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Effect of size of capsulorhexis on the outcome of cataract surgery: a protocol for systematic review and individual participant data meta-analysis

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ABSTRACT

Introduction In the era of functional intraocular lens (IOL) implantation, it is crucial to investigate the influence of different capsulorhexis sizes (including the diameter of the capsulorhexis, area of the anterior capsule opening, anterior capsule coverage, centration and circularity of the capsulorhexis) on the postoperative outcomes (eg, visual acuity, capsule shrinkage, IOL stability and intraocular pressure) in patients undergoing cataract surgery. This is particularly important in patients with high myopia or diabetes mellitus. The proposed protocol aims to enhance the transparency of our research and offer references for future studies.

Methods and analysis A comprehensive search of PubMed, Embase, Cochrane Library, Web of Science, SinoMed, China National Knowledge Infrastructure, Wanfang Data Knowledge Service Platform and China Science and Technology Journal Database is performed from inception to 4 July 2024. Data of individual participants will be collected from relevant clinical trials, both completed and ongoing. The collected data will be analysed using multilevel regression models to examine the association between capsulorhexis size and surgical outcomes. Potential demographic and clinical factors that may influence the results of cataract surgery, including postoperative visual acuity and IOL rotational stability, will also be explored. Any future modification to this protocol will include the date and rationale for the change.

Ethics and dissemination Ethical approval is not required because the study does not involve individual patients. The study results are to be disseminated via professional journals as well as academic media.

Trial registration number CRD42023459903.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A dedicated team of up to five members will be established to address the discrepancies of two independent reviewers.
⇒ A multistep contact protocol is employed for collecting individual patient data.
⇒ A refined Quality in Prognosis Studies tool is applied to assess the risk of bias in the included studies.
⇒ All potential unpublished data is to be obtained during the process.
⇒ A potential limitation is that studies influenced by different economic and social factors are analysed together.

INTRODUCTION

Approximately 20 million cataract surgeries are performed annually worldwide.[1] Surgeons are focusing on improving preoperative measurements and calculations, standardising intraoperative manipulations and optimising postoperative care to achieve satisfactory visual outcomes. Capsulorhexis is one of the key steps during cataract surgery. A complete continuous curvilinear capsulorhexis (CCC) is crucial for successful phacoemulsification[2]: (a) CCC aids containing ultrasonic turbulence and protects the endothelium against high-velocity lens fragmentation and cavitation. (b) CCC prevents asymmetrical contracture of the rim, which can lead to uneven tension on the capsule and zonules and helps maintain the stability of the capsular bag and intraocular lens (IOL), which in turn enables more accurate prediction of postoperative refraction. (c) A regular capsulorhexis rim helps prevent or reduce the occurrence of posterior capsule opacification.

In addition to a contact CCC, the size of capsulorhexis has long been a concern in clinical practice. Usually, a smaller capsulorhexis (less than 5 mm in diameter or less than the diameter of the optical area of IOL) is correlated to less damage and is accepted by most surgeons.[3 4] Moreover, the size of capsulorhexis may influence the stability of IOLs via its effect on postoperative capsule opacification.[5] The capsule opacification, namely, the fibrotic response of the posterior and anterior capsule, can lead to capsular shrinkage, which in turn affects IOL stability. After cataract surgery, lens epithelial cells located in the remaining peripheral anterior capsule can transform into myofibroblasts, resulting in fibrotic

anterior/posterior capsule opacification (ACO and PCO) and shrinkage of the capsular bag.[5] It is supposed that a smaller capsulorhexis size and less polishing are associated with better stability IOL because the ACO, to some extent, could increase the adhesion between the anterior capsule and IOL and restrict IOL movement.[4] Some researchers have argued that even a slight alteration in the diameter of the capsulorhexis can significantly affect the grade of ACO. However, in Grade 4 ACO, the capsular bag undergoes excessive constriction; the haptics of the IOL curls forward and the stability of IOL is impaired.[6] In addition, in patients with high myopia, a large capsulorhexis may improve the long-term stability of IOL.[7]

Highly myopic eye is characterised by an axial length of ≥26 mm, with weak zonules and a large capsular bag. Usually, the likelihood of postoperative capsule shrinkage is greater in such patients, and the conventional capsulorhexis size is no longer appropriate. Studies have demonstrated that a longer axial length is associated with a higher risk of PCO.[8] A relatively larger capsulorhexis (6 mm for an IOL with a diameter of 7 mm) may provide better stability for the special consideration of patients with highly myopia eyes.[7] However, the proper size of the capsulorhexis and the extent of anterior capsule coverage in these patients remain unclear.

The size of capsulorhexis is also specifically concerned in patients with cataract with diabetes mellitus (DM). These patients are at risk of developing retinopathy and may require intensified fundus examinations. Theoretically, patients with DM need to maintain good visual acuity while achieving the largest possible capsulorhexis size. Reduction of the anterior capsule aperture may hinder fundus visibility in pseudophakic eyes.[9] In particular, DM is a risk factor for anterior capsule contraction, severe intraoperative corneal endothelial damage and slow postoperative recovery.[10 11] Thus, three aspects should be considered when deciding the size of capsulorhexis: postoperative corneal recovery, IOL stability and fundus visualisation. At present, there are very few studies concerning the optimal size of capsulorhexis in patients with DM.

As described above, the exact capsulorhexis size is important considering the rotational stability of the IOL and in patients with high myopia or DM. The number of relevant studies is very limited to date and there is no literature directly addressing this question, so we used raw data from individual relevant clinical trials to address this issue, that is, the individual patient data meta-analysis (IPD-MA), as employed by similar researches.[12–14] The goal is to determine the optimal size of capsulorhexis to minimise the refractive changes caused by capsular contraction and maximise the benefits for patients with cataract with regular corneal astigmatism, high myopia or DM.

METHODS

Before outlining this protocol, we strictly adhere to predetermined search methods and thoroughly review the text of relevant studies. The planned start date for this study is 4 July 2024, with an anticipated end date of 1 June 2025.

Registration

This study is registered in the PROSPERO International Prospective Register of Systematic Reviews (registration number CRD42023459903). We follow the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols statement when reporting this article. Any protocol changes that may have occurred will be described in the final report.

Types of studies

This meta-analysis aims to identify eligible clinical trials, including observational studies and randomised controlled trials, involving adults undergoing phacoemulsification and IOL implantation with CCC and recorded capsulorhexis size. There are no restrictions on the year when the study is conducted, language of publication, date of publication or publication status.

To be included in the IPD-MA, the study must provide the following information:

1. Capsulorhexis size: diameter or area of the capsulorhexis, anterior capsule cover, centration and circularity of capsulorhexis.
2. Primary outcomes: IOL stability or postoperative visual acuity.
3. Secondary outcomes: capsule shrinkage and all the other outcomes.

Information sources and search strategy

A systematic search is conducted from inception until 4 July 2024 in the following databases: PubMed, Embase, Cochrane Library, Web of Science, SinoMed, China National Knowledge Infrastructure, Wanfang Data Knowledge Service Platform and China Science and Technology Journal Database. The structured search algorithm is: (((((((((continuous curvilinear capsulorhexis) OR (capsulorhexis size)) OR (diameter of capsulorhexis)) OR (area of capsulorhexis)) OR (anterior capsule opening)) OR (capsulorhexis position)) OR (shapes of capsulorrhexis)) OR (anterior capsule cover*)) OR (centration of capsulorrhexis)) OR (circularity of capsulorrhexis). The strategies of the search plan to be applied to all databases are detailed in online supplemental file S1). The reference lists of the selected studies are reviewed to identify additional relevant studies. A final search will be conducted immediately before submission to ensure that no recent publications have been overlooked.

Selection, management and collection process of data included in IPD study

Selection process

A dedicated team of five persons is formed with two key members responsible for developing the process and standards. The two assessors conduct the processes of

study screening, selection, data extraction and bias risk assessment independently. The final plan will be determined through a group discussion. All team members should receive training before data extraction and collection. The titles and abstracts of potential studies are compared with the eligibility criteria and thoroughly assessed by two appraisers to determine their suitability. Subsequently, these two appraisers will carefully review the full text of the potential studies. Any discrepancies between the two appraisers are to be resolved through a consensus meeting involving the entire study team. During the screening process, we first use software to remove duplicate references, followed by manual deletion. After removing duplicates, the two assessors independently perform manual screening, excluding case series, conference reports, grey literature, news articles and literature reviews from the analysis.

After screening, a total of 94 articles meeting the inclusion criteria have been identified, including five articles focusing highly on patients with myopia and six articles focusing on patients with diabetics (see online supplemental file S2 for specific flow diagram). Readers who possess knowledge in this field and are aware of studies that have not yet been included are encouraged to contact us.

Data management

The data collection protocol employed at the group consensus meeting will be continuously adjusted by two key members based on various studies. When possible, we will contact the corresponding author of the study via email to acquire, if any, original data that were not mentioned in their article. The data collection process will be divided between two members with respective roles. All data will be sent to the data manager in the most convenient format and stored in an Access database. The data will be uniformly organised by two team members responsible for this task. All information will be securely maintained and treated as strictly confidential. The data will not be allowed to be used in any publication without permission from original trialists.

Data collection process

IPD can be obtained from data-sharing databases, such as Yale University Open Data Access, Clinical Study Data Request and Vivli (https://vivli.org/).[15] In cases where data are not available in data-sharing databases, we will directly obtain data from the authors of the respective study.

Once it is established that the study meets the eligibility criteria, the authors of the study will be contacted via a secure university-registered email address. To collect as much individual patient (raw) data as possible from the included studies, we will use a multistep contact protocol that has been proven effective in previous studies.[16] The steps for obtaining raw data from the authors of the included studies are summarised in figure 1. We will obtain the contact information of the corresponding author by (a) gathering it from relevant publications, (b) conducting a web search and (c) reaching other researchers. An email will be sent to the corresponding author, clearly stating the study's objectives and providing clinical and methodological justifications for IPD. We will also convey our intentions to the authors through in-person meetings, as this may increase their willingness to share raw data.[17] The corresponding author is given 9 weeks to respond to our email. If no response is received after 3 weeks, a second email will be sent. Similarly, if there is no response after another 3 weeks, a third email will be sent. If the corresponding author does not respond within these 9 weeks, we will repeat the aforementioned steps with other authors in the following order: first, last, second, third, fourth, etc. When the above steps are unsuccessful, the corresponding author will be contacted via letter and telephone to obtain the raw data. Letters will be sent at 3-week intervals. We will contact other authors in the same manner only when the corresponding author cannot be reached. Finally, if there is still no response, we will attempt to establish communication with colleagues who may be acquainted with the authors. Study data will be considered unavailable only if all the methods have failed or if authors indicate that the raw data have not been retained or that they refuse to share these data.

Data items collected in IPD study

All prognostic indicators accessible in a sufficient number of included studies that may affect the outcome of cataract surgery are included. The elements included in the achieved studies are summarised in box 1. The information provided in the text and tables will be combined into a systematic narrative synthesis that will explain and summarise the characteristics and conclusions of the included investigations.

Information about the included studies

For the included studies, we will collect basic information (author, publication date, country, number of eyes/patient per study and special populations), intervention description (diameter of the capsulorhexis, area of anterior capsule opening, anterior capsule cover, centration and circularity of capsulorhexis), outcome description (refraction, capsule shrinkage, stability of IOL intraocular pressure) and follow-up time, as summarised in box 1.

Baseline characteristics of the included studies

- Participant-level data items: we request that investigators provide the following original data, to the extent possible, for the subjects in the included studies: age, sex, axial length, anterior chamber depth (ACD), grade of the lens nucleus or lens opacity, capsular bag diameter, IOL power, predicted refraction and preoperative visual acuity. Data collected at the follow-up visit include the area of capsulorhexis and/or anterior capsule opening, circularity of capsulotomy or CCC, visual acuity, intraocular pressure, corneal oedema, postoperative aqueous flare intensity, corneal

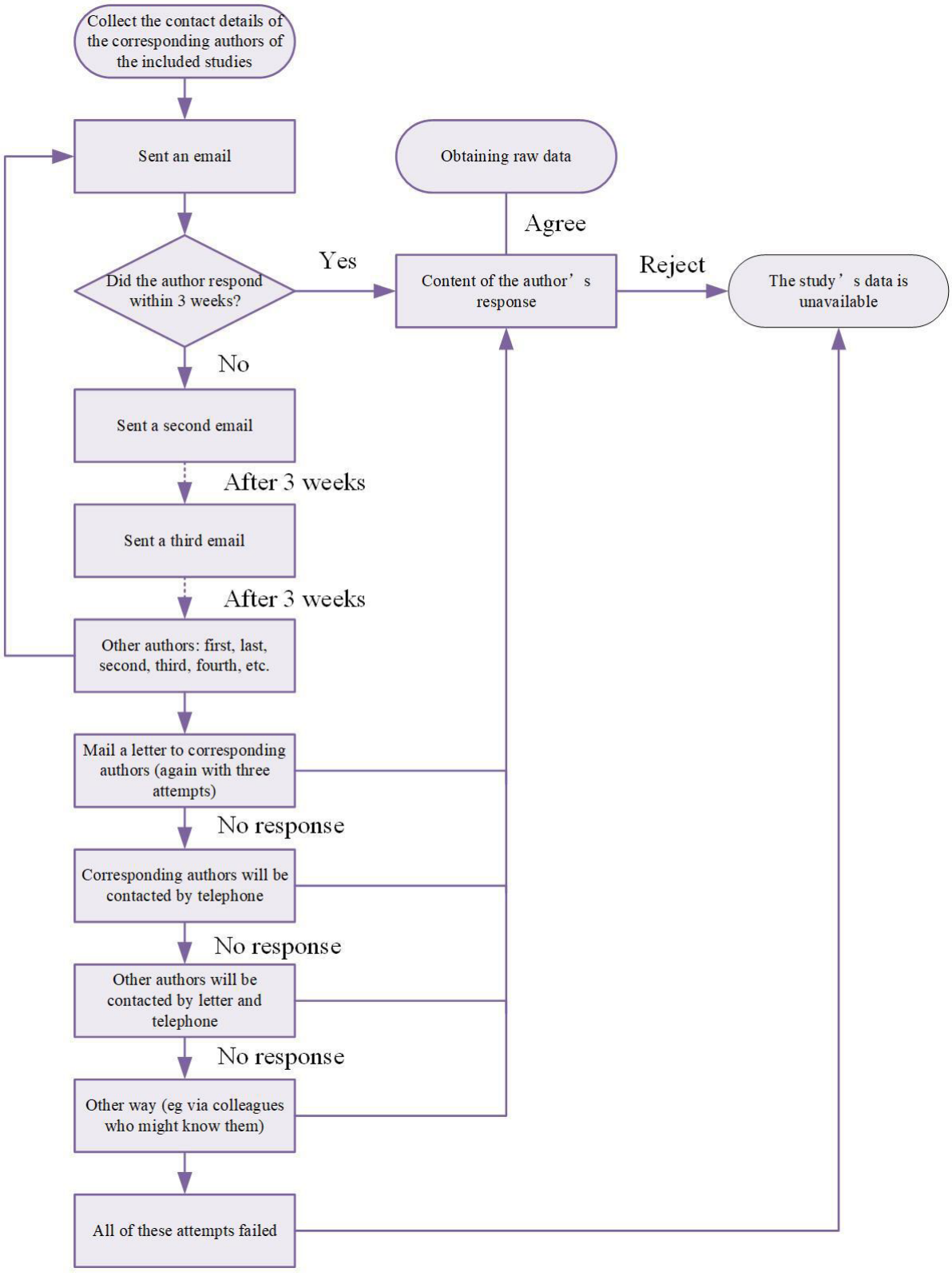

Figure 1 Flow chart showing the process of obtaining the raw data from the authors of the included studies.

endothelial cell density (ECD), central corneal thickness (CCT), ACO, PCO, surgically induced astigmatism and the rate of anterior capsule contraction.

- Surgical-level data: the surgical time and cumulative ultrasound energy used during the operation are recorded.

Information to be explained

- Capsule shrinkage: the percentage reduction in anterior capsule opening at follow-up is calculated as follows: (previous anterior capsule opening–anterior capsule opening at this follow-up) × 100/anterior capsule opening at the last follow-up.

Box 1 Information and baseline characteristics of the included clinical studies

Information about the included trials:

⇒ Study (primary author, published date)
⇒ Eyes/patients per study (N)
⇒ Country
⇒ Special populations: high myopic eyes, patients with diabetes mellitus
⇒ Types of capsulorhexis size included diameter, anterior capsule opening area, anterior capsule cover, centration and circularity
⇒ Refraction: uncorrected distant visual acuity, best-corrected distant visual acuity
⇒ Capsule shrinkage
⇒ Stability of IOL: tilt, decentration, rotation and anteroposterior IOL shift
⇒ Types of IOL
⇒ Postoperative time points (months)

Baseline characteristics of the included studies:

⇒ **Participant-level data items:**
⇒ Age
⇒ Gender
⇒ Axial length
⇒ Anterior chamber depth
⇒ Grade of the lens nucleus or grade of lens opacity
⇒ Capsular bag diameter
⇒ IOL power
⇒ Predicted refraction
⇒ Capsulorhexis area and/or anterior capsule opening area
⇒ Capsulotomy or CCC circularity
⇒ Visual acuity, logMAR
⇒ Intraocular pressure
⇒ Corneal edema
⇒ Postoperative aqueous flare intensity
⇒ Corneal endothelial cell density
⇒ Central corneal thickness
⇒ Anterior capsule opacification
⇒ Posterior capsule opacification
⇒ Surgically induced astigmatism
⇒ Rate of anterior capsule contraction
⇒ **Surgical-level data items:**
⇒ Surgical time
⇒ Cumulative ultrasound energy

Abbreviations: CCC, continuous curvilinear capsulorhexis; IOL, intraocular lens.

- Types of IOLs: capsule contraction is affected by IOL optic material, haptic design, and size.[10]
- Anterior chamber depth: the distance between the anterior surface of the IOL and central corneal endothelium is known as ACD.
- Circularity: 4π (area/perimeter^2).
- Calculation of the capsulorhexis diameter.

Actual diameter = (maximum diameter+minimum diameter)/2

Relative diameter=actual diameter/expected diameter

- Stability of the IOL:

Tilt: an IOL tilt of 7° or more is considered clinically significant.

Decentration: clinically significant decentration of the IOL is defined as 0.4 mm or greater.

Rotation (suitable for toric IOL): this parameter refers to the angle between the IOL axial position at the postoperative follow-up and the expected position of the IOL axis before the operation. An angle greater than 1° indicates axial rotation.

Anteroposterior IOL shift

- Visual acuity: for analysis, all measurements of visual acuity are transformed into logMAR units.

Data integrity and outcomes and prioritisation

The primary analysis of each article will be replicated, and the endpoint values will be compared with those of the original publication. In cases of missing data, investigators from the included studies will be contacted to determine the reasons for loss to follow-up and to request any incomplete data if available.

The primary outcomes of this study are IOL stability and visual parameters during follow-up. The main objective is to evaluate the impact of different capsulorhexis sizes on IOL status and visual acuity. Secondary outcomes include capsule shrinkage during follow-up and any other outcomes (eg, ACD, corneal oedema, aqueous flare intensity, corneal ECD, CCT, ACO or PCO) that will require assessment in at least two studies.

Risk of bias and confidence in cumulative evidence

Risk of bias in individual studies

The standard risk of bias assessments is not applicable to these studies because we will use data from clinical trials for purposes unrelated to their original research topic. Previous studies have identified the refined Quality in Prognosis Studies (QUIPS) tool as suitable for assessing the risk of bias in studies of prognostic factors.[18] Six domains are evaluated: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding, and statistical analysis and reporting.[19] The outcomes are classified as yes, partial, no or uncertain, based on the prompting items within each domain. The answers will be then summed, and each domain will be rated as having a high, moderate or low risk of bias.

Two independent appraisers will use the QUIPS tool to assess the risk of bias in the included studies. The entire research team will convene a consensus meeting to resolve any disagreements among appraisers.

A study will be classified as having a low risk of bias when all six domains are rated as low or moderate, with at least four items rated as low, including the outcome measurement domain. Studies that receive high scores in two or more domains will be classified as having a high risk of bias. The remaining studies will receive a moderate rating.[20]

Confidence in cumulative evidence

The overall certainty of the evidence will be assessed by two independent reviewers using a modified Grading of

Recommendation, Assessment, Development and Evaluation (GRADE) approach. This modified approach is specifically designed to evaluate prognostic evidence, including study design, risk of bias, inconsistency, imprecision, indirectness and publication bias. Effect sizes and trends will also be considered. In the event of any disagreement, consensus meetings will be held with the group members to resolve them.

We will take the following steps to implement the modified GRADE framework:

- Determine the type of study: we will first classify the outcomes based on the study design (eg, randomised controlled trials and observational studies). This classification will assist us in establishing a baseline for assessing the quality of evidence.
- Assess the risk of bias: we will use standardised tools, such as the Cochrane Bias Risk Tool, to evaluate the risk of bias for each study. Studies identified as having a high risk of bias will be considered for downgrading.
- Assessment of consistency: we will compare the consistency of results across studies. In cases where significant differences are observed, we will consider downgrading the quality of evidence.
- Indirectness of evidence: we will conduct an indirect assessment of whether the results apply to our study population or the intervention. Downgrading will be considered if the intervention or population in the study is deemed distant from our own.
- Precision assessment: we will evaluate the precision of the results, including the width of the confidence intervals. If the confidence intervals are wide, indicating insufficient precision, we will consider downgrading.
- Publication bias: we will check for signs of publication bias, for example, by employing a funnel plot. Should evidence of bias be identified, a downgrade will be considered.
- Upgrade or downgrade: on completion of the assessments, we will synthesise all factors to determine whether to upgrade or downgrade the quality of evidence. For instance, if a particular study demonstrates strong performance in terms of risk of bias and consistency but exhibits issues with precision, we may opt to maintain the current quality of evidence.
- Transparent recording: we will meticulously document each step of the evaluation process and the final grading of evidence quality to ensure transparency and reproducibility.

Publication or data-sharing bias

To assess the concern regarding publication or data-sharing bias, we will implement several strategies:

- Literature review: we will undertake an extensive literature review to identify all pertinent studies, including smaller ones that might be excluded from IPD analyses.
- Tool: for analyses involving 10 or more trials, we assess the potential publication bias by examining asymmetry in funnel plots using Egger's test. Funnel plots will also be generated to visually inspect for potential bias in smaller studies.
- Sensitivity analysis: we will perform sensitivity analyses to evaluate the impact of including or excluding smaller studies on the overall results.
- Meta-biases: In 2016, Smith *et al* compared IPD-MA outcomes with aggregate data meta-analysis outcomes and reported inconsistent results.[21] To assess potential bias in data availability, we will perform t-tests for continuous variables and $\chi 2$ tests for categorical variables to compare characteristics across studies that received IPD and those that did not. The effect size information obtained from the publications will be used to calculate Cohen's d effect sizes. To compare effect sizes between studies with and without IPD, the effect sizes are pooled and analysed across studies using the traditional 'subgroup analysis' approach of meta-analysis.

Data synthesis and (statistical) analysis

High statistical power indicates a high feasibility of the project. However, due to the inclusion of various study types and the fact that some studies did not primarily focus on the outcomes of interest, there is a lack of standardised power calculation method in this study. Meanwhile, the assessment of bias risk and overall certainty of evidence can, to some extent, validate the reliability of our findings.

Appropriate tabular and graphical summaries can be used to present the descriptive statistics. Quantitative variables are summarised using means and SD, whereas qualitative variables are summarised using frequencies and percentages.

Strategy for data synthesis

A one-stage IPD-MA using multilevel regression model[22] will be chosen based on previous experience. The effect measures will be converted to a standardised scale (z-scores) to facilitate visual comparisons. Notably, most clinical trials included in the IPD-MA did not assess the primary endpoint. A multilevel regression model will be established based on all available data, with the size of the capsulorhexis, preoperative visual acuity and other prognostic indicators as independent variables, and postoperative visual acuity as a dependent variable. A similar multilevel regression model will be used to examine the impact of capsulorhexis size on the rotational stability of the IOL or other outcome variables. Multilevel linear regression models will be used for continuous outcomes, while multilevel logistic regression models will be used for categorical outcomes. To evaluate their moderating effect on treatment outcomes, the model will incorporate the interaction between the intervention group and the moderators of interest. If heterogeneity is permitted, raw data will be combined into a single set. To address data clustering, a study

identification variable will be added as a random effect variable. When quantitative synthesis is not feasible, we will perform a narrative analysis.

Another analysis will investigate the short-term effects of capsulorhexis size on IOL rotation of less than 15° within 1-week period.

Sensitivity analysis

To conduct a sensitivity analysis, studies with an overall high risk of bias will be excluded. Further sensitivity analysis will use interaction terms to explore whether pairs of predictors show nonlinear effects on the primary outcome.

Subgroup analysis

Prespecified subgroup analysis will be conducted based on:

1. Presence or absence of high myopic eyes
2. Patients with or without DM
3. Types of IOL
4. Types of capsulorhexis size
5. Types of study

If sufficient data are available, the ocular axial length and the type of astigmatism will also be considered as factors in the grouping. By collecting individual patient data, it is possible to estimate potential differences between these subgroups. Analysing the reasons for these differences is more effective than relying solely on individual trial reports. The analyses will be conducted using Review Manager C.5.3.

Amendments to protocol

To ensure transparency and maintain the integrity of our research, the following plan will be implemented in case of documenting any amendments to the study protocol. This plan will include the following key components:

- Documentation: all amendments will be recorded in a designated section of the study protocol, detailing the nature of the change, the rationale behind it and the date of the amendment.
- Reporting: any amendments are to be explicitly reported in future publications. This will include a summary of the changes made, along with an explanation of their significance in relation to the study's objectives.
- Justification: for each amendment, a point-by-point justification is to be provided which outlines the reasons for the changes, whether they are based on emerging evidence, feedback from peer reviewers or unforeseen circumstances encountered during the study.

Patient and public involvement

None.

Ethics and dissemination

Ethical approval is not required because the study does not involve individual patients. The study results are to be disseminated via professional journals as well as academic media.

Contributors SW: Conceptualisation, data curation, formal analysis, investigation, methodology, project administration, validation, visualization, writing—original draft and writing—review and editing. TW: Formal analysis, methodology, project administration, software, visualisation, writing— original draft and writing—review and editing. YZ: Formal analysis, investigation, methodology, supervision, writing—original draft and writing—review and editing. YL: Data curation, supervision, validation and writing—original draft. XQ (the manuscript's guarantor): Conceptualization, funding acquisition, resources, supervision, writing—original draft and writing—review and editing.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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