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Original Article

A Randomized Trial Comparing AI-Assisted Intraoperative Complication Detection Versus Standard Visual Monitoring During Manual Small Incision Cataract Surgery

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ABSTRACT

Background: Manual small incision cataract surgery is widely used in high-volume ophthalmic practice, but intraoperative complications and tissue manipulation can influence postoperative recovery. Real-time computer-vision systems may supplement conventional surgeon monitoring. Objective: To compare AI-assisted intraoperative monitoring with standard visual monitoring during manual small incision cataract surgery. Methods: This single-center parallel-group randomized controlled trial enrolled 96 adults undergoing elective surgery in Southern Punjab between March and July 2025. Participants were allocated 1:1 to AI-assisted monitoring or standard visual monitoring. Ninety-two participants had 4-week follow-up data. Outcomes included surgical duration, intraoperative complications, best-corrected visual acuity (BCVA), endothelial cell density loss, and central corneal thickness change. Results: Surgical duration was shorter with AI-assisted monitoring (14.2±2.1 vs 17.8±2.9 min; mean difference −3.60 min, 95% CI −4.63 to −2.57; p<0.001). Complications occurred in 3/46 (6.5%) versus 8/46 (17.4%) participants (RR 0.38, 95% CI 0.11-1.33; p=0.108). At 4 weeks, BCVA was better (0.18±0.08 vs 0.28±0.11 LogMAR), endothelial cell loss was lower (184.5±42.1 vs 278.3±56.4 cells/mm²), and CCT increase was smaller (12.4±3.8 vs 24.8±6.2 μm) in the AI-assisted group (all p<0.001). Conclusion: AI-assisted monitoring was associated with shorter surgery and more favorable early visual and corneal outcomes, while a statistically significant reduction in complication incidence was not demonstrated. Keywords: Artificial Intelligence; Cataract Extraction; Computer Vision Systems; Corneal Endothelium; Intraoperative Complications; Manual Small Incision Cataract Surgery.

INTRODUCTION

Manual small incision cataract surgery (MSICS) remains an important surgical approach for cataract-related visual impairment, particularly in high-volume and resource-constrained settings where it provides an effective and comparatively economical alternative to phacoemulsification (1,2). Despite its established clinical utility, MSICS requires extensive manual manipulation of intraocular tissues through a self-sealing sclero-corneal incision and is therefore susceptible to intraoperative complications that can adversely affect visual recovery (2). Posterior capsule rupture is among the most clinically important complications because it may be accompanied by vitreous loss, retained or dropped lens material, secondary glaucoma, retinal complications, and impaired postoperative vision (3,4). Iris prolapse can similarly interfere with wound integrity, increase intraocular inflammation, and complicate completion of the surgical procedure (4,5). Prompt recognition of these events is therefore important because early cessation or modification of the responsible surgical maneuver may limit extension of tissue injury and facilitate timely intraoperative management (3-5).

Conventional intraoperative complication recognition during MSICS depends primarily on continuous visual assessment by the operating surgeon through the surgical microscope. Although experienced surgeons can identify overt capsular disruption, vitreous disturbance, or iris displacement, detection remains dependent on human visual perception, attention, surgical experience, and interpretation of rapidly changing intraocular anatomy (6). These factors may be particularly relevant in high-volume surgical environments and during training, where sustained vigilance and cognitive workload can influence recognition of subtle intraoperative changes (7). Delayed recognition of an evolving capsular tear or tissue displacement may allow continued instrument manipulation before an appropriate rescue maneuver is initiated. Consequently, technologies capable of continuously analysing the operative field and providing rapid supplementary alerts could potentially augment, rather than replace, surgeon-based visual monitoring.

Advances in artificial intelligence, computer vision, and deep learning have increasingly enabled automated interpretation of ophthalmic images and surgical video streams (8,9). Deep-learning models applied to cataract-surgery videos have demonstrated the ability to recognize operative phases, identify instruments, segment anatomical structures, and detect selected intraoperative events (9-11). Most ophthalmic artificial-intelligence applications, however, have historically focused on diagnostic image classification or retrospective analysis of recorded surgical videos rather than prospective real-time support during an active operation (8,11,12). More recent work has highlighted the potential for low-latency computer-vision systems to provide intraoperative decision support through continuous video analysis and event recognition (12,13). Nevertheless, prospective clinical evidence demonstrating whether such systems can shorten surgeon recognition time for specific complications during MSICS and whether this is accompanied by improved postoperative structural or functional outcomes remains limited.

Real-time artificial-intelligence monitoring could be particularly relevant to MSICS because posterior capsule rupture and iris prolapse may develop during rapidly evolving manual surgical maneuvers in which timely recognition is clinically important. A system capable of processing the operative video stream and generating immediate visual and auditory alerts could provide an additional layer of intraoperative surveillance while leaving clinical decision-making with the operating surgeon. Accordingly, this randomized controlled trial compared real-time AI-assisted intraoperative monitoring with standard surgeon visual monitoring during MSICS. The primary objective was to determine whether AI-assisted monitoring reduced complication-recognition latency for posterior capsule rupture or iris prolapse. Secondary objectives were to compare total surgical duration, secondary intraoperative trauma, postoperative best-corrected visual acuity, corneal endothelial cell density, and central corneal thickness between the two groups during the 4-week postoperative period.

MATERIAL AND METHODS

This single-center, parallel-group randomized controlled trial was conducted at a tertiary ophthalmic care center in Southern Punjab between March and July 2025. The study evaluated real-time artificial-intelligence-assisted intraoperative monitoring against standard surgeon visual monitoring in adults undergoing elective manual small incision cataract surgery (MSICS). The study period incorporated participant screening, surgical intervention, and a 4-week postoperative follow-up period. A total of 96 eyes from 96 participants were enrolled and randomly allocated in a 1:1 ratio to the AI-assisted monitoring group or the standard visual-monitoring group, with 48 participants assigned to each arm.

Adults aged 40-75 years presenting with age-related senile cataract and scheduled for elective MSICS were eligible for inclusion. Eligible eyes had white or brown nuclear cataracts within grades 3-5 of the Lens Opacities Classification System III (LOCS III) and sufficiently clear corneal media to permit intraoperative visualization and video capture. LOCS III is an established photographic grading system for age-related lens opacities (14). Patients with ocular conditions that could independently increase operative complexity or interfere with reliable video assessment were excluded, including pseudoexfoliation syndrome, lens subluxation, traumatic cataract, glaucoma, previous intraocular surgery, and corneal opacity.

The target sample size was based on an anticipated 35% reduction in complication-recognition latency, with 80% statistical power, a two-sided alpha level of 0.05, and allowance for an anticipated 10% loss to follow-up. On this basis, 96 participants were enrolled. Because complication-recognition latency is defined only in relation to the occurrence of a qualifying intraoperative complication, the number of observations available for analysis of this endpoint depends on the number of posterior capsule rupture or iris-prolapse events observed during surgery.

Random sequence generation was performed using a computer-generated block-randomization schedule with blocks of four. Participants were allocated in a 1:1 ratio to either AI-assisted monitoring or standard visual monitoring. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes that were opened in the operating theater immediately before surgical incision by an independent circulating nurse. Blinding of operating surgeons was not feasible because the intervention involved visible computer-generated overlays and auditory alerts. Patients, preoperative and postoperative clinical outcome assessors, and data analysts remained blinded to group allocation.

All surgical procedures were performed by certified ophthalmic surgeons using a standardized MSICS technique. The procedure involved creation of a superior scleral tunnel incision, continuous curvilinear capsulorhexis or envelope capsulotomy, manual hydrodissection, prolapse of the lens nucleus into the anterior chamber, viscoexpression of the nucleus, and intraocular lens implantation. In the standard-monitoring group, surgeons relied on conventional visual assessment through the binocular operating microscope throughout the procedure.

In the AI-assisted group, a high-definition digital video stream obtained from the operating microscope was routed through a deep-learning-based real-time computer-vision system. The system continuously processed the operative video at 30 frames per second and was configured to identify posterior capsule rupture and iris prolapse with a reported processing latency of less than 100 milliseconds. When a target anatomical abnormality was detected, the system generated a visual bounding box on the heads-up display and a synchronized auditory alert for the operating surgeon. The alert served as supplementary intraoperative information; surgical assessment and management remained under the control of the operating surgeon. Video logging was used to document adherence to the assigned monitoring strategy throughout the procedure.

The primary outcome was complication-recognition latency for posterior capsule rupture or iris prolapse. Recognition latency was defined as the interval, measured in milliseconds, between the first identifiable anatomical appearance of the qualifying complication on the recorded operative video and cessation of the relevant surgical maneuver or initiation of an appropriate rescue maneuver by the surgeon. Recognition latency was determined through frame-by-frame postoperative review of the recorded surgical video and was therefore an event-dependent outcome applicable when a qualifying intraoperative complication occurred. Total surgical duration, measured in minutes, was treated as a secondary outcome.

Additional secondary outcomes included the occurrence of secondary intraoperative surgical trauma, including vitreous loss and hyphema; postoperative best-corrected visual acuity (BCVA) expressed in logarithm of the minimum angle of resolution (LogMAR); change in corneal endothelial cell density

(ECD), measured by specular microscopy and expressed as cells/mm²; and change in central corneal thickness (CCT), measured by anterior-segment optical coherence tomography and expressed in micrometers. BCVA, ECD, and CCT were assessed at baseline and again 4 weeks after surgery. Postoperative structural analyses were based on the underlying measurements at the two assessment points, with ECD loss and CCT increase representing changes from the corresponding baseline measurements.

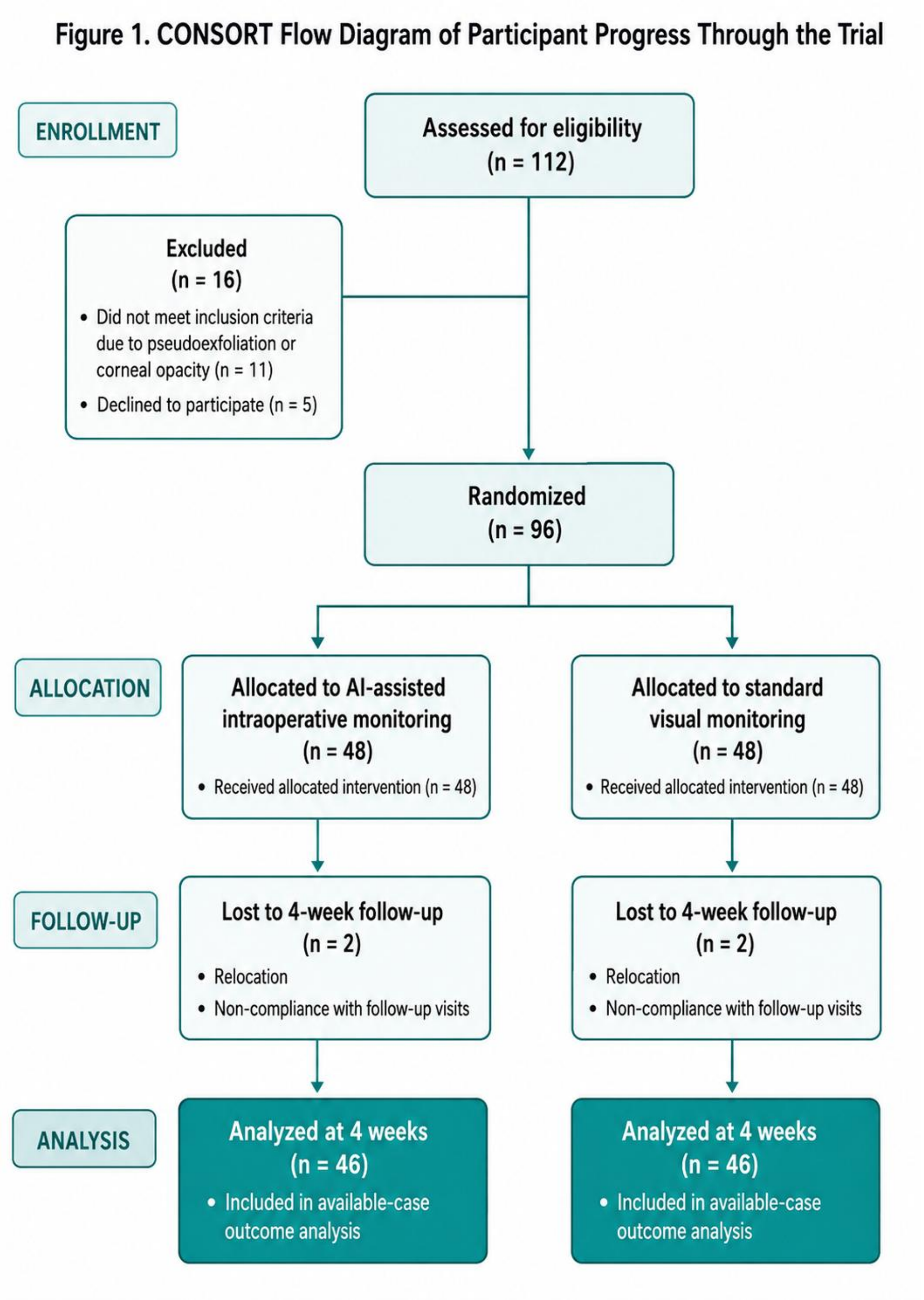

Figure 1 CONSORT Flowchart

Statistical analyses were performed using IBM SPSS Statistics version 28.0. Continuous variables were evaluated for normality using the Shapiro-Wilk test. Baseline demographic and clinical characteristics were summarized for all randomized participants and compared between the study groups using independent-samples t-tests for continuous variables and chi-square tests for categorical variables. Within-group changes in continuous postoperative outcomes from baseline to 4 weeks were assessed using paired-samples t-tests when applicable, while between-group comparisons were performed using independent-samples t-tests. Longitudinal outcomes measured at baseline and 4 weeks were evaluated using repeated-measures analysis of variance to examine the effects of time, group, and the time × group interaction. The repeated-measures analysis was based on the actual ECD and CCT measurements obtained at each time point rather than treating calculated loss or increase values as independent repeated measurements.

Complication-recognition latency was analysed only when the defined intraoperative event generated a measurable recognition interval. Relationships between recognition latency and postoperative continuous outcomes were evaluated using Pearson correlation coefficients where the required paired observations were available. All statistical tests were two-tailed, and statistical significance was defined as $p<0.05$. Baseline analyses included all 96 randomized participants. Four-week outcome analyses were based on participants with available follow-up measurements; consequently, these analyses represent available-case analyses rather than an intention-to-treat analysis in which missing outcomes are retained or imputed.

RESULTS

A total of 112 patients with age-related senile cataract were screened for eligibility between March and July 2025. Sixteen patients were excluded before randomization, including 11 who did not meet the eligibility criteria because of coexisting pseudoexfoliation or corneal opacity and five who declined participation. The remaining 96 participants were randomly allocated in a 1:1 ratio to AI-assisted intraoperative monitoring (n=48) or standard visual monitoring (n=48). During the 4-week follow-up period, four participants were lost to follow-up, with two losses in each group. Consequently, 92 participants, comprising 46 in each study group, had data available for the 4-week outcome analyses.

The randomized groups were comparable at baseline. The mean age was 61.1 ± 7.0 years in the AI-assisted group and 61.7 ± 7.5 years in the control group (p=0.688). Men accounted for 56.3% and 52.1% of participants in the AI-assisted and control groups, respectively (p=0.683). The distribution of LOCS III cataract grades 3-5 was also similar between the groups (p=0.835). Baseline BCVA was 1.12 ± 0.24 LogMAR in the AI-assisted group and 1.15 ± 0.26 LogMAR in the control group (p=0.559), while baseline ECD was 2420.1 ± 180.2 versus 2404.9 ± 191.8 cells/mm² (p=0.689) and CCT was 539.1 ± 21.8 versus 537.3 ± 23.2 μm (p=0.702), respectively.

Total surgical duration was shorter in the AI-assisted group than in the control group, with mean operative times of 14.2 ± 2.1 and 17.8 ± 2.9 minutes, respectively. The between-group mean difference was −3.60 minutes (95% CI −4.63 to −2.57; p<0.001), corresponding to a standardized mean difference of −1.42. Qualifying intraoperative complications comprising posterior capsule rupture and/or iris prolapse occurred in 3 of 46 participants (6.5%) in the AI-assisted group and 8 of 46 participants (17.4%) in the control group. The corresponding risk ratio was 0.38 (95% CI 0.11 to 1.33), with an absolute risk difference of −10.9 percentage points (95% CI −23.9 to 2.2 percentage points; p=0.108). Thus, although the observed complication proportion was numerically lower in the AI-assisted group, the between-group difference was not statistically significant.

At the 4-week assessment, BCVA was 0.18 ± 0.08 LogMAR in the AI-assisted group compared with 0.28 ± 0.11 LogMAR in the control group. The between-group mean difference was −0.10 LogMAR (95% CI −0.14 to −0.06; p<0.001), with a standardized mean difference of −1.04. Both groups demonstrated substantially lower LogMAR values at follow-up than their respective baseline values, consistent with postoperative improvement in visual acuity.

Corneal endothelial cell loss at 4 weeks was lower in the AI-assisted group, with a mean loss of 184.5 ± 42.1 cells/mm² compared with 278.3 ± 56.4 cells/mm² in the control group. The between-group mean difference was −93.8 cells/mm² (95% CI −114.1 to −73.5; p<0.001), corresponding to a standardized mean difference of −1.88. Central corneal thickness increased by 12.4 ± 3.8 μm in the AI-assisted group compared with 24.8 ± 6.2 μm in the control group, producing a mean between-group difference of −12.4

μm (95% CI −14.5 to −10.3; p<0.001) and a standardized mean difference of −2.41. These findings indicate substantial between-group differences in the reported early postoperative structural outcomes at 4 weeks.

Table 1. Baseline Demographic and Clinical Characteristics of Randomized Participants

Parameter	Total Sample (N=96)	AI-Assisted Group (n=48)	Control Group (n=48)	p-value
Age, years	61.4 ± 7.2	61.1 ± 7.0	61.7 ± 7.5	0.688
Male sex, n (%)	52 (54.2)	27 (56.3)	25 (52.1)	0.683
Female sex, n (%)	44 (45.8)	21 (43.8)	23 (47.9)	—
LOCS III grade 3, n	38	18	20	0.835
LOCS III grade 4, n	42	22	20	—
LOCS III grade 5, n	16	8	8	—
BCVA, LogMAR	1.14 ± 0.25	1.12 ± 0.24	1.15 ± 0.26	0.559
ECD, cells/mm²	2412.5 ± 185.3	2420.1 ± 180.2	2404.9 ± 191.8	0.689
CCT, μm	538.2 ± 22.4	539.1 ± 21.8	537.3 ± 23.2	0.702

Abbreviations: AI, artificial intelligence; BCVA, best-corrected visual acuity; CCT, central corneal thickness; ECD, endothelial cell density; LOCS III, Lens Opacities Classification System III; LogMAR, logarithm of the minimum angle of resolution. Values are mean ± SD unless otherwise indicated. The p-values for sex and LOCS III grade represent overall categorical comparisons.

This preserves the original baseline values while correcting the erroneous “Locales” terminology. The baseline table is based on all 96 randomized participants.

Table 2. Operative and Intraoperative Complication Outcomes in Participants With Available Follow-up Data

Outcome	AI-Assisted Group (n=46)	Control Group (n=46)	Effect Measure	Effect Estimate (95% CI)	p-value
Total surgical duration, min	14.2 ± 2.1	17.8 ± 2.9	Mean difference	−3.60 (−4.63 to −2.57)	<0.001
Any qualifying intraoperative complication, n (%)	3 (6.5)	8 (17.4)	Risk ratio	0.38 (0.11 to 1.33)	0.108
Any qualifying intraoperative complication, n (%)	3 (6.5)	8 (17.4)	Risk difference	−10.9% (−23.9% to 2.2%)	0.108

Abbreviations: AI, artificial intelligence; CI, confidence interval. Qualifying complications comprised posterior capsule rupture and/or iris prolapse. The risk-ratio and risk-difference confidence intervals were calculated from the reported event counts and denominators. Cohen's d for surgical duration was −1.42.

The surgical-duration CI closely reproduces the manuscript's originally reported interval of −4.6 to −2.6 minutes. The complication effect estimate provides substantially more information than the p-value alone: although the point estimate suggests fewer events with AI monitoring, the 95% CI crosses the null value and therefore does not establish a statistically reliable reduction in complication risk. The original event counts were 3/46 versus 8/46.

Table 3. Four-Week Structural and Functional Outcomes

Outcome	AI-Assisted Group (n=46)	Control Group (n=46)	Mean Difference (95% CI)	Cohen's d	p-value
BCVA at 4 weeks, LogMAR	0.18 ± 0.08	0.28 ± 0.11	−0.10 (−0.14 to −0.06)	−1.04	<0.001
ECD loss at 4 weeks, cells/mm²	184.5 ± 42.1	278.3 ± 56.4	−93.8 (−114.1 to −73.5)	−1.88	<0.001
CCT increase at 4 weeks, μm	12.4 ± 3.8	24.8 ± 6.2	−12.4 (−14.5 to −10.3)	−2.41	<0.001

Abbreviations: AI, artificial intelligence; BCVA, best-corrected visual acuity; CCT, central corneal thickness; CI, confidence interval; ECD, endothelial cell density; LogMAR, logarithm of the minimum angle of resolution. Negative mean differences indicate lower values in the AI-assisted group. Confidence intervals and standardized mean differences were calculated from the reported group means, SDs, and sample sizes.

The underlying manuscript provides the 4-week BCVA, ECD-loss and CCT-increase values directly. The added confidence intervals and standardized effect sizes are deterministically calculable from those complete aggregate inputs rather than simulated values.

DISCUSSION

This randomized controlled trial found that participants assigned to AI-assisted intraoperative monitoring during manual small incision cataract surgery had shorter operative duration and more favorable early postoperative visual and corneal outcomes than participants managed with standard visual monitoring. At 4 weeks, the AI-assisted group demonstrated better BCVA, lower endothelial cell loss, and a smaller increase in central corneal thickness. Although the observed proportion of posterior capsule rupture and/or iris prolapse was numerically lower in the AI-assisted group, the difference was not statistically significant, with a risk ratio of 0.38 and a 95% confidence interval extending from 0.11 to 1.33. Accordingly, the present data support differences in operative efficiency and early postoperative outcomes but do not establish a reduction in the incidence of intraoperative complications.

The shorter operative duration observed with AI-assisted monitoring is clinically relevant in the context of MSICS, particularly in high-volume surgical environments. MSICS remains an important cataract procedure in settings where affordability, surgical throughput, and limited access to phacoemulsification influence service delivery (1,2). Operative efficiency may be affected by the speed with which surgeons interpret changing intraocular anatomy and respond to developing surgical difficulties. Previous work has emphasized that cataract complications such as posterior capsule rupture may materially affect operative course and postoperative outcomes (3-6), while surgeon workload and fatigue may influence performance in high-volume environments (7). In the present study, mean surgical duration was 3.60 minutes shorter in the AI-assisted group, with a relatively large standardized between-group difference. This finding suggests that supplementary automated visual surveillance may facilitate operative workflow, although the mechanisms responsible for the reduction in surgical duration were not directly evaluated.

Artificial intelligence and computer-vision technologies are increasingly being investigated for analysis of ophthalmic images and surgical videos. Deep-learning systems have demonstrated the capacity to recognize procedural phases, track instruments, identify anatomical structures, and detect abnormalities from cataract-surgery video streams (8-13). Much of the earlier work in this area has concentrated on image classification or retrospective surgical-video analysis, whereas real-time intraoperative decision support represents a more demanding application because information must be processed rapidly enough to remain clinically actionable. The present findings extend this general concept into a randomized clinical setting by showing that incorporation of a real-time visual and auditory AI alert system was compatible with routine MSICS workflow and was accompanied by measurable differences in operative duration and early postoperative outcomes. These results should nevertheless be interpreted as evidence regarding the evaluated system and clinical setting rather than as proof that all AI-assisted cataract-surgery platforms provide equivalent benefits.

Postoperative endothelial cell preservation represents an important finding because corneal endothelial injury is a recognized consequence of intraocular surgery and can be influenced by the extent and duration of intraocular manipulation (15,16). At 4 weeks, mean endothelial cell loss was 184.5 ± 42.1 cells/mm² in the AI-assisted group compared with 278.3 ± 56.4 cells/mm² in the control group, corresponding to a between-group difference of −93.8 cells/mm². Previous studies have identified surgical trauma, manipulation within the anterior chamber, and intraoperative mechanical stress as contributors to endothelial cell loss after cataract extraction (15,16,19). The lower endothelial cell loss observed in the AI-assisted group is therefore compatible with reduced intraoperative tissue exposure or more efficient surgical manipulation, although the present analysis does not establish a causal mediation pathway between AI alerts, surgeon responses, operative duration, and endothelial preservation.

The difference in central corneal thickness provides complementary evidence regarding early postoperative corneal response. Mean CCT increased by 12.4 ± 3.8 μm in the AI-assisted group compared with 24.8 ± 6.2 μm in the control group, producing a between-group difference of −12.4 μm. Postoperative corneal thickening may reflect transient endothelial dysfunction and stromal hydration following intraocular manipulation. Strategies that minimize endothelial trauma during cataract surgery are therefore relevant to early corneal recovery (15,19). The smaller increase in CCT together with the lower endothelial cell loss observed in the AI-assisted group indicates a consistent pattern of more favorable early structural recovery, although longer follow-up would be required to determine whether these differences persist.

Visual recovery also differed between the groups. At 4 weeks, mean BCVA was 0.18 ± 0.08 LogMAR in the AI-assisted group and 0.28 ± 0.11 LogMAR in the control group, corresponding to a mean difference of −0.10 LogMAR. Both groups demonstrated substantial postoperative improvement relative to their respective baseline values, confirming that MSICS was associated with marked visual rehabilitation in both treatment arms. The between-group difference may reflect differences in postoperative corneal clarity, endothelial preservation, intraoperative manipulation, or other perioperative factors. Because these pathways were not individually modelled, the visual-acuity difference should not be attributed exclusively to automated complication alerts.

The incidence of posterior capsule rupture and/or iris prolapse was 6.5% in the AI-assisted group and 17.4% in the control group. Although this represents an absolute difference of approximately 10.9 percentage points, the confidence interval around the effect was wide and included no difference. The result therefore indicates statistical uncertainty rather than definitive prevention of complications. Posterior capsule rupture and iris prolapse are clinically heterogeneous events whose occurrence may depend on cataract characteristics, surgical anatomy, surgeon experience, and intraoperative technique (3-6). Larger trials with adequate numbers of complication events are required before a preventive effect of real-time AI monitoring can be established.

The findings also have potential implications for surgical training and clinical decision support. Automated video-analysis systems may provide an additional stream of intraoperative information for surgeons while preserving the surgeon's responsibility for interpretation and intervention. Prior research has demonstrated the technical feasibility of automated phase recognition, instrument tracking, and event detection in cataract surgery (9,10,12,17,18). Such systems may eventually contribute to surgical auditing, training, workflow standardization, and quality assurance, but these applications require robust external validation, assessment of false-positive and false-negative alerts, evaluation across different surgeons and microscope systems, and demonstration that technical performance translates into clinically meaningful outcomes (13,20).

Several methodological strengths support the study, including randomized allocation, concealed treatment assignment, a standardized MSICS protocol, blinding of patients and postoperative assessors, and the use of objective postoperative measures including BCVA, specular-microscopy-derived endothelial cell density, and anterior-segment optical coherence tomography-derived corneal thickness. The use of digital operative video also provides an objective source from which intraoperative events can be evaluated.

The findings should nevertheless be interpreted within important limitations. The study was conducted at a single center and included patients with relatively uncomplicated age-related cataracts, limiting generalizability to patients with pseudoexfoliation, traumatic cataract, lens instability, previous intraocular surgery, and other complex ocular conditions. Operating surgeons could not be blinded to AI allocation, creating the possibility that awareness of supplementary monitoring altered operative behavior. Only four weeks of postoperative follow-up were available, preventing assessment of longer-term visual, endothelial, retinal, or other delayed outcomes. The number of recorded posterior capsule rupture or iris-prolapse events was small, producing substantial uncertainty around estimates of complication risk. In addition, technical performance characteristics of the AI system, including diagnostic sensitivity, specificity, false-alert frequency, external validation, and performance across different surgical conditions, were not available for evaluation. These factors are particularly important when assessing the potential scalability of real-time intraoperative AI systems.

Future multicenter trials should therefore include larger and more clinically heterogeneous populations, multiple surgeons with varying levels of experience, prespecified event-level analyses, standardized reporting of AI diagnostic performance, and longer postoperative follow-up. Evaluation across different microscope platforms and surgical environments would help establish external validity. Future research should also distinguish between technical model performance, surgeon behavioral response, operative efficiency, complication prevention, and patient outcomes so that the specific pathways through which AI assistance may influence cataract surgery can be determined.

CONCLUSION

In this randomized controlled trial, AI-assisted intraoperative monitoring during manual small incision cataract surgery was associated with shorter surgical duration and more favorable 4-week visual and corneal outcomes than standard visual monitoring. Participants in the AI-assisted group demonstrated better postoperative BCVA, lower endothelial cell loss, and a smaller increase in central corneal thickness. Although intraoperative complications occurred less frequently in the AI-assisted group, the difference was not statistically significant and should not be interpreted as evidence of complication prevention. These findings support further evaluation of real-time AI-assisted surgical monitoring as an adjunct to surgeon-based intraoperative assessment, particularly through larger multicenter trials with rigorous event-level analysis and longer follow-up.

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