

Evidence-based Synthesis Program (ESP)

Benefits and Harms of Femtosecond Laser Assisted Cataract Surgery

A Systematic Review of the Evidence

VA Evidence-based Synthesis Program
Portland VA Medical Center
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VA Evidence-based Synthesis (ESP) Program Overview

- Sponsored by VA Quality Enhancement Research Initiative (QUERI) Program.
- Established to provide timely and accurate syntheses/reviews of healthcare topics identified by VA clinicians, managers and policy-makers, as they work to improve the health and healthcare of Veterans.
- Builds on staff and expertise already in place at the Evidence-based Practice Centers (EPC) designated by AHRQ. Four of these EPCs are also ESP Centers:
 - Durham VA Medical Center; VA Greater Los Angeles Health Care System; Portland VA Medical Center; and Minneapolis VA Medical Center.

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- **Provides evidence syntheses on important clinical practice topics relevant to Veterans, and these reports help:**
 - develop clinical policies informed by evidence,
 - the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
 - guide the direction for future research to address gaps in clinical knowledge.
- **Broad topic nomination process – e.g. VACO, VISNs, field – facilitated by ESP Coordinating Center (Portland) through online process:**

<http://www.hsrd.research.va.gov/publications/esp/TopicNomination.cfm>

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- **Steering Committee** representing research and operations (PCS, OQP, ONS, and VISN) provides oversight and guides program direction.
- **Technical Expert Panel (TEP)**
 - Recruited for each topic to provide content expertise.
 - Guides topic development; refines the key questions.
 - Reviews data/draft report.
- **External Peer Reviewers & Policy Partners**
 - Reviews and comments on draft report
- **Final reports posted on VA HSR&D website and disseminated widely through the VA.**

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

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Current Report

Benefits and Harms of Femtosecond Laser Assisted Cataract Surgery (FLACS): A Systematic Review (December 2013)

Full-length report available on the ESP website:

<http://www.hsrd.research.va.gov/publications/esp/femtosecond.cfm>

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Overview of Today's Presentation

- **Background**
- **Scope of the review**
- **Results**
- **Limitations**
- **Future research**
- **Implications - panel discussion**

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Background

- Current preferred method of removing cataracts includes creating manual corneal incisions and anterior capsulotomies, followed by phacoemulsification.
- Recently these three manual procedures have been performed in an automated fashion with the use of the femtosecond laser (FSL).
- Studies have suggested decreased phacoemulsification energy use with FSL cataract surgery and have examined the potential advantages of more precise corneal incisions and capsulotomy formation.

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Background

- Cataract surgery is frequently performed in the VHA: more than 49,000 performed in 2012.
- The VHA National Surgery Office has been tasked with making a recommendation on whether femtosecond lasers provide appropriate cost-benefit and risk-benefit ratios to support implementation for cataract surgery in the VA.
- The purpose of this systematic review is to examine the effectiveness and safety of femtosecond laser assisted cataract surgery (FLACS) relative to conventional cataract surgery.

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Scope of the Review: Key Questions

- **Key Question 1:** What is the evidence that FLACS is associated with better outcomes than conventional cataract surgery?
- **Key Question 2:**
 - a) What are the adverse effects that have been reported for FLACS?
 - b) What is the risk of adverse effects from FLACS compared to the risk associated with conventional cataract surgery?
- **Key Question 3:** What is the evidence that the experience of the surgeon is associated with adverse effects of FLACS?

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Scope of the Review: Inclusion Criteria

Patients: Adults undergoing cataract surgery.

Intervention: FSL technology used to assist or replace aspects of conventional cataract surgery, including corneal incisions, capsulotomy, and lens fragmentation.

Comparator: Conventional cataract surgery, defined as small-incision, phacoemulsification with posterior-chamber intraocular lenses (IOL) implantation.

Outcomes:

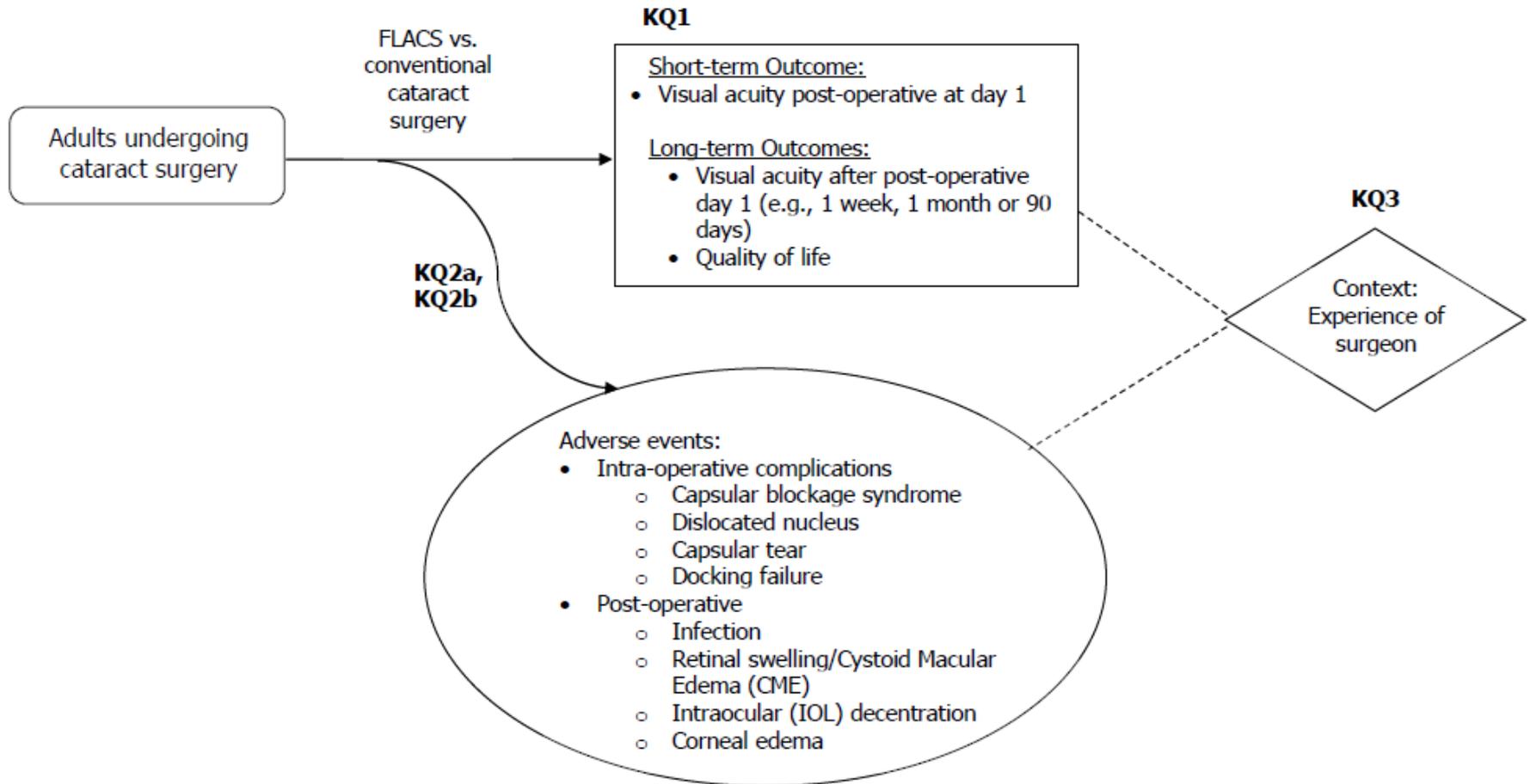
- Visual acuity, short-term (post-op day 1) and long-term (after postop day 1, no upper limit)
- Quality of life
- Harms

Study design:

- Controlled trials – randomized or non-randomized
- Observational studies comparing FLACS to conventional cataract surgery

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Scope of the Review: Analytic Framework



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Scope of the Review: Exclusions

- Non-English language
- Non-adult study population
- No primary data (e.g., editorials) or non-systematic review article
- Outcomes not in scope (e.g., ex-vivo studies)

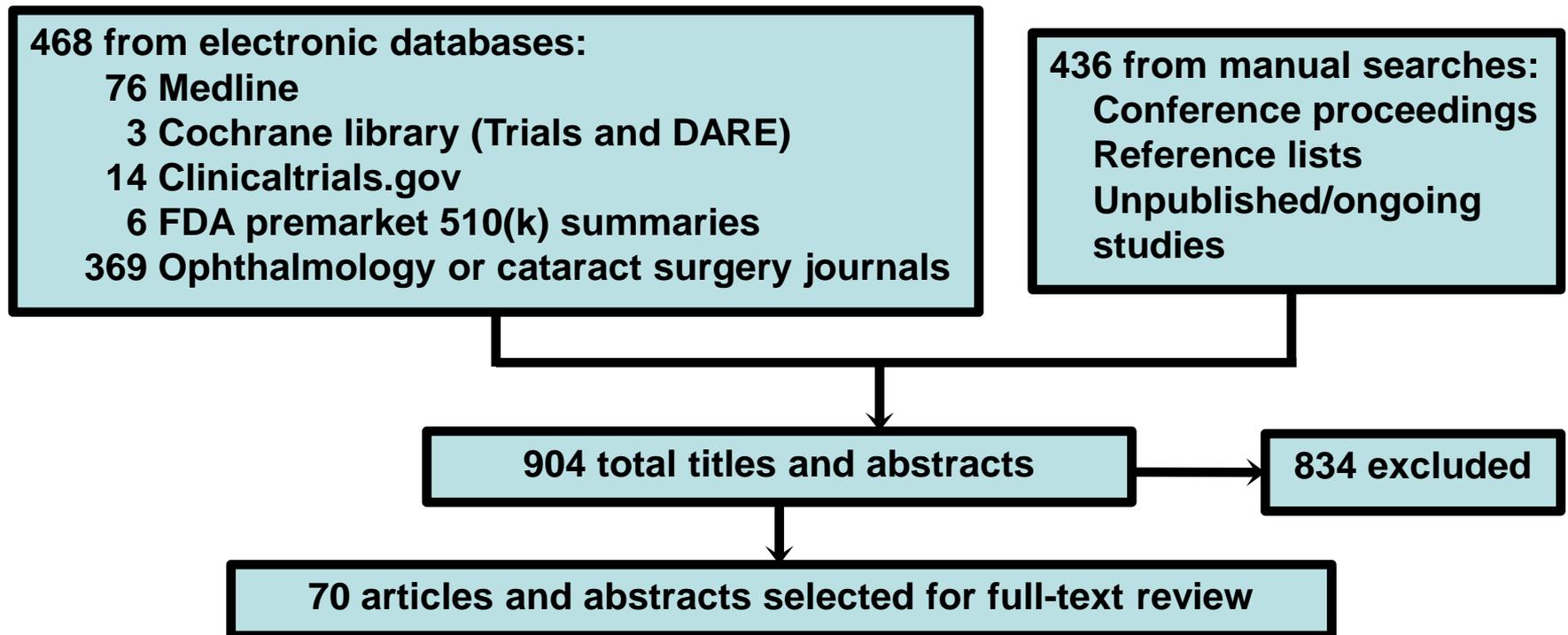
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Methods

- **Search of databases (May 2013, updated October 2013)**
 - MEDLINE
 - Cochrane library Database of Systematic Reviews and Central Register of Controlled Trials
 - Clinicaltrials.gov
 - FDA premarket notification 510(k) summaries
 - Conference proceedings of ophthalmologic societies and topic specific journals
 - Additional articles and reviews obtained from reference lists and reviewers
- **Data abstraction**
- **Assessment of study quality**
- **Review of evidence: qualitative synthesis and meta-analysis**

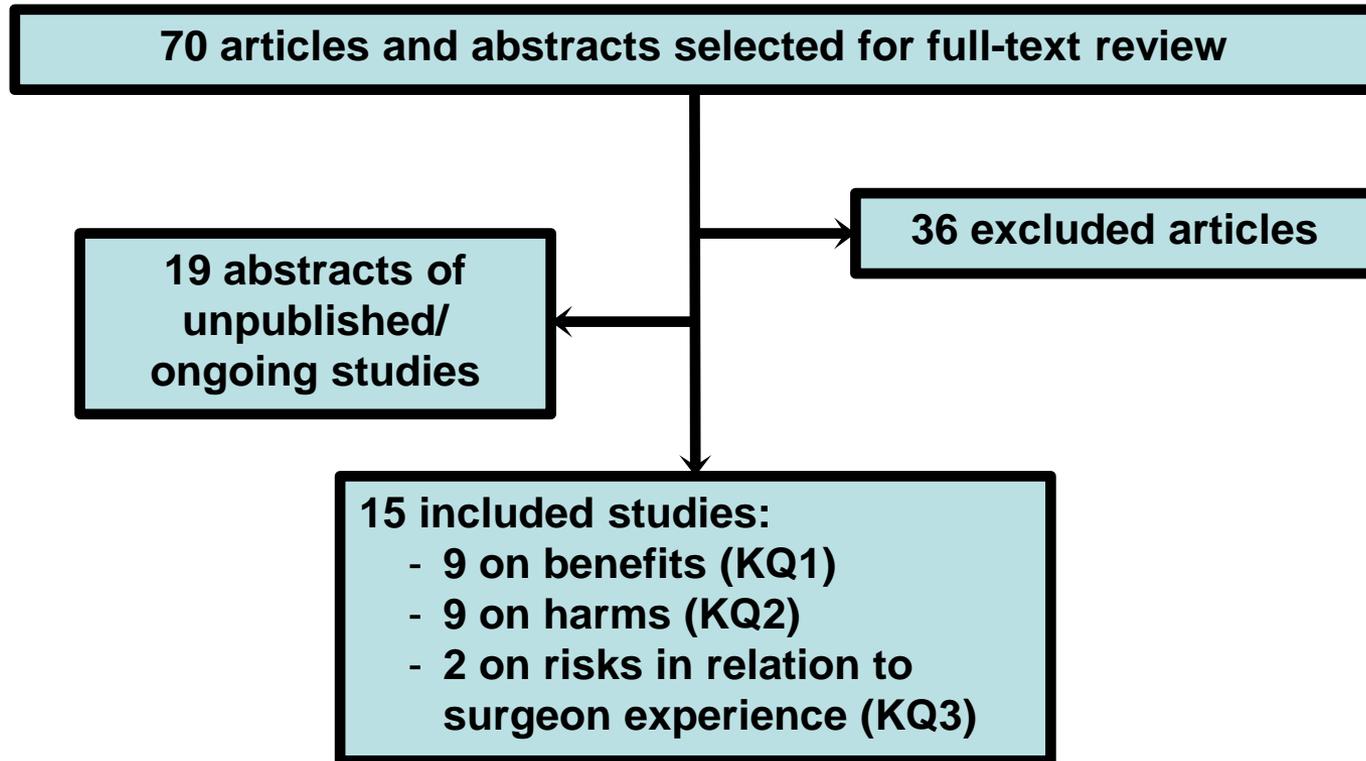
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Results: Search Yield



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Results: Search Yield, continued



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Poll Question (Pick one answer)

What best describes your professional training?

1. **Ophthalmologist**
2. **Optometrist**
3. **Researcher**
4. **Other**

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**Poll Question (Practicing ophthalmologists
pick one answer)**

**What best describes your experience with
FLACS?**

- 1. Practicing ophthalmologist with FLACS experience**
- 2. Practicing ophthalmologist planning to perform FLACS in the future**
- 3. Practicing ophthalmologist not planning to perform FLACS in the future**

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Results: Key Question 1

What is the evidence that FLACS is associated with better outcomes than conventional cataract surgery?

- Visual outcomes (CDVA) were similar between groups
- EPT outcomes were mixed; results were either comparable between groups, or favoring FSL groups
- Meta-analysis of CDVA and EPT outcomes noted heterogeneity precluding calculation of reliable summary effect estimate
- No studies addressed quality of life measures

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Results: Forest Plot of CDVA Studies

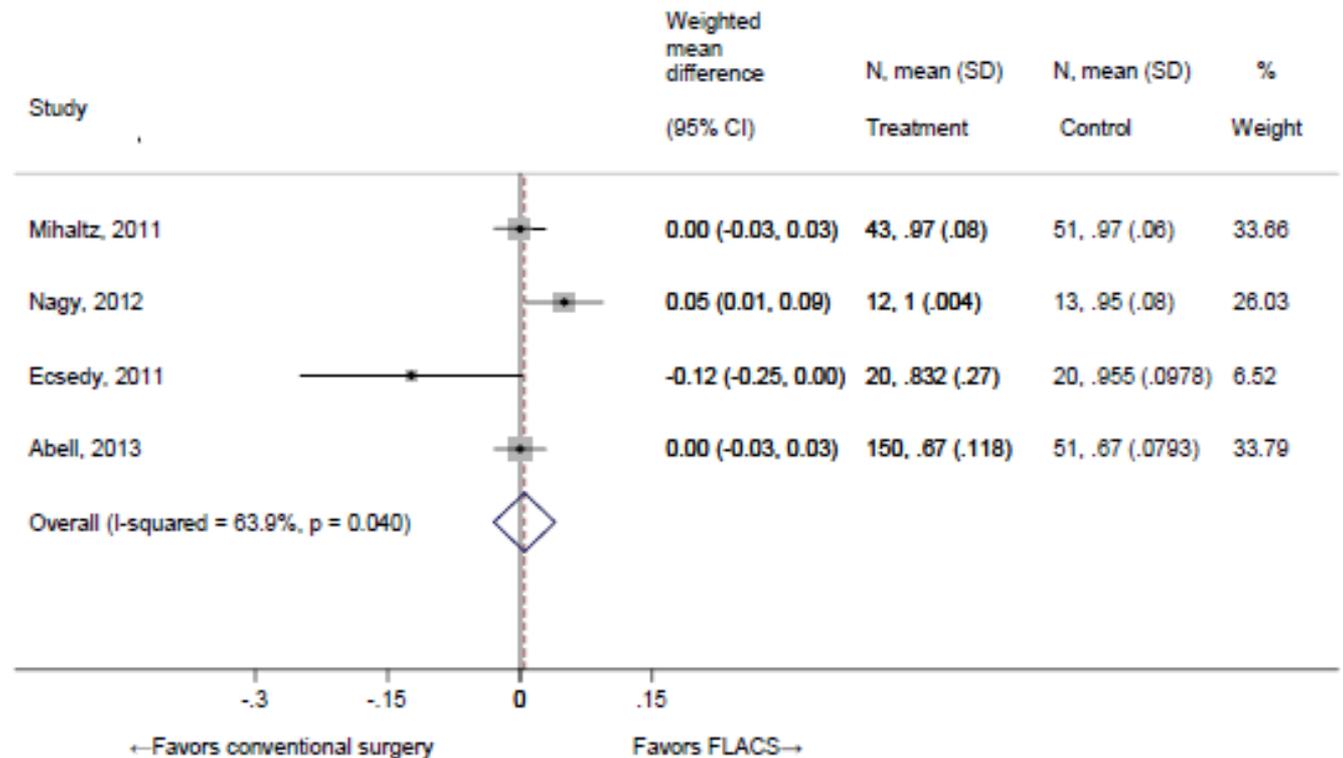
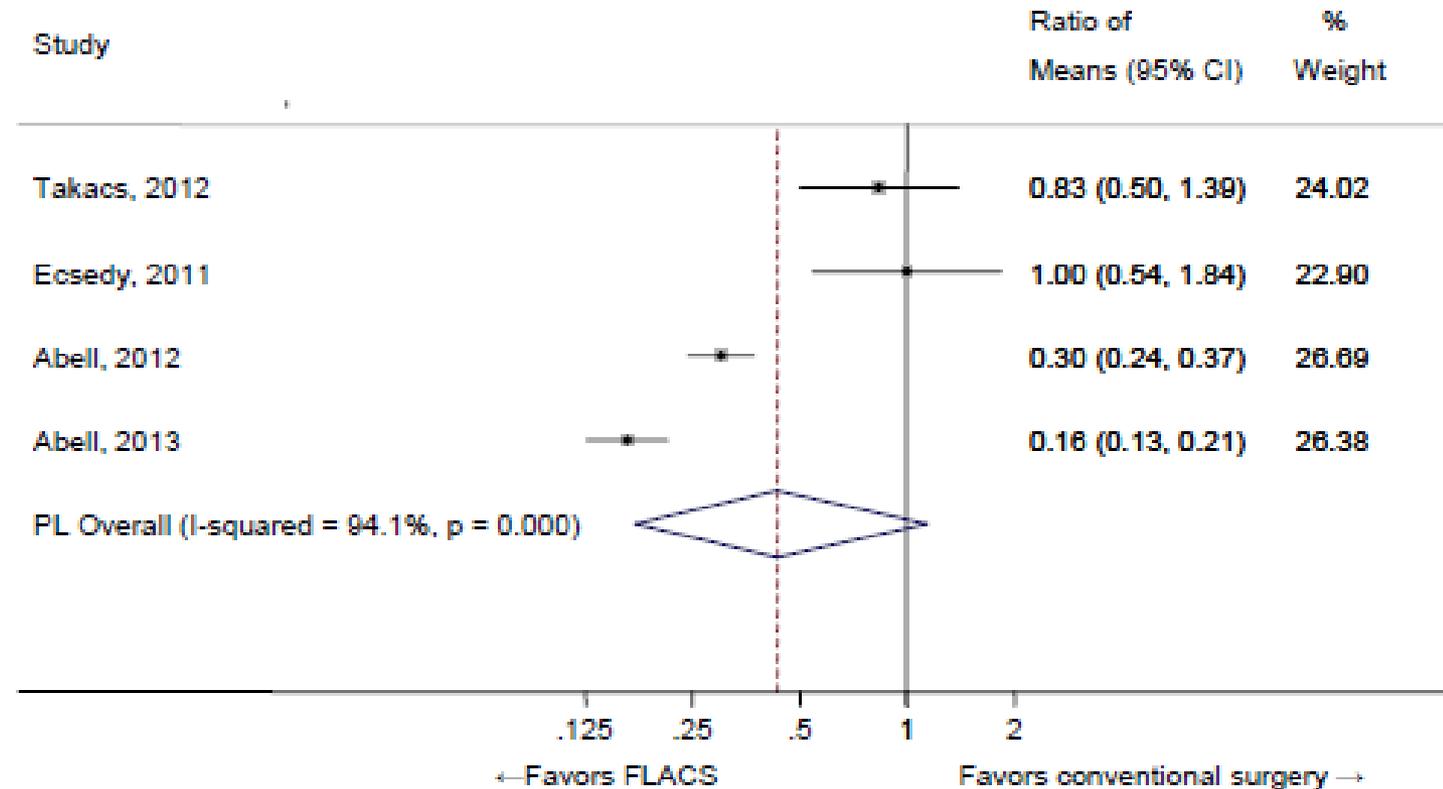


Figure 1. Corrected distance visual acuity in studies comparing FLACS with conventional cataract surgery

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Results: Forest Plot of EPT Studies

Figure 2.
 Effective phacoemulsification time in studies comparing FLACS with conventional cataract surgery



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Results: Key Question 2a

What are the adverse effects that have been reported for FLACS?

- Laser interface events
 - Several studies noted significant numbers of patients required a second docking attempt without adverse effects
 - Patients with corneal scarring or distortion, kyphosis, claustrophobia, and excessive movements were excluded from Laser treatment groups

- Intraocular pressure events (IOP)
 - All FSL docking platforms have been shown to cause increases in IOP; a concern for patients with coexistent glaucoma
 - Two studies of IOP effects were included in this review which used only the Catalys FSL platform
 - One case series (N=100) noted mean IOP increased to 27.6±5.5mm Hg
 - Another case series (N=25) noted mean IOP increased to 36.0±4.4 mm Hg

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Results: Key Question 2b

What is the risk of adverse effects from FLACS compared to the risk associated with conventional cataract surgery?

- Comparative risks noted similar findings for post-operative corneal edema, macular thickness and morphology
- Methodological concerns were noted for these comparative results as enrollment criteria varied between conventional and FSL surgery groups

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Results: Key Question 3

What is the evidence that the experience of the surgeon is associated with adverse effects of FLACS?

- Overall findings were mixed in studies comparing initial to subsequent groups of patients undergoing FLACS
- One study noted surgeons who had “extensive” refractive surgery experience had fewer complications in their initial FLACS patient groups than did surgeons without previous refractive surgery experience
- Methodological concerns were noted in enrollment criteria used for the FSL versus conventional surgery groups

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Limitations of the evidence

- **Methodological concerns**
 - Small sample sizes
 - Selected samples excluded patients unsuitable for FLACS, e.g.,
 - Patients with dense cataracts
 - Orbital anatomy incompatible with successful laser docking
- **Conflicts of interest**
 - Same team replication
 - Most studies funded by industry

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Summary of the evidence: benefits

Outcome	N studies (combined sample size)	Findings	Strength of Evidence	Comments
Visual acuity	2 RCTs (N=189) 4 NRCS (N=306)	No significant differences	Low	No differences found in the randomized trials. Unclear risk of bias for trials. Low consistency, coherence, and applicability of estimated effects across studies, small to medium sample sizes, and conflicts of interest.
Effective phaco-emulsif. time	1 RCT (N=76) 4 NRCS (N=615) 1 NCS (N=160)	Mixed findings	Low	Trial found no significant reduction in EPT with FSL. Two large nonrandomized studies (N=550) reported significant reductions with FLACS. No significant differences in other studies. Unclear risk of bias for trial. Low consistency, coherence, and applicability of estimated effects across studies. Conflicts of interest.
Quality of life	None	None	No evidence	None of the included studies reported on quality of life outcomes.

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Summary of the evidence: harms

Outcome	N studies (combined sample size)	Findings	Strength of Evidence	Comments
Intraoperative complications	3 NRCS (N=1,900) 3 NCS (N=285)	Higher IOP for FLACS; Few additional complications for FLACS	Moderate to Low	Low incidence of complications with FLACS, though increases in IOP reported across studies. Low applicability of estimated effects.
Postoperative complications	1 RCT (N=76) 1 NRCS (N=150) 1 NCS (N=160)	Mixed findings	Low	Trial found no significant differences. Cohort study (N=150) found significantly reduced endothelial loss with FLACS. Unclear risk of bias for trial. Low consistency and coherence of estimated effects across studies, small to medium sample sizes. Conflicts of interest.
Costs	None	None	No evidence	No studies reported data on costs of FLACS compared to conventional cataract surgery.

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Future Research Suggestions

- RCTs with larger sample sizes to detect rare events
- Applicability of FSL technology to patients with dense cataracts, glaucoma, and corneal pathology
- Head to head trials between FSL platforms
- Cost-benefit ratio

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Questions?

**If you have further questions,
feel free to contact:**

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The full report and cyber seminar presentation is available on the ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>

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Panel Discussion