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Authors

Lin, Charles C
Rose-Nussbaumer, Jennifer R
Al-Mohtaseb, Zaina N
et al.

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Femtosecond Laser-Assisted Cataract Surgery:

A Report by the American Academy of Ophthalmology

Charles C. Lin, MD[1], **Jennifer R. Rose-Nussbaumer, MD**[1,2], **Zaina N. Al-Mohtaseb, MD**[3], **Seth M. Pantanelli, MD, MS**[4], **Walter Allan Steigleman III, MD**[5], **Kathryn M. Hatch, MD**[6], **Marcony R. Santhiago, MD**[7], **Stephen J. Kim, MD**[8], **Julie M. Schallhorn, MD**[9]

[1]Department of Ophthalmology, Byers Eye Institute, Stanford University, Stanford, California

[2]Francis I. Proctor Foundation, University of California, San Francisco

[3]Department of Ophthalmology, Baylor College of Medicine, Houston, Texas

[4]Department of Ophthalmology, Penn State College of Medicine, Hershey, Pennsylvania

[5]Department of Ophthalmology, University of Florida College of Medicine, Gainesville, Florida

[6]Department of Ophthalmology, Massachusetts Eye and Ear, Boston, Massachusetts

[7]Department of Ophthalmology, University of Sao Paulo, Sao Paulo, Brazil

[8]Department of Ophthalmology, Vanderbilt University School of Medicine, Nashville, Tennessee

[9]Department of Ophthalmology, University of California, San Francisco, California

Abstract

Purpose: To evaluate refractive outcomes, safety, and cost-effectiveness of femtosecond laser-assisted cataract surgery (FLACS) compared with phacoemulsification cataract surgery (PCS).

Methods: A PubMed search of FLACS was conducted in August 2020. A total of 727 abstracts were reviewed and 33 were selected for full-text review. Twelve articles met inclusion criteria and were included in this assessment. The panel methodologist assigned a level of evidence rating of I to all 12 studies.

Results: No significant differences were found in mean uncorrected distance visual acuity, best-corrected distance visual acuity, or the percentage of eyes within ± 0.5 and ± 1 diopter of intended refractive target between FLACS and PCS. Intraoperative and postoperative complication rates were similar between the 2 groups, and most studies showed no difference in endothelial cell loss between FLACS and PCS at various time points between 1 and 6 months. In large randomized controlled studies in the United Kingdom and France, FLACS was less cost-effective than PCS.

Correspondence: Andre Ambrus, MLIS, American Academy of Ophthalmology, Quality and Data Science, P. O. Box 7424, San Francisco, CA 94120-7424. aambrus@aao.org.

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Conclusions: Both FLACS and PCS have similar excellent safety and refractive outcomes. At this time, one technique is not superior to the other, but economic analyses performed in some populations have shown that FLACS is less cost-effective.

Ophthalmic Technology Assessments (OTAs) published by the American Academy of Ophthalmology evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an OTA is to review the available research systematically for clinical efficacy, effectiveness, and safety. After appropriate review by all contributors, including legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this assessment by the Ophthalmic Technology Assessment Committee Refractive Management/Intervention Panel is to review the published literature on the refractive outcomes, safety profile, and cost-effectiveness of femtosecond laser-assisted cataract surgery (FLACS) compared with conventional phacoemulsification cataract surgery (PCS).

Background

Femtosecond laser-assisted cataract surgery is a technology introduced in 2011[1] in which several steps of cataract surgery can be performed by a femtosecond laser, including creation of corneal wounds and capsulorrhexis, nuclear fragmentation, and corneal relaxing incisions. Ophthalmologists have debated the advantages and shortcomings of FLACS since it was introduced. Compared with PCS, FLACS has been shown to produce a precisely circular, centered capsulotomy[1] and to reduce the amount of ultrasound energy delivered within the eye during phacoemulsification.[2]

However, in several meta-analyses, these benefits have not translated into improved refractive outcomes or reduced complications.[3,4] In addition, additional costs are associated with FLACS as compared with PCS. Most payors in the United States market have not expanded their policies to cover FLACS, and its cost-effectiveness from a public health perspective is uncertain. A Cochrane review of FLACS in 2016 found unclear or high risk of bias in the 16 randomized controlled trials (RCTs) reviewed, leading to the conclusion that large, adequately powered, well-designed, independent RCTs comparing the safety and efficacy of FLACS with that of PCS are needed.[5]

Lingering questions remain for ophthalmologists regarding the efficacy and cost-effectiveness of FLACS, in turn affecting practice patterns. Since the Cochrane review in 2016,[5] several rigorously conducted RCTs have been published with short- and long-term follow-up, making this an opportune time to revisit the data.

Questions for Assessment

The objective of this assessment was to address the following questions: (1) Are refractive outcomes for FLACS superior to those for PCS? (2) Does FLACS offer an improved safety profile compared with PCS? and (3) Is FLACS cost-effective compared with PCS?

Description of Evidence

A PubMed literature search of FLACS was conducted in August 2020. The search strategy used the following terms: (*femtosecond*[tiab]) OR *femtosecond laser assisted*[tiab]), ((*cataract*[tiab] AND *surgery*[tiab]) OR (*cataract extraction* [mh] OR *cataract*[tiab])), ((*femcat*) OR (*femtosecond laser assisted cataract*[tiab] OR *femtosecond laser assisted cataract surgery*[tiab] OR *femtosecond laser assisted cataract surgery flacs*[tiab] OR *flacs*[tiab])), searching for MeSH keywords (mh) and free text in the title and abstract (tiab). This search resulted in 727 citations that were reviewed in abstract form, of which 33 articles were selected for full-text review. Of these, 16 articles met the following inclusion criteria: (1) RCT comparing FLACS and PCS and (2) primary objective of the study was to compare refractive or safety outcomes between FLACS and PCS. Meta-analyses of primary literature were excluded.

For cataract surgery, refractive outcome and safety are inextricably linked, but are 2 distinctly separate topics with regard to data analysis. Studies that are powered to analyze safety metrics may not be powered sufficiently to detect differences in visual acuity. Thus, addressing the separate topics of refractive outcome and safety profile required different sample size criteria for study inclusion in this OTA.

Studies with refractive outcome data were included if they had a minimum sample size of 322, which provides 80% power to detect a 0.1 difference in logarithm of the minimum angle of resolution (logMAR) visual acuity (5 letters) between FLACS and PCS, assuming a 2-tailed α value of 0.05 and a standard deviation of 0.32 logMAR. This standard deviation is from the British Royal College of Ophthalmologists' National Ophthalmic Database uncorrected distance visual acuity[6] and was used for sample size calculations for 2 of the 3 largest RCTs comparing FLACS and PCS.[7–10]

Among the potential safety benefits of FLACS, reduced phacoemulsification energy, time, and endothelial cell loss are the most compelling. Because the primary goal of reducing phacoemulsification energy and time is to minimize endothelial cell loss, the latter is the most clinically relevant metric, and in fact the focus of most studies. Thus, sample size determination for inclusion of studies with safety data was calculated to ensure sufficient power for endothelial cell loss analysis. From Bascaran et al,[11] based on an estimated preoperative cell density of 2300 cells/mm^2, a 5% difference between groups with mean postoperative cell counts of 2200 cells/mm^2 in FLACS and 2100 cells/mm^2 in PCS and a standard deviation of 200 cells/mm^2, a sample size of 126 would achieve 80% power using a 2-tailed analysis at a 5% significance level.

After applying sample size criteria, a total of 10 RCTs were included in this OTA. In 2 of these RCTs, short-term and long-term data were presented in separate publications, so 12 total publications were analyzed. Three of these RCTs were included for the refractive outcome analysis, and 8 of these RCTs were included for the safety profile analysis. Two of the RCTs were included in both the refractive outcome and safety profile analyses. The panel's methodologist (J.R.N.) assessed the quality of the 12 studies using the American Academy of Ophthalmology's guidelines, which are based on the 2011 level of evidence rating developed by the Oxford Centre for Evidence-Based Medicine.[12] Randomized controlled trials and systematic reviews are deemed level I evidence. Cohort studies and nonrandomized controlled cohort or follow-up trials are graded as level II evidence. Case series and case-control studies and reports based on inferences are rated as level III evidence. All 12 articles were assigned a level I rating.

Published Results

Listed chronologically in Table 1, the 12 studies analyzed in this OTA represent 10 distinct RCTs. Two of these RCTs, the Femtosecond laser assisted Cataract Trial (FACT) FACT[7,10] and the St. Thomas study,[8,9] report short- and long-term results separately in 2 different articles. Two articles were published by Conrad-Hengerer et al,[2,13] but the authors did not specify whether these were separate or overlapping study populations.

Given the sample size considerations as discussed previously, refractive outcomes data were abstracted from the 3 largest RCTs: Femtosecond laser-assisted versus phacoemulsification cataract trial (FEMCAT)[14] (a 5-site multicenter RCT from France), FACT[7,10] (a 3-site multicenter RCT from the United Kingdom), and the St. Thomas study[8,9] (a single-center RCT from the United Kingdom). Table 2 presents short-term (1—3 months) and long-term (1 year) mean uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA). In all 3 studies, no statistically significant difference was found in any of these measures between FLACS and PCS. In FEMCAT,[14] the largest trial with 907 patients, mean short-term UCDVA and BCDVA were nearly identical for the 2 groups, 0.14 logMAR and 0.02 logMAR, respectively, for FLACS and 0.13 logMAR and 0.02 logMAR, respectively, for PCS. These findings were confirmed with similar results in the FACT[7] and St. Thomas[8,9] studies. Similarly, long-term (1 year) mean UCDVA and BCDVA reported by the FACT[10] and St. Thomas[8,9] studies showed no difference between FLACS and PCS.

The proportions of eyes within ± 0.5 and ± 1 diopter (D) of refractive target from the FEMCAT,[14] FACT,[7] and St. Thomas[8,9] studies were very similar and are presented in Figure 1. No difference was found in the proportion of eyes achieving these refractive targets between the FLACS and PCS groups in any of these trials at any of the short- or long-term time points. Between 1 and 3 months, 67% to 75% of FLACS eyes and 71% to 75% of PCS eyes were within 0.5 D of intended refractive target. An even tighter range of the percentage of eyes within 1 D of refractive target was found, with 91% to 93% of FLACS eyes and 92% to 94% of PCS eyes achieving this target between 1 and 3 months. One-year data from the FACT[10] and St. Thomas[8,9] studies showed nearly identical results between the FLACS and PCS groups.

Among the 12 articles presenting safety information, data were presented heterogeneously in a mostly descriptive fashion. Two trials included significantly larger samples sizes (785 eyes in FACT[7] and 400 eyes in St. Thomas[8]) than the other studies,[2,11,13,15–18] where the sample sizes ranged between 134 and 202 eyes. Because complications from cataract surgery are infrequent, the studies were not sufficiently powered to analyze them with the exception of endothelial cell loss, which was the most commonly evaluated metric. Endothelial cell density or loss was abstracted from 8 articles and is presented in Figure 2. In 6 of 8 studies, no difference was reported in endothelial cell loss between FLACS and PCS at various time points between 1 and 6 months. This included the St. Thomas study,[8] in which endothelial cell loss was reported to be 10.7% in FLACS eyes and 9.7% in PCS eyes at 1 month. In the FACT study,[7] while not statistically significant there was a trend toward less endothelial cell loss in PCS eyes (7.68%) compared with FLACS eyes (9.17%) at 3 months ($P = 0.06$). A statistically significant difference in endothelial cell loss favoring FLACS.

Intraoperative and postoperative complications such as anterior capsular abnormalities, zonular dialysis, vitreous loss, anterior uveitis, corneal edema, and endophthalmitis were rare. Although the studies were not powered to evaluate these complications, no significant differences were reported between FLACS and PCS. The St. Thomas trial[9] was the only one to report a statistically significant higher rate of posterior capsular rupture in PCS eyes (3%) compared with FLACS eyes (0%). Several studies reported advantageous phacoemulsification parameters for FLACS, including reduced ultrasound energy time and cumulative dissipated energy,[2,11,17] whereas other studies reported unfavorable intraoperative characteristics for FLACS such as increased volume of balanced salt solution and additional time for cortical removal.[15,16]

Economic analyses were performed in 2 trials, FEMCAT[14] and FACT,[10] and concluded that FLACS was not cost-effective in health care systems in France and the United Kingdom, respectively. FEMCAT was the only trial to include a primary economic end point in its original study design and found an incremental cost-effectiveness ratio of €10 703 saved per additional patient who showed treatment success with PCS compared with FLACS in France.[14] In all sensitivity analyses, FLACS was more expensive and less cost-effective than PCS. In the neighboring British health care system, an incremental cost-effectiveness ratio of £167 620 per additional patient undergoing FLACS with treatment success compared with those undergoing PCS was calculated in FACT, which concluded that FLACS was not cost-effective.[10]

Discussion

The 2016 Cochrane review of FLACS concluded that not enough evidence existed to determine equivalence or superiority of FLACS compared with PCS, leading the authors to emphasize the need for well-designed, adequately powered RCTs.[5] A substantial number of recently published RCTs subsequently have been reported in the literature and are reviewed here.

The 10 RCTs included in this OTA represent a broad spectrum of patients, surgeon experience, practice environment, and technology, strengthening the generalizability of the conclusions reached in this assessment. These RCTs were conducted in a range of countries (Germany, Spain, Denmark, India, France, the United Kingdom, and the United States), diverse practice settings (private practice, academic centers, and government public hospitals), and among surgeons with various levels of training (ophthalmology residents, beginning FLACS surgeons, and experienced, high-volume FLACS surgeons). In addition, all 5 of the currently commercially available FLACS platforms were represented:

Catalys (Johnson & Johnson), Femto LDV Z8 (Ziemer Ophthalmic Systems AG), LensAR (LensAR), LenSx (Alcon Laboratories, Inc.), and Victus (Bausch & Lomb).

In reviewing these RCTs, this OTA answers the 3 fundamental questions regarding FLACS as outlined below.

Are Refractive Outcomes for Femtosecond Laser-Assisted Cataract Surgery Superior to Those for Phacoemulsification Cataract Surgery?

Results from the well-designed FEMCAT, FACT, and St. Thomas studies, the 3 RCTs adequately powered to evaluate refractive outcomes, provide compelling evidence that no difference exists in these outcomes between FLACS and PCS.[7–10,14] Best-corrected distance visual acuity for FLACS and PCS spanning the postoperative period from 3 months to 1 year were remarkably similar in FACT and FEMCAT, with a narrow range from 0.02 logMAR to −0.01 logMAR (Table 2), equivalent to 20/20 on the Snellen chart.[7,10,14] As a proxy for BCDVA, pinhole acuity of 0.04 logMAR at 1 month was reported in the St. Thomas study,[8] in line with FACT and FEMCAT.

Although FLACS has the ability to achieve a perfectly centered and sized capsulotomy, whether this translates to a more reliable effective lens position remains an intriguing question. One way to explore this issue is by evaluating UCDVA. In all 3 studies, minimal (0.03 logMAR) to no difference in mean UCDVA was found between FLACS and PCS eyes at any time point. In fact, spanning the postoperative period from 1 month to 1 year, mean UCDVA in FLACS and PCS eyes was remarkably similar, with a tight range from 0.12 to 0.17 logMAR, equivalent to 20/25 to 20/30 on the Snellen chart.[7–10,14] Another approach to answering this question is to analyze the proportion of eyes achieving a spherical equivalent within ± 0.5 D and ± 1 D of the refractive target. As shown in Figure 1, the proportions of patients achieving these targets in all 3 studies were nearly identical between FLACS and PCS groups. Taken together, these data indicate that FLACS does not achieve greater refractive accuracy compared with PCS, at least with monofocal intraocular lenses (IOLs), which were used in these 3 studies. A perfect femtosecond capsulotomy still has conceptual appeal, however, and may be advantageous with newer IOL technology not evaluated in the studies reviewed in this OTA, such as multifocal, extended depth-of-focus, and light-adjustable IOLs.

These 3 studies, FEMCAT, FACT, and St. Thomas, stand out from the others in this OTA because of their substantially larger sample sizes, which provide sufficient power to evaluate refractive outcomes.[7,8,10,14] Collectively, results from these 3 studies indicate clinical equivalency in that patients achieve excellent visual acuity and refractive accuracy with both FLACS and PCS, but one technique is not superior to the other.

Astigmatic correction influences UCDVA, but was not specifically addressed in the FACT, FEMCAT, or St. Thomas studies.[7–10,14] Of the 3 studies, toric IOLs were used only in the FACT study and accounted for only 6% and 5% of FLACS and PCS cases, respectively.[7,10] Monofocal IOLs were used otherwise in the studies. Femtosecond astigmatic keratotomy has been reported to be more accurate in astigmatic correction compared with manual limbal relaxing incisions, but very limited information was presented in these studies, thereby precluding any meaningful analysis. In the St. Thomas study,[8] eyes with more than 0.9 D of astigmatism were offered femtosecond paired astigmatic keratotomies (in FLACS) or manual limbal relaxing incisions (in PCS), but no astigmatism results were provided. The accuracy of femtosecond astigmatic keratotomy is an important topic in itself and outside the scope of this OTA.

Does Femtosecond Laser-Assisted Cataract Surgery Offer an Improved Safety Profile Compared with Phacoemulsification Cataract Surgery?

Assessment of the safety benefits of FLACS depends on which metric is being evaluated. Endothelial cell loss has been analyzed the most because of early evidence that FLACS can reduce the amount of phacoemulsification energy.[2] In 6 of the 8 studies that were powered sufficiently to analyze endothelial cell loss (Fig 2), no difference was reported between FLACS and PCS at any of the time points between 1 and 6 months, ranging from 6.4% to 11.2% in FLACS and from 6.33% to 9.85% in PCS.[7–9,11,15,16,18] In 2 studies,[2,17] a statistically significant higher endothelial cell loss was observed in the PCS group compared with the FLACS group, but in both studies, notably more phacoemulsification energy was used in the PCS group. This is likely because of the use of nuclear disassembly techniques that require higher ultrasound energy as a result of sculpting: stop and chop[2] and divide and conquer.[17] Conrad-Hengerer et al[2] found a positive correlation between effective phacoemulsification time and endothelial cell loss at 3 months. Similarly, Krarup et al[17] reported an increased cumulative dissipated energy of 9.77 units of cumulative dissipated energy (CED) in PCS versus 6.55 units of CED in FLACS, and this may underlie their report of a significantly higher endothelial cell loss at day 180 in the PCS group (17.03%) versus the FLACS group (13.56%; $P = 0.036$).

The mixed results from these 8 studies regarding endothelial cell loss provide some suggestion that the benefits of FLACS are dependent on surgeon and technique. Moreover, for mature cataracts that require more phacoemulsification energy, FLACS may result in less endothelial cell loss. None of the articles reviewed in this OTA specifically analyzed dense, brunescent cataracts.

Although none of the studies were powered specifically to evaluate corneal thickness, several of them provide postoperative corneal pachymetry at various time points. With the exception of 1 study reporting decreased corneal thickness among patients undergoing FLACS early in the postoperative course at day 1 and week 1,[18] no significant difference in pachymetry at any time point was found between the FLACS and PCS groups,[11,15] even in the study in which the difference in endothelial cell loss was greatest between FLACS (13.7%) and PCS (8.1%).[2] This can be accounted for by rapid corneal recovery resulting from abundant remaining endothelial cell reserve.

Several other intraoperative and postoperative complications were reported, including irregularities in anterior capsulotomy, vitreous loss, anterior uveitis, and macular edema.[7–9,11,13–15,18] No significant differences in any of these complications was observed in any of the studies, [7–9,11,13–15,18] but none of the studies were powered sufficiently to evaluate these rare adverse events. In the St. Thomas study,[7] the 3% rate of posterior capsular rupture in the PCS group was significantly higher compared with the 0% rate reported for the FLACS group, but falls within the reported range of 0% to 5% of posterior capsule rupture during phacoemulsification.[19,20] This difference was not observed in any other study, and the authors postulated that this finding may be related to the higher surgical complexity of cases in their study.[8]

Is Femtosecond Laser-Assisted Cataract Surgery Cost-effective Compared with Phacoemulsification Cataract Surgery?

In light of the lack of differences in refractive and safety outcomes between FLACS and PCS, as well as the additional cost of FLACS, both FEMCAT and FACT concluded that FLACS was not cost effective in the respective French and British health care systems in which they were carried out.[7,10,14] The cost-effectiveness analysis in FEMCAT deserves particular consideration because of its rigorous evaluation with a microcosting approach. This study, even with sensitivity analyses, showed that FLACS was not superior to PCS with regard to refractive outcomes and complication rates, but more expensive.[14] Prior research reached a similar conclusion in Australia.[21] Although recognizing that practice patterns are influenced by many considerations, it may be reasonable to extend these conclusions to the United States, where the cost of FLACS and health care delivery is similar, if not higher.

Limitations of this OTA include that a financial conflict of interest is common in the FLACS literature and was present in 3 of the articles included in this assessment (Table 1).[2,11,13] This potential source of bias was considered, but ultimately, results from these articles did not change any conclusions. Second, comparison of the safety profile of FLACS versus PCS was limited because the only complication for which studies were powered sufficiently to analyze was endothelial cell loss. Other complications such as posterior capsular tear, dropped lens, or vitreous loss were so infrequent that the studies were not powered sufficiently to address differences adequately. Nevertheless, complications from cataract surgery do occur rarely and a strong consensus was found among the RCTs reviewed that FLACS and PCS yield comparable results from a safety perspective. Third, despite all studies receiving a level of evidence of I, many of them have design shortcomings such as unmasked outcomes, no intention-to-treat analysis, and high loss to follow-up. In light of this, greater consideration was given to findings reported from the RCTs with more robust study design and statistical analyses. Finally, the potential benefit of increased refractive accuracy of femtosecond astigmatic keratotomy over manual limbal relaxing incisions was not evaluated because it was outside the scope of this OTA.

Conclusions

Excellent refractive outcomes were achieved after cataract surgery with both FLACS and PCS. In the included studies, no significant differences were found between FLACS and PCS with regard to UCDVA, BCDVA, or refractive accuracy as measured by the proportion of eyes within ± 0.5 D and ± 1.0 D of target. The rates of intraoperative and postoperative complications are similar between FLACS and PCS. In particular, most studies, including the most robustly powered RCTs, show no significant difference in endothelial cell loss between FLACS and PCS. From a health care economic perspective, FLACS was not shown to be cost-effective in studies conducted in 2 large European nations, a finding that may generalize to other countries with similar health care costs.

Future Research

Specific subsets of patients and surgeons may derive greater benefit from FLACS. In particular, FLACS may be helpful in complex cases, including in those with a history of trauma, zonulopathy, narrow angles, mature or intumescent cataracts, or Fuchs dystrophy, where minimizing endothelial cell loss takes on greater importance. Future research can focus on RCTs evaluating FLACS versus PCS in these groups. Finally, the potential beneficial impact of femtosecond technology to corneal astigmatism correction and refractive outcomes in newer IOL technology deserves further investigation.

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No animal subjects were included in this study.

Abbreviations and Acronyms:

BCDVA	best-corrected distance visual acuity
D	diopter
FLACS	femtosecond laser-assisted cataract surgery

IOL	intraocular lens
logMAR	logarithm of the minimum angle of resolution
OTA	Ophthalmic Technology Assessment
PCS	phacoemulsification cataract surgery
RCT	randomized controlled trial
UCDVA	uncorrected distance visual acuity.

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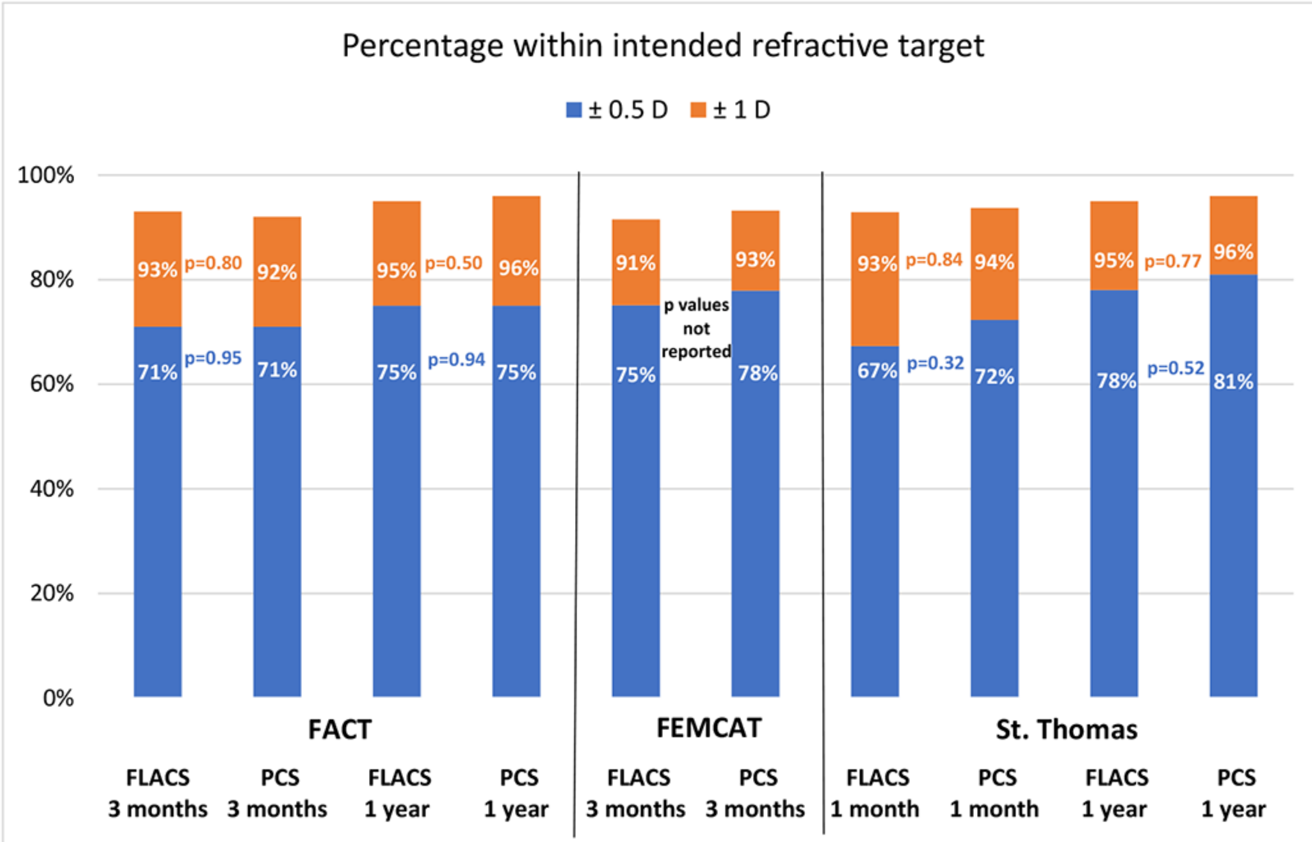

Figure 1.

Bar graph showing the proportion of eyes within ± 0.5 and ± 1.0 diopter (D) of intended short-term refractive target for femtosecond laser-assisted cataract surgery (FLACS) and phacoemulsification cataract surgery (PCS) in the Femtosecond Laser-Assisted Cataract Trial (FACT), Femtosecond Laser-Assisted versus phacoemulsification cataract surgery (FEMCAT), and St. Thomas studies.

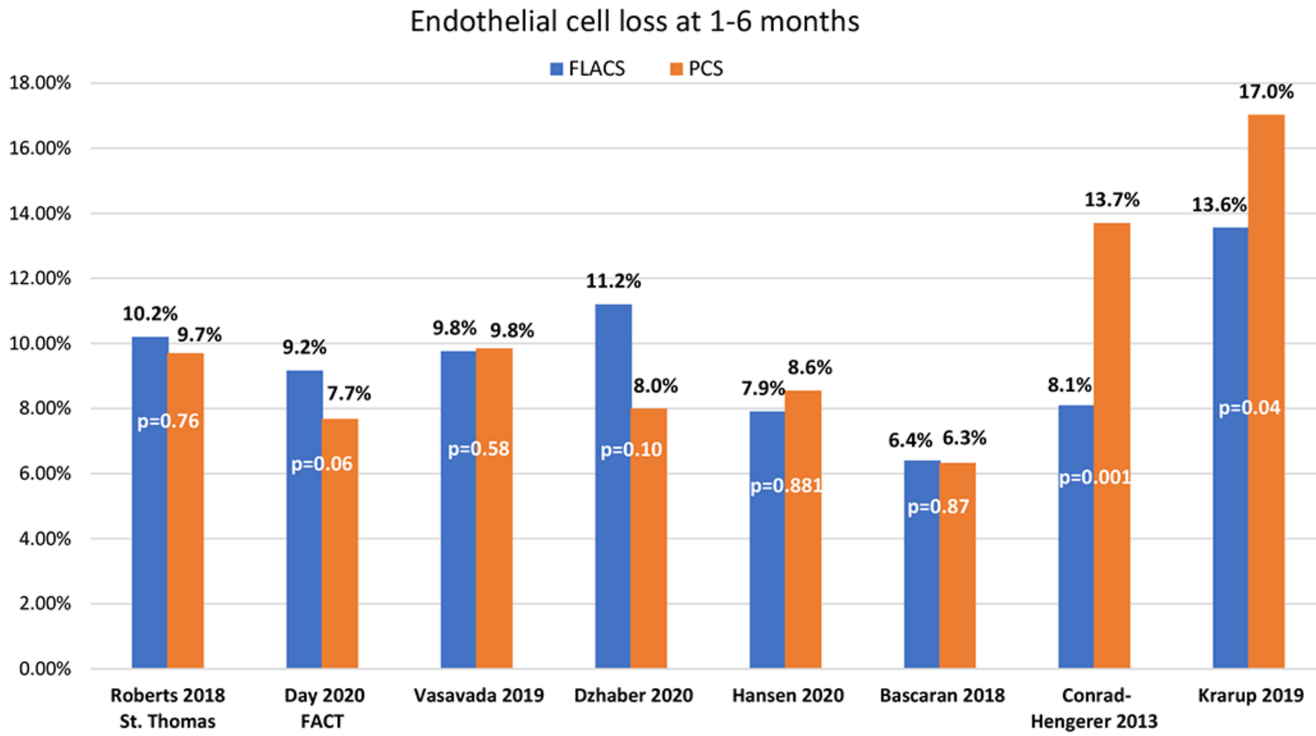

Figure 2.

Bar graph showing the endothelial cell loss (ECL) in femtosecond laser-assisted cataract surgery (FLACS) and phacoemulsification cataract surgery (PCS) at 1 to 6 months. When a study reports multiple ECL values at various time points, the earliest one is used.

Table 1.

List of Articles Included in the Assessment

Authors (Year)	Level of Evidence	Femtosecond Laser-Assisted Cataract Surgery Device	No. of Eyes: *Femtosecond Laser-Assisted Cataract Surgery*	No. of Eyes: *Phacoemulsification Cataract Surgery*	Outcome Category Specific Metrics	Study Design	Limitations
Conrad-Hengerer et al (2013)[2]	I	Catalys	73	73	Safety: Endothelial cell loss Corneal pachymetry	Single surgeon Germany Intraindividual RCT	Limited statistics description No power calculation Conflict of interest
Conrad-Hengerer et al (2014)[13]	I	Catalys	101	101	Safety: Macular edema	Single surgeon Germany Intraindividual RCT	Limited statistics description No power calculation Conflict of interest
Bascaran et al (2018)[11]	I	Victus	100	100	Safety: Endothelial cell density at 6 mos	Single surgeon Spain Intraindividual RCT	Conflict of interest
Krarup et al (2019)[17]	I	LensAR	96	96	Safety: Endothelial cell loss at days 40 and 180 Refractive predictability by mean absolute error	Single surgeon Denmark Intraindividual RCT	Outcome not masked No intent to treat analysis Excluded patients could affect outcome significantly
Vasavada et al (2019)[18]	I	LenSx	91	91	Safety: Corneal pachymetry	Single center (India) Shallow anterior chamber (< 2.5 mm)	Limited statistics description No power calculation
Hansen et al (2020)[16]	I	LenSx	64	71	Safety: Numerous efficacy measures	Single center Dallas, Texas Resident cases	Outcome not masked No power calculation Unclear loss to follow-up Unclear intention-to-treat analysis
Dzhaber et al (2020)[15]	I	LenSx	67	67	Safety: At 1 and 3 mos, endothelial cell density and corneal pachymetry	Single surgeon Baltimore, Maryland Intraindividual RCT	Outcome not masked
Roberts et al (2018),[8] St. Thomas Study	I	LenSx	200	200	Safety and refractive: At 1 mo: visual acuity, refractive error, endothelial cell loss, corneal pachymetry, complications, quality of life	Single center (United Kingdom) 2 surgeons	Outcome not masked
Stanojcic et al (2020),[9] St. Thomas Study	I	LenSx	116	118	Safety: At 12 mos: visual acuity, refractive error, endothelial cell loss, corneal pachymetry, complications, quality of life	Single center (United Kingdom) 2 surgeons Follow-up study	Outcome not masked 12-mo results not a prespecified outcome Significant loss to follow-up at 12 mos, but intention-to-treat analysis

Authors (Year)	Level of Evidence	Femtosecond Laser-Assisted Cataract Surgery Device	No. of Eyes: *Femtosecond Laser-Assisted Cataract Surgery*	No. of Eyes: *Phacoemulsification Cataract Surgery*	Outcome Category Specific Metrics	Study Design	Limitations
Schweitzer et al (2020),[14] FEMCAT Study	I	Catalys	704	685	Safety and refractive Composite primary outcome at 3 mos: no complications, -BCDVA ≤ 0 logMAR, Absolute SE ≤ 0.75 D, postoperative astigmatism, cost-effectiveness	Multicenter 5 hospitals in France 21 surgeons Superiority study Cost-effectiveness analysis	Unclear modified intention-to-treat analysis Composite primary outcome
Day et al (2020),[10] FACT Study	I	Catalys or Ziemer	392	393	Safety and refractive UCDVA at 3 mos	Multicenter 3 hospitals in United Kingdom Multiple surgeons Majority monofocal IOL, some toric IOL	Noninferiority study Unclear noninferiority threshold Outcome not masked
Day et al (2020),[7] FACT Study	I	Catalys or Ziemer	311	292	Safety and refractive UCDVA at 12 mos	Multicenter 3 hospitals in United Kingdom Multiple surgeons Majority monofocal IOL, some toric IOL	Noninferiority study Unclear noninferiority threshold Outcome not masked High loss to follow-up

BCDVA = best corrected distance visual acuity; D = diopter; IOL = intraocular lens; FACT = Femtosecond Laser-Assisted Cataract Trial; FEMCAT = Femtosecond laser-assisted versus phacoemulsification cataract surgery; logMAR = logarithm of the minimum angle of resolution; RCT= randomized controlled trial; SE = spherical equivalent; UCDVA = uncorrected distance visual acuity

Table 2.

Short- and Long-Term Mean Uncorrected Distance Visual Acuity and Best-Corrected Distance Visual Acuity in Eyes Undergoing Femtosecond Laser-Assisted Cataract Surgery and Phacoemulsification Cataract Surgery

	FACT			FEMCAT			St. Thomas		
Variable	***Femtosecond Laser-Assisted Cataract Surgery***	***Phacoemulsification Cataract Surgery***	**P *Value***	***Femtosecond Laser-Assisted Cataract Surgery***	***Phacoemulsification Cataract Surgery***	**P *Value***	***Femtosecond Laser-Assisted Cataract Surgery***	***Phacoemulsification Cataract Surgery***	**P *Value***
UCDVA									
1 mo							0.15 ± 0.19	0.15 ± 0.21	1.0
3 mos	0.13 ± 0.23	0.14 ± 0.27	0.63	0.14 ± 0.19	0.13 ± 0.18	NR			
1 yr	0.14 ± 0.22	0.17 ± 0.25	0.17				0.12 ± 0.18	0.13 ± 0.19	0.68
BCDVA									
1 mo pinhole							0.04 ± 0.12	0.04 ± 0.12	1.0
3 mos	−0.01 ± 0.19	0.01 ± 0.21	0.34	0.02 ± 0.08	0.02 ± 0.05	NR			
1 yr	0.003 ± 0.18	0.03 ± 0.23	0.11				−0.01 ± 0.1	0 ± 0.1	0.45

BCDVA = best-corrected distance visual acuity; FACT = Femtosecond Laser-Assisted Cataract Trial; FEMCAT = Femtosecond laser-assisted versus phacoemulsification cataract surgery; NR = not reported; UCDVA = uncorrected distance visual acuity.

Data are presented as mean ± standard deviation in logarithm of the minimum angle of resolution units, unless otherwise indicated.