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REVIEW

Optimal Timing for Intraocular Pressure Measurement Following Femtosecond Laser-Assisted Cataract Surgery: A Systematic Review and Meta-Analysis

William J Herspiegel[1,*], Brian E Yu[1,*], Monali S Malvankar-Mehta[1,2,*], Cindy ML Hutnik[1,2,*]

[1]Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada; [2]Ivey Eye Institute, St. Joseph's Health Care, London, Ontario, Canada

*These authors contributed equally to this work

Correspondence: William J Herspiegel, Schulich School of Medicine & Dentistry, Western University, London, Ontario, Canada, Email wherspiegel2026@meds.uwo.ca

Purpose: Femtosecond laser-assisted cataract surgery (FLACS) has increasingly been adopted worldwide. Lagging behind is evidence-based consensus regarding optimal timing for intraocular pressure (IOP) measurement following FLACS. The purpose of this study was to determine if enough evidence currently exists to guide best practice.

Methods: A comprehensive literature search was performed on MEDLINE and EMBASE until February 6th, 2023. Articles reporting IOP measurements following uncomplicated FLACS were screened. For change in IOP at various post-operative timepoints, standardized mean difference (SMD) was calculated as the mean difference in IOP from baseline. Risk of Bias Assessment was conducted following data extraction.

Results: The meta-analysis incorporated six randomized clinical studies involving a total of 1356 eyes from 1032 participants. Post-operative day one was the only timepoint with a non-significant increase in IOP (SMD = −0.08 [95% CI: −0.41 to +0.24]) compared to the 7-days, 30-days, 60 to 90-days, and 180-days follow-up periods. All studies except one utilized an ophthalmic viscosurgical device (OVD) in their procedure; this was the only publication that reported a decrease in IOP from baseline within the 1-day follow-up period.

Conclusion: The results suggest that the optimal time to measure IOP is within the first 24 hours after FLACS. However, these findings are limited by a small study sample. Future prospective clinical trials may be beneficial to determine if specific timepoints within the first 24 hours exist to optimize outcomes and patient reported experiences.

Keywords: IOP, FLACS, preferred practice, tonometry, Goldmann applanation tonometry

Introduction

Cataract is considered to be a natural physiologic change associated with aging that affects 95 million people globally, making it the leading cause of reversible visual impairment worldwide.[1,2] Cataract's incidence is expected to increase as a consequence of continuously aging North American and global populations.[3,4] Visual impairments caused by cataracts can be treated with minimal complications through cataract extraction surgery, which is a prevalent procedure that is rapidly growing both in North America and globally.[1,3,5] Femtosecond laser-assisted cataract surgery (FLACS) is one such cataract extraction technique that is gaining popularity among eye care professionals and patients.[6] Reported benefits of FLACS include a reduced use of emulsifying ultrasound energy, improved precision and quality of incision, and increased reliability of capsulotomy construction and positioning.[7]

A common complication of non-FLACS phacoemulsification cataract surgery is elevation in the eye's intraocular pressure (IOP). IOP spikes can cause increased morbidities, which includes ocular pain, nausea, vomiting, corneal edema, and blurred

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vision, in the acute period immediately following, and up to one month after, cataract surgery.[8–11] Additionally, IOP spikes can further worsen pre-existing optic nerve damage, such as that experienced in glaucoma, even if experienced over a short period.[12] Patients' perception of outcomes and expectations are increasingly becoming associated with how quickly they achieve improved visual acuity as well as their overall experience. Complications associated with acute IOP spikes may cause patients to worry that something went wrong during surgery, even with an excellent final visual outcome.

The American Academy of Ophthalmology (AAO) makes recommendations regarding optimal timing of IOP checks post-phacoemulsification cataract surgery in the 2021 Cataract in the Adult Eye Preferred Practice Patterns.[12] The AAO recommends IOP should be measured within the first 48 hours after uneventful low-risk surgery in patients with no signs or symptoms of possible complications. Additionally, it is recommended that functionally monocular patients and those at high risk of early post-operative complications should have IOP measured within the first 24 hours post-surgery. These recommendations are based on publications focusing on phacoemulsification, rather than FLACS. There are several differences between FLACS and non-laser assisted phacoemulsification, which include technique, cumulative dissipated energy, and mechanical manipulation, with differences in the risk of corneal injury and edema.[13,14]

Therefore, this study was conducted as currently there are no definitive clinical practice guidelines specifying the optimal time to measure IOP after FLACS. Additionally, it remains unclear whether FLACS varies from the more conventional phacoemulsification extraction method in terms of elevated IOP risk. Determining the optimal time to measure IOP after FLACS will aid surgeons in identifying acute post-operative IOP spikes and prevent their associated morbidities. The purpose of this meta-analysis was to determine the status of evidence which may help guide best practice, and if not available, to inform prospective trials to specifically answer this question.

Methods

Search Strategy

A literature search was conducted in two databases, MEDLINE and EMBASE. The search was conducted until February 6th, 2023. Sets of keywords relating to Intraocular Pressure, after (ie post, following), and Cataract Surgery (ie cataract surgery, cataract surgeries) were used with restrictions placed on adult human subjects, English-published literature, randomized controlled trials, and randomized clinical trials. Articles were then imported into Covidence (Veritas Health Innovation, n.d)., a web-based systematic review screening tool, which removed duplicates and created two levels of screening: title and abstract screening, and full-text screening.

After importing articles into Covidence, two reviewers (WJH and BEY) independently screened titles and abstracts for articles that measured IOP following uncomplicated cataract surgery. Articles that passed the first level of screening then proceeded through a second level where independent full texts were reviewed for studies that accurately measured IOP following uncomplicated FLACS. Conflicts at both levels of screening were resolved through discussion to find consensus between the reviewers. After each screening level, chance-corrected kappa statistic was used to assess interobserver agreement for the inclusion of studies.

Inclusion and Exclusion Criteria

The population of interest consisted of human adults who, following routine cataract surgery, had IOP measured. Included publications had to measure IOP by tonometry prior to and after completion of cataract surgery. Included studies extraction method of choice had to be FLACS. Included publications had to be randomized clinical trials, written in English. Studies were excluded if the cataract surgery was combined with another ophthalmologic surgery. Publications focusing on participants younger than 18 or those with an ophthalmologic condition other than cataract were excluded. No limits were placed on study location, publication date, or sex.

Risk of Bias Assessment

The quality of each study was assessed using the CLARITY risk of bias instrument for randomized controlled trials.[15] This assessment tool measures the risk of bias based on six factors: 1) adequacy of allocation sequence generation, 2) adequacy of allocation concealment, 3) study blinding, which is further subdivided into 3a. patient blinding, 3b.

healthcare provider blinding, 3c. data collectors blinding, 3d. outcome assessors blinding, and 3e. data analysts blinding, 4) frequency of missing outcome data lost during follow-up, 5) degree of selective outcome reporting, and 6) other potential problems that could influence risk of bias.

Data Extraction

For included studies, quantitative and qualitative information related to participants' IOP was collected independently. Extracted data included: study information (ie, author and year), study characteristics (ie, mean age of participants, location of study), and surgical outcomes (ie, FLACS system used, fragmentation pattern used, visualization system used, ophthalmic viscosurgical device (OVD) usage, time of IOP measurement, and IOP measured). Data entry was extracted manually into Microsoft Excel.

Statistical Analysis

Meta-analysis was completed using STATA v. 18.0 (StataCorp, 2018). The main outcome of interest was a change in IOP from baseline over different measurement times. Change in IOP was evaluated using the standardized mean difference (SMD), which was determined as the mean deviation in IOP from baseline. To test heterogeneity, statistics, *Z*-value, and χ^2 statistics were computed. A value below 50% indicates low heterogeneity, and in such instances a fixed-effect model was applied. A statistic of 50% or higher signifies high heterogeneity, prompting the calculation of a random-effects model. Additionally, a high *Z*-value, a low p-value (<0.01), and a large value implies significant heterogeneity and, therefore, a random-effect model using DerSimonian and Laird methods was computed. The study adopted a significance level of 0.05. Forest plots were created for each case. Funnel plots were produced to examine publication bias. The sources of heterogeneity were also investigated.

Results

Search Results

Database searches resulted in 855 published literature records, with 230 duplicates being removed. At the end of the title and abstract screening, the remaining 237 articles moved on to full-text screening. After full-text screening, six randomized controlled trials and randomized clinical trials were included.[16–21] The Kappa statistic for the first and second levels of screening came to 0.439 and 1.0, respectively. The meta-analysis study retrieval process is detailed in a Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram (Figure 1).[22]

Study Characteristics

This meta-analysis includes six randomized clinical trial studies with a total of 1356 eyes of 1032 participants (Table 1). [16–21] 46.9% of the included eyes were from female participants, with the mean age of included participants being 69.6 years old. One study did not report mean age of participants. Three studies were performed in Germany, two in China, and one in the United States. All studies were published within the last 10 years.

Risk of Bias Assessment

Five of the six studies were classified as a moderate risk of bias and one study was considered low risk of bias (Wang et al, 2021) (Table 2). The biggest concerns stemmed from unclear information about study blinding, as only two studies reported data collectors and outcome assessors were blinded.

Publication Bias

To assess the risk of publication bias, a funnel plot was generated for studies that measured change in IOP following FLACS (Figure 2). Included studies are scattered around the top left, top middle, top right, and bottom right portions of the funnel plot. However, there appears to be studies missing from the bottom left and bottom middle portions of the plot. As such, the funnel plot suggests asymmetry and implies that small studies with non-significant results may not be published. However, publication bias is only one of many reasons that may account for funnel plot asymmetry. Other potential reasons include difficulty in interpretation of the funnel plot for a small group of studies, high heterogeneity, and small effect sizes. Thus, the presence of publication bias could not be concluded.

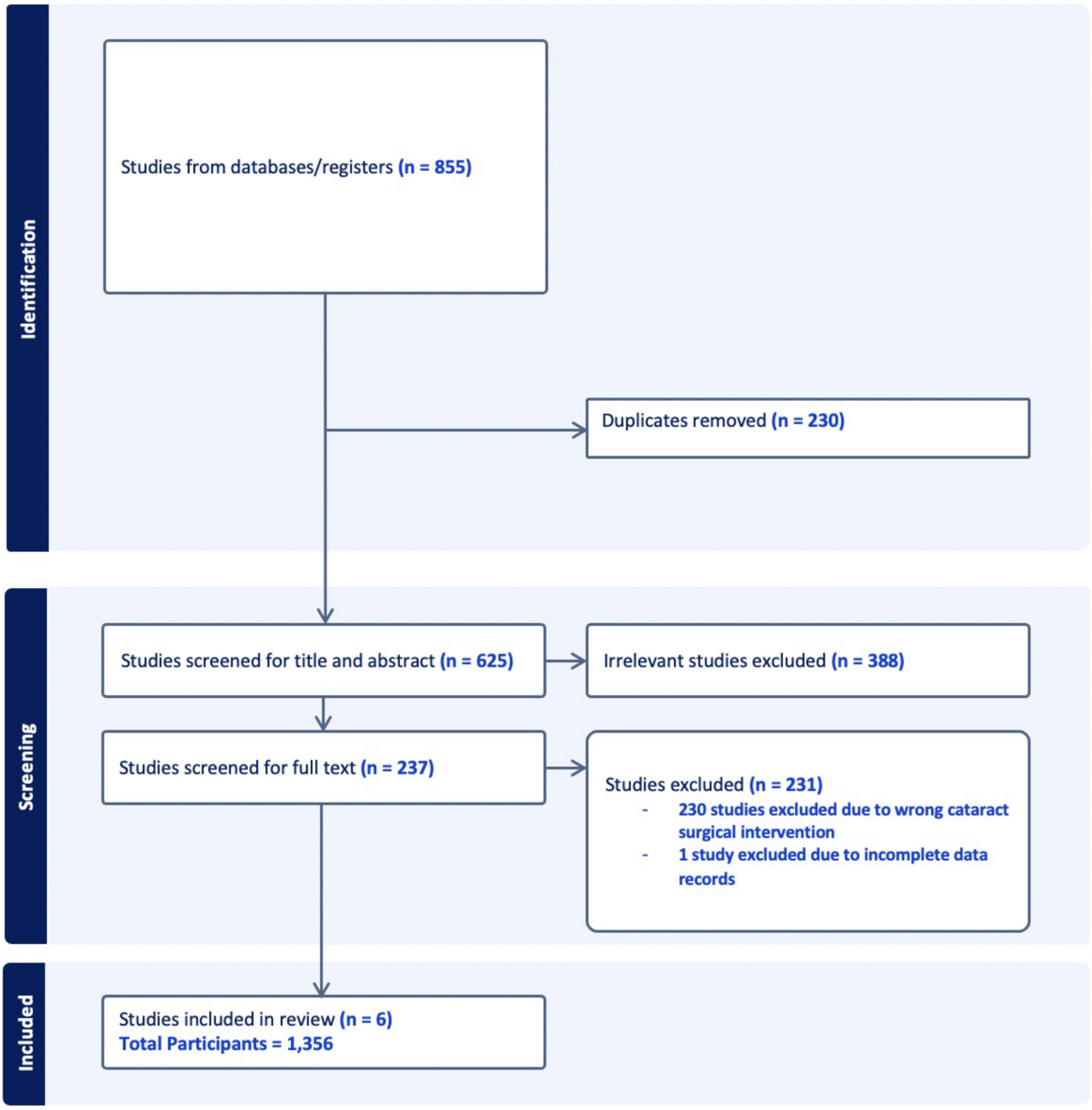

Figure 1 PRISMA flow diagram for optimal timing for intraocular pressure measurement following femtosecond laser-assisted cataract surgery showing the number (n) of included articles at each level of article screening.
Notes: PRISMA figure adapted from Liberati A, Altman D, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. Journal of clinical epidemiology. 2009;62(10). Creative Commons.[23]

Effect on IOP

In Figure 3, a meta-analysis was performed to evaluate the impact of FLACS on IOP over multiple timepoints throughout follow-up. Supplementary Table 1 outlines the mean IOP measurements at baseline and at each post-operative follow-up day for each included study. Significant heterogeneity was found between studies at 1-day, 7-days, 30-days, 60 to 90-days, and 180-day follow-up periods (I^2 = 85.2%, 90.0%, 56.0%, 80.5%, and 92.7%, respectively). Thus, a random-effects meta-analysis was performed using the DerSimonian and Laird method, given the significant heterogeneity among included articles. At 1-day follow-up, results indicate a non-significant increase in IOP (SMD = −0.08 [95% CI: −0.41 to +0.24]). At 7-days follow-up, results indicate a significant reduction in IOP (SMD = 0.58 [95% CI: 0.08–1.08]). At 30-

Table 1 Study Characteristics of Included Studies

Author	Year	Study Design	Study Location	Total number of participants, N	Total number of eyes, N	Age, Mean (SD); Range; N (%), etc.	Female eyes, N (%)
Dzhaber et al[16]	2020	Randomized Clinical Trial	Germany	55	55	68(9.6)	23 (41.9)
Khodabakhsh et al[17]	2018	Randomized Clinical Trial	United States	50	100	69.9(8.61)	62 (62)
Lyu et al[18]	2020	Randomized Clinical Trial	China	661	894	Mean (range)69 (61–78)	360 (59.7)
Schargus et al[19]	2015	Randomized Clinical Trial	Germany	37	37	Mean (range)71.8 (48–85)	22 (59.5)
Schojai et al[20]	2017	Randomized Clinical Trial	Germany	28	28		19 (67.9)
Wang et al[21]	2021	Randomized Clinical Trial	China	201	242	(group a) 69.61(12.32) (group b) 69.40(11.82)	150 (74.6)

days follow-up, results indicate a significant reduction in IOP (SMD = 0.66 [95% CI: 0.24–1.08]). Between 60 to 90-days follow-up, results indicate a significant reduction in IOP (SMD = 1.13 [95% CI: 0.49–1.77]). Finally, at 180-days follow-up, results indicate a non-significant reduction in IOP (SMD = 1.01 [95% CI: −0.38 to +2.40]). Therefore, our results indicated non-significant changes in IOP at 1-day and 180-days follow-up. However, our results also indicated significant decreases in IOP after the FLACS procedure at 7-days, 30-days, and 60–90-days follow-up.

Surgical Parameters

Five of the six included studies made use of an OVD in their cataract surgery procedure, while one study (Schargus et al, 2015) did not (Table 3). Only two studies reported which type of OVD was used as one study used 4.0% Chondroitin sulphate-3.0% sodium hyaluronate (Dzhaber et al, 2020) and one study used Sodium hyaluronate 1% (Schojai et al, 2017). In terms of FLACS system used, three studies used the LenSx, one study used the Catalys, one study made use of both by comparing the LenSx and the Catalys systems, and one study did not report which FLACS system was used (Table 3). Five studies used traditional microscope as their visualization system of choice, while one study examined traditional microscope compared to 3D heads-up display in two different sample groups. Finally, in terms of FLACS fragmentation pattern utilization, one study made use of Concentric cylinders and Segment cuts, one study used Quadrant and Grid, and one study compared quadrant, sextant, and grid patterns. Four studies did not report the FLACS fragmentation pattern used.

Medications Administered

Five of the six studies reported medications administered while one study did not report which medications were used in their protocol (Khodabakhsh et al, 2018) (Table 4). Pre-operatively, three out of the six studies reported administering a fluoroquinolone antibiotic, while one study reported using a non-steroidal anti-inflammatory (NSAID). Intra-operatively, one study reported administering a non-preserved adrenaline intracameral injection in 3.4% of patients who developed miosis during the procedure. Post-operatively, five studies reported administering an antibiotic, with ofloxacin or tobramycin being the only two medications reported. Four studies reported prescribing a steroid post-operatively, with dexamethasone or prednisolone being the two medications reported. Finally, three studies reported using a NSAID post-operatively, with pranoprofen being the only medication reported.

Discussion

A systematic review and meta-analysis were conducted to determine the status of evidence which may help guide best practices regarding the optimal time following FLACS to measure post-operative IOP, and if not available, to inform prospective trials to answer this question. Various database searches of randomized clinical trial studies measured the change

Table 2 Results of Risk of Bias Assessment for Studies Included

Author Name and Year	1. Was the Allocation Sequence Adequately Generated?	2. Was the Allocation Adequately Concealed?	3.a. Were Patients Blinded?	3.b. Were Healthcare Providers Blinded?	3.c. Were Data Collectors Blinded?	3.d. Were Outcome Assessors Blinded?	3.e. Were Data Analysts Blinded?	4. Was Loss to Follow-up (Missing Outcome Data) Infrequent?	5. Are Reports of the Study Free of Selective Outcome Reporting?	6. Was the Study free of Other Problems that could put it at a Risk of Bias?	Overall Risk of Bias
Dzhaber et al 2020[16]	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Probably no	Definitely no (high risk of bias)	Probably no	Probably no	Probably no	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Moderate
Khodabakhsh et al 2018[17]	Probably no	Probably no	Probably no	Definitely no (high risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely no (high risk of bias)	Moderate
Lyu et al 2020[18]	Definitely yes (low risk of bias)	Probably no	Probably no	Definitely no (high risk of bias)	Probably no	Probably no	Probably no	Probably yes	Definitely yes (low risk of bias)	Probably yes	Moderate
Schargus et al 2015[19]	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Probably no	Definitely no (high risk of bias)	Probably no	Probably no	Probably no	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely no (high risk of bias)	Moderate
Schojai et al 2017[20]	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Probably no	Definitely no (high risk of bias)	Probably no	Probably no	Probably no	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Moderate
Wang et al 2021[21]	Definitely yes (low risk of bias)	Probably no	Probably no	Definitely no (high risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Definitely yes (low risk of bias)	Probably yes	Definitely yes (low risk of bias)	Probably yes	Low

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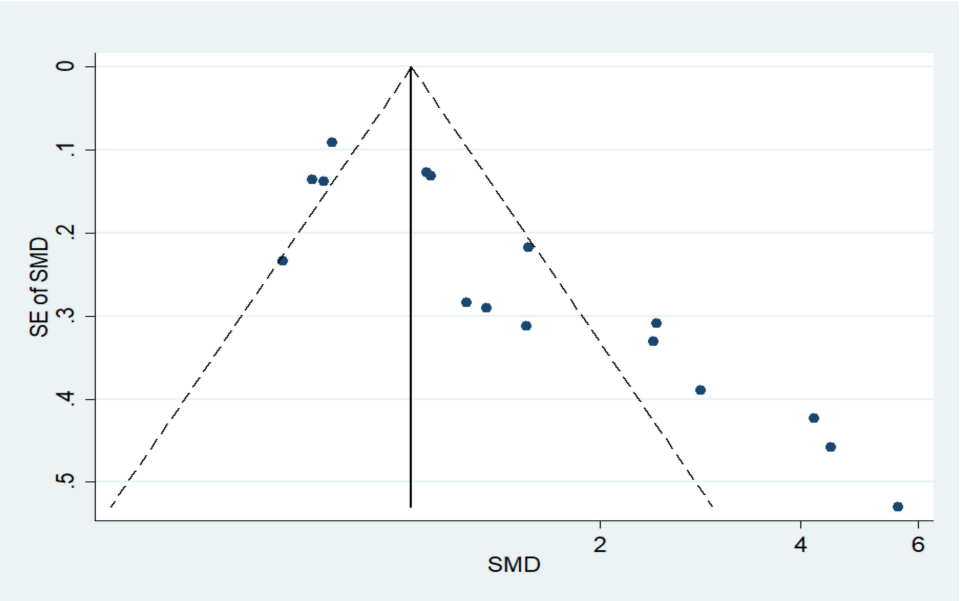

Figure 2 Funnel plot for included meta-analysis studies that provided data on the change in IOP following FLACS.

in post-operative IOP from pre-operative baseline measurements. Some studies also reported on the use of OVD, the FLACS system employed during cataract extraction, and the medications used.

According to this study, the 1-day follow-up was the only post-operative timepoint to see an increase in IOP, even though it was considered non-significant. In addition, three out of the four papers that reported a 1-day follow-up period saw a significant increase in IOP. This suggests that, compared to baseline, IOP is most elevated 1-day following FLACS. The available data indicate that the optimal time to measure IOP is within the first 24 hours post-operation. These findings are comparable to current literature surrounding conventional phacoemulsification, as a recent study found IOP to be significantly elevated only at 1 day following phacoemulsification extraction, compared to 7 days and 30 days post-operation.[24]

7-days, 30-days, and 60–90-days follow-up periods all saw a significant reduction in IOP, while the 180-days follow-up saw a non-significant reduction in IOP. These findings support a continuous long-term decrease in IOP after the initial acute increase following FLACS. Furthermore, these findings align with previous literature demonstrating FLACS to be comparable to phacoemulsification in terms of a long-term decrease in IOP.[25]

Schargus et al was the only included publication that had a surgical procedure that did not involve the use of an OVD during FLACS. Additionally, this was the only publication to show a decrease in IOP from baseline during a 1-day follow-up. This suggests that acute elevation following FLACS is likely due primarily to retained OVD, resulting in a mechanical obstruction of the trabecular meshwork which impedes outflow and causes IOP spikes.[26] This is the same mechanism for conventional phacoemulsification.[7,26] Similar to FLACS, the optimal time to measure post-operative IOP is within the first 4 to 8 hours following phacoemulsification.[27]

Therefore, despite differences in technique, cumulative dissipated energy, and mechanical manipulation, the traditional use of an OVD in both procedures may be one explanation to their similar optimal timings for post-operative IOP measurements.[13,14]

Five studies reported medications used at pre-operative, intra-operative, and post-operative stages of their respective protocols (Table 4). The most common pre-operative medications were either an antibiotic or a NSAID. Intra-operatively, only one study reported medication use, with only 3.4% of their sample receiving a non-preserved adrenaline (1:10,000) intracameral injection. Post-operatively, five out of the six studies used a combination of either an antibiotic, steroid, or NSAID, which is the current standard treatment post-cataract extraction. None of the studies reported the routine use of intra-operative or post-operative IOP lowering medications. The medication combinations listed have been shown to have a small effect on IOP in the immediate days following cataract surgery.[28] Therefore, the medications would have a minimal impact on our IOP findings within the first 24 hours following FLACS.

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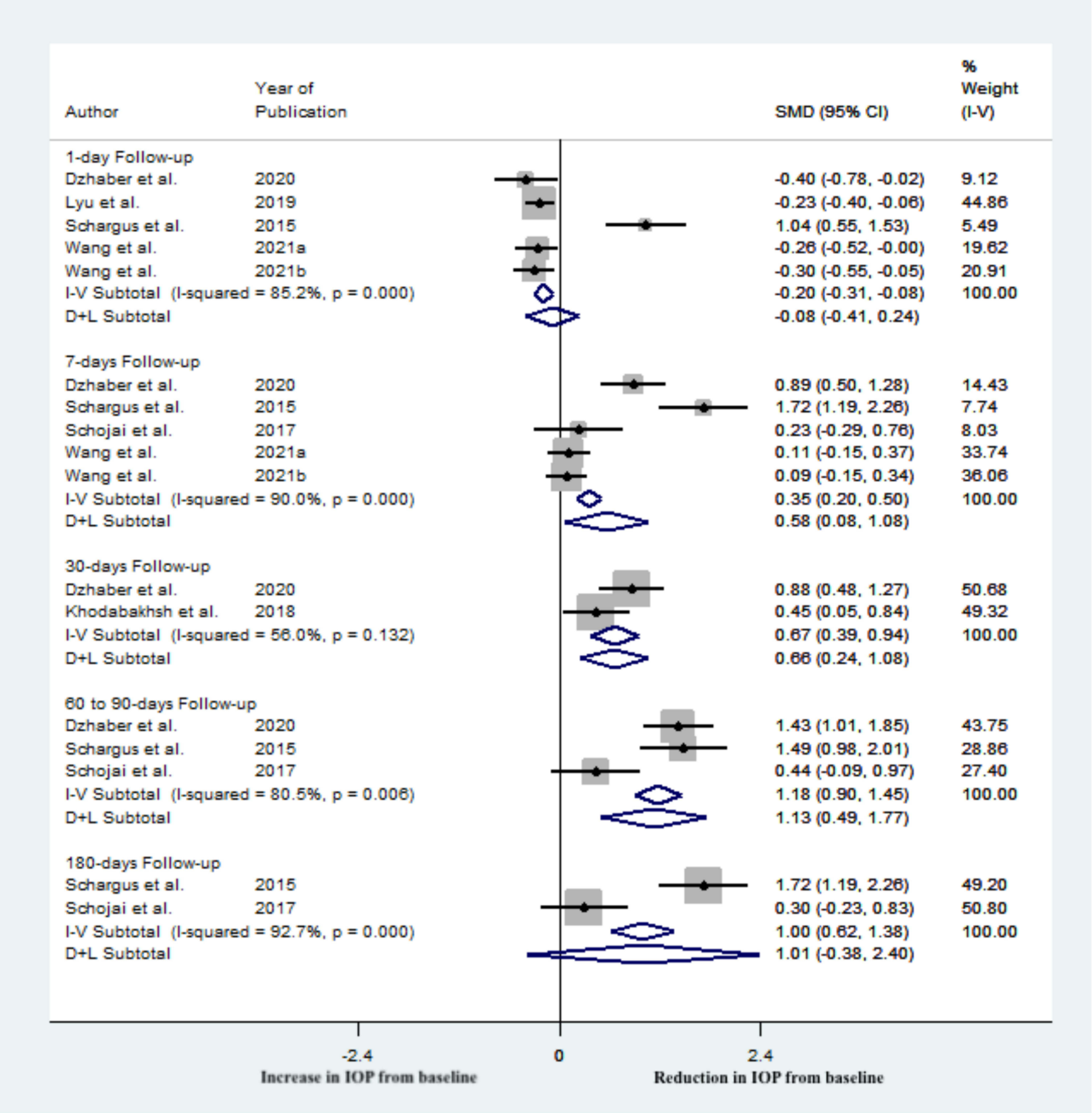

Figure 3 Forest plot for included meta-analysis studies that provided data on the change in IOP following FLACS in standardized mean difference (SMD) (95% CI).

The following limitations should be considered in understanding the context of the results. First, as a result of only two studies reporting which type of OVD was used, no conclusions can be made regarding the effect different types of OVDs used during FLACS have on post-operative IOP. Second, there was some variability in the quality scoring of the included studies as five out of the six studies had a moderate risk of bias. This can be seen in the risk of bias assessment, as multiple studies provided unclear information surrounding blinding (Table 2). As the current literature only offered a small number of relevant publications, all were included, irrespective of their quality score. The resulting asymmetry of the funnel plot was most likely due to few clinical studies currently available. Due to the paucity of published data, no conclusion can be made regarding optimal timing of IOP checks for time periods shorter than 24 hours as this remains a knowledge gap. Additionally, the paucity of published data prevented further subgroup analysis regarding the effect either the Catalys or LenSX FLACS systems had on IOP.

Table 3 Surgical Parameters for Included Studies

Author	Fragmentation Pattern used (Eyes, N)	Type of OVD Used (Eyes, N)	Visualization System Used (Eyes, N)	FLACS System Used (Eyes, N)
Dzhaber et al[16]	Concentric cylinders and Segment cuts (55)	4.0% Chondroitin sulphate-3.0% sodium hyaluronate (55)	Traditional Microscope (55)	LenSx (55)
Khodabakhsh et al[17]	-	OVD Used but type not reported (100)	Traditional Microscope (100)	Catalyst(50) LenSx (50)
Lyu et al[18]	Quadrant (267) Sextant (330) Grid (297)	OVD Used but type not reported (894)	Traditional Microscope (894)	LenSx (894)
Schargus et al[19]	Quadrant and Grid (37)	No OVD Used (37)	Traditional Microscope (37)	Catalyst(37)
Schojai et al[20]	-	Sodium hyaluronate 1% (28)	Traditional Microscope (28)	-
Wang et al[21]	-	OVD Used but type not reported (242)	Traditional Microscope (125) 3D Heads up display (117)	LenSx (242)

Table 4 Medications Used for Included Studies

Author	Pre-operative	Intra-operative	Post-operative
Dzhaber et al[16]	-	-	Combination steroid-antibiotic ointment (placed once immediately post-op), Antibiotic (1 week, 4 times a day), Steroids and NSAID drops (1 week for 4 times a day then gradually tapered over the next 3 weeks)
Khodabakhsh et al[17]	-	-	-
Lyu et al[18]	Topical levofloxacin and pranoprofen (Regimen not mentioned)	Non-preserved adrenaline (1:10,000) injected intracamerally in 3.4% of patients who developed miosis	Topical dexamethasone tobramycin (2 weeks, 4 times a day), and pranoprofen (1 month, 4 times a day)
Schargus et al[19]	Topical ofloxacin (3 days pre-op, 4 times a day)	-	Topical ofloxacin eye drops (5 days, 3 times a day), and Dexamethasone eye drops (1 week for 4 times a day then gradually tapered over the next 6 weeks)
Schojai et al[20]	-	-	Ofloxacin and Prednisolone (Regimen not mentioned)
Wang et al[21]	Topical levofloxacin (1 day pre-op, 4 times a day)	-	Topical dexamethasone tobramycin (2 weeks, 4 times a day), and pranoprofen (1 month, 4 times a day)

Conclusion

Current literature consistently indicates a noticeable but statistically insignificant rise in IOP from the baseline within the first day of follow-up, as compared to other timepoints. This suggests that the optimal time when IOP should likely be measured is within the first 24 hours following FLACS. When IOP spikes are most likely to occur within that 24-hour period cannot be answered from the available published evidence. This highlights the relative lack of evidence to guide best practice of IOP checks following FLACS. Therefore, future prospective clinical trials to determine the optimal time of IOP monitoring post FLACS may be useful, especially if combined with patient reported experience measures.

Disclosure

The author(s) report no conflicts of interest in this work. This study received no external funding.

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