

INPLASY PROTOCOL

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None declared.

LASER-BASED REFRACTIVE SURGERY TECHNIQUES TO TREAT MYOPIA IN ADULTS. AN OVERVIEW OF SYSTEMATIC REVIEWS AND META-ANALYSES

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Review question / Objective: Study design - The units of analysis were systematic reviews with or without meta-analyses, and those with network meta-analysis, if any. All of them were based on randomized controlled trials (RCTs) or non-randomized studies of interventions (NRSI) in adults (≥ 18 years of age). On the other hand, narrative reviews without systematic electronic searches and evidence appraisals were excluded. For the present overview, a systematic review was defined as such based on the following methodological criteria: - It must be a secondary analysis of primary studies, consulting at least two main databases and critically assessing the methodological quality of the included studies. - It must have a clearly formulated question or aim. - It must use systematic and explicit methods to identify, select, extract and analyze data from the studies. - When two SRs involving the same topic and the same authors are found, the most recent SR is considered.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 May 2021 and was last updated on 26 May 2021 (registration number INPLASY202150095).

INTRODUCTION

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Rationale: Evidence-based medicine seeks to base clinical decisions as much as possible on the most current and highest level of evidence. Systematic reviews (SRs) and meta-analyses (MAs) constitute powerful tools for decision making, because they are able to overcome the limitations of underpowered studies, and allow professionals to keep abreast of the literature while basing their decisions on the available specific evidence. Nowadays, in consonance with the technological innovations and changes in surgery techniques, the synthesis of healthcare information constitutes a challenge, since over 75 clinical trials and 11 systematic reviews are published on a daily basis¹³. An overwhelming number of primary studies and systematic reviews on refractive surgery for the treatment of myopia in adults have been published in recent years. Regrettably, SRs and MAs are often not correctly conducted, and their findings may be affected by design and execution bias, causing them to not truly represent what was published in the first place. The number of people with myopia worldwide is expected to reach 4.76 billion by 2050 – a trend that has important economic¹⁵ and public health implications. Since there appear to be no overviews of systematic reviews (OoSRS) in the available literature, it is of great importance to appraise the methodological quality and summarize the best available SRs and MAs on laser-based refractive surgery for myopia control in adults.

Condition being studied: Adults (>18 years) diagnosed with myopia, considered as the spherical equivalent of ≤ 0.50 diopter.

METHODS

Search strategy: Google Scholar ("Myopia"[Mesh] OR myopia OR nearsightedness) AND (LASIK OR LASEK OR PRK OR SMILE OR Epi-LASIK OR FLE_x) AND (UCVA OR spherical equivalent OR CDVA OR visual acuity OR haze OR pain OR dry-eye OR halo) AND (Systematic review OR Meta analysis).

Participant or population: Adults (>18 years) diagnosed with myopia, considered as the spherical equivalent of ≤ 0.50 diopter 1, with or without astigmatism, but without any other comorbidities (e.g., strabismus, amblyopia, keratoconus, pathological myopia subjected to photocoagulation therapy) were included. Also, systematic reviews focused on myopia but including study subgroups with myopic astigmatism or hyperopia were also considered.

Intervention: Studies assessing two or more laser-based refractive surgery techniques for myopia with/out astigmatism, as well as publications assessing the use of mitomycin C or adjuncts, were included.

Comparator: Studies assessing two or more laser-based refractive surgery techniques for myopia with/out astigmatism, as well as publications assessing the use of mitomycin C or adjuncts, were included.

Study designs to be included: Systematic reviews with or without meta-analysis.

Eligibility criteria: The units of analysis were systematic reviews with or without meta-analyses, and those with network meta-analysis, if any. All of them were based on randomized controlled trials (RCTs) or non-randomized studies of interventions (NRSI) in adults (≥ 18 years of age). On the other hand, narrative reviews without systematic electronic searches and evidence appraisals were excluded. For the present overview, a systematic review was defined as such based on the following methodological criteria: - It must be a secondary analysis of primary studies,

consulting at least two main databases and critically assessing the methodological quality of the included studies. - It must have a clearly formulated question or aim. - It must use systematic and explicit methods to identify, select, extract and analyze data from the studies. - When two SRs involving the same topic and the same authors are found, the most recent SR is considered.

Information sources: A search was made in duplicate (SPO and RSP) of the main electronic databases and grey literature, including Medline (via PubMed), EMBASE, Web of Science (WOS), Cochrane Library, Google Scholar, and Open Grey, up until April 2020. The search included thesauruses such as Mesh (PubMed) and Emtree (EMBASE), as well as other free-text terms that were combined whenever possible and adapted for each database (Appendix Table S1). In addition, complementary sources such as topic-related journals and reference lists of included studies were consulted to retrieve titles not detected through the electronic search. In order to identify new potential titles consistent with the research strategy, the electronic search was kept updated using the Really Simple Syndication (RSS) feed appliance for PubMed. Ongoing review protocols were also sought in the PROSPERO database. No restrictions referred to language or year of publication were imposed.

Main outcome(s): The primary outcomes of the present OoSRs was to determine the methodological quality of the eligible systematic reviews, the degree of study overlap, the meta-biases during review process, the disclosure of the methodological quality of the index titles included among less biased systematic reviews.

Additional outcome(s): Determine the evidence certainty of the following parameters, as secondary outcomes: Efficacy was measured in terms of the mean change in refractive error, uncorrected visual acuity (UCVA 20/20 or better, UCVA 20/40 or better), the UCVA

Logarithm of the Minimum Angle of Resolution (LogMar), corrected distance visual acuity (CDVA) LogMar, spherical equivalent refraction changes ± 0.5 diopter, the proportion of eyes within ± 0.50 diopter / ± 0.1 diopter of target refraction, loss of one or more lines of best-corrected visual acuity (BCVA), and final BCVA (20/40 or less).

Data management: Kappa scores are used to determine the level of agreement between reviewers and were interpreted according to the Landis and Koch scale. Discrepancies were resolved by discussion with a third advisor (A.V-I).

Quality assessment / Risk of bias analysis: Risk of bias assessment - Risk of bias was assessed taking into account the methodological appraisal, the presence of meta-biases, certainty of evidence, and the degree of overlap between studies. The methodological quality of index titles included among less biased systematic reviews was summarized using the original risk of bias tools reported. If the full-report of quality appraisal is not provided in the original paper, it is completed using the same tool. - Methodological appraisal (AMSTAR-2) - The Assessing of the Methodological Quality of Systematic Reviews version 2 (AMSTAR-2) tool was used to appraise the quality of the included systematic reviews¹⁸. This tool is suitable for reviews including randomized and non-randomized studies. It comprises 16 domains relating to the research question, review design, search strategy, study selection, data extraction, justification for excluded studies, description of included studies, risk of bias, sources of funding, meta-analysis, heterogeneity, publication bias, and conflicts of interest. The appraisal process was performed in duplicate (SPO and RSP) throughout the electronic checklist of the AMSTAR-2 website (www.amstar.ca) to establish overall rating of the methodological quality of each review. Depending on its completeness, each review was rated as "high", "moderate", "low", or "critically low"¹⁸. Then, each individual assessment was printed and transferred to Excel

spreadsheets in duplicate (SPO and RSP). Discrepancies between reviewers were resolved by discussion with a third advisor (AAA). - Meta-biases Two reviewers (SPO and RSP) assessed the hints for meta-biases and retrieved data on the statistical software, the meta-analytical approach, the handling of inconsistency and publication bias, additional analysis strategies, the risk of bias assessment tool used, the assessment of selective outcome reporting, the hints of dual co-authorship, other sources of bias and the unit of analysis. In those reviews using the indirect comparisons based on network meta-analysis (NMA), the appropriateness of the analysis was assessed using the ISPOR criteria for indirect comparisons. - Certainty of evidence - Certainty of evidence was evaluated by two reviewers (SPO and RSP) using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) tool, which integrates the risk of bias of individual studies, inconsistency, indirectness and imprecision of meta-evidence (trial sequential analysis TSA). Summary of findings tables were created for each outcome of interest using the GRADEpro | GDT application (<https://gdt.gradepro.org>) to establish the level of certainty as high, moderate, low or critically low. Using the GRADE approach, the a priori defined outcomes of the less biased reviews were summarized.

Strategy of data synthesis: The characteristics and conclusions of the included systematic reviews and meta-analyses were summarized using tables, as well as the AMSTAR-2 rating. In addition, a citation matrix for the degree of study overlap was employed. The narrative synthesis and discussion of a priori defined outcomes was based on the results of the less biased reviews (those with better methodological quality), and summary of findings (SoF) tables according to the GRADE approach were generated to determine certainty of evidence.

Subgroup analysis: No planned.

Sensitivity analysis: No planned.

Language: English.

Country(ies) involved: Spain, Peru.

Other relevant information: The present study is part of a PhD project in medicine.

Keywords: Systematic review, Evidence-based medicine, Myopia, Refractive surgery, Refractive error, Adults.

Dissemination plans: The present overview of systematic reviews will be submitted to a leading journal in ophthalmology.

Contributions of each author:

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