A Prospective Comparative Study of Surgical Outcomes between Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification in Dense Cataracts: A 12-Month Follow-Up

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Abstract

Objective: To compare the cumulative dissipated energy (CDE) and long-term corneal endothelial cell loss (ECL) between femtosecond laser-assisted cataract surgery (FLACS) and conventional phacoemulsification cataract surgery (CPCS) in patients with very dense cataracts over 12 months.

Materials and Methods: This prospective comparative study included patients aged 40-85 years with unilateral or bilateral cataracts of nuclear opalescence grade ≥5 according to the Lens Opacities Classification System III. Participants were consecutively recruited, with surgical technique and surgeon assigned according to a predetermined allocation table. In bilateral cases, each eye underwent a different surgical technique performed by a different surgeon (contralateral-eye design). Primary outcomes were CDE and ECL at 1, 3, 6, and 12 months postoperatively.

Results: A total of 55 patients (88 eyes) were included (45 CPCS and 43 FLACS). Mean CDE did not differ significantly between CPCS and FLACS in the overall cohort (18.48 vs. 21.18, p=0.38) or the bilateral subgroup (16.83 vs. 17.52, p=0.78). At 1 month, ECL was significantly greater with FLACS than CPCS (199.33±221.14 vs. 76.75±229.08 cells/mm^2, p=0.04), corresponding to 8.50% and 2.18%, respectively. No significant differences were observed at 3, 6, or 12 months (all p≥0.39). The bilateral subgroup showed a similar pattern without significant differences between techniques.

Conclusion: FLACS did not demonstrate a statistically significant reduction in CDE compared with CPCS. The greater early ECL with FLACS was transient and was not sustained through 12 months, suggesting no long-term endothelial advantage over CPCS in very dense cataracts.

Keywords: Femtosecond; FLACS; CDE; Endothelial cell count; Phacoemulsification

Received 22 March 2026 | Revised 15 September 2026 | Accepted 30 September 2026

J Med Assoc Thai 2026;109(11):894-901

https://doi.org/10.35755/jmedassocthai.2026.11.04482

Cataract remains the leading cause of preventable blindness and visual impairment worldwide. In Thailand, the 5th National Eye Survey (2013) reported that cataracts account for nearly 70% of blindness cases, with an estimated surgical backlog exceeding 70,000 individuals[1]. Conventional phacoemulsification (CPCS) has been the gold standard treatment for decades, relying on a manually created anterior capsular opening, or continuous curvilinear capsulorhexis (CCC), and ultrasound energy to emulsify the lens. However, the high prevalence of dense cataracts in the Thai population poses significant surgical challenges. These cases often require increased ultrasound energy and prolonged operative time, thereby increasing the risk of complications, including corneal endothelial damage, persistent corneal edema, thermal wound injury, and posterior capsular rupture with subsequent vitreous loss[2].

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How to cite this article:

Na Pombejara F, Sothornwit N, Srisuwanporn S, Chanlalit W. A Prospective Comparative Study of Surgical Outcomes between Femtosecond Laser-Assisted Cataract Surgery and Conventional Phacoemulsification in Dense Cataracts: A 12-Month Follow-up. J Med Assoc Thai 2026;109:894-901.

What is already known about this topic?

FLACS has been shown to reduce intraoperative ultrasound energy compared with CPCS. However, these endothelial benefits are inconsistent and generally diminish with longer follow-up.

What does this study add?

In patients with very dense cataracts (LOCS III grade ≥5), FLACS did not result in a significant reduction in CDE or improved endothelial cell preservation compared with CPCS over 12 months. Although greater ECL was observed with FLACS at 1 month, this difference was transient and was not sustained during longer-term follow-up. These findings suggest that the theoretical advantages of FLACS may not translate into meaningful long-term clinical benefits over conventional phacoemulsification when surgery is performed by experienced surgeons, even in very dense cataracts.

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In recent years, femtosecond laser technology, originally developed for corneal refractive procedures, has been introduced to improve the precision of cataract surgery. Femtosecond laser-assisted cataract surgery (FLACS) uses ultra-short laser pulses to automate key steps, including corneal incisions, capsulotomy, and lens fragmentation. This pre-fragmentation of the lens nucleus may reduce intraoperative ultrasound energy, potentially minimizing endothelial injury.

Notably, cumulative dissipated energy (CDE) is a platform-specific parameter not available on all phacoemulsification systems; therefore, some earlier studies reported effective phacoemulsification time (EPT) instead, although both parameters reflect intraoperative ultrasound energy. Given these advantages, FLACS is theoretically expected to be superior to CPCS by enhancing surgical safety and postoperative recovery.

However, controversy exists in the literature regarding the CDE associated with these two surgical techniques. Several meta-analyses and systematic reviews report a 15% to 30% reduction in CDE with FLACS and a 21% to 36% reduction in endothelial cell loss (ECL) compared with CPCS[3-5]. In contrast, other studies have found no significant differences in CDE or ultrasound-energy parameters between the two techniques[6]. These discrepancies may be attributed to differences in cataract density, surgical techniques, and surgeon experience across studies. Some researchers have suggested that the energy-saving benefits of FLACS appear more pronounced in dense cataracts, with minimal or no advantage observed in lower-grade lenses[7,8].

A recent meta-analysis by Ramos[9] demonstrated reduced CDE with FLACS in dense cataracts, though no significant differences in ECL were found. These findings were largely confined to moderate cataract densities, particularly grade 3-4 according to the Lens Opacity Classification System III (LOCS III), and were limited to 6-month follow-up data. Evidence regarding long-term outcomes in very dense cataracts remains limited. Furthermore, such data have not yet been reported in the Thai population. Therefore, the authors aim to compare CPCS and FLACS in patients with very dense cataracts (LOCS III grade ≥5), focusing on intraoperative CDE and ECL over a 12-month follow-up period.

Materials and Methods

The present study was a prospective comparative study conducted at the Division of Ophthalmology, Priest Hospital, Bangkok, Thailand. The data collection phase was performed between August 2017 and May 2024 under the initial ethical approval from the Human Research Ethics Committee of Priest Hospital (Protocol No. 6/2560). To cover the extended data analysis period, a subsequent approval was granted in March 2025, under Protocol No. 1/2568.

The sample size was calculated using a cluster-eye design that included both unilateral and bilateral cases, based on Léda et al.[10]. Using a reported mean CDE of 7.03 (±0.57 SD) for moderate-to-dense cataracts, a clinically significant difference between CPCS and FLACS was set at 0.4. At a 0.05 significance level and 90% power, the required sample size was 44 eyes per group (88 eyes in total). This calculation included a design-effect adjustment (inter-eye correlation=0.80) to account for within-patient correlation in bilateral participants.

This present study employed a mixed-design approach, with consecutive recruitment and predetermined allocation. Eligible participants were aged 40-85 years with unilateral or bilateral cataract of nuclear opalescence grade ≥5 according to the LOCS III. Exclusion criteria included ocular comorbidities affecting visual outcomes (e.g., corneal, glaucomatous, or retinal disease), prior intraocular surgery, endothelial cell count (ECC) <2000 cells/mm², or inability to complete a 12-month follow-up. All patients underwent a comprehensive preoperative assessment, including best-corrected visual acuity (BCVA), which was converted to logarithm of the minimum angle of resolution (logMAR) units, intraocular pressure (IOP), and detailed anterior and posterior segment examinations. Corneal ECC and central corneal thickness (CCT) were measured using a specular microscope (EM-4000; Tomey Corp, Nagoya, Japan).

Surgical techniques (CPCS and FLACS) and two surgeons (A and B) were allocated according to a predetermined assignment table, resulting in four treatment groups. To minimize selection and operator bias, bilateral cases utilized a contralateral-eye design where each eye underwent a different technique performed by a different surgeon. Unilateral cases were assigned a single technique and surgeon according to the predetermined table. All procedures were performed by two ophthalmologists (SS and NS), each with more than 20 years of surgical experience (Figure 1).

The surgical procedures were identical between groups except for two steps. In the CPCS group, CCC and quick-chop nucleus fragmentation were performed manually. In the FLACS group, these manual steps were replaced by femtosecond laser-assisted capsulotomy

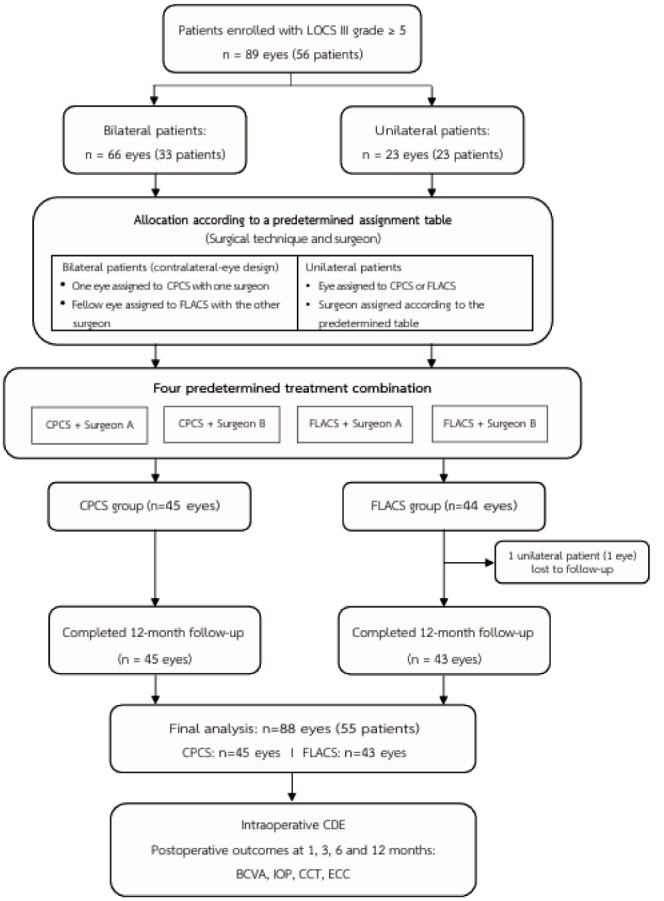


Figure 1. Flowchart of study design and predetermined treatment allocation.

and lens fragmentation using the LenSx system (Alcon Vision LLC), with a 5.2-mm capsulotomy and six-segment pie-pattern fragmentation. All remaining surgical steps were performed according to the same standardized protocol in both groups, including corneal incision, phacoemulsification using the Centurion® Vision System (Alcon Laboratories), irrigation/aspiration, intraocular lens implantation (Tecnis ZCB00; Johnson & Johnson Vision), and postoperative care.

Subject characteristics for both unilateral and bilateral cases were summarized using descriptive statistics. Categorical variables were presented as frequencies and percentages, while continuous variables were reported as means and standard deviations. Baseline categorical characteristics were compared between the CPCS and FLACS groups using the chi-square test, whereas continuous variables were compared using the independent-samples t-test. For demographic characteristics, patients undergoing bilateral surgery were counted only once to avoid duplicate counting. Preoperative ocular parameters, including BCVA, IOP, CCT, and ECC, were analyzed at the eye level, with all eligible eyes included in the analyses. Blinding of the surgical procedure was not feasible; however, outcome assessment was performed by an independent investigator. Follow-up examinations included corneal ECC at 1, 3, 6, and 12 months postoperatively, while BCVA (logMAR), IOP, and CCT were assessed at 12 months as the final postoperative outcomes.

The primary outcomes of the study were intraoperative CDE and ECL at 1, 3, 6, and 12 months postoperatively. ECL was calculated separately for each eye at each follow-up visit as both the absolute reduction from baseline ECC and the percentage ECL (%ECL), calculated as [(preoperative ECC – postoperative ECC) / preoperative ECC] × 100. A linear mixed-effects model (LMM) was used to analyze the overall cohort, including both unilateral and bilateral cases. Intraoperative CDE was compared between techniques, while ECL was analyzed across

Table 1. Comparison of demographic and preoperative clinical characteristics

Characteristic	CPCS group (n=45 eyes)	FLACS group (n=43 eyes)	p-value
Age (years); mean±SD	73.43±4.76	71.96±8.77	0.51
Sex (male/female); n	42/3	41/2	1.00
Unilateral/bilateral (patients); n	12/33	10/33	-
BCVA (logMAR); mean±SD	0.75±0.65	0.88±0.67	0.39
IOP (mmHg); mean±SD	12.57±3.47	12.12±3.41	0.57
CCT (μm); mean±SD	507.14±31.38	494.05±54.13	0.18
ECC (cells/mm^2); mean±SD	2,427.00±336.37	2,462.09±238.69	0.69

CPCS=conventional phacoemulsification; FLACS=Femtosecond laser-assisted cataract surgery; BCVA=best corrected visual acuity; IOP=intraocular pressure; CCT=central corneal thickness; ECC=endothelial cell count; SD=standard deviation

The p-values were calculated using the chi-square test for categorical variables and the independent-samples t-test for continuous variables. Age and sex were analyzed at the patient level, with bilateral patients counted once; BCVA, IOP, CCT, and ECC were analyzed at the eye level. A p-value <0.05 was considered statistically significant.

Table 2. Comparison of postoperative endothelial cell loss (ECL) and percentage ECL between CPCS and FLACS

Postoperative	ECL (cell/mm^2); mean±SD (% ECL)					
	Total eyes (n=88)			Bilateral eyes (n=66)		
	CPCS group (n=45)	FLACS group (n=43)	p-value	CPCS group (n=33)	FLACS group (n=33)	p-value
1 month	76.75±229.08 (2.18)	199.33±221.14 (8.50)	0.04	60.00±205.68 (1.44)	169.79±204.00 (7.19)	0.07
3 months	153.96±212.23 (6.34)	143.14±190.01 (5.95)	0.86	137.35±181.95 (5.76)	138.85±193.90 (5.81)	0.98
6 months	115.10±211.74 (4.72)	137.11±147.06 (5.68)	0.71	114.74±206.02 (4.77)	136.28±151.2 (5.68)	0.72
12 months	139.33±226.84 (5.56)	85.09±187.91 (3.35)	0.39	160.18±226.47 (6.59)	97.75±171.72 (4.04)	0.34

CPCS=conventional phacoemulsification; FLACS=Femtosecond laser-assisted cataract surgery; SD=standard deviation

ECL from baseline (preoperative ECC – postoperative ECC). % ECL was calculated separately for each eye as [(preoperative ECC – postoperative ECC) / preoperative ECC] × 100. The p-values for the overall cohort were obtained using a linear mixed model (LMM), with patient included as a random effect to account for within-patient correlation; bilateral-eye subgroup comparisons were performed using a paired t-test. A p-value <0.05 was considered statistically significant.

postoperative visits. Patient was included as a random effect to account for correlation between fellow eyes, and repeated ECL measurements within each eye were modeled using an unstructured covariance structure. A subgroup analysis of bilateral cases undergoing both techniques was performed using a paired t-test, allowing each patient to serve as their own control, thereby reducing between-patient variability and providing an additional assessment of the consistency of the overall findings. For all tests performed, a two-tailed p-value less than 0.05 was considered statistically significant. Stata/SE version 14.1 (StataCorp LP, College Station, TX, USA) and IBM SPSS Statistics, version 31.0 (IBM Corp., Armonk, NY, USA) were used for all statistical analyses.

Results

One patient (unilateral eye) in the FLACS group was lost to follow-up and excluded from the analysis. Therefore, the final analysis included 55 patients (88 eyes), comprising 52 (94.5%) males and 3 (5.5%) females. The mean age of the patients was 72.71±8.1 years (range 49-85 years). Of these, 33 patients underwent bilateral surgery, and 22 patients underwent unilateral surgery (12 CPCS and 10 FLACS). When classified by surgical method, there were 45 eyes in the CPCS group and 43 eyes in the FLACS group. Baseline demographic and preoperative clinical characteristics showed no statistically significant differences between the two groups in terms of age, sex, BCVA, IOP, ECC, or CCT (Table 1).

The mean intraoperative CDE was 18.48±8.36 in the CPCS group and 21.18±12.65 in the FLACS group in the overall cohort, with no statistically significant difference between the groups (p=0.38). Similarly, bilateral-eye subgroup analysis showed similar CDE between CPCS and FLACS (16.83±8.89 vs. 17.52±8.38, respectively, p=0.78).

Postoperative ECL at 1, 3, 6, and 12 months is presented in Table 2. At 1 month, ECL was significantly greater with FLACS than with CPCS in the overall cohort (p=0.04), whereas no significant differences were observed at 3, 6, or 12 months. In the bilateral-eye subgroup, greater ECL with FLACS was also observed at 1 month; however, the difference did not reach statistical significance (p=0.07); no

significant differences were observed at subsequent follow-up visits.

At 12 months postoperatively, ocular parameters were comparable between CPCS and FLACS. In the overall cohort, BCVA (logMAR) was 0.09±0.12 vs. 0.09±0.13 (p=0.83), IOP was 9.72±2.28 vs. 9.09±2.50 mmHg (p=0.31), CCT was 507.23±31.03 vs. 500.44±31.67 µm (p=0.33), and ECC was 2,360±274 vs. 2,362±347 cells/mm² (p=0.98), respectively. Similarly, in the bilateral-eye subgroup, BCVA (logMAR) was 0.09±0.13 vs. 0.08±0.11 (p=0.93), IOP was 9.78±2.23 vs. 9.18±2.39 mmHg (p=0.23), CCT was 501.03±30.74 vs. 504.00±25.83 µm (p=0.44), and ECC was 2,297.35±294.50 vs. 2,321.25±400.20 cells/mm² (p=0.83), respectively.

Intraoperative complications in the FLACS group included two cases of incomplete capsulotomy. Postoperatively, subconjunctival hemorrhage occurred in four FLACS cases and one CPCS case. No cases of posterior capsule rupture were observed in either cohort.

Discussion

In the present study, FLACS did not significantly reduce intraoperative CDE compared with CPCS. Although a significantly greater ECL was observed in the FLACS group at 1 month postoperatively, this was an isolated early finding that was not sustained at 3, 6, or 12 months, as endothelial outcomes were generally comparable between the two techniques during longer-term follow-up. The bilateral-eye subgroup also showed a similar pattern of greater early ECL with FLACS, although the difference was not statistically significant; nevertheless, no significant differences were observed at later follow-up, further supporting the overall pattern of the study. This early finding is consistent with Ranjini et al.[11], who reported significantly greater ECL with FLACS at 4 weeks (14.4% vs. 10.2%, p=0.032), despite a lower EPT. This apparent dissociation between ultrasound energy and endothelial injury suggests that early ECL may not be determined solely by ultrasound exposure but may also be influenced by other factors such as surgical manipulation, fluidics, cataract density, and other procedure-related factors.

Previous studies have reported variable endothelial outcomes. Although FLACS generally reduces phacoemulsification energy, some studies have demonstrated an associated endothelial benefit, whereas others have not. Studies have reported 33% to 84% reductions in intraoperative EPT with FLACS, with endothelial benefits observed at 3 weeks by Abell et al.[12]. At 3 months, Conrad-Hengerer et al.[13] (8.0% vs. 13.7% for FLACS and CPCS, respectively), and up to 6 months by Krarup et al.[4]. These findings are also supported by meta-analyses showing that FLACS reduces ultrasound energy and early corneal endothelial injury compared with CPCS, although these advantages tend to diminish with longer follow-up[14,15]. In contrast, Liu et al.[6] reported a significantly lower ECL with FLACS that persisted at 12 months (8.2% vs. 11.2%). These heterogeneous findings suggest that the relationship between reduced phacoemulsification energy and endothelial preservation is not consistent across studies and may depend on surgical technique, laser parameters, cataract density, and other procedural factors.

Dense cataracts typically require greater phacoemulsification energy, thereby increasing the risk of endothelial injury and providing a rationale for evaluating the potential benefits of FLACS, as specifically addressed in the present study (LOCS III grade ≥5). Similarly, in a study of dense cataracts, Chee et al.[8] found no significant overall difference in EPT between FLACS and CPCS, although higher nuclear density was associated with greater EPT. Endothelial outcomes varied according to the laser fragmentation pattern, with the 600-µm grid pattern of FLACS resulting in significantly less ECL than CPCS, whereas the 16-segment pattern did not; however, endothelial outcomes were not evaluated beyond 1 month. These findings suggest that the potential benefit of FLACS in dense cataracts may also depend on the fragmentation pattern rather than laser pretreatment alone. Notably, He et al.[16] reported findings that contrasted with most previous studies, demonstrating that CPCS required less ultrasound energy and provided better endothelial preservation than FLACS in hard cataracts, with these differences persisting up to 1 year postoperatively. These findings challenge the proposed advantage of FLACS in reducing ultrasound energy and endothelial injury, suggesting that the additional laser steps may increase intraocular stress and that laser fragmentation may be less effective in very dense cataracts, resulting in a continued need for ultrasound energy and thereby diminishing the expected benefit of FLACS. Consistent with this variability, a recent meta-analysis by Ramos[9] focusing on dense cataracts highlighted the inconsistency in the literature, demonstrating that while FLACS may reduce ultrasound energy, it provided no additional corneal endothelial benefits compared with CPCS.

Overall, these discrepancies may reflect differences in cataract density, fragmentation patterns,

surgical platforms, and surgeon experience. Despite the theoretical reduction in ultrasound energy with FLACS, current evidence from studies of very dense cataracts, particularly those with longer follow-up, suggests that this does not consistently translate into sustained endothelial protection or a clear clinical advantage over CPCS.

Regarding surgical complications, incomplete capsulotomies occurred only in the FLACS group, potentially related to suboptimal docking, eye tilt, corneal fold formation, or intraoperative suction loss during laser delivery[17]. Postoperatively, subconjunctival hemorrhage was more frequent in the FLACS group, possibly related to the docking interface and vacuum application[18]. Nevertheless, both complications were manageable and did not result in clinically significant adverse outcomes.

The present study has several limitations related to patient inclusion and sample size. Recruitment was challenging due to the strict eligibility criteria (LOCS III grade ≥5), which limited the number of eligible patients, as cataracts of this severity were relatively uncommon in the study setting. Combined with disruptions during the COVID-19 pandemic, these highly selective criteria further restricted the available sample pool, resulting in an extended study period and the inclusion of both unilateral and bilateral cases. To address the combined analysis of unilateral and bilateral cases, a linear mixed-effects model was used for the overall cohort to account for within-patient correlation between eyes. In addition, a bilateral-eye subgroup analysis (33 eyes) was performed, allowing each patient to serve as their own control and reducing between-patient variability, with findings generally consistent with those of the overall cohort. Furthermore, because one patient in the FLACS group was lost to follow-up, the final sample size did not fully reach the planned target of 44 eyes per group. Consequently, the limited statistical power may have been insufficient to detect small or subclinical differences that might otherwise be identified in larger studies or meta-analyses. In addition, the study was conducted by two highly experienced surgeons at a hospital serving predominantly Buddhist monks. This expert-led, predominantly male study population, together with the highly selective eligibility criteria, may limit the generalizability of the findings to less experienced surgeons and more diverse patient populations.

Taken together, these findings suggest that the long-term clinical advantages of FLACS may be limited, particularly when surgery is performed by experienced surgeons, even in very dense cataracts. Future studies should investigate whether different femtosecond laser fragmentation patterns influence surgical efficiency and clinical outcomes. In addition, evaluating FLACS in high-risk eyes, such as those with Fuchs' endothelial dystrophy or very low endothelial cell density, through prospective multicenter trials with larger sample sizes and standardized surgical parameters may help determine whether FLACS provides greater benefit in more vulnerable eyes.

Conclusion

FLACS did not demonstrate a statistically significant reduction in CDE or provide sustained endothelial preservation compared with CPCS in very dense cataracts. Although greater ECL was observed with FLACS at 1 month, this difference was transient and was not sustained through 12 months. These findings suggest that the theoretical benefit of FLACS in reducing phacoemulsification energy may not translate into sustained endothelial protection when conventional phacoemulsification is performed efficiently by experienced surgeons.

Acknowledgement

All authors express sincere gratitude to Priest Hospital, Department of Ophthalmology, Ministry of Public Health, for providing the necessary facilities, administrative support, and clinical data for this study. The present study was supported by a research grant from the National Research Council of Thailand.

Authors Contributions

All authors meet ICMJE authorship criteria. FNP: Study conception and design; data acquisition; analysis and interpretation; drafting the manuscript; corresponding author responsibility. NS: Study conception and design; surgical intervention; post-operative care; data acquisition. SS: Study conception and design; surgical intervention; post-operative care; data acquisition. WC: Data analysis and interpretation; drafting the manuscript. All authors provided critical revision of the manuscript, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Clinical Trial Registration

The present study was registered at the Thai Clinical Trial Registry (TCTR20260423001)

Conflicts of interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request with appropriate ethics approval.

Ethics Approval and Consent to Participate

The present study was approved by the Human Research Ethics Committee of Priest Hospital, Department of Medical Services, Ministry of Public Health (Protocol No. 6/2560 [2017]), with a subsequent extension approved for data analysis (Protocol No. 1/2568 [2025]). All participants provided informed consent before enrollment.

Funding disclosure

This study was funded by a research grant from the National Research Council of Thailand.

Use of Artificial Intelligence

During the preparation of this work, the authors used Gemini 3.1 Pro solely for grammar and language refinement. The authors performed all conceptual frameworks, manuscript structure, data interpretation, and original drafting. The authors take full responsibility for the content, originality, and accuracy of the published article.

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