
Comparative Effectiveness of Multifocal, Accommodative, and Monofocal Intraocular Lenses for Cataract Surgery and Lens Replacement

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of four ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the [program website](#).

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

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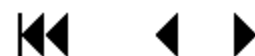


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EVIDENCE REPORT

INTRODUCTION

Cataract is an eye condition in which the natural crystalline lens becomes cloudy and can ultimately lead to poor vision. Usually associated with aging, cataract affects more than 24.4 million Americans age 40 and older.¹ It is estimated that half of all Americans over 75 have cataract or have had cataract surgery. Surgical removal of cataract and implantation of a prosthetic lens can lead to improved vision and is one of the most common surgeries performed in the United States. In the past decade, the rate of cataract surgery has risen 20%.

Cataract surgery typically involves placement of a monofocal intraocular lens implant, which has a single focal point and is meant to correct vision at a single distance. For most patients, monofocal lens implants are used to correct far distance vision. However, this results in an inability to focus at near distance without the use of spectacle correction (*ie*, when reading a book or newspaper). More advanced intraocular lens implants involve optics that provide the ability for a patient to focus at distance and near without the use of spectacles correction.

The most commonly used type of advanced intraocular lens implants in the United States is the multifocal lens, which utilizes concentric rings with graduated power to produce multiple focal points at far and near distances. The 2 main types include refractive and diffractive optics, the latter of which is more commonly used. Another advanced design is the accommodative lens, which uses the muscle tone of the ciliary body to move the lens optic either forward or backward within the eye to achieve multiple focal points. More recently, another class of lens implants known as “extended depth of focus” lenses utilize concentric rings to induce improved range and depth of focus rather than distinct focal points.

Additional lens designs are available internationally and are currently under development in the United States.

While there are potential advantages to these newer lenses in terms of improved spectacle independence, there may be downsides including increases in unwanted visual symptoms such as glare, halo, and decreased contrast sensitivity. Also, many pre-existing ocular conditions are considered contraindications to their use.

Another consideration is the added cost of these advanced lens implants. Medicare and other private insurances do not cover the additional cost associated with these lenses. Typically, a patient choosing to have this type of lens would incur the additional cost out of pocket. However, within VA, there is no mechanism for balance billing. Currently, the use of these lenses in VA is limited and approved on a case-by-case basis. This systematic review has been requested to assess the benefits and harms of these types of intraocular lens implants so that further guidance on their use within VA can be provided.

METHODS

TOPIC DEVELOPMENT

This topic was developed in response to a nomination by Dr. Donald Higgins, Acting Chief Consultant for Specialty Care Services (10P4E), and Dr. William Gunnar, National Director of Surgery (10NC2). Key questions were then developed with input from the topic nominator, the ESP coordinating center, the review team, and the technical expert panel (TEP).

The Key Questions were:

1. What is the effectiveness of multifocal or accommodative versus monofocal lenses with spectacle correction for distance vision in the setting of cataract surgery?
2. What is the effectiveness of multifocal or accommodative versus monofocal lenses with spectacle correction for near vision in the setting of cataract surgery?
3. What are the harms associated with multifocal or accommodative lenses versus monofocal replacement in the setting of cataract surgery?
4. If feasible, what resources are required to best care for patients who choose multifocal or accommodative lens implants in the setting of cataract surgery?

The review was submitted to PROSPERO: CRD42017069949

The Technical Expert Panel consisted of the following people: Donald Higgins, MD, Acting Chief Consultant for Specialty Care Services, VA Central Office; William Gunnar, MD, National Director of Surgery, VA Central Office; Amy Chomsky, MD, Chair, Ophthalmology Surgical Advisory Board; Glenn Cockerham, MD, National Program Director, VA Ophthalmology Service; Mary Daly, MD, Chief of Ophthalmology, VA Boston Healthcare System; Martha Farber, MD, Chief of Ophthalmology, Albany VA Medical Center; and Paul Greenberg, MD, MPH, Providence VA Medical Center.

Topic refinement with the TEP established that not all multifocal or accommodative lenses were of interest to VA: only lenses that are FDA-approved for use in the US are of interest. Furthermore, because of the pace of change in technology, priority was given to studies published within the past 10 years. “Effectiveness” was defined as spectacle independence: that is the goal of using a multifocal or accommodative lens. Visual acuity, survey measures of visual function, and quality of life were of also of interest. Harms included both the harms of the surgery itself, but also visual aberrations such as glare, halos, contrast sensitivity, and other optical phenomena. The timing of outcome measures was determined to be not particularly crucial. While 3-month or 6-month outcomes were desirable, earlier time points were considered adequate for the purposes of inclusion.

SEARCH STRATEGY

We conducted searches in PubMed from 1/1/2006 to 4/30/2017 (see Appendix A for full search strategy). The search in PubMed used a broad set of terms relating to “cataract” or “cataract

extraction” and “lenses, intraocular” or “lens implantation, intraocular” and terms of multifocal or accommodative lenses.

STUDY SELECTION

Two team members independently screened the titles of retrieved citations. Citations deemed relevant by at least 1 reviewer were then screened at the full-text level by 2 independent reviewers. Any disagreements were resolved by consensus decision after study team discussion. To be included, full texts needed to be randomized controlled trials of adults undergoing cataract extraction and comparing a multifocal or accommodative lens with a standard monofocal lens and reporting an outcome of interest. Included studies had to assess at least one lens that is FDA-approved for use in the VA.

The following PICOTS framework describes our inclusion criteria:

Participants/population: Adult patients undergoing cataract surgery with placement of intraocular lenses

Intervention(s): Placement of either multifocal or accommodative intraocular lenses

Comparators: Standard monofocal lenses

Outcomes: The primary outcome was spectacle independence. Additional outcomes were uncorrected and corrected distance vision, uncorrected near vision, validated measures of vision function (such as the VF-14) or quality of life. Harms included the harms of the surgery itself plus effects such as contrast sensitivity and aberrations like glare and halos.

Timing: Outcomes measured at any time point following surgery were included. When multiple time points were reported, later time points were preferred to earlier time points.

Setting: Cataract surgery

DATA ABSTRACTION

Data extraction was completed in duplicate. All discrepancies were resolved with full-group discussion. We abstracted data on the following: study design, single versus multi-site study, patient characteristics, intervention lenses, comparison monofocal lens, sample size, duration of follow-up, outcomes, and data needed for the Cochrane Risk of Bias tool.

QUALITY ASSESSMENT

Included randomized controlled trials were assessed for quality (risk of bias) with the Cochrane Risk of Bias tool.² This tool requires an assessment of whether a study is at high or low (or unknown) risk of bias in 7 domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other. We used the “other” category to assess whether authors specifically stated there was no loss to follow-up in studies for which only a single sample size number was reported (for example, a study might say “there were 50 patients in our study” and no additional information is ever given about how many were enrolled versus how

many completed the study). As a study of a surgical procedure, it is impossible or impractical to blind the surgeons to what kind of IOL is being implanted, or to blind the patient about what kind of IOL they are receiving. We did consider it possible to blind the outcome assessor if the outcome required the interpretation of a third party and that third party was kept blinded to treatment assignment.

DATA SYNTHESIS

The sample size, mean, and standard deviation for each treatment group was extracted from articles that reported visual acuity using Snellen or logMAR measurements. Data that reported visual acuity using Snellen charts were converted into logMAR values. A mean difference (MD) was calculated for each comparison of multifocal and monofocal lenses. Similar data was collected for quality of life measures but since the scales varied, a standardized effect size (SMD) was calculated for each comparison. The sample size and number or percent of patients with spectacle independence was collected and a risk ratio (RR) was calculated for each comparison.

Meta-analyses were conducted for the visual acuity and quality of life outcomes using trials that reported a monofocal lens comparator. Because several trials reported comparisons of more than one intervention, 2-level multilevel random effects models were estimated.³ For the two trials that reported a monovision comparator, a fixed-effects meta-analysis was performed.⁴

Test of heterogeneity were reported using the I^2 statistic.⁵ Values of the I^2 statistic close to 100% represent high degrees of heterogeneity. Begg rank correlation⁶ and Egger regression asymmetry test⁷ were used to examine publication bias. R version 3.4.1 was used for all statistical analyses.

There was only 1 study that used an accommodative lens, so the results of that study were presented narratively.

RATING THE BODY OF EVIDENCE

Where possible, a summary of findings and quality of evidence table was used to summarize the existing evidence. Based on the GRADE working group,⁸ the quality of the evidence was categorized as follows:

High: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate: 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: Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.

Very low/Insufficient: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

GRADE evaluates the quality of the evidence across all identified studies contributing to the outcome of interest.

PEER REVIEW

A draft version of the report was reviewed by technical experts and clinical leadership. Reviewer comments and our responses are documented in Appendix B.

RESULTS

LITERATURE FLOW

Our literature searches, expert recommendations, and reference mining identified 760 potentially relevant citations, of which 93 were included at the abstract screening. All 93 abstracts were included and obtained as full-text publications. Eighty-one studies were excluded for the following reasons: no monofocal comparison group (n=21); not intervention of interest (n=9); not lens of interest (n=30); not outcome of interest (n=2); not RCT (n=16); commentary (n=1); background (n=1); duplicate (n=1). A total of 12 publications were identified at full-text review as includes that contributed to our final sample (See Figure 1). Details of included studies are provided in the Evidence Table in Appendix C. A full list of these excluded studies from the full-text review is included in Appendix D.

DESCRIPTION OF THE EVIDENCE

All of the studies were single-site with 3 exceptions.⁹⁻¹¹ No study was performed in the USA; 4 studies were performed in China.¹²⁻¹⁵ Sample sizes were modest: 5 studies enrolled 75 patients or less,^{11,13,16-18} and only 1 study enrolled more than 200 patients.⁹ The mean age of patients enrolled was 60-75 years of age, and patients were 50-60% female. All but one study assessed multifocal IOLs.¹¹ Two studies compared the interventions lenses to monovision or mini-monovision,^{9,18} where the 2 eyes have monofocal IOLs of different focal lengths, such that one eye sees predominantly distance vision and the other eye sees predominantly near vision. Nearly all studies reported visual acuity; 6 studies reported spectacle independence^{9,14-16,18,19}; other outcomes were variably reported. We considered the 2 studies by Alio and colleagues^{10,17} to potentially have overlapping patients, and for the purposes of statistical pooling only used the results from the study with the larger sample size.

The quality of studies was in general low – no study was judged to be at low risk of bias across all domains, though one study was at low risk of bias in all domains except one.¹⁶ Since only 2 studies were reported as having had their protocol prospectively registered,^{9,18} for example on clinicaltrials.gov, our ability to assess selective reporting bias is limited.

Figure 1. Literature Flow Chart

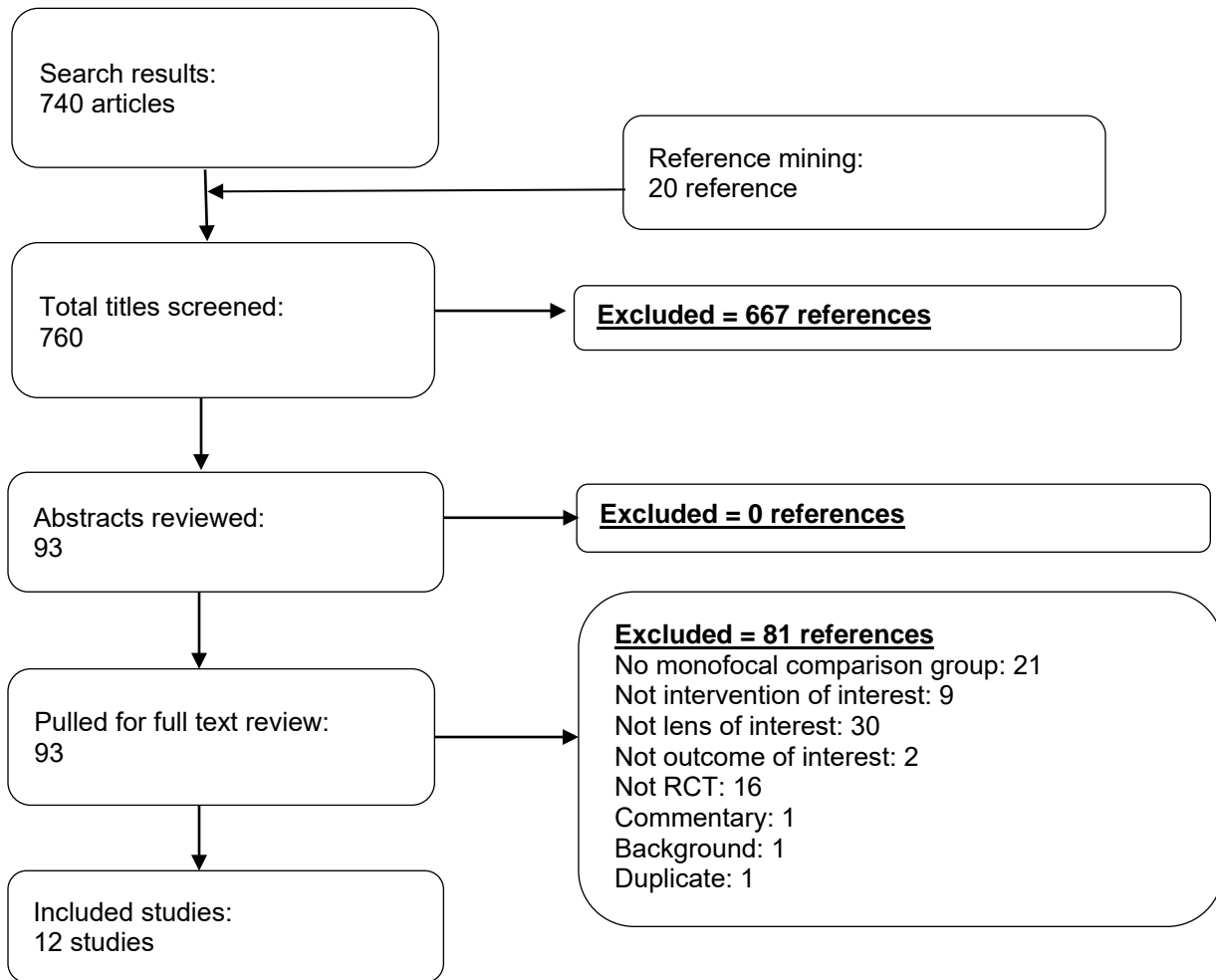


Table 1. Quality Assessment for Included Studies

Author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources of bias
Marchini, 2007 ¹¹	~	-	-	½	~	TM	-
Zeng, 2007 ¹²	½	½	-	-	½	TM	-
Cillino, 2008 ¹⁶	TM	TM	½	TM	TM	TM	
Palmer, 2008 ¹⁹	TM	½	½	TM	½	TM	
Zhao, 2009 ¹⁵	TM	-	½	TM	TM	TM	
Alio, 2011 ¹⁰	TM	½	-	-	½	TM	-
Alio, 2011 ¹⁷	TM	½	-	-	½	TM	-
Ji, 2012 ¹³	½	-	-	-	TM	TM	
Peng, 2012 ¹⁴	TM	-	-	-	½	TM	
Rasp, 2012, ²⁰	½	-	-	½	~	TM	
Wilkins, 2013 ⁹	TM	TM	-	-	TM	TM	TM
Labiris, 2015 ¹⁸	TM	½	-	-	½	TM	-

TM = low risk of bias ~ = risk of bias ½ = unknown

KEY QUESTION 1: What is the effectiveness of multifocal or accommodative versus monofocal lenses with spectacle correction for distance vision in the setting of cataract surgery?

Multifocal IOLs Compared to Monofocal IOLs

We identified 6 studies (with 15 comparisons and 885 patients) and 7 studies (with 17 comparisons and 899 patients) that reported uncorrected and corrected distance vision, respectively, when comparing multifocal IOLs to monofocal IOLs (that were not used for monovision). Figure 2 presents the data for uncorrected distance vision and figure 3 presents the data for corrected distance vision. For both outcomes, there were no statistically significant differences in vision between the multifocal and monofocal IOLs. There was no statistical evidence for publication bias (Begg’s test p value = 0.55, Eggar’s test p value = 0.78).



Figure 2. Multifocal IOLs Compared to Monofocal IOLs Uncorrected Distance VA (logMAR)

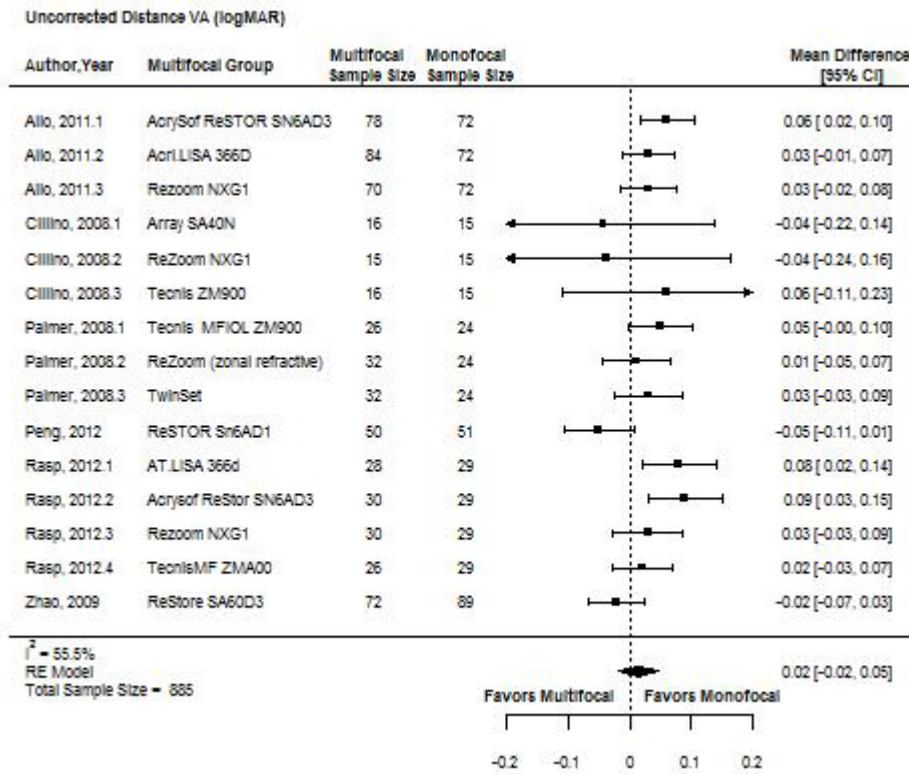
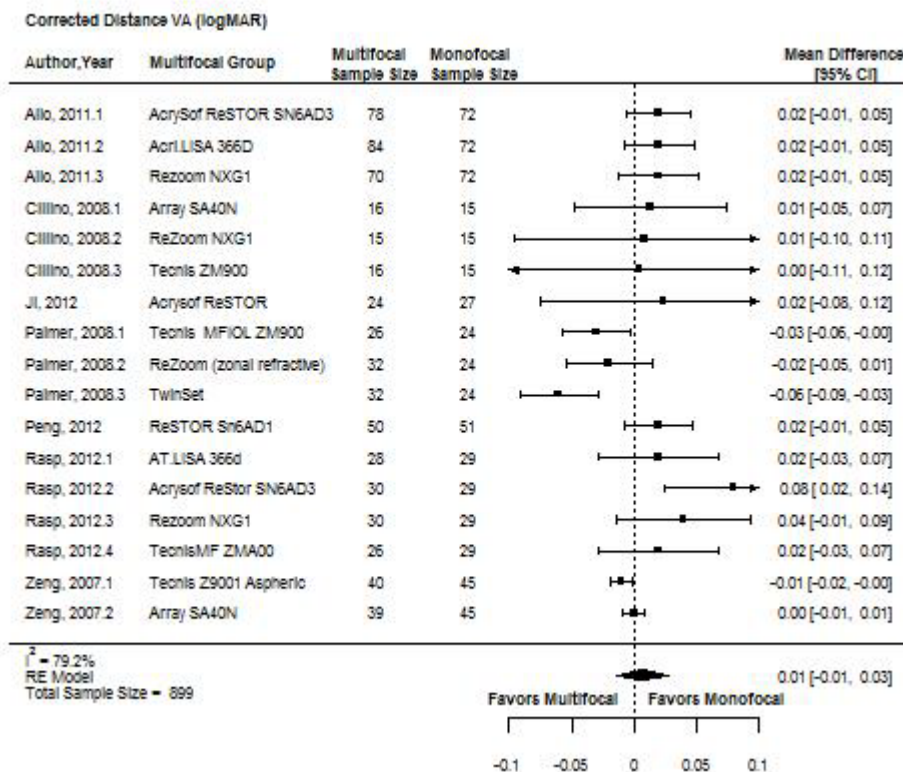


Figure 3. Multifocal IOLs Compared to Monofocal IOLs Corrected Distance VA (logMAR)



Multifocal IOLs Compared to Monofocal IOLs as Monovision

We identified 2 RCTs that compared multifocal IOLs to monofocal IOLs for monovision.^{9,18} We pooled these using a fixed effects model. There was no statistically significant difference in uncorrected distance vision (see appendix). Corrected distance vision was not reported. There was no statistical evidence of publication bias.

Accommodative IOLs Compared to Monofocal IOLs

One RCT was identified that compared the use of accommodative IOLs to a standard monofocal IOL during routine cataract surgery.¹¹ This trial was a three-arm comparison of 2 different accommodative IOLs compared to a single monofocal IOL during cataract surgery in patients with visually significant cataract. In group 1, 19 subjects (30 eyes) received the 1CU accommodative IOL (HumanOptics, Erlangen, Germany); in group 2, 19 subjects (29 eyes) received the AT-45 Crystalens accommodative IOL (Eyeonics Vision, Aliso Viejo, CA); and in group 3, 21 subjects (21 eyes) received the ACR6D monofocal IOL (Corneal, Paris, France). Patients were recruited from a single university-based ophthalmology practice and were determined to have any type of cataract as the sole cause of decreased vision less than or equal to 20/40 and no other preexisting ocular comorbidities. The enrolled sample of 59 subjects (80 eyes) was 47.4% female with a mean age of 66 ± 10 years. All subjects underwent pre-operative evaluation including slit-lamp evaluation, indirect funduscopy, applanation tonometry, keratometry, and immersion A-scan biometry. Two surgeons performed all surgeries based on standardized techniques. The authors state that no major surgical complications occurred.



Outcome measures included: uncorrected far-distance visual acuity; best-corrected far-distance visual acuity; uncorrected near-distance visual acuity; best-corrected near-distance visual acuity; distance-corrected near visual acuity; near-distance refractive addition (NDRA); accommodative amplitude (AA); variation in anterior chamber depth (ACD); and variation in sclerociliary process angle (SCPA). Outcomes were measured at post-operative months 1, 6, and 12.

At 12 months, statistically significant differences were found in the following areas:

- The NDRA needed to reach best-corrected near visual acuity was significantly lower in the accommodative IOL groups versus the monofocal IOL group (although no difference was found between the 2 accommodative IOL groups)
- Distance-corrected near visual acuity was significantly better in the accommodative IOL groups versus the monofocal group. DCNVA was better in the 1CU group versus the AT-45 group.
- The variation in anterior chamber depth was significantly greater in the AT-45 group compared to the monofocal group.

No significant differences were found in the following areas: BCDVA; BCNVA; uncorrected near-distance VA; AA variation; and SCPA variation.

Summary of Findings

From 9 RCTs the evidence supports a conclusion that there is no difference in uncorrected or corrected distance vision between multifocal or accommodative IOLs and monofocal IOLs. The evidence for accommodative IOLs is restricted to only 1 trial. Two trials comparing multifocal IOLs to monovision found no difference in uncorrected distance vision.

Quality of Evidence for Key Question 1

We judged the evidence for the outcomes of distance vision with multifocal IOLs as moderate (downgraded due to methods limitation in the RCTs), and for accommodative IOLs as low due to sparseness of data (1 RCT).

Table 2. GRADE Quality of Evidence Table (Outcomes of Distance Vision)

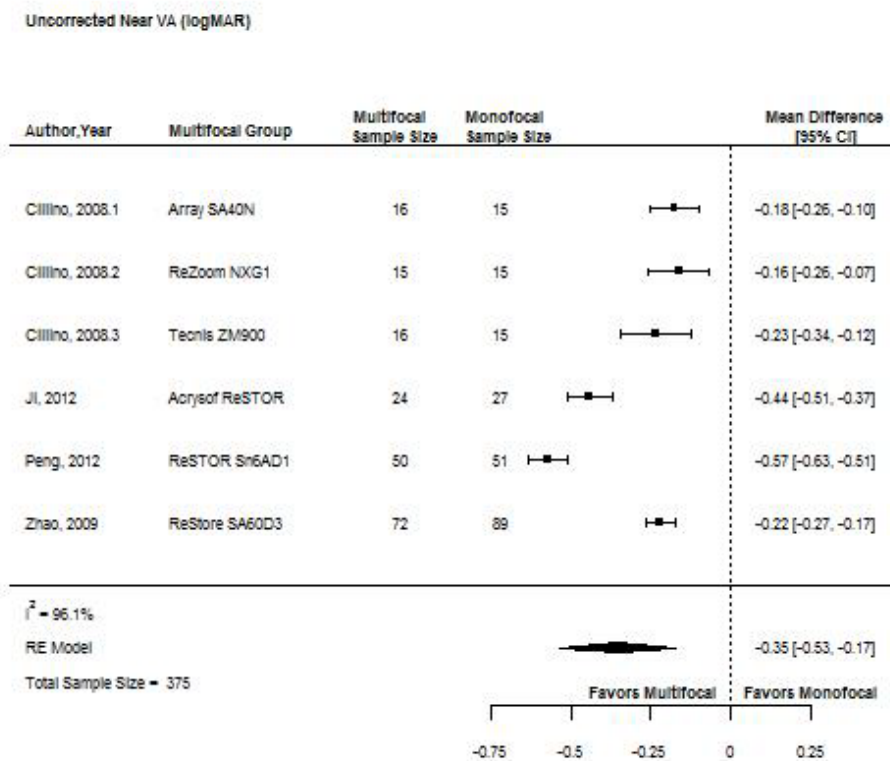
Outcome	Number of Studies and Design	Methodological Quality of Studies	Consistency Across Studies	Directness of Evidence	Other Considerations	Qualitative Description of Effect Size	Quality of Evidence
Multifocal IOLs – Uncorrected distance vision	6 RCTs	Serious limitation	No serious limitations	No serious Limitations	None	No difference	Moderate
Multifocal IOLs – Corrected distance vision	7 RCTs	Serious limitation	No serious limitations	No serious limitations	None	No difference	Moderate
Accommodative IOLs – Uncorrected distance vision	1 RCT	Serious limitation	N/A	No serious limitation	Sparse data	No difference	Low
Accommodative IOLs – Corrected distance vision	1 RCT	Serious limitation	N/A	No serious limitation	Sparse data	No difference	Low

KEY QUESTION 2. What is the effectiveness of multifocal or accommodative versus monofocal lenses with spectacle correction for near vision in the setting of cataract surgery?

Multifocal IOLs Compared to Monofocal IOLs

We identified 4 studies (with 6 comparisons and 375 patients) that reported uncorrected near vision comparing multifocal IOLs to monofocal IOLs (that were not used for monovision).¹³⁻¹⁶ Figure 4 presents the results. The random effects pooled estimate of effect in logMAR was -0.35 (95% CI -0.93, -0.17) favoring multifocal IOLs. There was significant heterogeneity ($I^2 = 96.1\%$). There was no statistical evidence of publication bias (Begg's test p value = 1, Eggar's test p value = 0.61).

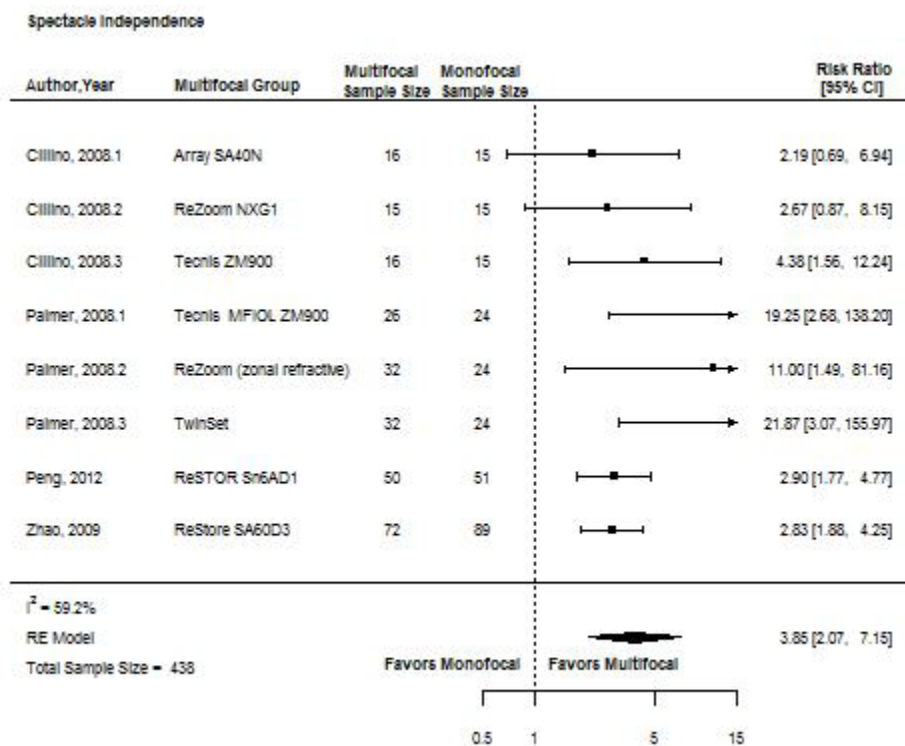
Figure 4. Multifocal IOLs Compared to Monofocal IOLs Uncorrected Near VA (logMAR)



We identified 4 studies (with 8 comparisons and 438 patients) that reported spectacle independence comparing multifocal IOLs to monofocal IOLs (that were not used for monovision).^{14-16,19} Figure 5 presents the results. The random effects pooled estimate was a relative risk of 3.85 (95% CI 2.07, 7.15) favoring spectacle independence with multifocal IOLs. There was moderate heterogeneity. ($I^2 = 59.2\%$). Begg’s test for publication bias was not statistically significant ($p = .11$); however, Eggar’s test was significant ($p = 0.008$). This was probably due to the results of the study by Palmer showing 5-10 times greater benefits for spectacle independence than the other 3 studies.



Figure 5. Multifocal IOLs Compared to Monofocal IOLs Spectacle Independence

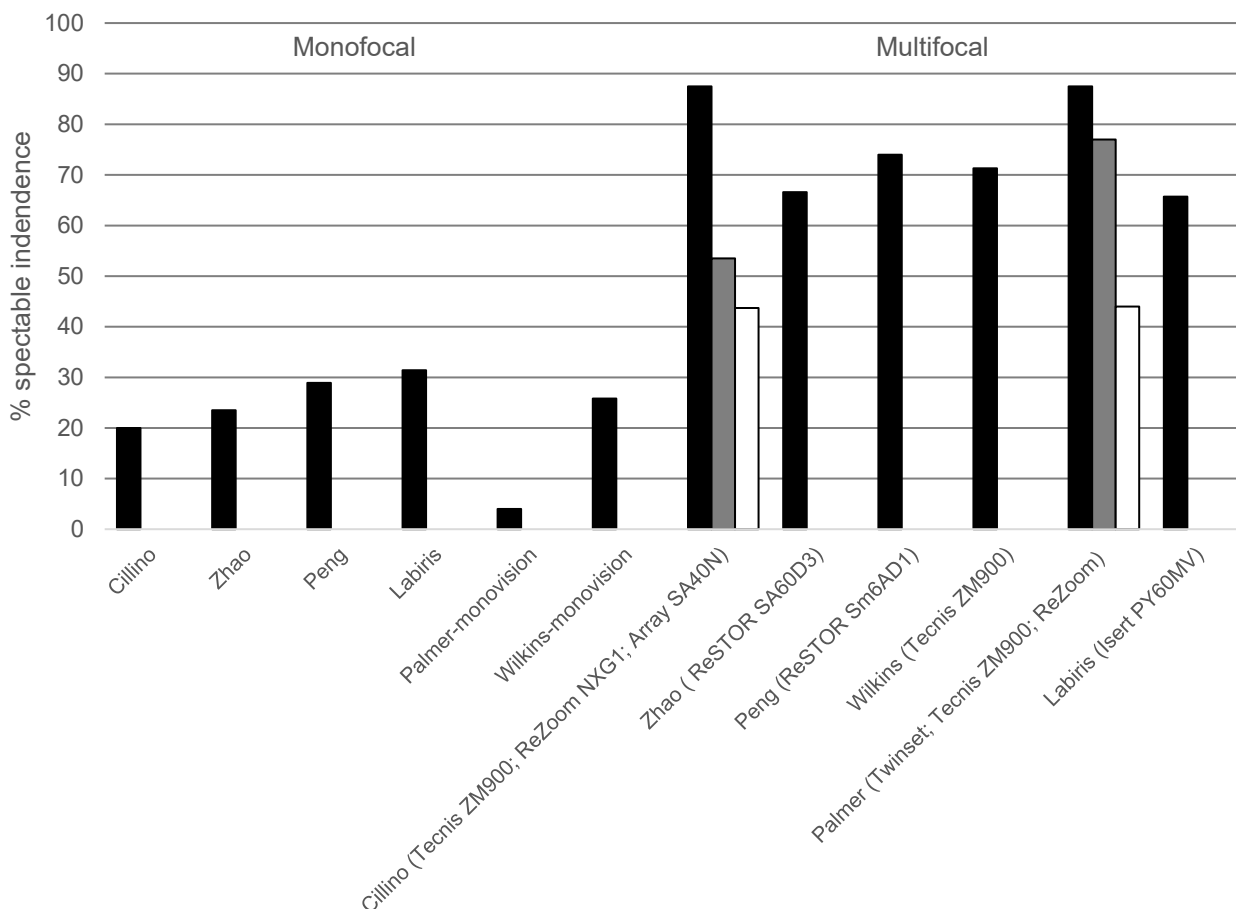


Multifocal IOLs Compared to Monofocal IOLs as Monovision

We identified 2 RCTs that compared multifocal IOLs to monofocal IOLs as monovision.^{9,18} We pooled these studies with a fixed effect model. The pooled fixed effect logMAR for uncorrected near vision was -0.03 (95% CI -0.07, 0.00) favoring multifocal IOLs (see Appendix E). For spectacle independence, the pooled fixed effect was a risk ratio of 2.52 (95% CI 1.87, 3.41) favoring multifocal IOLs.

As another means of displaying the results for spectacle independence, the bar graph (Figure 6) presents the proportion of patients who achieved spectacle independence in the 6 studies reporting this outcome. On the left is the standard monofocal IOL patients (or monovision patients) and on the right are multifocal IOL patients (some studies tested more than 1 multifocal IOL). The proportion of patients achieving spectacle independence with multifocal IOLs is 2- or 3-fold higher than with monofocal IOLs or monovision.

Figure 6. Spectacle Independence



Accommodative IOLs Compared to Monofocal IOLs

We identified 1 RCT comparing accommodative IOLs to monofocal IOLs.²¹ It is discussed in the prior section. No statistically significant differences were found for uncorrected near visual acuity. However, distance-corrected near visual acuity was significantly better in the accommodative IOL group.

Other Outcomes

Two RCTs were identified that evaluated bilateral reading performance after implantation of different types of multifocal IOLs as compared to a control monofocal IOL.^{10,20} The authors of both studies contend that reading performance provides a better means of assessing functional near vision after cataract surgery as compared to visual acuity measurements based on single letters.

Rasp et al evaluated 143 patients (286 eyes) undergoing routine bilateral cataract surgery for visually significant cataract randomized to receive 1 of 4 different multifocal IOLs or a control monofocal IOL.²⁰ Alio et al evaluated 152 patients (304 eyes) undergoing bilateral cataract surgery who received 1 of 3 different multifocal IOLs or a control monofocal IOL.¹⁰ All patients

underwent bilateral implantation of the same IOL model. Exclusion criteria for both studies included any coexisting ocular disease and illiteracy.

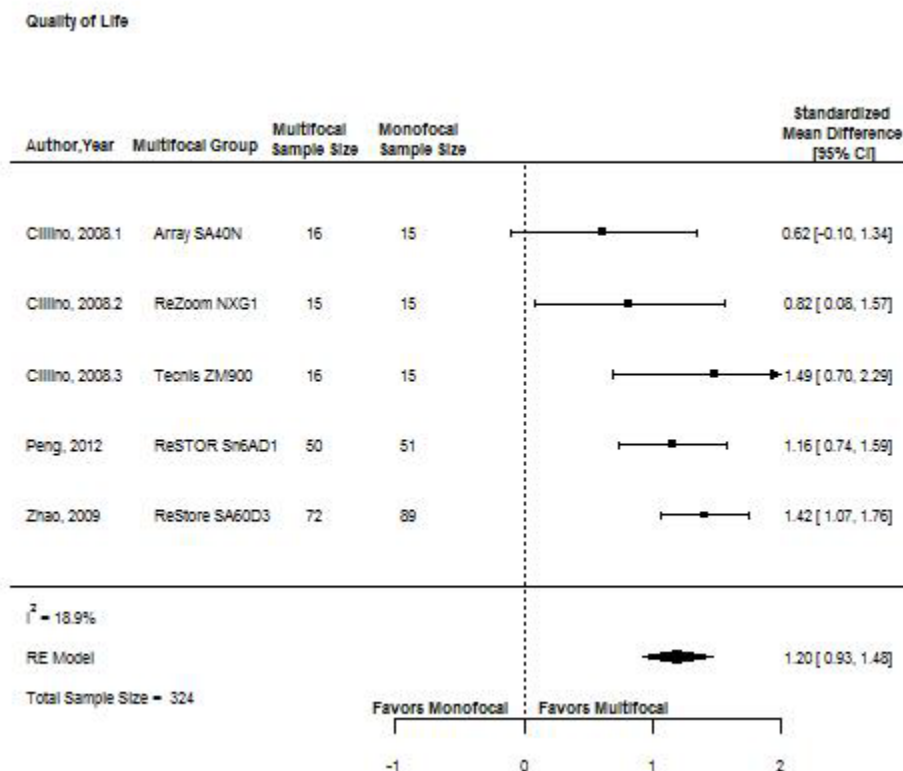
Both studies utilized the Salzburg Reading Desk system to measure reading performance. The Salzburg Reading Desk utilizes a reading desk, computer, and proprietary software to measure various aspects of reading performance including reading acuity, reading distance, reading speed, and smallest print size. This system is automated and provided testing under standardized conditions while simulating a natural reading process.

Rasp et al found significantly improved uncorrected reading acuity and uncorrected smallest print size in the diffractive multifocal IOL groups compared to the monofocal and refractive multifocal IOL groups.²⁰ Uncorrected reading distance was decreased in the diffractive multifocal IOL groups (32 cm) as compared to the monofocal (38.9 cm) and refractive IOL groups (37.1 cm). One specific diffractive IOL demonstrated the best reading speed values as compared to all other groups. Outcomes were measured at 12 months.

Alio et al found similar outcomes based on their comparison groups followed for 6 months.¹⁰ Uncorrected reading acuity was significantly better in the diffractive multifocal IOL groups as compared to the monofocal and refractive IOL groups ($p < 0.1$). Uncorrected reading speed was significantly worse in the refractive multifocal IOL group than in the monofocal IOL group. Reading distance was significantly worse in the monofocal group as compared to all other multifocal groups.

Three studies presented data on visual function or quality of life for multifocal IOLs compared to monofocal IOLs.¹⁴⁻¹⁶ These studies included 5 comparisons and 324 patients. The pooled random effects standardized mean difference was 1.20 (95% CI 1.07, 1.76) favoring multifocal IOLs (Figure 7). There was no significant heterogeneity ($I^2 = 18.9\%$). There was no statistical evidence for publication bias (Begg's test p value = 0.82, Egger's test p value = 0.20).

Figure 7. Multifocal IOLs Compared to Monofocal IOLs Quality of Life



Summary of Evidence

4 RCTs support the conclusion that multifocal IOLs are better than monofocal IOLs for uncorrected near vision. This conclusion is also supported by better outcomes for reading accurately and speed and visual function. In the few studies that have measured visual function or vision-related quality of life, this has been better in patients receiving multifocal IOLs. Data on accommodative IOLs are very sparse. Two studies found that multifocal IOLs result in better spectacle independence than monovision.

Quality of Evidence for Key Question 2

We judged the evidence for the outcomes of uncorrected near vision and spectacle independence with multifocal IOLs as moderate, downgraded due to methods limitations in the RCTs and for accommodative IOLs as low due to sparseness of data.

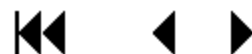


Table 3. GRADE Quality of Evidence Table (Outcomes of Uncorrected Near Vision and Spectacle Independence)

Outcome	Number of Studies and Design	Methodological Quality of Studies	Consistency Across Studies	Directness of Evidence	Other Considerations	Qualitative Description of Effect Size	Quality of Evidence
Multifocal IOLs – Uncorrected near vision	4 RCTs	Serious limitation	No serious limitations	No serious Limitations	None	Multifocal IOLs better	Moderate
Multifocal IOLs – Spectacle independence	4 RCTs	Serious limitation	No serious limitations	No serious limitations	None	Multifocal IOLs better	Moderate
Accommodative IOLs – uncorrected near vision	1 RCT	Serious limitations	N/A	No serious limitations	Sparse data	No difference	Low
Multifocal IOLs – quality of life	3 RCTs	Serious limitations	No serious limitations	No serious limitations	Sparse data	Multifocal IOLs better	Low

KEY QUESTION 3. What are the harms associated with multifocal or accommodative lenses versus monofocal replacement in the setting of cataract surgery?

Surgical Complications

Six of the 10 multifocal IOL studies addressed whether any surgical adverse events occurred in the study with varying degrees of detail.^{9,12,14-17} We considered the 2 studies by Alio to have potentially overlapping patients, and so include here only the 1 study by Alio that reported adverse events. The one study of accommodative IOLs only reported “no major surgical complications occurred.”¹¹ Zeng commented that patients with posterior capsule rupture or suboptical rhexis size were excluded but did not comment on intraoperative or postoperative complications from the included eyes.¹² Peng commented that no intraoperative or postoperative complications occurred.¹⁴ Alio commented no complication occurred intraoperative or postoperative and capsule remained clear until 3 months follow up.¹⁷ Cillino and Zhao excluded intraoperative complications but also specifically commented that no post-operative complications occurred including high pressure, infection, and swelling, as well as IOL decentration and development of posterior capsule opacification in the 6-month follow-up.^{15,16} Wilkins described 5 patients randomized to MFIOL who received a monofocal IOL instead due to intraoperative complications or administrative error.⁹ The study also described 12.2% of MFIOL cases had an IOL exchange at the time of surgery due to damage of the IOL during injections. The authors add that the injector system was changed after the study following reports of this issue. One patient in each arm needed LASIK for refractive error. More importantly, 6 patients with MFIOL had a second surgery to exchange the lens for a monofocal due to dissatisfaction with the lens.

Contrast Sensitivity

Eight of the 10 multifocal IOL studies reported contrast sensitivity.^{9,12-16,18,19} Zeng showed statistical significant contrast sensitivity issues for the Tecnis multifocal lens (Z9001) compared to the monofocal lens then followed by the second multifocal lens (SA40N).¹² Cillino showed better contrast with the monofocal lens (AR40) and multifocal lens (ZM9000) compared to the Array and ReZoom lenses ($p=0.038$).¹⁶ Palmer showed monofocal IOLs with statistically significant better contrast compared to the ZM9000 and Twin set lens at all frequencies and luminance.¹⁹ Meanwhile the difference was only significant between the monofocal and ReZoom at high frequencies in scotopic conditions.

Ji showed lower contrast sensitivity with the ReSTOR lens compared to monofocal lens under all 6 spatial frequencies with mesopic and photopic conditions.¹³ Compared to monovision, multifocal lenses had less contrast sensitivity according to Wilkins.⁹ Meanwhile Peng showed worse contrast with the ReSTOR lens at low MTF but no difference at higher MTF.¹⁴ On the other hand, Zhao showed no difference in contrast sensitivity between the ReSTOR lens (SA60AD3) and the monofocal lens (SA60AT).¹⁵ Labiris et al showed no difference in contrast comparing “mini-monovision” with a refractive multifocal lens.¹⁸

Table 4. Contrast Sensitivity Results in Studies Comparing Multifocal IOLs to Monofocal IOLs

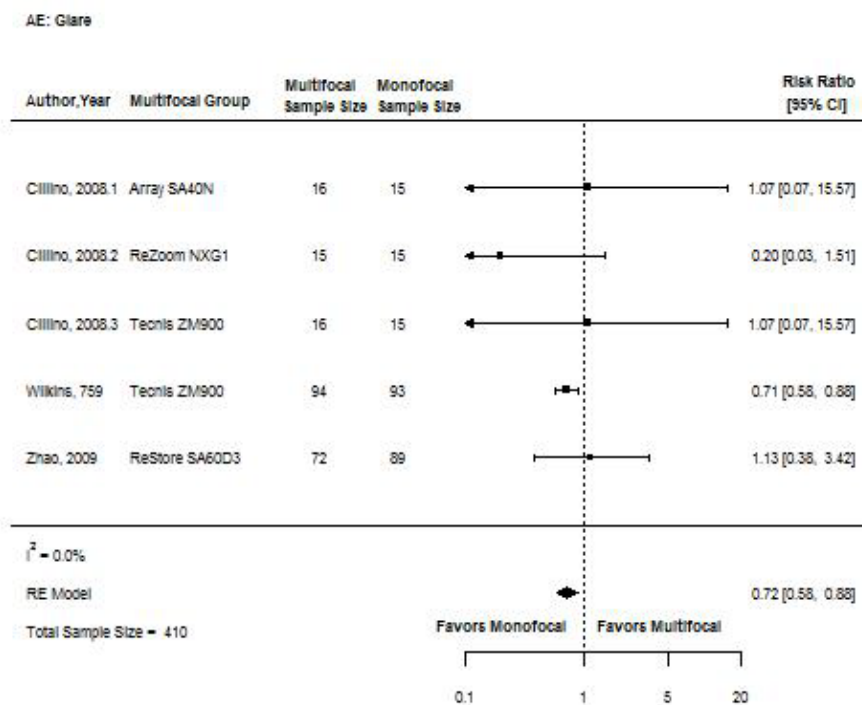
Studies	Favors Multifocal IOLs	No difference	Favors Monofocal IOLs
Zeng, 2007 ¹²			x
Cillino, 2008 ¹⁶			x
Palmer, 2008 ¹⁹			x
Zhao, 2009 ¹⁵		x	
Ji, 2012 ¹³			x
Peng, 2012 ¹⁴			x
Wilkins, 2013 ⁹			x
Labiris, 2015 ¹⁸		x	

Glare

Six of 10 multifocal IOL studies reported glare following surgery.^{9,12,14-16,18} Zeng showed significantly worse glare with the Tecnis multifocal lens (Z9001) compared to the Array multifocal lens (SA40N), followed by the monofocal lens which had the least glare ($p=0.004$).¹² Cillino showed no significantly higher reported cases of glare following surgery amongst the multifocals and monofocal lenses, although the ReZoom had the most cases reported (5 compared to 1 in each other group).¹⁶ Peng et al showed worse reported glare in the ReSTOR lens compared to the monofocal lens on an impact rating score.¹⁴ Wilkins grouped glare with “dazzle” and showed the ReSTOR had more “debilitating” and “annoying” glare following surgery compared to the monovision patients.⁹ Labiris showed not statistically significant difference in reported glare on a 4-point scale of a refractive MFIOL compared to mini-monovision.¹⁸ Zhao found 5 cases with glare in the multifocal IOL group compared to 7 cases in the monofocal IOL group.¹⁵

We pooled the 3 studies reporting binary outcomes for glare which totaled 410 patients.^{9,15,16} The random effects pooled estimate was a risk ratio of 0.72 (95% CI 0.58, 0.88) favoring monofocal IOLs. There was no heterogeneity ($I^2 = 0\%$).

Figure 8. Multifocal IOLs Compared to Monofocal IOLs Glare



Halos

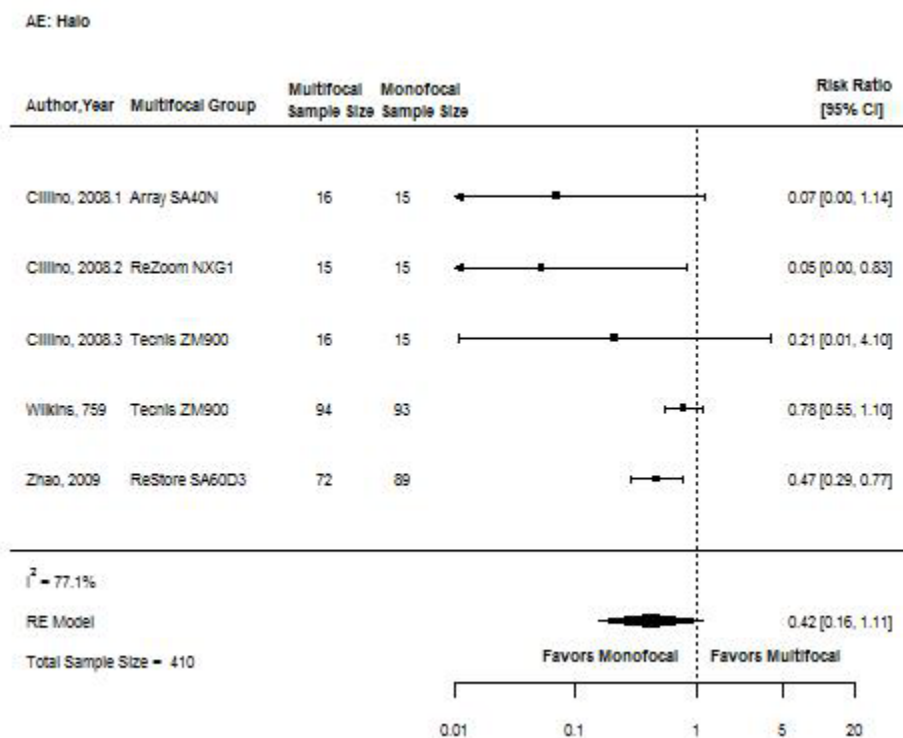
There were 3 of 10 multifocal IOL studies reporting halos following surgery.¹⁴⁻¹⁶ Cillino showed significantly worse reported halos following surgery in the Rezoom and Array compared to monofocal.¹⁶ Zhao determined 43.1% of patients who had a ReSTOR had halos compared to only 20.2% of the monofocal patients ($p < 0.01$).¹⁵ Peng determined the ReSTOR had more halos than the monofocal on its impact rating score.¹⁴ One additional trial reported the outcome, “have you noticed any unwanted images?” and reported about 10% greater occurrence of this in patients receiving multifocal IOLs.⁹

We pooled the 3 studies reporting binary outcomes for halo/unwanted images, which totaled 410 patients.^{9,15,16}

The random effects pooled estimate was a risk ratio of 0.42 (95% CI 0.16, 1.11) favoring multifocal IOLs. Heterogeneity was high ($I^2 = 77\%$).



Figure 9. Multifocal IOLs Compared to Monofocal IOLs Halo



Other Visual Phenomena

Palmer noted that more patients had complaints of dysphotopias in the ZM900 group (81%) compared to the TwinSet (47%) and ReZoom (53%) and monofocal groups (48%).¹⁹ The authors also point out that no patient in the monofocal group complained on their own about photopias compared to 16-18% of the MFIOL patients. Labiris commented on complaints of shadows following surgery being higher in the MFIOL group compared to mini monovision.¹⁸ The study also commented there was no difference in stereopsis between MFIOL and mini monovision.

Summary of Findings

Between 3 and 8 RCTs support the following conclusions:

1. The intraoperative risks of surgery are probably no greater for multifocal IOLs than monofocal IOLs in the patient population and lenses included in these trials.
2. Multifocal IOLs may increase the risk of IOL exchange due to patient dissatisfaction.
3. Multifocal IOLs are associated with worse contrast sensitivity.
4. Multifocal IOLs are associated with greater risk of glare.
5. Multifocal IOLs are associated with a greater risk of halos.
6. The need for further procedures following multifocal IOL such as corneal refractive surgery or IOL exchange is not addressed in these studies and requires additional research.
7. Data on accommodative IOLs are too sparse to draw conclusions.



Quality of Evidence for Key Question 3

Table 5. GRADE Quality of Evidence Table (Harms)

Outcome	Number of Studies and Design	Methodological Quality of Studies	Consistency Across Studies	Directness of Evidence	Other Considerations	Qualitative Description of Effect Size	Quality of Evidence
Multifocal IOLs – Operative risk	6 RCTs	Serious limitations	No serious limitation	No serious Limitations	None	No difference	Moderate
Multifocal IOLs – IOL exchange	1 RCT	No serious limitations	N/A	No serious limitation	Sparse data	Multifocal IOLs worse	Low
Multifocal IOLs – Contrast sensitivity	8 RCTs	Serious limitations	No serious limitation	No serious limitations	None	Multifocal IOLs worse	Moderate
Accommodative IOLs – glare	6 RCT	Serious limitations	No serious limitation	No serious limitations	None	Multifocal IOLs worse	Moderate
Multifocal IOLs - halo	4 RCTs	Serious limitations	Serious limitation	No serious limitation	None	Multifocal IOLs worse	Low
Accommodative IOLs – all outcomes	1 RCT	Serious limitations	N/A	No serious limitation	Sparse data	None	Very low

KEY QUESTION 4. If feasible, what resources are required to best care for patients who choose multifocal or accommodative lens implants in the setting of cataract surgery?

None of the 12 studies specifically addressed Key Question 4.

However, 6 out of 12 studies included pre-op corneal astigmatism greater than 1 diopter as an exclusion criterion. Residual refractive error due to uncorrected corneal astigmatism is thought to decrease the effectiveness of multifocal lenses. While these studies did not further elaborate on the method by which corneal astigmatism was measured, this is commonly done with specialized equipment, specifically a corneal topographer.

Residual post-operative astigmatism plays an important role in quality of vision and spectacle independence following cataract surgery. Of the 11 studies looking at multifocal IOLs, 8 excluded patients in whom pre-op corneal astigmatism was “high”. This number ranged from 1 to 3 diopters (D). Another study did not rule out astigmatism cases and instead used coupled incision to treat up to 2D of pre-op astigmatism.

Only 5^{9,14,16,17,20} of the 11 multifocal IOL studies reported post-operative astigmatism (cylinder). Although the average residual post-operative astigmatism was reported as 0.4-0.6D, the standard deviations were high and with a range up to 2.5D. The amount of residual astigmatism may contribute to patient satisfaction and vision following cataract surgery, further emphasizing the need for a future trial that addresses post-operative astigmatism.

One study included “age-related macular degeneration” as a specific exclusion criterion, which is often confirmed with additional testing such as ocular coherence tomography (OCT).¹¹

The American Society of Cataract and Refractive Surgeons (ASCRS) published a review article outlining best clinical practice for use of multifocal IOLs that included recommended pre-operative diagnostic testing.²² These tests include:

- Corneal topography to evaluate corneal astigmatism and screen for other ocular surface abnormalities;
- OCT to evaluate macular function; and
- Pupillometry.

These diagnostic tests would require additional resources in terms of equipment, technical support, and interpretation.

The ASCRS article also recommends detailed patient discussion and counseling regarding factors that may influence the perceived outcome of multifocal IOL implantation. These topics include:

- Limitations of multifocals;
- Risk of unwanted visual phenomenon (*ie*, glare/halo);
- Patient temperament; and
- Patient lifestyle considerations.

Such discussion/counseling would also require additional time and resources as compared to monofocal IOL.

Finally, the ASCRS article acknowledges that post-operative refractive error or intolerable visual phenomena may need to be managed with additional surgical intervention such as corneal refractive surgery or IOL exchange.

Summary of Findings

No hypothesis-testing study explicitly assessed the need for additional pre-operative or post-operative resources for patients receiving multifocal IOLS. However, several of the included trials used as exclusion criteria conditions that would require additional diagnostic tests that may go beyond the standard pre-operative evaluation for monofocal IOLs. Specialty society “best practice” recommendations for multifocal IOL procedures list a number of pre-operative and post-operative best practices that may not be included as part of standard monofocal IOL procedures.

Quality of Evidence for Key Question 4

As there were no hypothesis-testing studies found for Key Question 4, the evidence is judged as insufficient. However, clinicians wishing to follow the same inclusion/exclusion criteria used in many of the multifocal IOL RCTs will need to do additional pre-operative testing.

SUMMARY AND DISCUSSION

Moderate-strength evidence supports the conclusion that, compared to monofocal IOLs, multifocal IOLs achieve better outcomes on spectacle independence and uncorrected near visual acuity, without sacrificing uncorrected or corrected distance vision. Low-strength evidence supports the conclusion that multifocal IOLs result in better visual function/ quality of life than monofocal IOLs. More limited data support that multifocal IOLs achieve better spectacle independence than monovision. Moderate-strength evidence supports that multifocal IOLs result in worse contrast sensitivity and a greater risk of glare, and low-strength evidence supports that they result in a greater risk of halos. Low-strength evidence exists that monofocal IOLs result in greater IOL exchange due to dissatisfaction. A limitation of all these conclusions is that IOL technology is rapidly changing, and therefore newer IOLs may have differences in the benefits and harms we report here for older lenses. Data are very limited about accommodative IOLs, consisting of only 1 RCT.

SUMMARY OF EVIDENCE BY KEY QUESTION

Key Question 1

The evidence from 9 RCTs supports a conclusion that there is no difference in uncorrected or corrected distance vision between multifocal or accommodative IOLs and monofocal IOLs. The evidence for accommodative IOLs is restricted to only 1 trial. Two trials comparing multifocal IOLs to monovision found no difference in uncorrected distance vision.

Key Question 2

Four RCTs support the conclusion that multifocal IOLs are better than monofocal IOLs for uncorrected near vision. This conclusion is also supported by better outcomes for reading accurately and speed and visual function. In the few studies that have measured visual function or vision-related quality of life, this has been better in patients receiving multifocal IOLs. Data on accommodative IOLs are very sparse. Two studies found that multifocal IOLs result in better spectacle independence than monovision.

Key Question 3

Between 3 and 8 RCTs support the following conclusions: 1) The risks of surgery are no greater for multifocal IOLs than monofocal IOLs in the patient population and lenses included in these trials; 2) Multifocal IOLs may have an increased risk of IOL exchange due to patient dissatisfaction; 3) Multifocal IOLs are associated with worse contrast sensitivity; 4) Multifocal IOLs are associated with greater risk of glare; 5) Multifocal IOLs are associated with a greater risk of halos; and 6) Data on accommodative IOLs are too sparse to draw conclusions.

Key Question 4

No hypothesis-testing study explicitly assessed the need for additional pre-operative or post-operative resources for patients receiving multifocal IOLs. However, several of the included trials used as exclusion criteria conditions that would require additional diagnostic tests that may go beyond the standard pre-operative evaluation for monofocal IOLs. Specialty society “best practice” recommendations for multifocal IOL procedures list a number of pre-operative and

post-operative best practices that may not be included as part of standard monofocal IOL procedures.

LIMITATIONS

A limitation of all these conclusions is that IOL technology is rapidly changing, and therefore newer lenses may have differences in the benefits and harms we report here for older lenses.

Publication Bias

We were not able to test for publication bias and can make no conclusions about its possible existence.

Study Quality

The principal limitation to this review is the quality of the original RCTs. Most studies had methodologic limitations and were of small size. This contributed to our assessment of the quality of evidence being moderate rather than high.

Heterogeneity

Heterogeneity was in general not large in most of the pooled analyses.

Applicability of Findings to the VA Population

No studies were performed in VA populations, or even US populations, therefore the applicability of these results to VA patients with cataracts is uncertain.

RESEARCH GAPS/FUTURE RESEARCH

A VA-sponsored multi-site randomized clinical trial would provide higher quality evidence than that which currently exists about the benefits, harms, needed pre- and post-operative clinical resources, assessments of pre- and post-operative astigmatism, and costs of multifocal IOLs compared to monofocal IOLs in VA patients, using contemporary IOLs.

CONCLUSIONS

Multifocal IOLs compared to monofocal IOLs produce better uncorrected near vision and a greater proportion of patients who are spectacle-independent, but are associated with worse contrast sensitivity and a greater risk of glare and halos. Current evidence is insufficient to reach conclusions about resource requirements and other outcomes such as additional enhancements or IOL exchange.

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