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 <u>Nicole.Floyd@va.gov</u>.

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ABSTRACT

INTRODUCTION

The comparative effectiveness of multifocal, accommodative, and monofocal intraocular lenses for cataract surgery and lens replacement remains unclear. This review was requested to assess the evidence.

Key Questions

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?

METHODS

DATA SOURCES AND SEARCHES

We conducted searches in PubMed from 1/1/2006 to 4/30/2017.

STUDY SELECTION

Studies were included if they were randomized trials of a US FDA-approved lens that was either multifocal or accommodative and compared to standard monofocal IOLs (or monovision) in the setting of adult cataract extraction and reported visual acuity outcomes, spectacle independence, or visual function/quality of life.

DATA SYNTHESIS AND ANALYSIS

Data extraction was completed in duplicate, and included: 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.

RESULTS

RESULTS OF LITERATURE SEARCH

Our literature searches and reference mining identified 760 potentially relevant citations, of which 93 abstracts were included and obtained as full-text publications. Twelve publications provided some insight into the comparative effectiveness of multifocal, accommodative, and



monofocal intraocular lenses for cataract surgery and lens replacement, and are included in our final sample.

SUMMARY OF RESULTS FOR KEY QUESTIONS

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 accuracy, reading 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. The 2 studies comparing multifocal IOLs to monovision 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; 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 postoperative 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.

DISCUSSION

KEY FINDINGS AND STRENGTH OF EVIDENCE

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. Data are very limited about accommodative IOLs, consisting of only 1 RCT.

APPLICABILITY

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

RESEARCH GAPS/FUTURE RESEARCH

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

ABBREVIATIONS

Accommodative amplitude
Anterior chamber depth
Best corrected distance visual acuity
Best corrected intermediate visual acuity
Best corrected near visual acuity
Best corrected visual acuity
Corrected distance visual acuity
6 cycles per degree
Distance-corrected near visual acuity
Grading of Recommendations Assessment, Development and Evaluation
Intraocular Cataract Lenses
Laser-assisted in situ keratomileusis
Logarithm of the Minimum Angle of Resolution
Mean Difference
Multifocal Intraocular Lens
Modulation transfer function
Near-distance refractive addition
Near visual acuity
Root mean square

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RMS4	Root mean square four
RMSh	RMS high order
RR	Risk Ratio
SCPA	Sclerociliary process angle
SMD	Standardized effective size
TEP	Technical Expert Panel
UCNVA	Uncorrected near visual acuity
UDVA	Uncorrected distance visual acuity
UIVA	Uncorrected intermediate visual acuity
UNVA	Uncorrected near visual acuity
VF7	Visual function index (shortened)
VF11R	Rasch-modified National Eye Institute Visual Function questionnaire
VF14	Visual function index