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Meta-analysis

Safety of femtosecond laser-assisted cataract surgery versus conventional phacoemulsification for cataract: A meta-analysis and systematic review



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ABSTRACT

Keywords: Femtosecond laser assisted cataract surgery Conventional phacoemulsification surgery Safety Complication Capsular tear rate

Purpose: To compare the complications of femtosecond laser-assisted cataract surgery (FLACS) with those of conventional phacoemulsification surgery (CPS) for age-related cataracts. *Methods:* PubMed, Cochrane Library, and EMBASE were systematically searched for studies comparing FLACS and

CPS. Outcomes were operative complications, including the intraoperative capsule tear, postoperative corneal edema, macular edema, uncontrolled IOP, etc. The effect measures were weighted with odds ratios with 95% CIs. *Results*: Nineteen RCTs and 18 cohort studies, including 24,806 eyes (11,375 of the FLACS group and 13,431 of the CPS group), were identified. There were no significant differences between the two groups in anterior capsule tear, corneal edema, macular edema, uncontrolled IOP, vitreous loss, posterior vitreous detachment, etc. Posterior capsule tear rate showed a significantly lower in RCT subgroups (P = 0.04) and without differences in total (P = 0.63). Significant differences were observed in the incidence of descemet membrane tear/trauma (P = 0.02) and IFIS/iris trauma (P = 0.04. Additionally, The FLACS specific complications showed a significantly higher rate of miosis (P < 0.0001), corneal epithelial defect (P = 0.001), corneal haze (P = 0.002), and subconjunctival hemorrhage (P = 0.01).

Conclusions: FLACS maintains the same safety compared with CPS in terms of all intraoperative and postoperative complications. Although FLACS did show a statistically significant difference for several FLACS specific complications, it would not influence the visual outcome and heal itself.

1. Introduction

Cataract is the second leading cause of visual impairment and the first of blindness globally^{1-.2} The prevalence of cataracts is around 47.8% among people who are over 50 years of age and cause more than 40% of blindness cases.^{3–5} Currently, surgery is the most direct and effective treatment for cataracts. With the increased lifespan and elevated living standards, people pay more attention to visual outcomes. These demands promote cataract surgery from blindness prevention to refractive surgery.

With decades of exploration, phacoemulsification is considered the most successful surgical procedure for cataracts worldwide, performed with more excellent safety and shorter time than extracapsular cataract extraction (ECCE.).^{6–9} Conventional phacoemulsification surgery (CPS) involves the creation of corneal incisions with a keratome blade, a continuous curvilinear capsulorrhexis using forceps, and manual splitting of the nucleus. In recent years, femtosecond laser (FSL) was approved by FDA in 2010 and introduced to replace these steps to gain better

accuracy, safety, and refractive outcomes for cataract surgery.¹⁰ Studies show that the femtosecond laser-assisted cataract surgery (FLACS) could create a high-quality capsulorhexis and get a better stabilizing of intraocular lens (IOL), thus gaining a better visual outcome.^{11–13} The nuclear fragmentation with FSL could significantly reduce the phacoemulsification time and effective phacoemulsification time (EPT), thereby diminishing the corneal endothelial injury.

Although numerous benefits of FLACS have been reported, the safety of FLACS was still under dispute. Some studies found that FLACS might increase the risk of radial anterior capsular tears or posterior capsular tears, leading to a movement of IOL and a poor visual outcome.^{4,14,15} However, no significant differences for capsule tear between the FLACS and CPS have also been reported.^{16–18} Currently, nine meta-analyses have been conducted and focus on the efficiency and safety of FLACS and with disputation, especially the aspect of surgical safety. Additionally, lots of potential surgical complications were not included and discussed, and even several errors exist in some of the previous

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meta-analyses. Recently, several randomized controlled trials (RCTs) and clinical cohort studies have arisen, which would provide more information and evidence for surgical safety. Among them, most cohort studies only do not comply with random allocation when compared with RCTs, thus also with a high evidence level. In this study, we focus on the complications, review FLACS verse CPS from the incidence of various complications and assess the safety of the two techniques in a meta-analysis approach. Moreover, randomized controlled trials (RCTs) and high-quality clinical cohort studies were included in this meta-analysis to address a small sample size and provide more reliable and convincing evidence.

2. Methods

2.1. Search databases and strategy

Related English or Chinese publications until December 2021 were obtained from PubMed, EMBASE, and the Cochrane Controlled Trials Register. The publication list was built via searching with the following terms: femtosecond OR Femtolaser AND cataract. Reference lists of relevant reviews were also carefully scanned.

2.2. Inclusion and exclusion criteria

Studies included in this study should meet the following criteria: (1) randomized controlled trials, or prospective cohort studies; (2) comparative studies with FLACS versus CPS; (3) participants in the trials were diagnosed with cataracts without other eye disorders (e.g., amblyopia, glaucoma, diabetic retinopathy, or macular degeneration); (4) at least one of complications was reported. Abstracts, theses, case reports, opinion articles, correspondence articles were excluded.

2.3. Screening process

Two independent authors (JJ.X and HL.W) reviewed studies first by the titles and abstracts and then by full articles. Uncertainty articles were through careful discussion and affirmed by a third author (XY.C) finally. All studies that met our predefined criteria were included.

2.4. Data extraction and quality assessment

Three authors (JJ.X, HL.W, and XY.C) independently extracted relevant data from studies carefully. All data were collected into a standard form, including the authors, publication year, the type of study, sample size, complications, etc. All disagreements were resolved by discussion.

Cochrane Collaboration's tool for risk of bias was applied to evaluate the quality of included RCTs by two independent authors, which had random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases.⁶⁶

Newcastle-Ottawa Scale (NOS) was applied to assess the quality of cohort studies.^{67,68} The NOS is an 8-stars scale based on patient selection (four stars), comparability (one star), and outcomes (three stars).

2.5. Statistical analysis

All statistical analyses were analyzed using RevMan software (version 5.4; Cochrane Collaboration, Oxford, United Kingdom). The odds ratio (OR) with a 95% CI was used to compare the complications (dichotomous variables) between FLACS and CPS. P < 0.05 was considered statistically significant for an overall effect. The chi-square and I² assessed statistical heterogeneity. I² < 50% was considered no significant evidence of heterogeneity, fixed-effects models were used to evaluate the differences between the two groups. Otherwise, the random-effects meta-analysis was applied. The sensitivity analysis was performed by omitting one study per time and assessing the alter of the results.

3. Results

3.1. Literature search

Fig. 1 shows a total of 3281 articles were initially identified. After removing duplications, the titles and abstracts of 1671 potential studies were reviewed, and 1139 articles were excluded. One hundred forty-five studies were eligible further identified with full texts. Nine of them were excluded because the data were not relevant to our outcomes of interest, and 3 of them were excluded because it was without effective data. Finally, 37 articles^{19–57} were selected for this meta-analysis.

3.2. Characteristics of included studies

Nineteen random clinical trials (RCTs) and 18 prospective cohort studies were included in our meta-analysis. The overall characteristics of these studies are shown in Table 1. The quality assessment of RCTs was conducted by Revman and shown in S2 Figure. And the Newcastle-Ottawa Scale (NOS) was used to assess the quality of cohort studies (S3 Table). Overall, 24,806 eyes (11,375 of the FLACS group and 13,431 of the CPS group) were included. The duration of follow-up ranged from one week to twelve months.

4. Capsule related complications

4.1. a. Anterior capsule tear

Fifteen studies, ^{14,21,23,28,30–32,34,35,42,45,48,50–52} including 11,007 eyes, recorded the complication of anterior tear. The meta-analysis from all studies suggested there was no significant difference between FLACS and CPS (OR = 1.75, 95% CI 0.82 to 3.73, P = 0.15: Fig. 2A). However, time subgroup meta-analysis showed that the risk of anterior capsule tear was significantly high before 2015 years (OR = 4.58, 95% CI 1.42 to 14.77, P = 0.01; Fig. 2A) and without no significant difference after 2015(OR = 1.22, 95% CI 0.53 to 2.80, P = 0.64; Fig. 2A).

4.2. b. Posterior capsule tear

7 RCT^{21,24,25,27,28,45,48} and 6 prospective studies^{21,24,25,28,45,48} were included. Pooled data suggested no significant difference between the two groups in total (OR = 0.88, 95% CI 0.59 to 1.31, P = 0.53; Fig. 2B). Then two subgroups (non-RCT and RCT) were added to analyze as shown in (Fig. 3). FLACS revealed a significantly lower tear rate in the RCT subgroup and without differences in the non-RCT subgroup (subgroup of non-RCT: OR = 1.30, 95% CI 0.77 to 2.20, P = 0.32, subgroup of RCT OR = 0.49, 95% CI 0.26 to 0.95, P = 0.04).

5. FLACS specific complications

5.1. a. Corneal epithelial defect

Across two studies^{14,51} by two different research teams, the risk ratio of the corneal epithelial defect was significantly higher for eyes receiving FLACS relative to CPS (OR = 4.94, 95% CI 1.91 to 12.80, P = 0.001; Fig. 3A).

5.2. b. Corneal haze

Two studies, 14,58 including 5956 eyes, assessed the ratio of postoperative corneal haze. The pooled data showed the risk of corneal haze was significantly higher in the FLACS group (OR = 13.51, 95% CI 2.55 to 71.47, P = 0.002; Fig. 3B).

5.3. c. Subconjunctival hemorrhage

Six studies^{20,37,40,44,51,56} evaluated the occurrence of subconjunctival

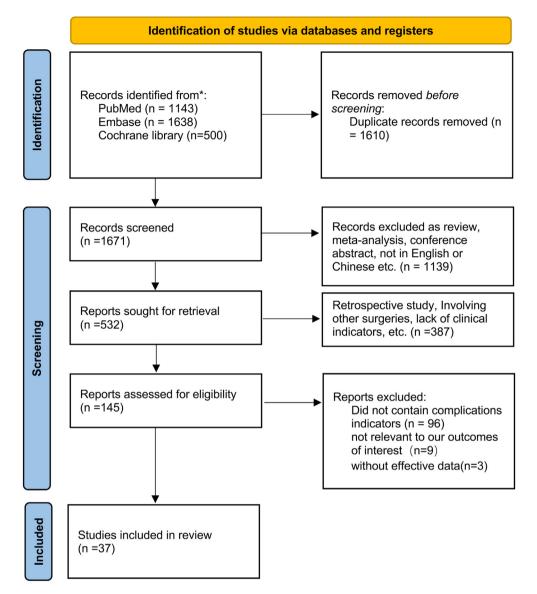


Fig. 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

hemorrhage. Pooled data revealed that the risk of subconjunctival hemorrhage was higher in eyes receiving FLACS relative to CPS (OR = 6.42, 95% CI 1.48 to 27.86, P = 0.01; Fig. 3C).

5.4. d. Small pupil

Eight studies^{24,28,29,33,34,37,40,56} assessed the pupil size during operation and recorded the events of the small pupil. The risk of small pupil in FLACS was significantly higher than that in the CPS group (OR = 3.05, 95% CI 1.83 to 5.07, P < 0.0001; Fig. 3D). However, pooled data shows no statistically significant differences between the group of FLACS and CPS for using iris hooks or malyugin ring (OR = 5.27, 95% CI 0.88 to 31.50, P = 0.07; Fig. S1K).

6. Other intraoperative and postoperative complications

6.1. a. Descemet membrane tear/trauma

The subgroup was divided by the incision approaches (corneal incision with laser or not). Although no significant difference was found in total (OR = 0.64, 95% CI 0.26 to 1.56, P = 0.33; Fig. 4A), a significantly lower incidence of Descemet membrane tear/trauma was revealed in

laser-assisted group (OR = 0.16, 95% CI 0.03 to 0.79, *P* = 0.02; Fig. 4A).

6.2. b. IFIS/iris trauma

The meta-analysis from three studies^{21,39,48} revealed that compared with the CPS group, IFIS/iris trauma incidence in the FLACS group was statistically significantly low (OR = 0.35, 95% CI 0.13 to 0.97, P = 0.04; Fig. 4B).

6.3. c. Macular edema

This part we included thirteen studies, including 9 RCT^{24,27,28,30,35,44–46,48} and 4 perspective studies.^{14,36,49,55} Although there was revealed a higher incidence of macular edema with FLACS in the subgroup of none-RCT (OR = 3.40 95% CI 1.12 to 10.33, P = 0.03; Fig. 4C), there was no significant differences were founded in the RCT subgroup and total (RCT subgroup: OR = 0.90, 95% CI 0.62 to 1.31, P = 0.57; Total: OR = 1.07, 95% CI 0.76 to 1.51, P = 0.71; Fig. 4C), which was more credible for less selection bias in RCT studies.

Besides, no significant difference was discovered with respect to the risk of suprachoroidal hemorrhage (OR = 3.35, 95% CI 0.35 to 32.34, P = 0.30; Fig. S1A), zonular dialysis/disinsertion (OR = 1.00, 95% CI 0.37

Table 1

Characteristics of included studies. FLACS, femtosecond laser-assisted cataract surgery; CPS, conventional phacoemulsification surgery; RCT, randomized controlled trial; None, not available.

Study ID	Country	Study design	Age of FLACS	Age of CPS(eyes)	No. of FLACS(eyes)	No. of CPS(eyes)	Follow up
Abell 2013	Australia	Cohort	$\textbf{72.8} \pm \textbf{10.5}$	71.8 ± 10.8	200	200	1 month
Abell 2014	Australia	Cohort	$\textbf{72.4} \pm \textbf{10.1}$	$\textbf{72.6} \pm \textbf{9.8}$	804	822	2 months
Wang 2018	China	Cohort	57 ± 15	58 ± 14	58	34	3 months
Zhu, 2019	China	Cohort	69.39 ± 13.50	66.26 ± 12.58	66	66	6 months
Chlasta 2019	Poland	RCT	79.08 ± 5.51	74.59 ± 8.10	26	61	6 months
Conrad 2013	Germany	RCT	70.9	70.9	73	73	6 months
Dzhaber 2020a	USA	RCT	68 ± 9.6	68 ± 9.6	55	55	6 months
Day 2020	UK	RCT	68 ± 10		391	389	6 months
Day 2020a	UK	RCT	None	None	391	389	12 months
Day 2021	UK	RCT	68 ± 10		353	317	1 month
Schweitzer 2020	France	RCT	72.4 ± 8.6	$72 \cdot 1 \pm 8.7$	582	581	3 months
Dzhaber 2020	USA	RCT	68.3 ± 9.1		67	67	2 months
Reddy 2013	India	RCT	None	None	56	63	210 days
Daya 2014	UK	Cohort	None	None	108	108	3 months
Abell 2015	Australia	Cohort	73.5 ± 9.5	72.6 ± 9.6	1852	2228	3 months
Conrad 2015	Germany	RCT	71.6		100	100	3 months
Gao 2017	China	Cohort	66.32 ± 6.12	65.12 ± 7.15	59	47	3 months
Hansen 2020	USA	RCT	68.7 ± 8.5	69.0 ± 14.1	64	71	3 months
Liu 2016	China	Cohort	50.1 ± 3.3	49.6 ± 2.6	21	21	None
Ewe 2015	Australia	Cohort	71.7 ± 9.5	$\textbf{72.5} \pm \textbf{10.8}$	833	458	3 months
Mursch 2017	Australia	RCT	72 ± 6		50	50	1 month
Oka 2021	USA	RCT	73.4 ± 6.5		53	53	None
Ewe 2016	Australia	Cohort	72.1 ± 9.3	73.6 ± 10.4	988	888	12 months
Manning 2016	Europe & Australia	Cohort	66.4 ± 10.2	67.5 ± 9.9	2814	4917	None
Ferreira 2018	Portugal	RCT	69 ± 8	71 ± 8	300	300	1 month
Roberts 2019	UK	RCT	69.9 ± 10.9	70.5 ± 9.8	200	200	1 month
Roberts 2018	UK	RCT	69.07 ± 11.55	69.78 ± 10.14	134	165	1 week
Titiyal 2018	India	Cohort	60.5 ± 10.8	59.5 ± 10.9	52	77	1 week
Roberts 2018a	UK	RCT	72.5 ± 10.5	69.7 ± 12.0	53	51	3 months
Vasavada 2019	USA	RCT	67.21 ± 11.11	63.70 ± 11.84	91	91	3 months
Chen 2019	China	Cohort	52.75 ± 3.18		47	47	None
Villavilla 2021	Spain	Cohort	68.92	69.1	63	57	None
Zhang 2016	China	Cohort	64.7 ± 16.7	66.6 ± 12.4	153	161	None
Yu 2015	China	Cohort	62.3 ± 11.6	56.5 ± 16.6	25	29	3 months
Yang 2019	China	Cohort	60.51 ± 3.41	61.43 ± 3.46	47	47	3 months
Zheng 2022	China	Cohort	68.53 ± 7.45	71.40 ± 8.50	30	30	1 month
Stanojcic 2021	UK	RCT	70.1 ± 9.4	69.8 ± 9.4	116	118	12 months

to 2.67, P = 1.00; Fig. S1B), lens drop (OR = 0.41, 95% CI 0.12 to 1.43, P = 0.16; Fig. S1C), vitreous loss (OR = 0.67, 95% CI 0.38 to 1.16, P = 0.15; Fig. S1D), posterior vitreous detachment (OR = 1.14, 95% CI 0.39 to 3.28, P = 0.81; Fig. S1E) and retinal detachment (OR = 1.60, 95% CI 0.52 to 4.91, P = 0.41; Fig. S1F). Additionally, the incidence of corneal edema (OR = 1.37, 95% CI 0.66 to 2.82, P = 0.39; Fig. S1G), uveitis (OR = 1.28, 95% CI 0.97 to 1.68, P = 0.08; Fig. S1H), PCO (OR = 0.89, 95% CI 0.17 to 4.67, P = 0.89; Fig. S1] and uncontrolled high IOP (OR = 1.77, 95% CI 0.28 to 11.26 P = 0.55; Fig. S1J) also had no significantly differences between FLACS and CPS group.

7. Discussion

The femtosecond laser is a novel and advanced assistant technology for cataract surgery. Although several studies have evaluated the safety and efficacy of FLACS, the safety concerns with FLACS still exist. Previously, studies still did not get consistent results for sample size limitations. This meta-analysis added more RCTs and high-quality cohort studies to review the risk of inter/postoperative complications. Our metaanalysis considered the FLACS is as safe as CPS for cataracts. We found that FLACS does not increase the risk of intraoperative capsule tear, postoperative corneal edema, macular edema, uncontrolled IOP, etc. Additionally, applying FLACS would decrease intraoperative Descemet membrane tear/trauma, IFIS syndrome, and iris trauma. Although a high incidence of miosis, corneal epithelial defect, corneal haze, and subconjunctival hemorrhage irritated by FLACS, we still could control these efficiently without any influence on visual outcomes.

The quality of the capsular bag is known to be one of the most critical factors for the outcome of cataract surgery. Any complications of the

capsule, including capsular tears and posterior capsular rupture, would cause vitreous loss and the IOL rotation, decentration, and, thus, the visual outcome. ^{59,60} Previously, several studies reported a higher incidence of anterior capsular tears in FLACS and suggested that anterior capsule tears more likely result from aberrant pulses and "postage-stamp" edge pattern perforated by femtosecond laser, as well as the unexpected eye movements.^{16,61} Additionally, a learning curve also may be associated with the high anterior capsule tear rate in the femtosecond laser group. However, our meta-analysis demonstrated no difference between the FLACS and CPS groups in total. Our subgroup analysis found a high anterior capsule tear rate in FLACS eyes before 2015 and without significant differences between two groups after 2015 or analysis with whole studies. Although the meta-analysis of Kolb suggested higher rates of anterior capsule tear might account for the Catalys laser platform, we are more likely to believe that these interesting results might account for software upgrades and optimizing the capsulotomy setting.¹⁵ Abell 2015 found a significant reduction in anterior capsulotomy tags after software upgrades, which might for a less capsulotomy time and lower chance of aberrant pulses.^{32,58} Moreover, a greater vertical spot spacing (up to 20 µm) setting would significantly decrease the risk of anterior capsule tear.^{55,56} These results might also account for a bias of different techniques and experiences that the two multicenter studies of Abell might induce. Moreover, the posterior capsule rupture rate in the FLACS group seemed the same as the CPS group, which is consistent with the Qian, Chen, and Popovic meta-analysis findings.^{4,16,18} However, the more interesting point is the posterior capsule rupture rate seemed less with FLACS in the RCT subgroup and without differences in the none-RCT subgroup or total. These results might be caused by the selected bias induced by non-randomized allocation. Laser-assisted capsulotomy and

Anteriol capsule		~	CPS			Odds Ratio	Odds Ratio
Study or Subgroup					Weight	M-H, Random, 95% Cl	M-H, Random, 95% CI
2.1.1 2014-2015							
Abell 2014	15	804	1	822	7.0%	15.61 [2.06, 118.44]	
Abell 2015	34	1852	5	2228	11.7%	8.31 [3.25, 21.30]	
Conrad-Hengerer 2013	1	73	0	73	4.0%	3.04 [0.12, 75.89]	
Conrad-Hengerer 2015	0	100	1	100	4.0%	0.33 [0.01, 8.20]	
Reddy 2013	1	56	1	63	4.8%	1.13 [0.07, 18.45]	
Subtotal (95% CI)		2885		3286	31.5%	4.58 [1.42, 14.77]	
Total events	51		8				
Heterogeneity: $Tau^2 = 0$.	60; Chi ² =	= 6.03,	df = 4 (F)	P = 0.20	$(1); 1^2 = 34$	1%	
Test for overall effect: Z	= 2.55 (P	= 0.01)				
2.1.2 2015-							
Day 2020	3	391	2	389	7.9%	1.50 [0.25, 9.00]	
Day 2021	3	353	2	317	7.9%	1.35 [0.22, 8.13]	<u> </u>
Ewe 2016	15	988	3	888	10.3%	4.55 [1.31, 15.76]	
Hansen 2020	0	64	2	71	4.3%	0.22 [0.01, 4.57]	
Roberts 2018	3	134	3	165	8.6%	1.24 [0.25, 6.23]	
Roberts 2018a	2	53	0	51	4.3%	5.00 [0.23, 106.73]	
Roberts 2019	6	200	3	200	9.6%	2.03 [0.50, 8.24]	
Villavilla-Castillo 2021	2	63	0	63	4.3%	5.16 [0.24, 109.73]	
Zhang, 2016	0	153	5	161	4.6%	0.09 [0.01, 1.69]	· · · · · · · · · · · · · · · · · · ·
Zhu 2019	1	66	8	66	6.8%	0.11 [0.01, 0.92]	
Subtotal (95% CI)		2465		2371	68.5%	1.22 [0.53, 2.80]	
Total events	35		28				
Heterogeneity: $Tau^2 = 0$.	72; Chi ² =	= 15.74	, df = 9	(P = 0.0)	$(77); I^2 = 4$	3%	
Test for overall effect: Z	= 0.46 (P	= 0.64)				
Total (95% CI)		5350		5657	100.0%	1.75 [0.82, 3.73]	
Total events	86		36				
Heterogeneity: $Tau^2 = 1$.	04; Chi ² =	= 29.93	df = 14	(P = 0)	.008); I ² =	= 53%	0.01 0.1 1 10 1
Test for overall effect: Z	= 1.45 (P	= 0.15)				Favor[FLACS] Favor[CPS]
Test for subgroup differe	ences: Chi	² = 3.2	6, $df = 1$	(P = 0	.07), $I^2 =$	69.4%	

B. Posterior capsule tear

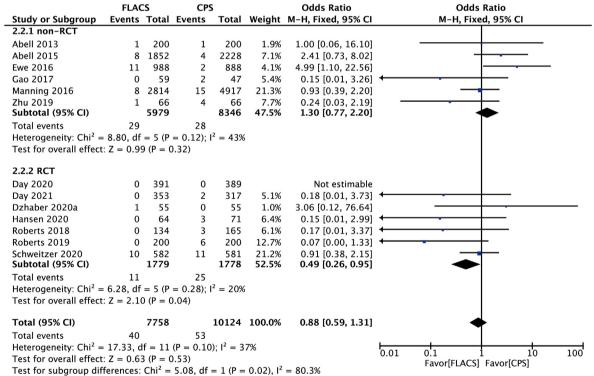


Fig. 2. Forest plot comparison of capsule tear rate after treatment with FLACS and CPS. A. Anterior capsule tear. B. Posterior capsule tear.

lens fragmentation with FLACS would greatly decrease the surgical difficulty. Patients would prefer to select FLACS and expect a better visual outcome. Meanwhile, a surgeon would choose laser-assisted pretreatment to down the surgical difficulty unconsciously. These possibilities might contribute to the selection bias and cover the potential benefit for

FLACS.

Additionally, the more interesting point is the incidence of posterior capsule rupture in FLACS was potentially lower in the analysis of the RCT subgroup. We should also pay attention to these beneficial features, and more well-designed RCTs, especially well-blinded RCTs, are still

A. Corneal epithelial defect FLACS CPS Odds Ratio **Odds** Ratio Events Total Events Total Weight Study or Subgroup M-H, Fixed, 95% CI M-H, Fixed, 95% CI Ewe 2016 988 0 888 10.8% 13.58 [0.77, 238.09] Zhang, 2016 17 153 161 89.2% 3.90 [1.40, 10.85] 5 Total (95% CI) 1049 100.0% 4.94 [1.91, 12.80] 1141 24 5 Total events Heterogeneity: $Chi^2 = 0.68$, df = 1 (P = 0.41); I^2 - 0% 0.01 0.1 10 100 Test for overall effect: Z = 3.29 (P = 0.001)Favor[FLACS] Favor[CPS] **B.** Corneal haze FLACS CPS **Odds Ratio Odds Ratio** M-H, Fixed, 95% Cl M-H, Fixed, 95% C **Study or Subgroup** Events Total Events Total Weight Abell 2015 12 1852 1 2228 63.3% 14.52 [1.89, 111.80] Ewe 2016 36.7% 11.76 [0.66, 208.98] 6 988 0 888 Total (95% CI) 2840 3116 100.0% 13.51 [2.55, 71.47] Total events 18 1 Heterogeneity: $Chi^2 = 0.01$, df = 1 (P = 0.91); I^2 0.01 100 10 0.1 Test for overall effect: Z = 3.06 (P = 0.002)Favor[FLACS] Favor[CPS] C. Subconjunctival hemorrhage FLACS CPS Odds Ratio Odds Ratio Study or Subgroup Weight M-H, Random, 95% CI M-H, Random, 95% C Events Total **Events** Total Chlasta-Twardzik 2019 3 26 0 61 13 2% 18.32 [0.91, 368.34] Mursch-Edlmayr 2017 27 50 1 50 18.7% 57.52 [7.36, 449.73] Oka 2021 12.2% 3.06 [0.12, 76.76] 1 53 0 53 Yang 2019 47 47 14.2% 1.00 [0.06, 16.47] 1 1 Yu 2015 5 0 29 13.5% 15.83 [0.83, 302.25] 25 Zhang, 2016 35 153 20 161 28.2% 2.09 [1.15, 3.82] Total (95% CI) 401 100.0% 6.42 [1.48, 27.86] 354 72 22 Total events Heterogeneity: $Tau^2 = 1.90$; $Chi^2 = 13.79$, df = 5 (P = 0.02); $I^2 = 64\%$ 0.01 100 0.1 10 Test for overall effect: Z = 2.48 (P = 0.01)Favor[FLACS] Favor[CPS] **D. Small pupil** CPS Odds Ratio FLACS **Odds Ratio** Study or Subgroup Events Total Events Total Weight M-H, Fixed, 95% CI M-H, Fixed, 95% CI Abell 2013 200 13.40 [0.75, 239,49] 200 2.5% 6 0 Abell 2015 30 1852 14 2228 65.8% 2.60 [1.38, 4.93] Day 2020 3 391 1 389 5.2% 3.00 [0.31, 28.97] Day 2021 3 353 1 317 5.5% 2.71 [0.28, 26.17] Dava 2014 3 108 0 108 2.5% 7.20 [0.37, 141.07] Mursch-Edlmavr 2017 7 2.55 [0.62, 10.49] 50 3 50 13.6% Yang 2019 1 47 0 47 2.5% 3.06 [0.12, 77.16] Yu 2015 29 3.61 [0.14, 92.71] 1 25 0 2.3% Total (95% CI) 3368 100.0% 3.05 [1.83, 5.07] 3026 19 Total events 54 Heterogeneity: $Chi^2 = 1.65$, df = 7 (P = 0.98); I^2 0% 0.01 0.1 10 100 Test for overall effect: Z = 4.30 (P < 0.0001)Favor[FLACS] Favor[CPS]

Fig. 3. Forest plot comparison of FLACS specific complications rates after treatment with FLACS and CPS. A. Corneal epithelial defect. B. Corneal haze. C. Subconjunctival hemorrhage. D. Small pupil.

necessary to provide more reliable evidence. Essentially, the clinical significance should be considered when discussing these results.

Using femtoseconds laser and direct contact with the ocular surface would bring out several FLACS specific complications.⁶² In this meta-analysis, we first reviewed and showed that FSL pretreatment could significantly increase the incidence of unexpected miosis, subconjunctival hemorrhage, corneal epithelial defect, and corneal haze. Miosis after FSL mainly accounts for the increased concentration of PGE in aqueous humor.⁶³ Although intraoperative miosis always bothers the surgery, an experienced surgeon would pretreat with topical NSAID and efficiently decrease the possible risk for intraoperative miosis.⁶⁴ The ocular surface injuries might partially result from the learning curve, and the fluorescein staining of the corneal would heal within 1 week, not affecting the visual outcome.⁶⁵ Overall, with more experience, the FLACS specific complication could be prevented efficiently and not affect the visual outcome. Additionally, our meta-analysis revealed more benefits from making corneal incisions with FLACS for a lower incidence of

Descemet membrane tear or trauma. Moreover, FLACS was superior in a lower rate of IFIS/iris trauma and with similar security on the incidence of macular edema. These data indicate that FLACS has the same safety as CPS.

However, several limitations are still presented in this study. Some of the limitations originate from the clinical trial. In some trials, it is difficult to blind the type of operation to participants and personnel, which might induce performance bias. The random sequence also lacked in some trials, which would result in a selection bias. Thus, we included high-quality cohort studies and reliable RCTs in our study. Additionally, the complication data were coming from different trials. It is hard to control the variances and heterogeneities from patients, surgeons, and even the type of femtosecond laser platform. Also, the follow time is different among the included studies, which might affect the incidence of part complications such as macular edema, uveitis, PCO, etc. Moreover, each complication in our study was extracted from different trails, which only interested in a specific field.

A. Descemet membrane tear/trauma

	FLAC	S	CPS	5		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI
1.2.1 manual							
Chlasta-Twardzik 2019	3	26	1	61	8.5%	7.83 [0.77, 79.13]	
Ewe 2016	3	988	0	888	6.2%	6.31 [0.33, 122.35]	
Mursch-Edlmayr 2017	13	50	19	50	17.1%	0.57 [0.24, 1.34]	
Roberts 2018	1	134	0	165	5.6%	3.72 [0.15, 92.04]	
Roberts 2019	2	200	0	200	6.0%	5.05 [0.24, 105.86]	
Vasavada 2019	9	91	16	91	17.0%	0.51 [0.21, 1.23]	
Subtotal (95% CI)		1489		1455	60.5%	1.30 [0.49, 3.44]	
Total events	31		36				
Heterogeneity: $Tau^2 = 0.5$	59; Chi ² =	= 9.61,	df = 5 (F)	P = 0.09	9); $I^2 = 48$	%	
Test for overall effect: Z =	= 0.53 (P	= 0.60)				
1.2.2 laser assisted							
Ferreira 2018	0	300	17	300	6.7%	0.03 [0.00, 0.45]	←
Titiyal 2018	5	52	38	77	16.0%	0.11 [0.04, 0.30]	
Wang 2018	33	58	24	34	16.8%	0.55 [0.22, 1.36]	
Subtotal (95% CI)		410		411	39.5%	0.16 [0.03, 0.79]	
Total events	38		79				
Heterogeneity: $Tau^2 = 1.3$	34; Chi ² =	= 8.46,	df = 2 (F	P = 0.02	1); $I^2 = 76$	%	
Test for overall effect: Z =	= 2.26 (P	= 0.02)				
Total (95% CI)		1899		1866	100.0%	0.64 [0.26, 1.56]	
Total events	69		115				<i></i>
Heterogeneity: $Tau^2 = 1.0$	01; Chi ² =	= 24.98	df = 8	(P = 0.0)	$(002); I^2 =$	68%	
Test for overall effect: Z =							
Test for subaroup differe				(P = 0)	$(03) I^2 = 1$	79 3%	Favor[FLACS] Favor[CPS]

Test for overall effect: Z = 0.98 (P = 0.33) Test for subgroup differences: Chi^2 = 4.83, df = 1 (P = 0.03), I^2 = 79.3%

B. IFIS/iris trauma

	FLAC	CS	CPS	5		Odds Ratio		Odds Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl		M-H, Fixed, 95% Cl	
Manning 2016	1	2814	5	4917	25.1%	0.35 [0.04, 2.99]	_		
Roberts 2018a	1	53	3	51	20.7%	0.31 [0.03, 3.06]			
Roberts 2019	3	200	8	200	54.3%	0.37 [0.10, 1.40]			
Total (95% CI)		3067		5168	100.0%	0.35 [0.13, 0.97]			
Total events	5		16						
Heterogeneity: Chi ² =	0.02, df	= 2 (P	= 0.99);	$I^2 = 0\%$	5		0.01	0.1 1 10	100
Test for overall effect:	Z = 2.0	2 (P = 0).04)				0.01	0.1 1 10 Favor[FLACS] Favor[CPS]	100

C. Macular edema

	FLAG	S	CPS			Odds Ratio	Odds Ratio
Study or Subgroup					Weight	M-H, Fixed, 95% CI	M–H, Fixed, 95% Cl
3.3.1 non-RCT					-		
Chen 2019	1	47	1	47	1.6%	1.00 [0.06, 16.47]	
Ewe 2015	7	833	1	458	2.0%	3.87 [0.48, 31.58]	
Ewe 2016	8	988	1	888	1.7%	7.24 [0.90, 58.01]	
Liu 2016	1	21	1	21	1.5%	1.00 [0.06, 17.12]	
Subtotal (95% CI)		1889		1414	6.8%	3.40 [1.12, 10.33]	
Total events	17		4				
Heterogeneity: $Chi^2 = 1.9$	97, df = 3	B (P = 0)	.58); I ² =	0%			
Test for overall effect: Z	= 2.15 (P	= 0.03)				
3.3.2 RCT							
Conrad-Hengerer 2013	2	73	1	73	1.6%	2.03 [0.18, 22.87]	
Conrad-Hengerer 2015	1	100	2	100	3.2%	0.49 [0.04, 5.55]	
Day 2020	8	391	7	389	11.0%	1.14 [0.41, 3.17]	
Day 2020a	9	391	14	389	21.9%	0.63 [0.27, 1.48]	
Day 2021	8	353	7	317	11.5%	1.03 [0.37, 2.86]	
Hansen 2020	1	64	0	71	0.7%	3.38 [0.14, 84.41]	
Oka 2021	1	53	0	53	0.8%	3.06 [0.12, 76.76]	
Roberts 2018a	2	53	0	51	0.8%	5.00 [0.23, 106.73]	
Schweitzer 2020	21	582	27	581	41.7%	0.77 [0.43, 1.37]	
Subtotal (95% CI)		2060		2024	93.2%	0.90 [0.62, 1.31]	+
Total events	53		58				
Heterogeneity: $Chi^2 = 4.3$	30, df = 8	B(P=0)	.83); I ² =	: 0%			
Test for overall effect: Z	= 0.56 (P	= 0.57)				
Total (95% CI)		3949		3438	100.0%	1.07 [0.76, 1.51]	
Total events	70		62				ĺ
Heterogeneity: $Chi^2 = 9.9$	97, df = 1	2 (P =	0.62); I ²	= 0%			0.01 0.1 1 10 100
Test for overall effect: Z	= 0.38 (P	= 0.71)				0.01 0.1 1 10 100 Favor[FLACS] Favor[CPS]
Test for subgroup differe	nces: Chi	i ² = 4.9	3, df = 1	(P = 0	.03), I ² =	79.7%	ravui[rlacs] ravui[crs]
-							

Fig. 4. Forest plot comparison of other intraoperative and postoperative complications rates after treatment with FLACS and CPS. A. Descemet membrane tear/trauma. B. IFIS/iris trauma. C. Macular edema.

8. Conclusion

In conclusion, our meta-analysis holds that FLACS maintain the same safety compared with CPS in terms of all intraoperative and postoperative complications. However, we expected more large patient populations and well-designed RCTs with longer follow-up periods to update the findings of this analysis.

Study Approval

Not Applicable.

Author Contributions

The authors confirm contribution to the paper as follows: Conception and design of study: KY, XYC; Data collection: JJX, HLW; Drafting the manuscript: JJX, XYC; All authors reviewed the results and approved the final version of the manuscript.

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Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Editorship Disclosure

Given his role as Editor-in-Chief, Ke Yao had no involvement in the peer-review of this article and has no access to information regarding its peer-review. Full responsibility for the editorial process for this article was delegated to Prof. Andrzej Grzybowski.

Abbreviations

- FLACS femtosecond laser-assisted cataract surgery
- CPS conventional phacoemulsification surgery
- RCT randomized controlled trial
- ECCE extracapsular cataract extraction
- FSL femtosecond laser
- IOL intraocular lens
- EPT effective phacoemulsification time
- NOS newcastle-Ottawa Scale

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://do i.org/10.1016/j.aopr.2022.100027.

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