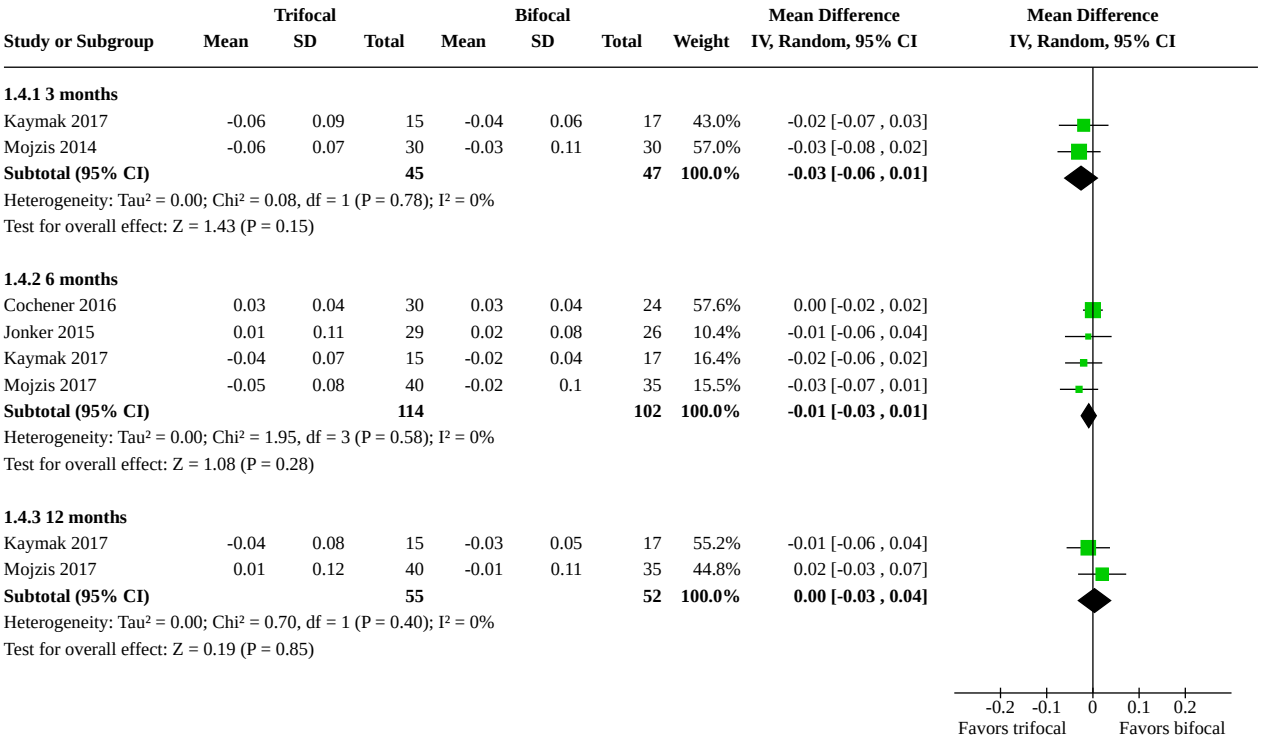
Figure 5. Forest plot of comparison: 1 Trifocal versus bifocal intraocular lenses after cataract extraction, outcome: 1.3 Mean uncorrected intermediate visual acuity (LogMAR).



Mean best-corrected distance visual acuity

At three months, available data from two studies suggested that trifocal IOL implantation had no evidence of effect on best-corrected distance visual acuity (BCDVA) compared bifocal IOL (MD −0.03, 95% CI −0.06 to 0.01; I^2 = 0%; 2 studies, 92 participants; Analysis 1.4; Figure 6). We observed similar findings at six months (MD −0.01, 95% CI −0.03 to 0.01; I^2 = 0%; 4 studies, 216 participants; Analysis 1.4; Figure 6). The estimates at both time points were also imprecise. The certainty of the evidence for both time points was low, downgraded for risk of bias and imprecision. At one year, available data from two studies also suggested no evidence of an effect of trifocal IOL compared to bifocal IOL (MD 0.00, 95% CI −0.03 to 0.04; I^2 = 0%; 2 studies, 107 participants; Analysis 1.4; Figure 6). The certainty of the evidence was low, downgraded for risk of bias and imprecision.

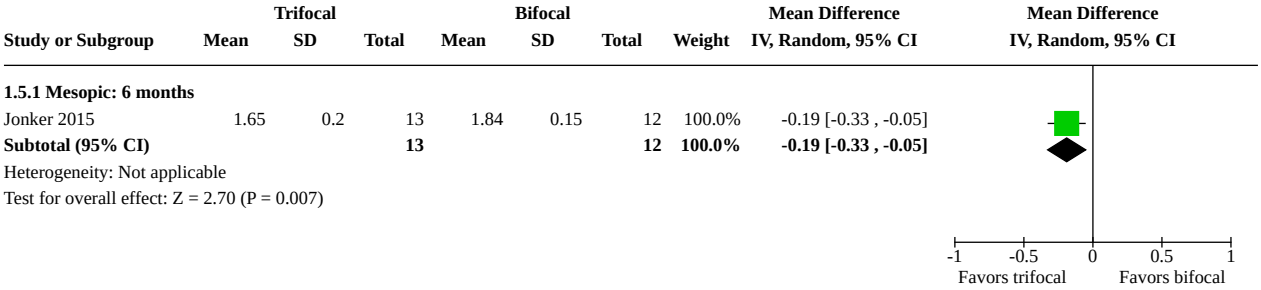
Figure 6. Forest plot of comparison: 1 Trifocal versus bifocal intraocular lenses after cataract extraction, outcome: 1.4 Mean best-corrected distance visual acuity (LogMAR).



Contrast sensitivity

Three studies assessed contrast sensitivity. However, at three months only one study reported data on mean contrast sensitivity in log contrast sensitivity function (logCSF) scale under both photopic and mesopic conditions at four spatial frequencies: 3, 6, 12, and 18 cycles per degree (Jonker 2015). Point estimates suggested no evidence of difference in contrast sensitivity between groups under photopic conditions at all four spatial frequencies. The certainty of the evidence was very low, downgraded for risk of bias and imprecision (−2). However, when contrast sensitivity was measured under mesopic conditions, point estimates suggested that trifocal IOL implantation had no evidence of a difference in contrast sensitivity at all spatial frequencies (data not shown), except one (6 cycles per degree), where participants treated with trifocal IOl did worse compared to those in the bifocal IOL group (MD −0.19, 95% CI −0.33 to −0.05; 1 study, 25 participants; Analysis 1.5; Figure 7). The certainty of the evidence was low, downgraded for risk of bias and imprecision. At three months, Mojzis 2014 observed no evidence of a difference between groups for contrast sensitivity for most frequencies analyzed. In Mojzis 2017, the authors reported observing minimal difference in contrast sensitivity between groups that was significant only for low to medium spatial frequencies at six months but not at one year.

Figure 7. Forest plot of comparison: 1 Trifocal versus bifocal intraocular lenses after cataract extraction, outcome: 1.5 Mean contrast sensitivity.



Quality of life

Three studies assessed other visual function such as reading speed (Jonker 2015), reading performance (Kaymak 2017), and spectacle independence (Jonker 2015; Cochener 2016). However, none of these studies provided data in a format that permitted formal analysis. In Jonker 2015, reading speed was assessed at six months using the Radner reading chart. Investigators found no evidence of a difference between groups in mean reading distance, mean reading speed, or maximum reading speed under 70% and 100% contrast. At six months, Kaymak 2017 observed no evidence of a difference between groups in reading performance. Similarly, investigators found no evidence of a difference between groups in spectacle dependence score at all distances (P ≥ 0.296) (Kaymak 2017). At six months, Cochener 2016 found that spectacle independence and participant satisfaction may be higher in the trifocal compared to the bifocal IOL group. In addition, Jonker 2015 observed that at six months all participants were spectacle-free for distance, and 80% of participants in the trifocal group (12 participants) reported complete spectacle independence at six months compared to 50% (6 participants) in the bifocal group, suggesting good-quality vision. The certainty of the evidence for these outcomes in each study at the time points examined was low, downgraded for risk of bias and imprecision.

Adverse events

One study reported no intraoperative or postoperative complications (Cochener 2016). Jonker 2015 reported that "side effects of trifocal IOLs such as glare and halos was similar to preoperative measurements". Another study reported that 4 eyes (11.4%) in the bifocal group and 3 eyes (7.5%) in the trifocal group developed significant posterior capsular opacification requiring YAG capsulotomy (Mojzis 2017). The remaining two studies did not report on adverse events such as glare/haloes.

DISCUSSION

Summary of main results

We included five studies that compared trifocal versus bifocal IOLs implantation during cataract surgery among participants 30 years or older with cataract and presbyopia. After reviewing the available evidence, we summarized our findings in Summary of findings 1 for the main comparison.

The evidence suggests that trifocal IOL implantation probably produces more improvement in UDVA at three and six months after surgery than bifocal IOL, but showed no evidence of an effect at one year. With regard to UNVA and BCDVA, there is no evidence of a difference between trifocal and bifocal IOL implantation for these outcomes at three months, six months, and one year after surgery. However, trifocal IOL implantation may improve UIVA at three months and one year but not at six months after surgery. There is also no evidence of a difference between trifocal and bifocal IOL implantation for contrast sensitivity. Spectacle independence and participant satisfaction were likely to be higher in the trifocal compared to the bifocal IOL group. Treatment with trifocal IOL appears to be well tolerated, as fewer eyes in the trifocal compared to the bifocal IOL group developed complications such as significant posterior capsular opacification requiring YAG capsulotomy.

Overall completeness and applicability of evidence

We included only RCTs with a minimum follow-up of three months in the review. The included studies differed in a number of characteristics. All participants were of European descent, and gender was not reported for most participants. The evidence from this review may not be applicable to certain racial groups or gender as well as people with certain ocular pathologies, as these groups were either underrepresented or excluded in the primary studies that contributed data for the review.

Quality of the evidence

The certainty of the evidence was mostly low across the outcomes examined in this review. Most studies did not report how random sequence was generated or the method of concealing treatment allocation. We assessed most studies as at unclear risk of performance and detection bias. Attrition bias was unclear for most studies. However, risk of bias for selective outcome reporting was low across all studies. Other limitations to the certainty of the evidence included wide confidence interval of the effect estimates, resulting in downgrading for risk of bias and imprecision. In addition to aspects of study design, we considered financial support as a potential source of bias. Two of the five included studies were sponsored by manufacturers of one of the study lenses under investigation, and some study investigators reported that they had a financial relationship with industry that marketed the study lens.

Potential biases in the review process

We performed a very broad literature search of multiple electronic databases with the help of an Information Specialist. To reduce potential bias arising during study selection, 'Risk of bias' assessment, and data extraction, two review authors working independently completed all steps of the review process outlined in the Methods section of this review. We decided post hoc to include studies with a two-eye design; none of these studies reported on how correlation between eyes from the two-eye design was accounted for in their analysis. Analyses that do not account for the correlation between eyes may appear to have more information than there actually is, and can overestimate the treatment effect with a false increase in precision (Murdoch 1998). Our post hoc decision to include data from studies with a two-eye design may have artificially overestimated the magnitude of the effect estimate, since four of the five included studies in this review were from studies with a two-eye design.

Agreements and disagreements with other studies or reviews

Our review is in general agreement with other reviews. For instance, we found several reviews comparing bifocal and trifocal IOL that reported similar findings. Jin 2019 included four RCTs and four cohort studies (489 eyes, 245 participants) that compared trifocal with bifocal IOL implantation among participants undergoing cataract surgery, and found that trifocal IOLs improve intermediate visual acuity but had no difference on distance or near visual acuity. Similar results were reported by Xu and colleagues (Xu 2017), who found improvement in intermediate vision in favor of trifocal compared with bifocal IOL. They observed that distant and near vision did not differ between groups at six months postoperatively (Xu 2017). Yoon 2018 also reported improvement in intermediate vision and no evidence of a difference between

trifocal and bifocal IOL implantation for distance and near vision. Additionally, evidence from Yang 2018 supported no evidence of a difference between trifocal and bifocal IOL in distance and near vision. Shen 2017 also observed results in favor of trifocal IOL implantation for intermediate vision.

AUTHORS' CONCLUSIONS

Implications for practice

We identified low-certainty evidence when comparing trifocal with bifocal intraocular lens (IOL) implantation among participants with presbyopia undergoing cataract surgery. Trifocal IOL may result in better intermediate distance visual acuity. Spectacle dependence may be less likely with trifocal IOL. We identified one study from a top-up search which we categorized as awaiting classification, the data for which were not included in data analysis for this review (de Carneros-Llorente 2019). This study suggests that compared with bifocal IOL implantation, trifocal IOLs provide better intermediate distance visual acuity. Inclusion of data from this study is thus unlikely to change the findings and conclusions of this review. Information on quality of life and adverse events was sparse. Consequently, caution is advised in the use of the current evidence in clinical practice decisions, considering the above limitations of the evidence. Such decisions should be based on patient preferences and provider judgement, given the variability of the results and risk of bias in the studies relevant to this topic.

Implications for research

Given the increasing interest in trifocal IOLs and in comparison with other presbyopic correcting options during cataract surgery, future research should compare trifocal IOL and specific bifocal IOLs that correct intermediate visual acuity in order to evaluate important outcomes such as visual acuity, contrast sensitivity, and quality of life. Our findings regarding contrast sensitivity and quality of life were inconclusive. We believe that evaluation of these outcomes and other adverse visual effects is necessary to permit definitive conclusions regarding the benefit of trifocal compared to bifocal IOL in clinical practice. Future research should examine these outcomes as well as incidence of adverse events such as glare/haloes.

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This review was managed by CEV@US and was signed off for publication by Tianjing Li and Richard Wormald.

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CHARACTERISTICS OF STUDIES

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

Cochener 2016

Study characteristics	
Methods	**Study design:** parallel-group randomized controlled trial **Number randomized:** total 54 eyes of 27 participants; FineVision trifocal: 30 eyes of 15 participants; Tecnis bifocal: 24 eyes of 12 participants **Exclusions after randomization:** none **Losses to follow-up:** none **Number analyzed (total and per group):** total 54 eyes of 27 participants; FineVision trifocal: 30 eyes of 15 participants; Tecnis bifocal: 24 eyes of 12 participants **Unit of analysis:** participant **How were the missing data handled?:** not reported **Power calculation:** yes, "to find a clinically significant difference between the two groups, investigators assumed a difference of 0.2 logMAR, and based on alpha of 0.05 and power of 0.8, it was determined that 12 patients were required for each group"
Participants	**Country:** France **Setting:** not reported **Age:** FineVision trifocal: mean (SD): 58.7 (6.4) years Tecnis bifocal: mean (SD): 60.6 (9.1) years

Cochener 2016 *(Continued)*

	Sex: not reported **Inclusion criteria:** age > 55 years, starting to show clouding of the crystalline lens (Lens Opacities Classification System III classification global score 2 or greater), corneal astigmatism of 1.00 D or less **Exclusion criteria:** pre-existing amblyopia, maculopathy, optic neuropathy or glaucoma, previous retinal detachment, or unrealistic expectations regarding the outcome of the surgery **Equivalence of baseline characteristics:** participants in the FineVision group were more myopic, whereas those in the Tecnis group were more hyperopic
Interventions	**Intervention 1:** FineVision Micro F trifocal IOL (PhysIOL, Liege, Belgium) **Intervention 2:** TecnisZMB00 bifocal IOL (Abbott Medical Optics, Santa Ana, CA) **Length of follow-up:** 6 months
Outcomes	**Primary outcomes, as defined:** 1. Mean uncorrected distance visual acuity at 6 months (monocular, binocular), LogMAR scale 2. Mean uncorrected near visual acuity at 6 months (monocular, binocular), LogMAR scale 3. Mean uncorrected intermediate visual acuity at 6 months (binocular), LogMAR scale 4. Mean best-corrected distance visual acuity at 6 months (monocular), LogMAR scale 5. Quality of life at 6 months, evaluated as spectacle independence using the VF-14 questionnaire **Secondary outcomes:** not reported
Notes	**Institution:** Morvan University Hospital **Email:** beatrice.cochener@ophtalmologie-chu29.fr **Address:** Department of Ophthalmology, CHU Morvan, 2 Av Foch 29609 Brest Cedex, France **Study period:** not reported **Funding sources:** not reported **Declarations of interest:** authors declare no financial or proprietary interest in study **Reported subgroup analyses:** not reported **Trial registration number:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization for the study was performed using the software provided by www.random.org, with the FineVision IOL assigned as 1 and the Tecnis IOL assigned as 2.
Allocation concealment (selection bias)	Unclear risk	Authors did not describe treatment allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Masking of participants or study investigators was not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Masking of outcome assessors was not reported.

Cochener 2016 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors did not report any losses to follow-up, and it was unclear whether all participants were analyzed in the group to which they had been randomized.
Selective reporting (reporting bias)	Low risk	No published protocol or study registration available, however the authors reported all outcomes specified in the methods section of the study.
Other bias	Low risk	No evidence of any other sources of bias detected.

Jonker 2015

Study characteristics	
Methods	**Study design:** parallel-group randomized controlled trial **Number randomized:** not reported **Exclusions after randomization:** not reported **Losses to follow-up:** not reported **Number analyzed (total and per group):** total 56 eyes of 28 participants; FineVision trifocal: 30 eyes of 15 participants; AcrySof ReSTOR bifocal: 26 eyes of 13 participants **Unit of analysis:** eyes **How were the missing data handled?:** not reported **Power calculation:** yes, "to find a clinically significant difference between the two groups, investigators assumed a difference of 0.2 logMAR, and based on alpha of 0.05 and power of 0.8, it was determined that 12 patients were required for each group, while assuming a dropout rate of 15% on the primary outcome measure, this resulted in a total requirement of 28 patients "
Participants	**Country:** the Netherlands **Setting:** University Eye Clinic Maastricht **Age:** FineVision trifocal: mean (SD): 62.6 (8.7) years AcrySof ReSTOR bifocal: mean (SD): 64.0 (8.8) years **Sex:** not reported **Inclusion criteria:** bilateral cataract, less than 1.0 D corneal astigmatism in both eyes, age > 42 years, and an expected postoperative corrected distance visual acuity of 0.3 LogMAR or less **Exclusion criteria:** combined ocular procedures, previous ocular surgery, ocular pathology that would limit postoperative visual outcome, suturing of the incision during surgery, and complications during surgery in the first eye **Equivalence of baseline characteristics:** yes
Interventions	**Intervention 1:** FineVision Micro F trifocal IOL (PhysIOL S.A.) **Intervention 2:** AcrySof ReSTOR IQ +3.0 bifocal IOL (Alcon Surgical Inc)

Jonker 2015 *(Continued)*

	Length of follow-up: 6 months
Outcomes	**Primary outcomes, as defined:** mean best-corrected intermediate visual acuity at 6 months, LogMAR scale **Secondary outcomes:** 1. Mean uncorrected distance visual acuity at 6 months (binocular), LogMAR scale 2. Mean uncorrected near visual acuity at 6 months (binocular), LogMAR scale 3. Mean uncorrected intermediate visual acuity at 6 months (binocular), LogMAR scale 4. Mean best-corrected distance visual acuity at 6 months (binocular), LogMAR scale 5. Other visual function at 6 months, (reading speed) using Radner reading chart 6. Contrast-sensitivity: measured using contrast-sensitivity chart (CSV-1000, VectorVision)
Notes	**Institution:** University Eye Clinic Maastricht **Email:** soraya.jonker@mumc.nl **Address:** University Eye Clinic Maastricht, Maastricht University Medical Center, P. Debyelaan 25, 6202 AZ Maastricht, the Netherlands **Study period:** not reported **Funding sources:** PhysIOL S.A., Liege, Belgium **Declarations of interest:** N Bauer received study grants from Alcon Laboratories, Carl Zeiss Meditec AG, and PhysIOL S.A. (study funder and creator of 1 of the tested lenses), and a lecture fee from Alcon Surgical (creator of 1 of the tested lenses). R Nuijts is a consultant to Alcon Surgical, Thea Pharma GmbH, and ASICO, and has received study grants from Acufocus, Alcon Surgical, Carl Zeiss Meditec AG, Ophtec BV, and PhysIOL S.A. **Reported subgroup analyses:** not reported **Trial registration number:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Authors did not describe random sequence generation.
Allocation concealment (selection bias)	Unclear risk	Authors did not describe treatment allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and investigators were masked.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Masking of outcome assessors was not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors did not report any losses to follow-up, and it was unclear whether all participants were analyzed in the group to which they had been randomized.
Selective reporting (reporting bias)	Low risk	No published protocol or study registration available, however the authors reported all outcomes specified in the methods section of the study.

Jonker 2015 *(Continued)*

Other bias	Unclear risk	At least one study investigator has relationship with manufacturers of one of the intervention devices

Kaymak 2017

Study characteristics	
Methods	**Study design:** parallel-group randomized controlled trial **Number randomized:** total 104 eyes of 52 participants; AT LISA bifocal: 38 eyes of 19 participants; AT LISA trifocal: 32 eyes of 16 participants, ReSTOR: 34 eyes of 17 participants **Exclusions after randomization:** not reported **Losses to follow-up:** total 6 eyes of 3 participants; AT LISA bifocal: 4 eyes of 2 participants; AT LISA trifocal: 2 eyes of 1 participant, ReSTOR: none **Number analyzed (total and per group):** total 98 eyes of 47 participants; AT LISA bifocal: 34 eyes of 17 participants; AT LISA trifocal: 30 eyes of 15 participants, ReSTOR: 34 eyes of 17 participants **Unit of analysis:** eyes **How were the missing data handled?:** not reported **Power calculation:** not reported
Participants	**Country:** Spain, Germany, France **Setting:** Vissum Instituto (Spain), Breyer Kaymak und Klabe Augenchirurgie (Germany), Hopital Morvan (France) **Age:** AT LISA bifocal group: mean (SD): 64.4 (7.5) years AT LISA trifocal group: mean (SD): 62.5 (6.9) years ReSTOR group: mean (SD): 62.4 (8.9) years **Sex** AT LISA bifocal group: n (%): 11 females (57.9%) AT LISA trifocal group: n (%): 12 females (75.0%) ReSTOR group: n (%): 8 females (47.1%) **Inclusion criteria:** patients with cataract who seek spectacle independence, aged 50 to 80 years, pre-existing refractive corneal astigmatism of less than 1.00 D **Exclusion criteria:** degenerative visual disorders that permanently limit the corrected distance visual acuity to 0.3 LogMAR (Snellen 20/40) or worse, glaucoma and/or intraocular pressure greater than 24 mmHg, intraoperative complications, and any other at-risk pathology **Equivalence of baseline characteristics:** yes
Interventions	**Intervention 1:** AT LISA 809M bifocal IOL (Carl Zeiss Meditec) **Intervention 2:** AT LISA tri 839MP trifocal IOL (Carl Zeiss Meditec) **Intervention 3:** ReSTOR SN6AD1 bifocal IOL (Alcon Laboratories Inc)

Kaymak 2017 *(Continued)*

	Length of follow-up: 1 year
Outcomes	**Primary outcomes, as defined:** not reported **Secondary outcomes:** 1. Mean uncorrected distance visual acuity at 3 months, 6 months, and 1 year (binocular), LogMAR scale 2. Mean uncorrected near visual acuity at 3 months, 6 months, and 1 year (binocular), LogMAR scale 3. Mean uncorrected intermediate visual acuity at 3 months, 6 months, and 1 year (binocular), LogMAR scale 4. Mean best-corrected distance visual acuity at 3 months, 6 months, and 1 year (binocular), LogMAR scale 5. Other visual function at 3 months and 1 year assessed as reading performance with the Radner Reading Charts at 40 cm
Notes	**Institution:** Breyer Kaymak und Klabe Augenchirurgie **Email:** h.kaymak@augenchirurgie.clinic **Address:** Berliner Allee 15, 40212 Dusseldorf, Germany **Study period:** not reported **Funding sources:** Carl Zeiss Meditec AG, Berlin, Germany **Declarations of interest:** authors state no proprietary or financial interest in study; however, the funder is the maker of AT LISA IOLs (Intervention 1 and Intervention 2) **Reported subgroup analyses:** none reported **Trial registration number:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomization code was administered centrally using a vocal server.
Allocation concealment (selection bias)	Low risk	"The randomization code was administered centrally using a vocal server and allocated to the patient in the chronological order of the surgery"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	All participants were unaware of the implanted lens type, but the authors do not report whether investigators were masked.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	An independent observer performed the postoperative measurements in each center.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Authors excluded 6 eyes of 3 (9%) of participants from the final analysis because the participants withdrew from study after surgery. We considered that excluding less than 10% of participants from the analysis may not introduce significant bias.
Selective reporting (reporting bias)	Low risk	No published protocol or study registration available, however the authors reported all outcomes specified in the methods section of the study.
Other bias	Unclear risk	At least one study investigator has relationship with manufacturers of one of the intervention devices

Mojzis 2014

Study characteristics	
Methods	**Study design:** parallel-group randomized controlled trial **Number randomized:** total 60 eyes of 30 participants; AT LISA bifocal: 30 eyes of 15 participants; AT LISA trifocal: 30 eyes of 15 participants **Exclusions after randomization:** not reported **Losses to follow-up:** none **Number analyzed (total and per group):** total 60 eyes of 30 participants; AT LISA bifocal: 30 eyes of 15 participants; AT LISA trifocal: 30 eyes of 15 participants **Unit of analysis:** eyes **How were the missing data handled?:** not reported **Power calculation:** not reported
Participants	**Country:** Czech Republic **Setting:** not reported **Age:** mean: 58.7 years AT LISA bifocal group: mean (SD): 62.3 (5.7) years AT LISA trifocal group: mean (SD): 55.2 (7.0) years **Sex:** not reported **Inclusion criteria:** patients with cataract or presbyopia/pre-presbyopia suitable for refractive lens exchange seeking spectacle independence **Exclusion criteria:** patients with a history of glaucoma or retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neuro-ophthalmic disease, ocular inflammation, or previous ocular surgery **Equivalence of baseline characteristics:** IOL power was significantly higher and participants were significantly younger in the trifocal group
Interventions	**Intervention 1:** AT LISA 809M bifocal IOL (Carl Zeiss Meditec) **Intervention 2:** AT LISA tri 839MP trifocal IOL (Carl Zeiss Meditec) **Length of follow-up:** 3 months
Outcomes	**Primary outcomes, as defined:** not reported **Secondary outcomes:** 1. Mean uncorrected distance visual acuity at 3 months (monocular), LogMAR scale 2. Mean uncorrected near visual acuity at 3 months (monocular), LogMAR scale 3. Mean uncorrected intermediate visual acuity at 3 months (monocular), LogMAR scale 4. Mean best-corrected distance visual acuity at 3 months (monocular), LogMAR scale 5. Contrast sensitivity at 3 months, measured using contrast-sensitivity chart (CSV-1000, VectorVision)
Notes	**Institution:** University of Alicante **Email:** david.pinyero@ua.es

Mojzis 2014 *(Continued)*

Address: University of Alicante, Crta San Vicente del Raspeig s/n 03016, San Vicente del Raspeig, Alicante 03690, Spain

Study period: not reported

Funding sources: not reported
Declarations of interest: authors state no financial or proprietary interest in study

Reported subgroup analyses: not reported

Trial registration number: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Authors did not describe random sequence generation.
Allocation concealment (selection bias)	Unclear risk	Authors did not describe treatment allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Authors did not report masking of participants and study personnel.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Authors did not reporting masking of outcome assessors.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors did not report any losses to follow-up, and it was unclear whether all participants were analyzed in the group to which they had been randomized.
Selective reporting (reporting bias)	Low risk	No published protocol or study registration available, however the authors reported all outcomes specified in the methods section of the study.
Other bias	Low risk	No evidence of any other sources of bias detected.

Mojzis 2017

Study characteristics

Methods

Study design: parallel-group randomized controlled trial

Setting: not reported

Number randomized: total 75 eyes of 38 participants; AT LISA bifocal: 35 eyes of 15 participants; AT LISA trifocal: 40 eyes of 20 participants

Exclusions after randomization: none

Losses to follow-up: not reported

Number analyzed (total and per group): total 75 eyes of 38 participants; AT LISA bifocal: 35 eyes of 15 participants; AT LISA trifocal: 40 eyes of 20 participants

Unit of analysis: eyes

Mojzis 2017 *(Continued)*

	How were the missing data handled?: not reported **Power calculation:** not reported
Participants	**Country:** Czech Republic **Age:** 44-70 years **Sex:** not reported **Inclusion criteria:** visually significant cataract, presbyopic/pre-presbyopic patients demanding refractive, and corneal astigmatism below 1.25 D **Exclusion criteria:** previous ocular surgery, antecedents of glaucoma, ocular inflammation or retinal detachment, active ocular disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, and neurophthalmic disease **Equivalence of baseline characteristics:** unclear
Interventions	**Intervention 1:** AT LISA 809M bifocal IOL (Carl Zeiss Meditec) **Intervention 2:** AT LISA tri 839MP trifocal IOL (Carl Zeiss Meditec) **Length of follow-up:** 1 year
Outcomes	**Primary outcomes, as defined:** not reported **Secondary outcomes:** 1. Mean uncorrected distance visual acuity at 6 months and 1 year (monocular), LogMAR scale 2. Mean uncorrected near visual acuity at 6 months and 1 year (monocular), LogMAR scale 3. Mean uncorrected intermediate visual acuity at 6 months and 1 year (monocular),LogMAR scale 4. Mean best-corrected distance visual acuity at 6 months and 1 year (monocular), LogMAR scale 5. Contrast sensitivity at 6 months and 1 year (monocular), measured using contrast-sensitivity chart (CSV-1000, VectorVision)
Notes	**Institution:** University of Alicante **Email:** david.pinyero@ua.es **Address:** University of Alicante, Crta San Vicente del Raspeig s/n 03016, San Vicente del Raspeig, Alicante 03690, Spain **Study period:** not reported **Funding sources:** not reported **Declarations of interest:** authors report no conflicts of interest **Reported subgroup analyses:** not reported **Trial registration number:** not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Authors did not describe random sequence generation.
Allocation concealment (selection bias)	Unclear risk	Authors did not describe treatment allocation concealment.

Mojzis 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Masking of participants or study investigators was not described.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors did not report any losses to follow-up, and it was unclear whether all participants were analyzed in the group to which they had been randomized.
Selective reporting (reporting bias)	Low risk	No published protocol or study registration available, however the authors reported all outcomes specified in the methods section of the study.
Other bias	Low risk	No evidence of any other sources of bias detected.

D: diopter
IOL: intraocular lens
LogMAR: logarithm of the minimum angle of resolution
SD: standard deviation
VF-14: Visual Function Index

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

Study	Reason for exclusion
ACTRN12607000601437	Not the interventions of interest
Aose 2006	Not the interventions of interest
Bilbao-Calabuig 2016	Not the interventions of interest
ISRCTN64155646	Not the interventions of interest
Kim 2019	Not a randomized controlled trial
Lesueur 2000	Not the interventions of interest
Leyland 2000	Not the interventions of interest
Leyland 2002	Not the interventions of interest
Liu 2018	Not a randomized controlled trial
Maurino 2015	Not the interventions of interest
NCT03117426	Not the interventions of interest
NTR3556	Not a randomized clinical trial
Paul 2016	Not the interventions of interest
Postolache 2015	Not a randomized clinical trial

Study	Reason for exclusion
Qu 2018	Not the interventions of interest
Richter-Mueksch 2002	Not the interventions of interest
Ruiz-Mesa 2017	Not the interventions of interest
Schmidinger 2006	Not the interventions of interest
Skiadaresi 2015	Not a randomized controlled trial
Szweda 1999	Not a randomized controlled trial
Yu 2016	Not a randomized controlled trial
Zamora-de-la-Cruz 2018	Not a randomized controlled trial

Characteristics of studies awaiting classification *[ordered by study ID]*

de Carneros-Llorente 2019

Methods	Randomized parallel-group design
Participants	**Inclusion criteria:** 160 patients with bilateral phacoemulsification and implantation of 1 of the 4 IOLs **Exclusion criteria:** Patients with history of glaucoma or retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration or retinopathy, neuro-ophthalmic disease, ocular inflammation, previous ocular surgery, axial length of 22.0 mm or less or more than 26.0 mm, and corneal astigmatism more than 1.00 D
Interventions	**Intervention 1:** FineVision IOL **Intervention 2:** TecnisZMB00 bifocal IOL (Abbott Medical Optics, Santa Ana, CA) **Intervention 3:** AcrySof IQ PanOptix, AT LISA tri 839MP, FineVision, and Tecnis ZLB00 **Intervention 4:** AT LISA tri 839MP IOL **Length of follow-up:** 6 months
Outcomes	**Primary outcome:** UDVA, CDVA (LogMAR scale), DCNVA using Early Treatment Diabetic Retinopathy Study charts under photopic conditions (85 cd/m^2); the CSF (CSV-1000 test) under photopic conditions (85 cd/m^2) and mesopic conditions (3 cd/m^2); reading acuity and reading performance (Radner-Vissum test10); and through-focus LogMAR visual acuity at 100%, 50%, and 12% contrast **Secondary outcome:** not reported **Maximum follow-up**: 1 year
Notes	**Start date:** October 2016 **Estimated end date:** September 2017

CDVA: corrected distance visual acuity
CSF: contrast sensitivity function
D: diopter

DCNVA: distance corrected near visual acuity
IOL: intraocular lens
LogMAR: logarithm of the minimum angle of resolution
UDVA: uncorrected distance visual acuity

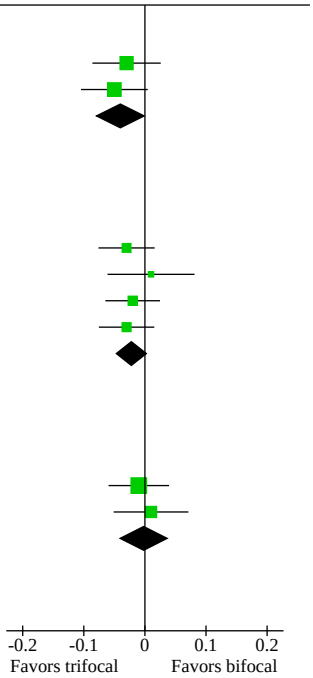
DATA AND ANALYSES

Comparison 1. Trifocal versus bifocal intraocular lenses after cataract extraction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Mean uncorrected distance visual acuity (LogMAR)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1.1 3 months	2	92	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.08, -0.00]
1.1.2 6 months	4	217	Mean Difference (IV, Random, 95% CI)	-0.02 [-0.05, 0.00]
1.1.3 12 months	2	107	Mean Difference (IV, Random, 95% CI)	-0.00 [-0.04, 0.04]
1.2 Mean uncorrected near visual acuity (LogMAR)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.2.1 3 months	2	92	Mean Difference (IV, Random, 95% CI)	-0.08 [-0.20, 0.03]
1.2.2 6 months	4	217	Mean Difference (IV, Random, 95% CI)	-0.02 [-0.06, 0.02]
1.2.3 12 months	2	107	Mean Difference (IV, Random, 95% CI)	0.01 [-0.04, 0.06]
1.3 Mean uncorrected intermediate visual acuity (LogMAR)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.3.1 3 months	2	92	Mean Difference (IV, Random, 95% CI)	-0.19 [-0.29, -0.09]
1.3.2 6 months	4	216	Mean Difference (IV, Random, 95% CI)	-0.07 [-0.16, 0.02]
1.3.3 12 months	2	107	Mean Difference (IV, Random, 95% CI)	-0.16 [-0.22, -0.10]
1.4 Mean best-corrected distance acuity (LogMAR)	5		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.4.1 3 months	2	92	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.06, 0.01]
1.4.2 6 months	4	216	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.03, 0.01]
1.4.3 12 months	2	107	Mean Difference (IV, Random, 95% CI)	0.00 [-0.03, 0.04]
1.5 Mean contrast sensitivity	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.5.1 Mesopic: 6 months	1	25	Mean Difference (IV, Random, 95% CI)	-0.19 [-0.33, -0.05]

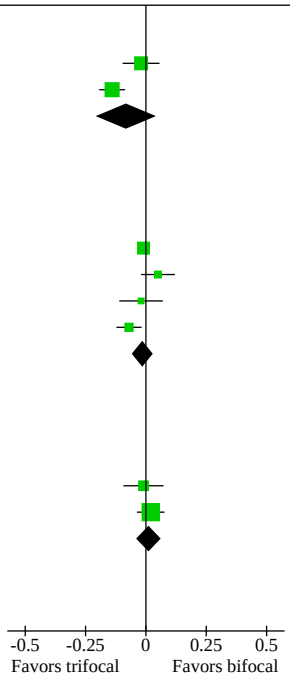
Analysis 1.1. Comparison 1: Trifocal versus bifocal intraocular lenses after cataract extraction, Outcome 1: Mean uncorrected distance visual acuity (LogMAR)

Study or Subgroup	Trifocal Mean	Trifocal SD	Trifocal Total	Bifocal Mean	Bifocal SD	Bifocal Total	Weight	Mean Difference IV, Random, 95% CI
1.1.1 3 months								
Kaymak 2017	-0.04	0.1	15	-0.01	0.05	17	48.8%	-0.03 [-0.09 , 0.03]
Mojzis 2014	-0.05	0.08	30	0	0.13	30	51.2%	-0.05 [-0.10 , 0.00]
Subtotal (95% CI)			**45**			**47**	**100.0%**	**-0.04 [-0.08 , -0.00]**
Heterogeneity: Tau² = 0.00; Chi² = 0.25, df = 1 (P = 0.62); I² = 0%								
Test for overall effect: Z = 2.02 (P = 0.04)								
1.1.2 6 months								
Cochener 2016	0.08	0.08	30	0.11	0.09	24	28.5%	-0.03 [-0.08 , 0.02]
Jonker 2015	0.09	0.16	30	0.08	0.11	26	11.9%	0.01 [-0.06 , 0.08]
Kaymak 2017	-0.03	0.08	15	-0.01	0.04	17	30.2%	-0.02 [-0.06 , 0.02]
Mojzis 2017	-0.03	0.1	40	0	0.1	35	29.3%	-0.03 [-0.08 , 0.02]
Subtotal (95% CI)			**115**			**102**	**100.0%**	**-0.02 [-0.05 , 0.00]**
Heterogeneity: Tau² = 0.00; Chi² = 1.02, df = 3 (P = 0.80); I² = 0%								
Test for overall effect: Z = 1.77 (P = 0.08)								
1.1.3 12 months								
Kaymak 2017	-0.02	0.08	15	-0.01	0.06	17	60.4%	-0.01 [-0.06 , 0.04]
Mojzis 2017	0.02	0.14	40	0.01	0.13	35	39.6%	0.01 [-0.05 , 0.07]
Subtotal (95% CI)			**55**			**52**	**100.0%**	**-0.00 [-0.04 , 0.04]**
Heterogeneity: Tau² = 0.00; Chi² = 0.25, df = 1 (P = 0.62); I² = 0%								
Test for overall effect: Z = 0.11 (P = 0.92)								



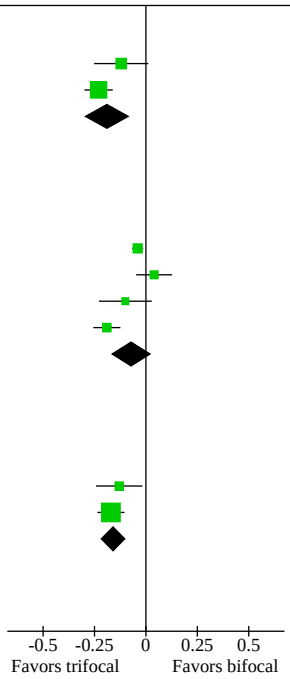
Analysis 1.2. Comparison 1: Trifocal versus bifocal intraocular lenses after cataract extraction, Outcome 2: Mean uncorrected near visual acuity (LogMAR)

Study or Subgroup	Trifocal Mean	Trifocal SD	Trifocal Total	Bifocal Mean	Bifocal SD	Bifocal Total	Weight	Mean Difference IV, Random, 95% CI
1.2.1 3 months								
Kaymak 2017	0.12	0.11	15	0.14	0.11	17	47.3%	-0.02 [-0.10 , 0.06]
Mojzis 2014	0.07	0.09	30	0.21	0.12	30	52.7%	-0.14 [-0.19 , -0.09]
Subtotal (95% CI)			**45**			**47**	**100.0%**	**-0.08 [-0.20 , 0.03]**
Heterogeneity: Tau² = 0.01; Chi² = 6.35, df = 1 (P = 0.01); I² = 84%								
Test for overall effect: Z = 1.39 (P = 0.16)								
1.2.2 6 months								
Cochener 2016	0.01	0.01	30	0.02	0.02	24	42.7%	-0.01 [-0.02 , -0.00]
Jonker 2015	0.25	0.17	30	0.2	0.09	26	18.7%	0.05 [-0.02 , 0.12]
Kaymak 2017	0.11	0.13	15	0.13	0.13	17	13.5%	-0.02 [-0.11 , 0.07]
Mojzis 2017	0.15	0.13	40	0.22	0.1	35	25.0%	-0.07 [-0.12 , -0.02]
Subtotal (95% CI)			**115**			**102**	**100.0%**	**-0.02 [-0.06 , 0.02]**
Heterogeneity: Tau² = 0.00; Chi² = 7.92, df = 3 (P = 0.05); I² = 62%								
Test for overall effect: Z = 0.74 (P = 0.46)								
1.2.3 12 months								
Kaymak 2017	0.12	0.12	15	0.13	0.12	17	31.9%	-0.01 [-0.09 , 0.07]
Mojzis 2017	0.21	0.15	40	0.19	0.1	35	68.1%	0.02 [-0.04 , 0.08]
Subtotal (95% CI)			**55**			**52**	**100.0%**	**0.01 [-0.04 , 0.06]**
Heterogeneity: Tau² = 0.00; Chi² = 0.34, df = 1 (P = 0.56); I² = 0%								
Test for overall effect: Z = 0.43 (P = 0.66)								
Test for subgroup differences: Chi² = 2.28, df = 2 (P = 0.32), I² = 12.2%								



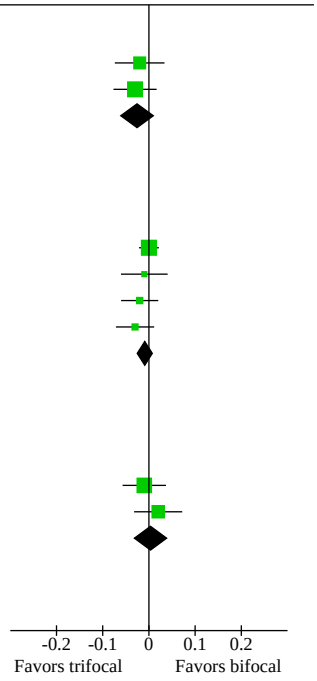
Analysis 1.3. Comparison 1: Trifocal versus bifocal intraocular lenses after cataract extraction, Outcome 3: Mean uncorrected intermediate visual acuity (LogMAR)

Study or Subgroup	Trifocal Mean	Trifocal SD	Trifocal Total	Bifocal Mean	Bifocal SD	Bifocal Total	Weight	Mean Difference IV, Random, 95% CI
1.3.1 3 months								
Kaymak 2017	0.1	0.17	15	0.22	0.21	17	36.5%	-0.12 [-0.25 , 0.01]
Mojzis 2014	0.06	0.07	30	0.29	0.18	30	63.5%	-0.23 [-0.30 , -0.16]
Subtotal (95% CI)			**45**			**47**	**100.0%**	**-0.19 [-0.29 , -0.09]**
Heterogeneity: Tau² = 0.00; Chi² = 2.10, df = 1 (P = 0.15); I² = 52%								
Test for overall effect: Z = 3.59 (P = 0.0003)								
1.3.2 6 months								
Cochener 2016	0.07	0.05	30	0.11	0.05	24	30.0%	-0.04 [-0.07 , -0.01]
Jonker 2015	0.45	0.18	29	0.41	0.15	26	24.1%	0.04 [-0.05 , 0.13]
Kaymak 2017	0.14	0.16	15	0.24	0.21	17	19.2%	-0.10 [-0.23 , 0.03]
Mojzis 2017	0.08	0.09	40	0.27	0.18	35	26.6%	-0.19 [-0.26 , -0.12]
Subtotal (95% CI)			**114**			**102**	**100.0%**	**-0.07 [-0.16 , 0.02]**
Heterogeneity: Tau² = 0.01; Chi² = 22.38, df = 3 (P < 0.0001); I² = 87%								
Test for overall effect: Z = 1.54 (P = 0.12)								
1.3.3 12 months								
Kaymak 2017	0.12	0.12	15	0.25	0.2	17	25.4%	-0.13 [-0.24 , -0.02]
Mojzis 2017	0.09	0.11	40	0.26	0.17	35	74.6%	-0.17 [-0.24 , -0.10]
Subtotal (95% CI)			**55**			**52**	**100.0%**	**-0.16 [-0.22 , -0.10]**
Heterogeneity: Tau² = 0.00; Chi² = 0.36, df = 1 (P = 0.55); I² = 0%								
Test for overall effect: Z = 5.51 (P < 0.00001)								
Test for subgroup differences: Chi² = 3.39, df = 2 (P = 0.18), I² = 41.0%								



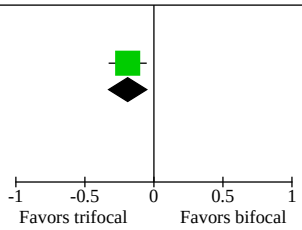
Analysis 1.4. Comparison 1: Trifocal versus bifocal intraocular lenses after cataract extraction, Outcome 4: Mean best-corrected distance acuity (LogMAR)

Study or Subgroup	Trifocal Mean	Trifocal SD	Trifocal Total	Bifocal Mean	Bifocal SD	Bifocal Total	Weight	Mean Difference IV, Random, 95% CI
1.4.1 3 months								
Kaymak 2017	-0.06	0.09	15	-0.04	0.06	17	43.0%	-0.02 [-0.07 , 0.03]
Mojzis 2014	-0.06	0.07	30	-0.03	0.11	30	57.0%	-0.03 [-0.08 , 0.02]
Subtotal (95% CI)			**45**			**47**	**100.0%**	**-0.03 [-0.06 , 0.01]**
Heterogeneity: Tau² = 0.00; Chi² = 0.08, df = 1 (P = 0.78); I² = 0%								
Test for overall effect: Z = 1.43 (P = 0.15)								
1.4.2 6 months								
Cochener 2016	0.03	0.04	30	0.03	0.04	24	57.6%	0.00 [-0.02 , 0.02]
Jonker 2015	0.01	0.11	29	0.02	0.08	26	10.4%	-0.01 [-0.06 , 0.04]
Kaymak 2017	-0.04	0.07	15	-0.02	0.04	17	16.4%	-0.02 [-0.06 , 0.02]
Mojzis 2017	-0.05	0.08	40	-0.02	0.1	35	15.5%	-0.03 [-0.07 , 0.01]
Subtotal (95% CI)			**114**			**102**	**100.0%**	**-0.01 [-0.03 , 0.01]**
Heterogeneity: Tau² = 0.00; Chi² = 1.95, df = 3 (P = 0.58); I² = 0%								
Test for overall effect: Z = 1.08 (P = 0.28)								
1.4.3 12 months								
Kaymak 2017	-0.04	0.08	15	-0.03	0.05	17	55.2%	-0.01 [-0.06 , 0.04]
Mojzis 2017	0.01	0.12	40	-0.01	0.11	35	44.8%	0.02 [-0.03 , 0.07]
Subtotal (95% CI)			**55**			**52**	**100.0%**	**0.00 [-0.03 , 0.04]**
Heterogeneity: Tau² = 0.00; Chi² = 0.70, df = 1 (P = 0.40); I² = 0%								
Test for overall effect: Z = 0.19 (P = 0.85)								



Analysis 1.5. Comparison 1: Trifocal versus bifocal intraocular lenses after cataract extraction, Outcome 5: Mean contrast sensitivity

Study or Subgroup	Trifocal Mean	Trifocal SD	Trifocal Total	Bifocal Mean	Bifocal SD	Bifocal Total	Weight	Mean Difference IV, Random, 95% CI
1.5.1 Mesopic: 6 months								
Jonker 2015	1.65	0.2	13	1.84	0.15	12	100.0%	-0.19 [-0.33 , -0.05]
Subtotal (95% CI)			**13**			**12**	**100.0%**	**-0.19 [-0.33 , -0.05]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.70 (P = 0.007)								



APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Cataract] explode all trees
#2 MeSH descriptor: [Cataract Extraction] explode all trees
#3 MeSH descriptor: [Pseudophakia] explode all trees
#4 pha?oemulsif* or (pha?o next/1 emulsif*) or Capsulorhexis or Capsulorrhexis
#5 phakectom* or lensectom*
#6 Pseudophak*
#7 (extract* or aspirat* or operat* or remov* or surg* or excis* or implant*) near/4 (cataract*)
#8 (extract* or aspirat* or operat* or remov* or surg* or excis*) near/4 (lens*)

#9 {or #1-#8}
#10 MeSH descriptor: [Lens Implantation, Intraocular] explode all trees
#11 MeSH descriptor: [Lenses, Intraocular] explode all trees
#12 MeSH descriptor: [Pseudophakia] explode all trees
#13 Pseudophak*
#14 (artificial* or implant* or acrylic) near/4 (lens*)
#15 artificial near/2 device*
#16 (intra*ocular or intra ocular) near/3 lens*
#17 (phakic near/3 lens*)
#18 IOL*
#19 {or #10-#18}
#20 multifocal* or (multi next/1 focal*) or bifocal* or (bi next/1 focal*)
#21 trifocal* or (tri next/1 focal*)
#22 diffractive* or refractive*
#23 toric* or finevision or "AT LISA tri 839MP" or "AT.LISA tri 839 MP" or "MIOL-Record" or MFIOL or "AcrySof IQ PanOptix"
#24 {or #20-#23}
#25 #9 and #19 and #24

Appendix 2. MEDLINE Ovid search strategy

1. Randomized Controlled Trial.pt.
2. Controlled Clinical Trial.pt.
3. (randomized or randomised).ab,ti.
4. placebo.ab,ti.
5. drug therapy.fs.
6. randomly.ab,ti.
7. trial.ab,ti.
8. groups.ab,ti.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. exp animals/ not humans.sh.
11. 9 not 10
12. exp Cataract Extraction/
13. exp Cataract/
14. exp Pseudophakia/
15. (pha?oemulsif* or (pha?o adj1 emulsif*) or Capsulorhexis or Capsulorrhexis).tw.
16. (phakectom* or lensectom*).tw.
17. Pseudophak*.tw.
18. ((extract* or aspirat* or operat* or remov* or surg* or excis* or implant*) adj4 cataract*).tw.
19. ((extract* or aspirat* or operat* or remov* or surg* or excis*) adj4 lens*).tw.
20. or/12-19
21. exp Lens Implantation, Intraocular/
22. Lenses, Intraocular/
23. exp Pseudophakia/
24. Pseudophak*.tw.
25. ((artificial* or implant* or acrylic) adj4 lens*).tw.
26. (artificial adj2 device*).tw.
27. ((intra*ocular or "intra ocular") adj3 lens*).tw.
28. (phakic adj3 lens*).tw.
29. IOL*.tw.
30. or/21-29
31. (multifocal* or (multi adj1 focal*) or bifocal* or (bi adj1 focal*)).tw.
32. (trifocal* or (tri adj1 focal*)).tw.
33. (diffractive* or refractive*).tw.
34. (toric* or finevision or "AT LISA tri 839MP" or "AT.LISA tri 839 MP" or "MIOL-Record" or MFIOL or "AcrySof IQ PanOptix").tw.
35. or/31-34
36. 20 and 30 and 35
37. 11 and 36

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville 2006.

Appendix 3. Embase.com search strategy

#1 'randomized controlled trial'/exp

#2 'randomization'/exp
#3 'double blind procedure'/exp
#4 'single blind procedure'/exp
#5 random*:ab,ti
#6 #1 OR #2 OR #3 OR #4 OR #5
#7 'animal'/exp OR 'animal experiment'/exp
#8 'human'/exp
#9 #7 AND #8
#10 #7 NOT #9
#11 #6 NOT #10
#12 'clinical trial'/exp
#13 (clin* NEAR/3 trial*):ab,ti
#14 ((singl* OR doubl* OR trebl* OR tripl*) NEAR/3 (blind* OR mask*)):ab,ti
#15 'placebo'/exp
#16 placebo*:ab,ti
#17 random*:ab,ti
#18 'experimental design'/exp
#19 'crossover procedure'/exp
#20 'control group'/exp
#21 'latin square design'/exp
#22 #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
#23 #22 NOT #10
#24 #23 NOT #11
#25 'comparative study'/exp
#26 'evaluation'/exp
#27 'prospective study'/exp
#28 control*:ab,ti OR prospectiv*:ab,ti OR volunteer*:ab,ti
#29 #25 OR #26 OR #27 OR #28
#30 #29 NOT #10
#31 #30 NOT (#11 OR #23)
#32 #11 OR #24 OR #31
#33 'cataract'/exp
#34 'cataract extraction'/exp
#35 'pseudophakia'/exp
#36 pha*oemulsif*:ab,ti OR (pha*o NEXT/1 emulsif*):ab,ti OR capsulorhexis:ab,ti OR capsulorrhexis:ab,ti
#37 phakectom*:ab,ti OR lensectom*:ab,ti
#38 pseudophak*:ab,ti
#39 ((extract* OR aspirat* OR operat* OR remov* OR surg* OR excis* OR implant*) NEAR/4 cataract*):ab,ti
#40 ((extract* OR aspirat* OR operat* OR remov* OR surg* OR excis*) NEAR/4 lens*):ab,ti
#41 #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40
#42 'lens implantation'/exp
#43 'lens implant'/exp
#44 'pseudophakia'/exp
#45 pseudophak*:ab,ti
#46 ((artificial* OR implant* OR acrylic) NEAR/4 lens*):ab,ti
#47 (artificial NEAR/2 device*):ab,ti
#48 ((intra*ocular OR 'intra ocular') NEAR/3 lens*):ab,ti
#49 (phakic NEAR/3 lens*):ab,ti
#50 iol*:ab,ti
#51 #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50
#52 multifocal*:ab,ti OR (multi NEXT/1 focal*):ab,ti OR bifocal*:ab,ti OR (bi NEXT/1 focal*):ab,ti
#53 trifocal*:ab,ti OR (tri NEXT/1 focal*):ab,ti
#54 diffractive*:ab,ti OR refractive*:ab,ti
#55 toric*:ab,ti OR finevision:ab,ti OR 'at lisa tri 839mp':ab,ti OR 'at.lisa tri 839 mp':ab,ti OR 'miol-record':ab,ti OR mfiol:ab,ti OR 'acrysof iq panoptix':ab,ti
#56 #52 OR #53 OR #54 OR #55
#57 #41 AND #51 AND #56
#58 #32 AND #57

Appendix 4. PubMed search strategy

#1 ((randomized controlled trial[pt]) OR (controlled clinical trial[pt]) OR (randomised[tiab] OR randomized[tiab]) OR (placebo[tiab]) OR (drug therapy[sh]) OR (randomly[tiab]) OR (trial[tiab]) OR (groups[tiab])) NOT (animals[mh] NOT humans[mh])
#2 phacoemulsif*[tw] OR phakoemulsif*[tw] OR phaco emulsif*[tw] OR phako emulsif*[tw] OR Capsulorhexis[tw] OR Capsulorrhexis[tw]
#3 phakectom*[tw] OR lensectom*[tw]
#4 Pseudophak*[tw]
#5 (extract*[tw] OR aspirat*[tw] OR operat*[tw] OR remov*[tw] OR surg*[tw] OR excis*[tw] OR implant*[tw]) AND (cataract*[tw])
#6 (extract*[tw] OR aspirat*[tw] OR operat*[tw] OR remov*[tw] OR surg*[tw] OR excis*[tw]) AND (lens*[tw])
#7 #2 OR #3 OR #4 OR #5 OR #6
#8 Pseudophak*[tw]
#9 (artificial*[tw] OR implant*[tw] OR acrylic[tw]) AND (lens*[tw])
#10 artificial[tw] AND device*[tw]
#11 (intraocular[tw] or intra ocular[tw]) AND lens*[tw]
#12 (phakic[tw] AND lens*[tw])
#13 IOL*[tw]
#14 #8 OR #9 OR #10 OR #11 OR #12 OR #13
#15 multifocal*[tw] OR multi focal*[tw] OR bifocal*[tw] OR bi focal*[tw]
#16 trifocal*[tw] OR tri focal*[tw]
#17 diffractive*[tw] OR refractive*[tw]
#18 toric*[tw] OR finevision[tw] OR "AT LISA tri 839MP"[tw] OR "AT.LISA tri 839 MP"[tw] OR "MIOL-Record"[tw] OR MFIOL[tw] OR "AcrySof IQ PanOptix"[tw]
#19 #15 OR #16 OR #17 OR #18
#20 #7 AND #14 AND #19
#21 #1 AND #20
#22 Medline[sb]
#23 #21 NOT #22

Appendix 5. LILACS search strategy

(MH:C11.510.245$ OR MH:E04.540.825.249$ OR MH:C23.888.681$ OR phaco$ OR phako$ OR Capsulorhexis or Capsulorrhexis OR phakectom$ OR lensectom$ OR Pseudophak$ OR cataract$) AND (MH:E04.540.825.600$ OR MH:E07.632.500.460$ OR MH:E07.695.460$ OR MH:VS2.006.001.009.003$ OR MH:C23.888.681$ OR Pseudophak$ OR IOL$ OR ((artificial$ OR implant$ OR acrylic OR intraocular OR "intra ocular" OR phakic) AND lens$) OR "artificial device" OR "artificial devices") AND (multifocal$ OR "multi focal" OR "multi focals" OR bifocal $ OR "bi focal" OR "bi focals" OR trifocal$ OR "tri focal" OR "tri focals" OR diffractive$ OR refractive$ OR toric$ OR finevision OR "AT LISA tri 839MP" OR "AT.LISA tri 839 MP" OR "MIOL-Record" OR MFIOL OR "AcrySof IQ PanOptix")

Appendix 6. ClinicalTrials.gov search strategy

(cataract OR phacoemulsification OR pseudophakia) AND (trifocal OR bifocal OR multifocal OR diffractive OR refractive OR toric OR finevision OR "AT LISA tri 839MP" OR "AT.LISA tri 839 MP" OR "MIOL-Record" OR MFIOL OR "AcrySof IQ PanOptix")

Appendix 7. WHO ICTRP search strategy

Cataract AND trifocal OR cataract AND bifocal OR cataract AND multifocal OR cataract AND diffractive OR cataract AND refractive OR phacoemulsification AND trifocal OR phacoemulsification AND bifocal OR phacoemulsification AND multifocal OR phacoemulsification AND diffractive OR phacoemulsification AND refractive OR pseudophakia AND trifocal OR pseudophakia AND bifocal OR pseudophakia AND multifocal OR pseudophakia AND diffractive OR pseudophakia AND refractive OR Cataract AND toric OR cataract AND finevision OR cataract AND "AT LISA tri 839MP" OR cataract AND "AT.LISA tri 839 MP" OR cataract AND "MIOL-Record" OR cataract AND MFIOL OR cataract AND "AcrySof IQ PanOptix" OR phacoemulsification AND toric OR phacoemulsification AND finevision OR phacoemulsification AND "AT LISA tri 839MP" OR phacoemulsification AND "AT.LISA tri 839 MP" OR phacoemulsification AND "MIOL-Record" OR phacoemulsification AND MFIOL OR phacoemulsification AND "AcrySof IQ PanOptix" OR pseudophakia AND toric OR pseudophakia AND finevision OR pseudophakia AND "AT LISA tri 839MP" OR pseudophakia AND "AT.LISA tri 839 MP" OR pseudophakia AND "MIOL-Record" OR pseudophakia AND MFIOL OR pseudophakia AND "AcrySof IQ PanOptix"

HISTORY

Protocol first published: Issue 5, 2017
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CONTRIBUTIONS OF AUTHORS

Diego Zamora-de la Cruz: developed the protocol, final approval of manuscript.
Karla Zúñiga-Posselt: critical review of the clinical sections, final approval of manuscript.

John Bartlett: critical review of the clinical sections, final approval of manuscript.
Mario Gutierrez: critical review of the clinical sections, final approval of manuscript.
Samuel A Abariga: critical review of the methodology and clinical sections, final approval of manuscript.

DECLARATIONS OF INTEREST

Diego Zamora-de la Cruz: none known.
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  The views expressed in this publication are those of the authors and not necessarily those of the NIHR, NHS, or the Department of Health.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We decided post hoc to include results from studies that used a paired-eye design without accounting for correlation in their analysis, and had planned to perform a sensitivity analysis to assess the impact of restricting our analysis to only studies that analyzed data at the participant level on the effect estimates when data was available.

NOTES

None

INDEX TERMS

Medical Subject Headings (MeSH)

Capsule Opacification [etiology]; *Cataract Extraction; Confidence Intervals; Contrast Sensitivity; Lens Implantation, Intraocular [adverse effects] [methods]; *Multifocal Intraocular Lenses [adverse effects]; Postoperative Complications [etiology]; Presbyopia [*rehabilitation]; Time Factors; *Visual Acuity

MeSH check words

Female; Humans; Male; Middle Aged