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A Scoping review of Global Core Outcomes in Full Thickness Macular Hole

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ADMINISTRATIVE INFORMATION

Support - N/A.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 December 2025 and was last updated on 9 December 2025.

INTRODUCTION

Review question / Objective What clinical variables, imaging parameters, surgical details, and outcome measures have been reported in randomized controlled trials involving adult patients undergoing treatment for full-thickness macular hole.
Objectives:
- To identify all randomized controlled trials from 1992 onwards that evaluate treatments for full-thickness macular hole in adults.
- To map the baseline and intraoperative variables collected in these trials, grouped into demographic variables, patient history variables, clinical examination–derived variables and OCT/imaging-derived variables.
- To describe all outcome domains, outcome definitions, measurement instruments, and time points used in these trials, grouped into visual outcomes, anatomical outcomes and patient-reported outcomes.
- To highlight gaps and inconsistencies in outcome reporting that may inform development of more standardised outcome sets in future macular hole research.
- To record how complications were collected, defined and reported in each trial.

Background Full-thickness macular hole (FTMH) is a disorder of the central retina that causes central visual distortion, reduced acuity and can significantly affect daily activities and quality of life. The current standard of care is pars plana vitrectomy with internal limiting membrane (ILM) manipulation and intraocular gas tamponade, and a number of refinements have been introduced over time, including ILM peeling and flap techniques, the use of different gas agents and tailored postoperative positioning. These

developments have been evaluated in multiple randomized controlled trials, which together form a substantial evidence base for contemporary FTMH surgery.

Rationale The condition of interest is adult full-thickness macular hole, including idiopathic, secondary, and persistent holes treated with surgical or pharmacologic interventions. Existing RCTs use heterogeneous definitions of anatomical success, visual acuity outcomes and imaging-derived metrics. A scoping review is needed to systematically map these variables and outcomes, rather than to compare the effectiveness of specific interventions. This will provide an overview of current outcome reporting practices and help identify priorities for standardisation and future core outcome set development in FTMH research.

METHODS

Strategy of data synthesis We will search PubMed, Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science from 1 January 1992 to the date of search execution. Search strategies will combine controlled vocabulary and free-text terms for macular hole (e.g. “macular hole”, “full-thickness macular hole”) with randomized trial filters (e.g. randomized, randomised, clinical trial). Searches will be limited to human studies and English-language publications. Reference lists of included trials and relevant reviews will be screened to identify additional studies. Clinical trial registries will be searched to identify ongoing or unpublished RCTs. This scoping review will use narrative and tabulated synthesis rather than quantitative meta-analysis.

Eligibility criteria Types of participants (Population): Adults (≥18 years) with full-thickness macular hole in at least one eye. Idiopathic, secondary, and persistent FTMH will be included as defined by the trial authors. Trials exclusively involving partial-thickness (e.g. lamellar) macular holes without a full-thickness component will be excluded.
Concept: Randomized controlled trials evaluating any treatment in which full-thickness macular hole is an indication, including surgical, procedural, or pharmacologic interventions. All reported outcomes and variables will be mapped.
Context: Hospital or clinical settings worldwide, with no geographical restrictions. Only full-text, peer-reviewed publications in English from 1992 onwards will be included.

Source of evidence screening and selection All records retrieved from the searches will be imported into reference management software for de-duplication and then into a screening platform (e.g. Covidence or Rayyan). Two reviewers will independently screen titles and abstracts against the eligibility criteria. Potentially relevant studies will undergo full-text screening by the same reviewers, again independently. Reasons for exclusion at the full-text stage will be recorded. Any disagreements at either screening stage will be resolved through discussion; if consensus cannot be reached, a senior reviewer (Professor David Steel or Ms Teresa Sandinha) will adjudicate. The selection process will be documented in a PRISMA-style flow diagram adapted for scoping reviews.

Data management De-duplicated search results will be stored in a reference manager (e.g., EndNote or Rayyan). Screening decisions will be recorded within the chosen screening platform. A standardised data extraction form will be developed in Microsoft Excel to chart study characteristics, variables collected, and outcomes reported.
The extraction form will display:

- Study-level characteristics (e.g., year, country, design, sample size, follow-up schedule).
- Interventions and comparators evaluated in each trial.
- Population aetiology, classified as primary, secondary, persistent or mixed full-thickness macular holes.
- Baseline/preoperative variables, grouped as:
  – Demographic variables (e.g., age, sex).
  – Patient history variables (e.g., symptom duration, previous ocular surgery).
  – Clinical examination–derived variables (e.g., baseline visual acuity)
  – OCT/imaging-derived variables (e.g., minimum and base hole diameter, macular hole configuration, associated traction).
- Outcomes grouped as:
  – Visual outcomes.
  – Anatomical outcomes.
  – Patient-reported outcomes.
- Complication reporting, including which complications were collected, how they were defined and at what time points they were assessed.

Reporting results / Analysis of the evidence Data will be analysed descriptively and reported using narrative synthesis, tables, and, where appropriate, simple graphical summaries. Outcomes will be grouped into three main domains

(visual outcomes, anatomical outcomes and patient-reported outcomes). Within each domain, we will summarise how outcomes are defined, which measurement instruments are used, and at what time points they are assessed. We will describe how comparators and population aetiology are characterised across trials. We will also explore patterns in outcome reporting over time and across intervention types. No meta-analysis or quantitative pooling of treatment effects is planned, as the focus is on mapping variables and outcomes rather than estimating comparative effectiveness.

Presentation of the results Results will be presented in structured tables and accompanying narrative text. Planned tables include:
- A study characteristics table summarising trial design, sample size, interventions and comparators, follow-up duration and population aetiology (primary, secondary, persistent or mixed).
- A baseline variables table showing preoperative variables grouped into demographic, patient history, clinical examination and OCT/imaging categories.
- Three outcome tables, respectively detailing:
  – Visual outcomes.
  – Anatomical outcomes.
  – Patient-reported outcomes.
- A complications table describing which complications were collected, how they were defined and how they were reported (including timing and whether pre-specified).

The narrative synthesis will be used to highlight patterns, gaps and inconsistencies in outcome and variable reporting across trials and over time.

Language restriction The review will be restricted to studies published in English.

Country(ies) involved United Kingdom.

Other relevant information The review will adhere to the PRISMA Extension for Scoping Reviews (PRISMA-ScR) for reporting. The findings are expected to support subsequent methodological work on standardising outcome reporting and may contribute to the groundwork for a future core outcome set for full-thickness macular hole trials.

Keywords full-thickness macular hole; idiopathic macular hole; vitrectomy; internal limiting membrane peel; gas tamponade; randomized controlled trial; optical coherence tomography.

Dissemination plans We plan to submit the completed scoping review for publication in a peer-reviewed ophthalmology journal. Findings will also be presented at national and international ophthalmology meetings where appropriate. If the results inform outcome standardisation efforts, they may be shared with relevant professional societies and guideline developers.

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