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Protocol for a systematic review and meta-analysis with trial sequential analysis: interventions for maintaining laparoscopic lens clarity during surgery

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ADMINISTRATIVE INFORMATION

Support - The review received no funding or financial support from any organization.

Review Stage at time of this submission - Other (retrospective registration). The protocol for this review was finalized on 26 August 2026, before the database searches were executed on the same day. Prospective registration on PROSPERO was planned but was not completed before data extraction began, which made the review ineligible for PROSPERO. No changes to the PICO, outcomes, or analysis plan were made after the results were known; all protocol deviations are declared in the review manuscript. The review was complete (data analysis finished) at the time of this registration.

Conflicts of interest - The authors are employees of Xsail Surgical Co., Ltd., a company with commercial interests in laparoscopic instruments. The employer had no role in the design, conduct, analysis, or reporting of this review. Two company-sponsored trials registered at ChiCTR (ChiCTR2500106050; ChiCTR2500101277) are unpublished, were not eligible for this synthesis, and were not included; they are listed as ongoing studies only. The review received no funding.

INPLASY registration number: INPLASY202680111

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 August 2026 and was last updated on 31 August 2026.

INTRODUCTION

Review question / Objective In adult patients undergoing laparoscopic surgery of any specialty (P), do interventions intended to maintain laparoscopic lens clarity—passive antifogging (scope warming; surfactant or antimicrobial solutions), active in-cavity lens-cleaning devices, or other approaches such as digital defogging and wiping materials (I)—compared with conventional care or head-to-head comparators (C), reduce fogging/soiling events, scope removals/cleaning interruptions per case, and operative time (O, primary), and affect time per cleaning event, total cleaning time per case, visual-clarity scores, surgeon workload, cost, and complications (O, secondary)? Randomized and non-randomized comparative clinical studies are eligible (S); simulation, bench, and preclinical comparative studies are eligible as a separately stratified evidence layer. Objectives: (1) to provide the first pooled effect estimates for the primary outcomes; (2) to test whether the accumulated evidence is conclusive using trial sequential

analysis; (3) to grade the certainty of evidence with GRADE as a basis for designing future trials.

Condition being studied Fogging and soiling of the laparoscopic lens during minimally invasive surgery. Condensation fogging, driven by the temperature and humidity gradient between the peritoneal cavity and the operating room, together with lens soiling by blood, fat, and surgical plume, forces the surgeon to withdraw the scope, clean it, and re-establish the view, repeatedly and unpredictably. These interruptions break the surgical team's line of sight during dissection, add unplanned steps and cost to the operation, and may contribute to visualization-related complications. The condition is not a disease but an intraoperative technical problem affecting essentially all laparoscopic and thoracoscopic procedures across specialties.

METHODS

Search strategy Databases (searched from inception to 26 August 2026, no language or date limits): PubMed/MEDLINE (n=156), Embase (n=237), Web of Science Core Collection (n=224), Cochrane CENTRAL (Trials, n=65), Europe PMC (n=205), ClinicalTrials.gov (n=7). PubMed master string (adapted per source): (laparoscop*[tiab] OR endoscop*[tiab] OR arthroscop*[tiab]) AND (fogging[tiab] OR fogged[tiab] OR antifog[tiab] OR anti-fog[tiab] OR "lens cleaning"[tiab] OR "lens cleaner"[tiab] OR "lens cleaning device"[tiab] OR "lens cleaning system"[tiab] OR "scope warming"[tiab] OR "scope warmer"[tiab] OR "in vivo cleaning"[tiab] OR "lens soiling"[tiab] OR "lens contamination"[tiab] OR FloShield[tiab] OR ClearView[tiab] OR EndoClear[tiab] OR ResoClear[tiab]). Reference lists of included studies and of the prior systematic review were citation-chased. Full per-source strings, hit counts, and search dates are reported per PRISMA-S in the review's supplementary appendix.

Participant or population Adult patients undergoing laparoscopic surgery of any specialty (colorectal, gynecological, upper-gastrointestinal/bariatric, urological, thoracoscopic). No restriction on setting or country. Simulation, bench, and preclinical comparative studies (ex vivo models, cadavers, animals) are eligible as a separately stratified evidence layer, never pooled with clinical data.

Intervention Any intervention intended to maintain laparoscopic lens clarity, in three families: (1) passive antifogging—scope warming (warm saline or water baths, warming devices) and surfactant or antimicrobial solutions (e.g., FRED, Ultra-Stop, chlorhexidine, povidone-iodine); (2) active cleaning devices that clear the lens without scope removal—in-cavity irrigation, air or water flow, sheath-mounted wipers, super-hydrophilic coatings or devices; (3) other approaches—digital defogging (software reconstruction) and wiping materials (e.g., microfiber cloths).

Comparator Conventional care (e.g., warm saline wiping, povidone-iodine, no treatment/blank control) or head-to-head comparators between lens-clarity interventions.

Study designs to be included Randomized controlled trials, non-randomized comparative studies, and prospective cohorts. Simulation, bench, and preclinical comparative studies are eligible as a separately stratified evidence layer. Conference abstracts eligible as grey literature (analyzed separately). Excluded: engineering-only bench tests without comparative data; reviews/editorials/letters; flexible-endoscope cleaning studies; heated/humidified CO2 insufflation studies; robotic scope-holder comparisons.

Eligibility criteria At least one eligible outcome required (fogging/soiling events; scope removals/cleaning interruptions; operative time; time per cleaning event; total cleaning time; clarity scores; workload; cost; complications). No language, date, or publication-status restrictions; non-English articles with obtainable full texts eligible. Exclusions beyond PICOS: studies of heated and humidified CO2 insufflation (outcomes are core temperature and pain, not lens clarity); robotic/mechanical scope-holder comparisons; flexible GI endoscope cleaning or disinfection; single-arm series without extractable comparative data; patent records.

Information sources Six electronic sources searched from inception to 26 August 2026: PubMed/MEDLINE, Embase, Cochrane CENTRAL, Web of Science Core Collection, Europe PMC (including preprints and grey material), and ClinicalTrials.gov (trial registry, used to trace publication status of completed trials). Reference lists of all included studies and of the prior systematic review (Nabeel 2022) were citation-chased. Conference abstracts were eligible as grey literature and analyzed separately. No author contact was required; all full texts were obtained.

Main outcome(s) (1) Fogging/soiling events (incidence or count per case; effect measure OR for binary, MD for counts). (2) Scope removals/cleaning interruptions per case—a composite

counting scope withdrawals for external cleaning in conventional/passive arms and avoided removals or in-cavity cleaning acts in active-device arms (MD). (3) Operative time in minutes (MD). Timing: intraoperative, per procedure. Trial sequential analysis was planned for all three primary outcomes.

Additional outcome(s) Time per cleaning event (seconds; MD); total cleaning time per case (seconds; MD); visual-clarity scores (non-commensurable instruments; narrative synthesis per SWiM); surgeon workload (e.g., SURG-TLX); cost; complications and length of stay. Timing: intraoperative or per hospital stay as reported.

Quality assessment / Risk of bias analysis Randomized controlled trials were assessed with the Cochrane RoB 2 tool (five domains); non-randomized studies with ROBINS-I. Industry-funded studies and studies with device-related conflicts were flagged for subgroup and sensitivity analysis. Traffic-light and weighted summary plots were produced with the robvis R package (v0.3.1). Simulation and bench studies were not formally rated with ROBINS-I (developed for human studies); their methodological safeguards, such as blinded outcome assessment, are reported narratively. Certainty per outcome was rated with GRADE, and a Summary of Findings table was constructed in GRADEpro GDT. Assessments were performed by one reviewer with AI assistance; every rating, with its supporting evidence, was verified against the full texts by the authors (declared in the manuscript).

Strategy of data synthesis Dichotomous outcomes pooled as odds ratios and continuous outcomes on common scales as mean differences, with 95% confidence intervals. Random-effects meta-analysis with REML estimation of tau-squared; I-squared, tau-squared, 95% prediction intervals, and Hartung-Knapp-Sidik-Jonkman adjusted CIs reported. Clinical and simulation/preclinical strata were pooled separately and never combined. Medians with IQRs or ranges were converted to means and SDs (Wan et al.; Hozo et al.); SDs back-calculated from 95% CIs where necessary, with a full audit trail. For multi-arm trials sharing one control group, the control was split evenly across comparisons (Cochrane Handbook 23.3.4). Trial sequential analysis (RTSA 0.2.2; two-sided alpha 0.05, 80% power, O'Brien-Fleming alpha-spending, heterogeneity-adjusted required information size) was performed for the three primary outcomes. The prespecified network meta-analysis was abandoned because the network was disconnected (declared deviation). Clarity scores on non-commensurable instruments were synthesized narratively (SWiM). Funnel plots and Egger's test were not performed because no outcome reached ten studies (stated in place of those analyses). Analyses implemented in Python/NumPy and independently cross-validated in R 4.5.3 (metafor 5.0.1).

Subgroup analysis Prespecified subgroups: (1) intervention class (passive antifogging; active cleaning devices; wiping or other approaches); (2) study setting (clinical versus simulation/preclinical); (3) industry funding (industry-funded versus not). The primary outcome is reported subgroup-first, with the omnibus pool across classes labeled a descriptive summary because of extreme heterogeneity.

Sensitivity analysis Prespecified: leave-one-out iterations; randomized-trials-only analysis; exclusion of high risk-of-bias studies and studies with data-level concerns; alternative SD-estimation methods (adding studies entering through Hozo range-estimated SDs). Post hoc (declared deviation): restriction to comparisons with directly reported mean +/- SD, excluding trials entering through median-to-mean conversion, to test whether conversion methods drive the pooled estimate.

Country(ies) involved China.

Keywords laparoscopy; lens fogging; lens cleaning; antifogging; surgical workflow; systematic review; meta-analysis; trial sequential analysis.

Dissemination plans The review will be submitted to Surgical Endoscopy (Springer). Results may also be presented at surgical conferences. The full replication package (per-database search outputs, screening and exclusion lists, extracted dataset, conversion audit trail, risk-of-bias ratings, analysis code in Python and R, statistical outputs, and figures) will be deposited in a public repository (Zenodo) under a CC BY 4.0 license upon publication.

Contributions of each author

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Author 2 - Yinting Hu - Screening, data extraction, risk-of-bias assessment, data curation.