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Femtosecond Laser-Assisted Cataract Surgery versus Conventional Phacoemulsification for Dense Cataracts: A Systematic Review and Meta-Analysis

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Abstract

Topic: Femtosecond-laser-assisted cataract surgery (FLACS) compared to conventional phacoemulsification surgery (CPS) in dense cataracts. **Clinical Relevance:** FLACS is a novel approach to cataract removal, offering potential advantages over CPS. Although these two techniques have been previously studied in patient populations with cataracts, their comparative efficacy in dense cataracts is still unknown. **Methods:** We systematically searched PubMed, Embase, and Cochrane Library for studies reporting visual and surgical outcomes of FLACS versus CPS in patients with dense cataracts. Patients were followed up for one month for outcomes of effective phacoemulsification time (EPT), cumulative dissipated energy (CDE), endothelial cell density (ECD), central corneal thickness (CCT), and % ECD loss. Data were pooled using weighted mean differences (MD) with 95% confidence intervals (CI) in random-effects model. All statistical analyses were conducted using R Studio version 4.4.1. **Results:** Our meta-analysis included 19 studies comprising a pooled population of 5433 eyes, of which 2315 (42.6%) were allocated to CPS group. The mean age ranged from 55.2 to 79.1 years. Compared to CPS, FLACS significantly reduced the EPT (MD 2.92 seconds; 95% CI −5.23 to −0.61; $p = 0.013$) and CDE (MD −3.23 J; 95% CI −5.11 to −1.34; $p < 0.01$). There were no statistically significant differences in ECD (MD 74.13 cells/mm²; 95% CI—93.52 to 241.77; $p = 0.39$), CCT (MD 1.11 um; 95 % CI—19.53 to 21.76; $p = 0.92$), and % ECD loss (MD—5.26%; 95% CI—22.34 to 11.83; $p = 0.55$). **Conclusion**: In this systematic review and meta-analysis of patients with dense cataracts, FLACS was associated with a reduction in EPT and CDE as compared with CPS, with no significant change in ECD, CCT, and %ECD loss.

Keywords

Dense Cataract, FLACS, Meta-Analysis, Phacoemulsification

1. Introduction

Cataracts remains a major cause of vision impairment and blindness globally, profoundly impacting patients' quality of life [1] [2]. Surgical techniques for cataract repair have increasingly improved, with conventional phacoemulsification surgery (CPS) emerging as the gold standard due to its minimally invasive nature and swift recovery times. Nonetheless, dense cataracts, marked by significant opacification, present unique surgical challenges that can elevate the risk of complications and extend the duration of surgery [3].

Femtosecond laser-assisted cataract surgery (FLACS) is a cutting-edge innovation that harnesses femtosecond lasers to perform critical steps in cataract surgery, including anterior capsulotomy, lens fragmentation, and corneal incisions [4] [5]. This procedure has been shown to provide superior precision, enhanced safety, and possibly improved visual outcomes compared to CPS, with a potential benefit in cases involving dense cataracts [5] [6].

Previous meta-analyses have compared FLACS and CPS in patients with cataracts, but not in those with dense cataracts specifically [7] [8]. FLACS achieves better visual outcomes in the early postoperative period and long-term follow-up, accompanied by more accurate capsulotomy and more optimized effective lens position than CPS [8]. However, no difference in visual outcomes has been shown after 6 months of follow-up. Despite this, the comparative effectiveness of FLACS versus CPS for dense cataracts remains a subject of lively debate [9] [10]. Numerous studies have explored this comparison and yielded inconsistent findings. While some indicate that FLACS may reduce the reliance on ultrasound energy and decrease surgical time, others show no significant differences in visual acuity or complication rates [6] [10].

Given this controversy, we aimed to perform a systematic review and meta-analysis of surgical outcomes associated with FLACS versus CPS for patients with dense cataracts.

2. Methods

This systematic review and meta-analysis adhered to the guidelines outlined in the

Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [11] and followed the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions [12]. This study did not involve the handling or processing of individual patient data. The protocol was prospectively registered at the International Prospective Register for Systematic Reviews (PROSPERO) in August 2024, ID: CRD42024579055.

2.1. Eligibility Criteria

Inclusion in this systematic review and meta-analysis was restricted to: 1) randomized or non-randomized controlled studies; 2) directly comparing FLACS with CPS; and 3) in patients undergoing routine dense cataract surgery. Only studies published in full form were considered for inclusion. This review excluded studies involving 1) animals; 2) ex-vivo samples; 3) pediatric patients (with a mean age of less than 18 years); 4) published only as an abstract; or 5) not in the English language. Furthermore, to avoid overlapping populations, studies that included cases which had already been reported in previous studies were removed.

2.2. Search Methods for Identifying Studies

We searched three databases, namely MEDLINE (Ovid), Embase, and Cochrane Central Library for studies published up to August 2024 using combinations of the following keywords and medical subject heading terms (MeSH): "Cataract", "Femtosecond Laser"; "FLACS" and Phacoemulsification". The full search strategy for each database can be found on **Supplementary Table S1**.

2.3. Studies Selection

Two reviewers (M.R. and O.H.) independently searched the reports extracted from the search in each database. After removal of duplicate entries, the reviewers independently screened studies for inclusion according to eligibility criteria.

We assessed the effectiveness of the interventions by the following parameters: 1) postoperative corneal endothelial cell density (ECD); 2) percentage loss of ECD; 3) central corneal thickness (CCT), indicating corneal edema that may delay visual recovery after cataract surgery; 4) cumulative dissipated energy (CDE); and 5) effective phacoemulsification time (EPT), a measure of the duration of phacoemulsification at 100% power in continuous mode.

2.4. Data Collection and Risk of Bias Assessment

Two authors (M.R. and L.B.) independently retrieved data from original studies following a pre-specified data sheet to collect information on demographic characteristics and outcome measures. Discrepancies were resolved between the authors in consensus.

Each study included was appraised using the revised Cochrane risk of bias tool for assessing bias in non-randomized trials (ROBINS-I) or the risk of bias tool to assess the quality of randomized controlled trials (RoB-2) [12]. Three authors

(M.R., M.A. and R.C.) individually evaluated the risk of bias in each trial included in the analysis and discrepancies were resolved by reaching a consensus in interpretation. As per Cochrane recommendations, we did not perform funnel plot analysis for publication bias due to the absence of any given outcome with >10 studies included.

2.5. Data Synthesis and Analysis

Continuous outcomes were compared using weighted mean differences (MD), standard deviations (SD) and 95% confidence intervals (CI). Given the clinical differences of studies included, a restricted maximum likelihood model was used. We assessed heterogeneity with I^2 statistics and Cochran's Q test; p-values < 0.10 were considered significant for heterogeneity, whereas I^2 values of 0%, 1% - 25%, 26% - 50%, and >50% were indicative of no heterogeneity, low, moderate, and substantial heterogeneity, respectively. When high heterogeneity was observed, we performed sensitivity analyses by 1) removing each individual study from the outcome assessment, in leave-one-out sensitivity analysis; and 2) using adjusted risk estimates from non-randomized studies, when available. R version 4.4.2 (R Foundation for Statistical Computing) was used for the statistical analysis.

3. Results

3.1. Study Selection and Baseline Characteristics

As shown in **Figure 1**, a total of 1565 articles were initially identified through database searches. After removing duplicates, 584 articles were excluded through screening titles and abstracts for relevant studies. Of the remaining 80 studies eligible for full text review, 19 studies, including two randomized controlled trials (RCTs), were ultimately selected for inclusion in this meta-analysis.

The 19 included studies involved a total of 5433 cases of dense cataracts, of which 2315 (42.6%) were performed using FLACS and 3118 (57.4%) were performed using CPS. These studies were conducted across 12 countries and had follow-up periods ranging from 3 to 66 months. Average age ranged from 55.2 to 79.1 years. All included studies directly compared FLACS with CPS. The overall characteristics of the included studies are described in **Table 1**.

3.2. Pooled Analysis of All Studies

FLACS was associated with a statistically significant reduction in EPT (MD 2.92s; 95% CI: −5.23 to −0.61; p = 0.013; I^2 = 97%; **Figure 2**) and CDE (MD −3.23 J; 95% CI: −5.11 to −1.34; p < 0.001; I^2 = 93%; **Figure 3**) compared to CPS among 651 eyes. There were no significant reductions in ECD (MD 74.13; 95% CI −93.52 to 241.77; p = 0.39; I^2 = 90%; **Figure 4**), % ECD loss at one week (MD −4.61; 95% CI −21.02 to 11.80; p = 0.58; I^2 = 95%; **Supplementary Figure S1(A)**) and one month (MD −5.26; 95% CI −22.34 to 11.83; p = 0.55; I^2 = 96%; **Supplementary Figure S1(B)**), or in CCT at day one (MD −11.34; 95% CI −40.12 to 17.43; p = 0.44; I^2 = 84%; **Supplementary Figure S2(A)**), one week (MD −1.84; 95% CI −20.07 to

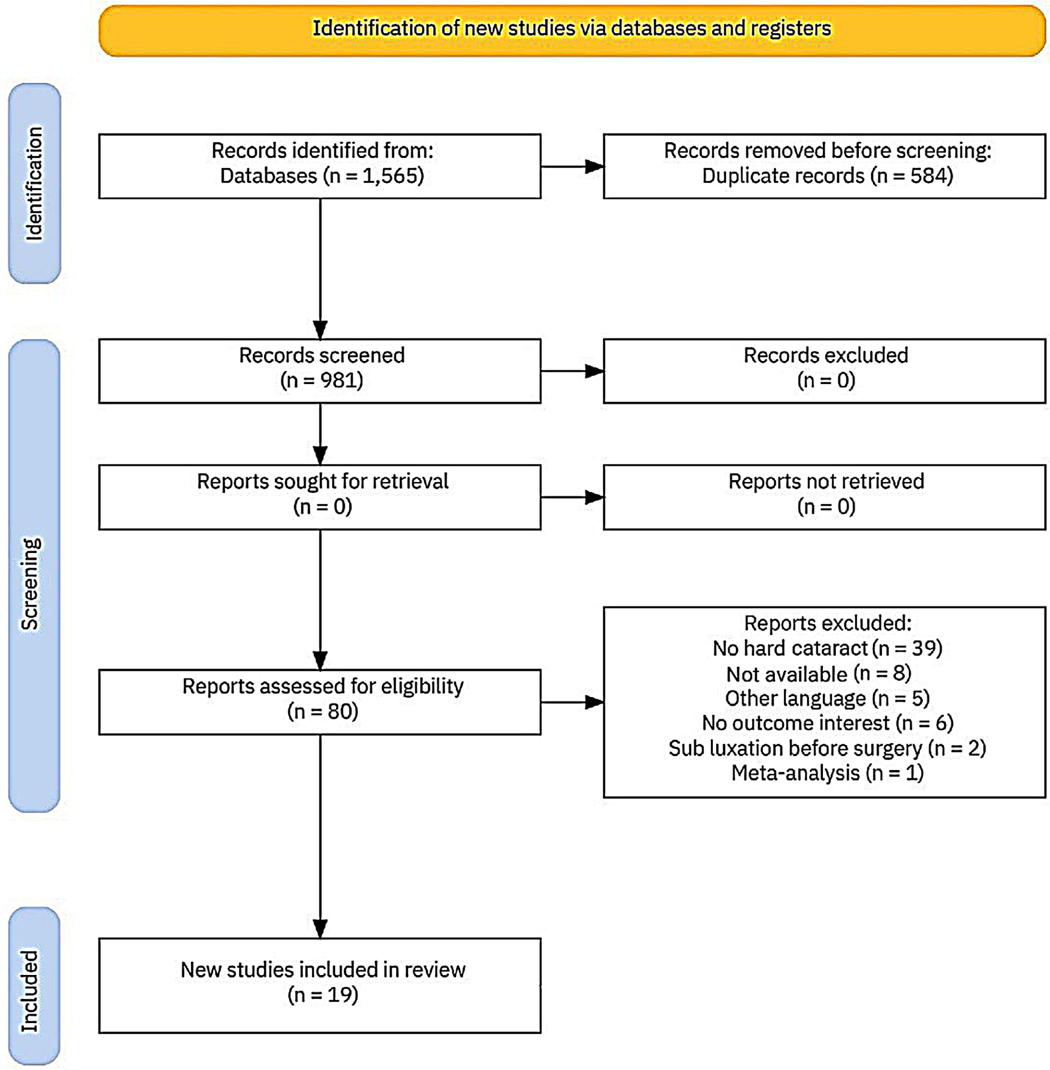

Figure 1. PRISMA 2020 flow diagram.

Table 1. Baseline characteristics of included studies.

Study	Study Design	Country	FLACS Platform	Age, years FLACS/CPS	Females, n (%) FLACS/CPS	Eye Cases, n FLACS/CPS	Follow-up, months
Assaf 2021	Prospective Cohort	Egypt	Catalys	62.5/62.4	NA8	117/133	12
Duan 2017	Prospective Cohort	China	NA	NA	NA	73/74	12
He 2021	Retrospective Cohort	China	Victus	70.0/69.7	19 (57.6%)/18 (58.1%)	47/49	24
Al-Mohtaseb 2017	Prospective Cohort	EUA	LenSx	66.7/69.5	34 (56.6%)/31 (51.6%)	60/60	24
Lin 2021	Case-control	China	LenSx	65.2/66.7	124 (57%)/161 (56%)	218/288	36
Titiyal 2016	Prospective Cohort	India	LenSx	62.9/64.8	20 (50.0%)/23 (57.5%)	40/40	NA
Hatch 2015	Prospective Cohort	Germany	Catalys	73.4/74.0	NA	NA	NA
Ganesh 2024	RCT	India	Lensar	68.0/66.4	NA	50/50	6
Ou 2023	Case-control	NA	LDV Z8	65.9/68.4	NA	NA	11

Continued

Salgado 2023	Retrospective Cohort	Portugal	LDV Z8	72.7/72.7	NA	NA	66
Léda 2023	Prospective Cohort	Brazil	LenSx	68.7/68.4	48 (57.1%)/48 (57.1%)	84/84	6
Medhi 2022	Retrospective Cohort	India	LenSx	55.2/55.7	635 (72.7%)/470 (37.5%)	873/1251	36
Baldascino 2022	Prospective Cohort	Italy	LenSx	66/66	34 (51.5%)/18 (52.9%)	66/34	9
Crozafon 2021	Retrospective Cohort	France		71.7/72.2	NA	496/811	60
Chee 2021	RCT	Singapore	Victus	72.8/75.8	21 (46.6%)/21 (43.7%)	45/48	16
Horta 2019	Prospective Cohort	Brazil	LenSx	NA	NA	73/87	6
Twardzik 2019	Prospective Cohort	Poland	LDV Z8	79.1/74.6	20 (76.9%)/43 (70.3%)	26/61	12
Chen 2017	Prospective Cohort	China	LenSx	68.4/70.3	29 (61.7)/27 (56.3)	47/48	NA
Hengerer 2013	RCT	Germany	NA	70.9/70.9	NA	NA	3

Data are presented as means, unless stated otherwise. CPS, conventional phacoemulsification surgery; FLACS, femtosecond laser-assisted cataract surgery; NA: not available; RCT, randomized controlled trial.

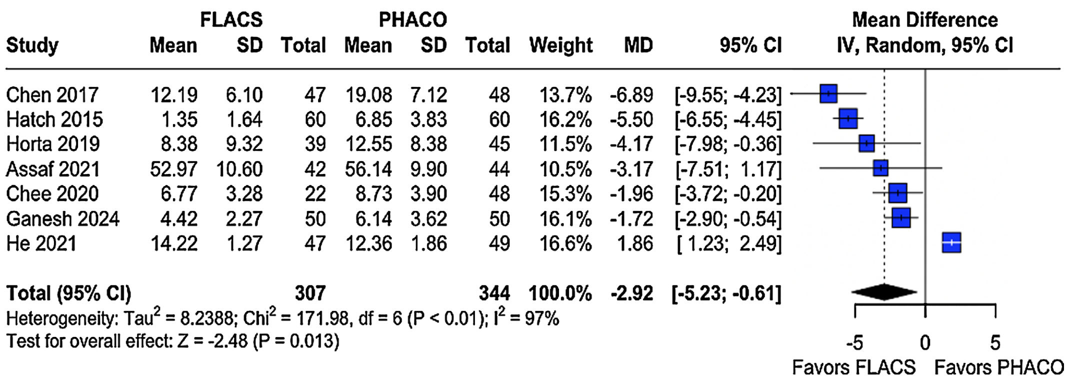

Figure 2. Femtosecond laser-assisted cataract surgery was associated with a significantly reduced effective phacoemulsification time compared to conventional phacoemulsification surgery.

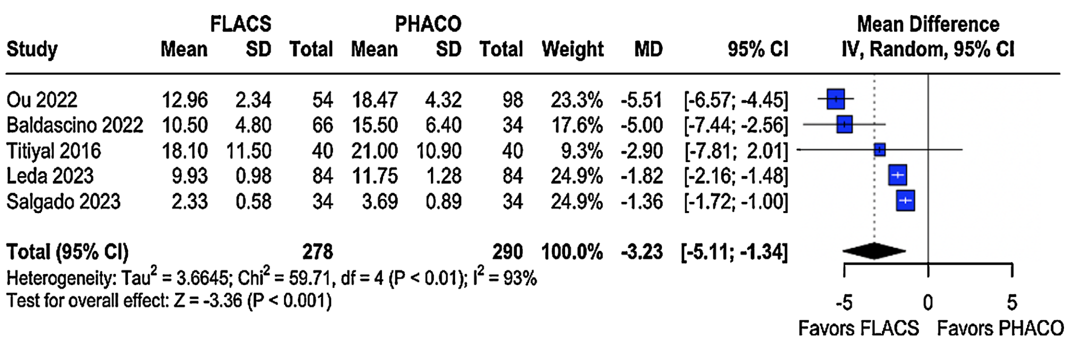

Figure 3. Femtosecond laser-assisted cataract surgery was associated with a significantly lower cumulative dissipated energy compared to conventional phacoemulsification surgery.

16.39; p = 0.84; I^2 = 78%; **Supplementary** Figure S2(B)), up to one month (MD −3.34; 95% CI −14.85 to 8.17; p = 0.57; I^2 = 81%; **Supplementary** Figure S2), or three months (MD 1.11; 95% CI −19.53 to 21.76; p = 0.92; I^2 = 85%; **Supplementary** Figure S2).

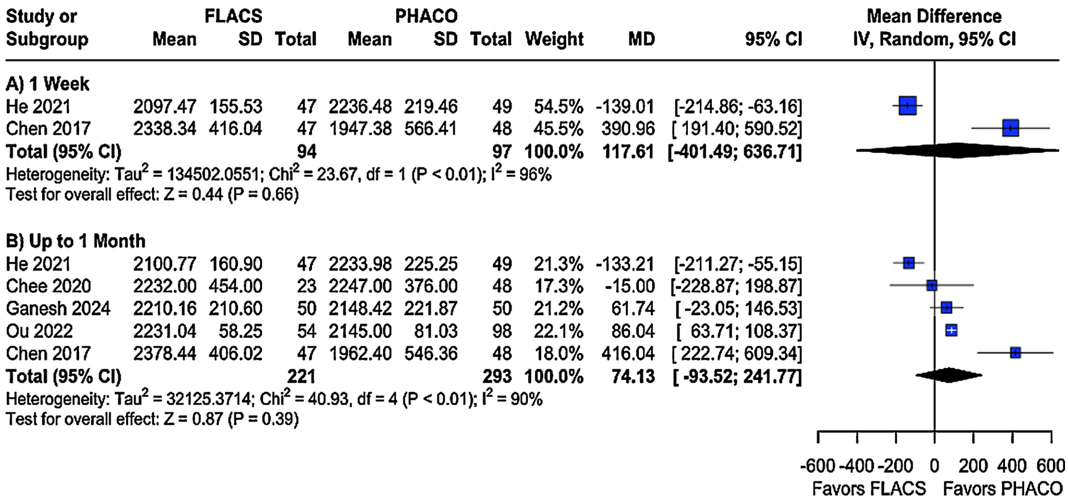

Figure 4. There were no significant differences in endothelial cell density between groups.

3.3. Sensitivity Analysis

We conducted leave-one-out sensitivity analyses for outcomes with high heterogeneity. For the outcomes of EPT, CDE, CCT, and ECD, the omission of each study, sequentially, did not change the overall analysis results (**Supplementary Figure S3**).

3.4. Quality Assessment

One RCT was classified as having a 'moderate risk' of bias [10] due to deviations from the intended interventions, while the other trial was assessed as having a 'low risk' [9] (see **Supplementary Figure S4**). Given the non-randomized nature of most studies, which are subject to confounding and selection biases, six were categorized as having a 'serious risk' of bias [13]-[18], whereas 13 studies were classified as having a 'moderate risk' of bias, [5] [19]-[29] attributed to confounding factors, participant selection, deviations from intended interventions, and the selection of reported results (see Supplementary Figure S4). Unfortunately, we could not perform funnel plot analysis to assess for publication bias due to the absence of any given outcome with > 10 studies.

4. Discussion

This meta-analysis compared the outcomes of FLACS and CPS for dense cataracts by pooling the data from 19 studies with a total of 5433 cases. Our findings indicate that FLACS significantly reduced EPT and CDE compared to CPS. However, there were no significant differences in ECD, percentage ECD loss, or CCT, regardless of time of follow-up.

Cataracts remains a major cause of vision impairment and blindness globally [1]. Importantly, dense cataracts challenge the surgeon due to the need for prolonged phacoemulsification time and increased ultrasound energy, often leading to endothelial cell damage and corneal edema [3]. Our findings indicate that the reduction in EPT and CDE associated with FLACS for patients with dense cataracts is noteworthy and clinically relevant. By pre-fragmenting the lens with femtosecond laser technology, FLACS minimizes the reliance on ultrasound energy, thereby reducing CDE. This reduction can potentially improve postoperative recovery by limiting collateral thermal damage to surrounding ocular tissues.

A previous meta-analysis compared both techniques in patients cataracts, although without a dedicated subgroup assessment of dense cataracts. Both FLACS and CPS were found to be effective and safe, although FLACS required less ultrasound energy, with a more precise treatment [30]. There was no significant difference in visual acuity between both methods at 6 months. Our results align with previous studies that reported advantages of FLACS over CPS for energy consumption and surgical efficiency, especially in complex cases [6]. For example, study by Hatch *et al.* [24] demonstrated similar reductions in EPT, supporting the hypothesis that FLACS may enhance surgical outcomes in cases of advanced lens opacification.

Despite the reduction in surgical energy, FLACS did not yield a significant benefit for ECD preservation or CCT reduction. These findings suggest that whilst FLACS reduces intraocular trauma associated with ultrasound energy, it may not directly impact endothelial cell loss in the short-term. The lack of significant ECD differences could be attributed to the cumulative effect of other surgical factors, including fluid turbulence and surgical manipulation during lens removal, which remain common to both FLACS and CPS.

The primary strength of this meta-analysis lies in its inclusion of 19 studies, which provides a robust pooled analysis of surgical outcomes in dense cataracts. By demonstrating significant reductions in EPT and CDE, our findings highlight the role of FLACS as a valuable tool in minimizing intraoperative energy use. This benefit is particularly relevant for patients with preexisting corneal compromise, where excessive energy usage may exacerbate endothelial cell loss [9]. Our findings support the use of FLACS as a preferable technique in cases of dense cataracts where minimizing phacoemulsification time and energy is critical. However, the decision to adopt FLACS must be balanced with cost considerations, equipment availability, and surgeon familiarity with the technology. Currently, in clinical practice, most surgeons use CPS due to the high cost of femtosecond laser equipment [31] [32].

This study is not without limitations. First, there was significant heterogeneity in outcomes, which may reflect differences in study design, surgical techniques, and patient populations between studies. Nevertheless, we performed leave-one-out sensitivity analyses and confirmed that findings were not dependent on one given study for any outcome. Second, most of the included studies were observational, which are associated with a higher risk of bias, particularly confounding. Due to the absence of patient-level data, we could not perform and multivariate adjusted analysis to minimize confounding in observational studies. Third, the follow-up duration was inconsistent across studies, with some failing to assess long-term endothelial outcomes or visual acuity. Lastly, variations in FLACS platforms (e.g., LenSx, Catalys, Victus) and differences in the definition of "dense cataract" may have influenced the results. Standardized protocols for assessing cataract density and surgical outcomes are needed to improve comparability among studies.

Reducing CDE is very important for cases of cornea with low endothelial cell count, guttata, in elderly patients. In the papers included in this meta-analysis, the surgeon's experience was not cited, contributing to the heterogeneity of the meta-analysis. Another limitation of this meta-analysis is the short follow-up time of patients for better assessment of corneal health. For future studies, it would be important to develop a single classification system for cataract staging to improve comparability between studies. Future studies could also investigate other variables such as posterior capsule rupture and posterior capsule opacity.

5. Conclusion

FLACS offers significant advantages over CPS in reducing ECT and CDE for dense cataracts. However, its impact on endothelial health remains inconclusive. While FLACS shows promise as a safer and more efficient surgical approach for dense cataracts, high-quality RCTs with standardized methodologies are warranted to validate our findings and explore the long-term impact of FLACS on visual outcomes, endothelial health, and patient satisfaction. Studies focusing on cost-effectiveness and learning curves associated with FLACS adoption will also be critical for broader clinical implementation.

Disclosure

All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations

CCT	Central Corneal Thickness
CDE	Cumulative Dissipated Energy
CI	Confidence Interval
CPS	Conventional Phacoemulsification Surgery
ECD	Endothelial Cell Density
EPT	Effective Phacoemulsification Time
FLACS	Femtosecond Laser-Assisted Cataract Surgery
MD	Mean Difference
MeSH	Medical Subject Heading Terms
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
PROSPERO	International Prospective Register of Systematic Reviews
RCT	Randomized Controlled Trial
ROBINS-I	Risk of Bias Tool for Assessing Bias in Non-Randomized Trials
RoB-2	Risk of Bias Tool for Assessing Bias in Randomized Controlled Trials
UC	Usual Care

Supplementary

Table S1. Search strategy.

Set	Terms	Results
PUBMED:		
Set	Terms	Results
#1 Cataracts	(Cataract OR "Cataract"[Mesh] OR Cataracts)	89,178
#2 FLACS	("femtosecond laser" OR FLACS OR femtolaser OR "fs-assisted")	9673
#3 Phacoemulsification	(Phacoemulsification OR Phacoemulsification [Mesh] OR phakoemulsification OR phaco OR CPS)	31,165
#4	1 AND 2 AND 3	586
EMBASE:		
Set	Terms	Results
#1 Cataracts	(Cataract OR "Cataract"[SH] OR Cataracts)	127,510
#2 FLACS	("femtosecond laser" OR FLACS OR femtolaser OR "fs-assisted")	9909
#3 Phacoemulsification	(Phacoemulsification OR Phacoemulsification [Mesh] OR phakoemulsification OR phaco OR CPS)	48,010
#4	1 AND 2 AND 3	816
Cochrane Central:		
Set	Terms	Results
#1 Cataracts	(Cataract OR Cataracts)	10,134
#2 FLACS	("femtosecond laser" OR FLACS OR femtolaser OR "fs-assisted")	570
#3 Phacoemulsification	(Phacoemulsification OR phakoemulsification OR phaco OR CPS)	5252
#4	1 AND 2 AND 3	163

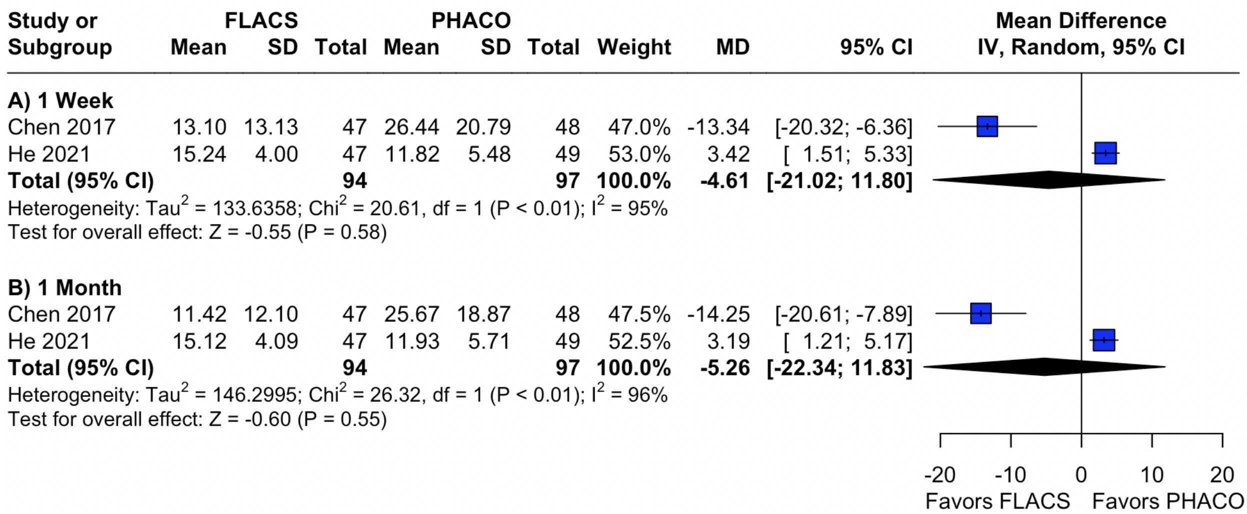


Figure S1. % ECD loss at one week and one month.

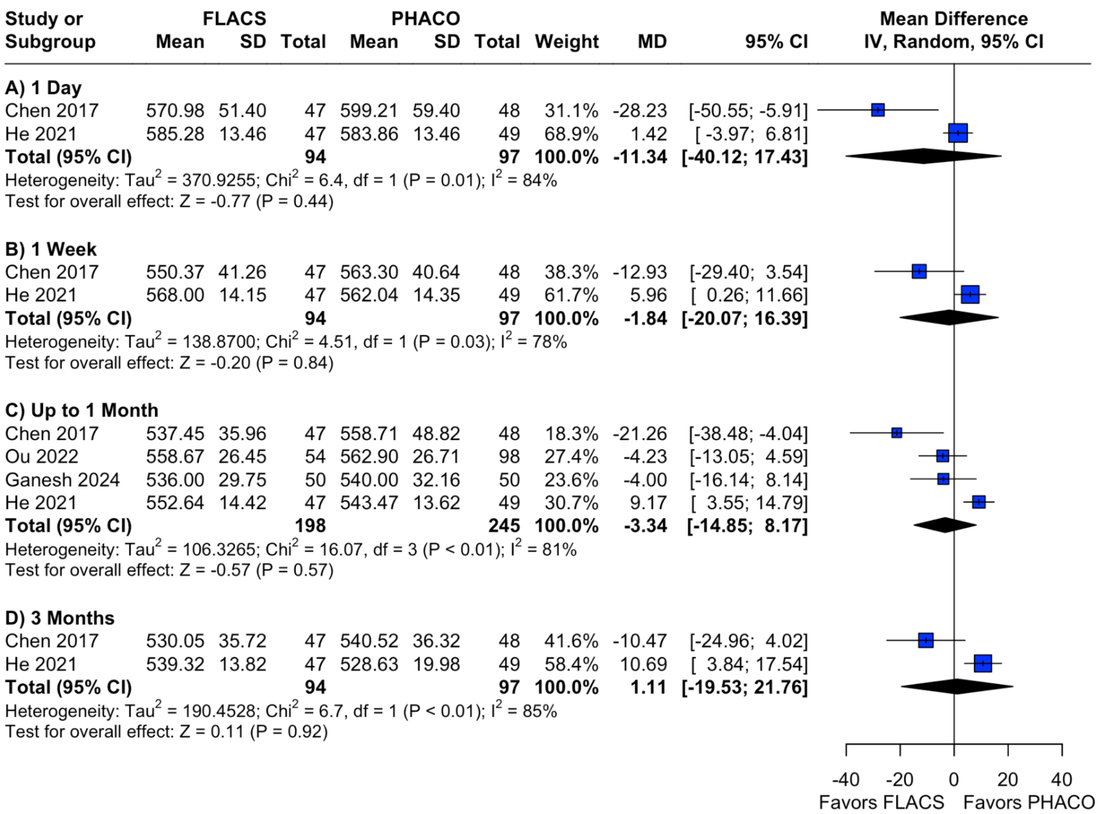
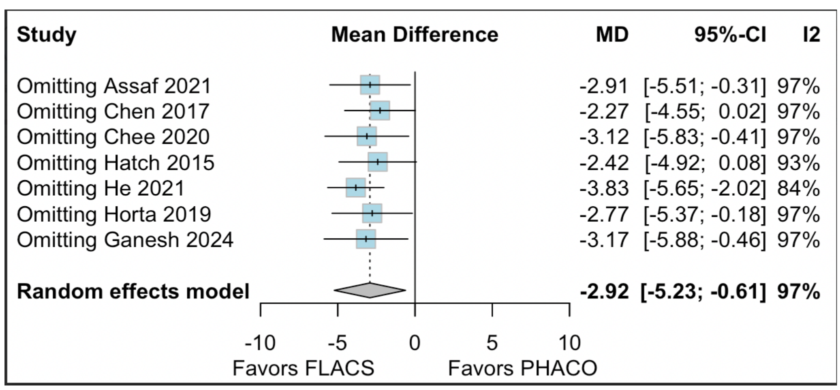
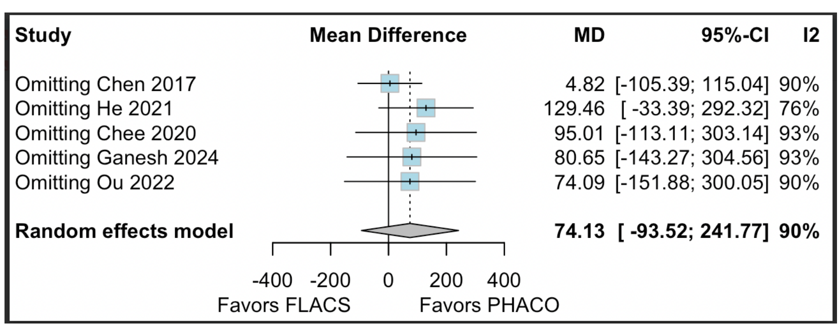


Figure S2. CCT at one day, one week, one month and three months.

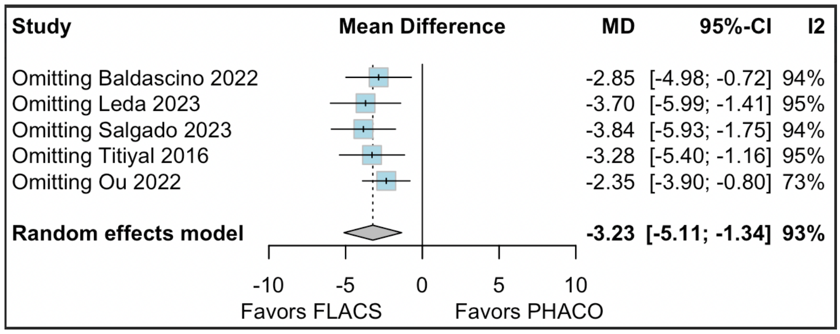
EPT



ECD



CDE



CCT

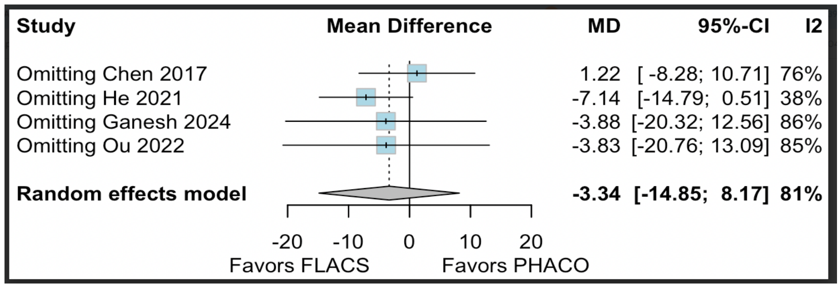


Figure S3. Risk of bias summary for randomized studies.

Risk of bias summary for randomized studies (RoB 2)

Study	Bias from randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcomes	Bias in selection of the reported result	Overall risk of bias
Soon-Phaik Chee 2020	Low	Some concerns	Low	Low	Low	Some concerns
Ganesh 2024	Low	Low	Low	Low	Low	Low

Risk of bias summary for non-randomized studies (ROBINS-I)

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias judgement
Al-Mohtaseb 2017	Moderate	Serious	Low	Moderate	Low	Moderate	Low	Serious
Assaf 2020	Moderate	Moderate	Low	Moderate	Low	Low	Low	Moderate
Assaf 2021	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Baldascino 2022	Moderate	Serious	Low	Low	Moderate	Low	Low	Serious
Chen 2017	Serious	Moderate	Low	Low	Moderate	Low	Low	Serious
Crozafon 2020	Moderate	Moderate	Low	Low	Moderate	Low	Low	Moderate
Duan 2017.	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Ebidalla 2020	Serious	Moderate	Moderate	Low	Moderate	Moderate	Low	Serious
Hatch 2015	Moderate	Low	Low	Moderate	Moderate	Low	Low	Moderate
He 2021	Moderate	Low	Low	Low	Low	Low	Low	Moderate
Hengerer 2013	Serious	Moderate	Low	Moderate	Low	Low	Low	Serious
Horta 2019	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Leda 2023	Serious	Moderate	Low	Low	Moderate	Moderate	Moderate	Serious
Lin 2022	Moderate	Low	Low	Low	Low	Low	Low	Moderate
Ou 2022	Moderate	Low	Low	Moderate	Moderate	Low	Low	Moderate
Rong 2019	-	-	-	-	-	-	-	-
Salgado 2016	Moderate	Moderate	Low	Low	Moderate	Low	Moderate	Moderate
Titiyal 2016	Moderate	Moderate	Low	Low	Low	Low	Moderate	Moderate
Twardzik 2019	Moderate	Low	Low	Low	Low	Low	Low	Moderate

Figure S4. Risk of bias summary for non-randomized studies.