

SYSTEMATIC REVIEW

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Meta-analysis: clinical outcomes of laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) in hyperopia

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Abstract

Background To evaluate differences in clinical outcome, safety, and efficacy of photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) in the correction of hyperopic refractive errors.

Methods We have adhered to PRISMA criteria in this systematic review, which is registered with PROSPERO (CRD42023469543). Our search with studies comparing PRK and LASIK for hyperopia was conducted through the databases PubMed, EMBASE, Web of Science, and the Cochrane Library. We used the Cochrane method to assess bias and evaluated variables like uncorrected distance visual acuity and mean spherical equivalent. Using fixed- or random-effects models, a meta-analysis was performed using RevMan 5.4 for evaluating heterogeneity and significance. Sensitivity analysis addressed the causes of heterogeneity to assure stability.

Results We included 6 articles (419 participants, 585 eyes) in this review five were retrospective and 1 case-series. The final mean refractive SE (WMD, -0.05; 95% confidence interval [CI], 0.42 to 0.31; $P=0.06$). patients achieving uncorrected distance visual acuity (UDVA) of 20/20 or better (OR, 0.58; 95% CI, 0.39–0.78; $P=0.33$). final UDVA of 20/40 or better (OR, 1.40; 95% CI, 0.65–3.02; $P=0.81$) were analyzed.

Conclusions In this meta-analysis, LASIK had no significant benefits over PRK in relation to clinical outcomes. Less corneal haze was observed in LASIK-treated eyes at 1 to 3 months after surgery.

Keywords Hyperopia, Laser-assisted in situ keratomileusis, LASIK, Photorefractive keratectomy, PRK, Refractive surgery

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Introduction

Hyperopia, also known as hypermetropia, long-sightedness, or far-sightedness, occurs when parallel light rays focus behind the retina instead of directly on it in an unaccommodating eye. Though this condition is usually treated using refractive glasses or contact lenses with the advent of numerous procedures to correct refractive errors since the late twentieth century there are multiple options for correction of hyperopia like laser-based procedures such as photorefractive keratectomy (PRK) laser-assisted in situ keratomileusis (LASIK), refractive corneal lenticule extraction procedures such as keratorefractive lenticule extraction (KLEx) or lens-based procedures like phakic intraocular lens (pIOLs), Refractive Lens Exchange surgery, etc. With the abundance of options, medical practitioners and patients face a significant challenge in selecting the appropriate method [1]. Selecting the best possible approach is a huge difficulty for both ophthalmologists and patients. Evidence-based medicine aims to base clinical decisions as much as possible on the most recent and best available data. Systematic reviews (SRs) and meta-analyses (MAs) are effective decision-making tools because they may mitigate the limitations of underpowered studies and allow specialists to stay up to date [2, 3]. There appear to be no recently published systematic reviews in the obtainable literature, so it is critical to assess the methodological quality and generate the best available SRs and MAs on laser-based refractive procedures for hyperopia. Furthermore, there is ongoing debate regarding whether PRK or LASIK is more effective for correcting hyperopia.

Limited diopter range, long-term instability, recovery period, and regression were and still are challenges for surgeons to decide which surgery to seek [4–6]. Nevertheless, multiple studies have concluded the efficiency of Laser In Situ Keratomileusis (LASIK) and Photorefractive Keratectomy (PRK) in correction of hyperopia [7–10]. Both procedures are applicable in hyperopic patients up to +5.0 diopter; beyond this, an assessment of the benefits in comparison to possible risks is needed, as higher refractive errors prompt a higher risk of complications and regression [1, 10–12].

Following the removal of the corneal epithelium, PRK uses laser excimer ablation on the corneal tissue. The ablation zone outlines the corneal stroma's peripheral edge, causing the central cornea to be steep. Despite the excellent results, it is widely recognized that PRK patients have a higher risk of corneal haze. In a prior study on hyperopic PRK with an 18-year follow-up, 40% of patients showed visible corneal haze [1]. Similarly, postoperative pain is more apparent in PRK compared to LASIK [10, 13]. On the contrary, LASIK creates a corneal flap of partial epithelium thickness using a microkeratome or

femtosecond laser; the flap is then reflected to ablate the underlying stromal tissue [14]. Although there is rapid recovery and less postoperative pain, LASIK patients may experience corneal flap-related complications, which could be a deterrent. These typically include an incomplete or dislocated cap, corneal ectasia, and irregular astigmatism. Similarly, dry-eye and visual aberrations such as halos and glares have been reported after LASIK surgery [15–19]. Moreover, the long-term efficacy of both methods in the context of hyperopia is still being determined due to the risks of instability and regression [20–23].

According to the literature, there needs to be more robust evidence of which procedure will be best for each condition. Therefore, this necessitates further evaluation and analysis of the available comparative studies on hyperopia correction using PRK and LASIK. To our knowledge, no systematic review or meta-analysis has been conducted regarding the question of which laser procedure for hyperopia yields better results, has better long-term outcomes & has fewer complications.

Materials and methods

Study registration

This systematic review was conducted according to a protocol pre-defined and registered with PROSPERO (CRD42023469543). The reporting of this review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [24].

Search strategy

Two reviewers separately searched the electronic databases PubMed, EMBASE, Web of Science, and Cochrane Library (A.O. and A.S.A) up to November 2023. The aim was to gather comprehensive data on studies that compare LASIK and PRK in treating hyperopia. For this purpose, key terms such as Laser-Assisted in Situ Keratomileusis, LASIK, photorefractive keratectomy, PRK, hyperopia, hypermetropia, and far-sightedness were utilized. Initial screening involved reviewing titles to identify relevant studies, followed by a thorough examination of abstracts to determine their suitability for this research. Full texts were obtained for studies whose title, abstract, or both aligned with this review's objectives. Additionally, a manual search of references in pertinent articles was done to uncover any studies not identified in the electronic search. Any disagreements regarding study inclusion between the two primary reviewers were subsequently examined by a third reviewer and resolved through discussion, leading to a consensus on the final data interpretation.

Eligibility Criteria and outcome measures

Population In our review, we focused on studies that compared patients who underwent PRK or LASIK for the treatment of all degrees of hyperopia, including cases with hyperopic astigmatism. We excluded patients who had a history of prior refractive or other eye surgeries, as well as those with coexisting ocular pathologies or systemic diseases that could impact wound healing. We selected comparative studies that had objectives like ours. To our knowledge, no randomized controlled trials (RCTs) or controlled clinical trials on this topic have been published up to the point of our study screening.

Quality assessment of retrieved articles

Reviewers used the modified Cochrane Collaboration assessment tool to assess the risk of bias of eligible studies and classified them into the following categories: low risk of bias, moderate risk of bias, serious risk of bias, critical risk of bias, and no information [25].

Outcome measures

Primary outcome measures, which aimed at assessing efficacy and safety, were the final mean spherical equivalent at the end of each study, percentages of patients achieving an uncorrected distance visual acuity (UDVA) of 20/20 or better, a UDVA of 20/40 or better, as well as the mean spherical equivalent ± 0.50 D. Due to the variability in follow-up durations, which ranged from 1 month to 2 years, and the limited number of published articles available, we pooled the data reported at the final follow-up point for the purpose of comparison.

Meta-analysis

The meta-analysis was conducted through RevMan (Review Manager) version 5.4 (Cochrane Collaboration) employing the fixed-effect model. Unless there is high heterogeneity we switched to the random-effect model with inverse variance for the continuous and dichotomous outcomes. We have assessed the potential of statistical heterogeneity (I^2) and the p of the Chi2 test. We have adopted 95% as a significance confidence level ($P < 0.05$ as a threshold). We have presented the dichotomous outcomes, proportion of eyes achieving uncorrected distance acuity 20/20 or better and 20/40 or better, eyes achieving refraction within ± 0.5 D and within ± 1 D, complications like corneal haze and loss of 2 Snellen lines or more of BCVA as odds ratio (OR) and the continuous outcomes preoperative spherical equivalent, postoperative spherical equivalent at 1 month, 6 months, and 12 months as standardized mean difference (SMD). A sensitivity analysis was performed by removing the source of heterogeneity when the statistical heterogeneity was

significant to ensure the stability of the results for each outcome.

Results

Study selection

Figure 1 shows the detailed steps of the study selection process. The search process yielded 536 publications in total. Upon reviewing the abstracts, 492 studies were excluded. Initially, 44 publications seemed potentially relevant, but ultimately, only 6 were included in the final selection. These studies, published between 2000 and 2023 as depicted in Fig. 1, were all non-randomized comparative studies. They collectively involved 419 patients who underwent either LASIK or PRK. The baseline characteristics of these 6 studies are detailed in Table 1.

Quality assessment

The 6 studies showed an overall low risk of bias and two showed some concerns. Of the studies that had some concerns, one had issues with confounding & selection bias. The later study had a moderate risk of missing data (Figs. 2 and 3).

6 studies reported preoperative spherical equivalent (SE). 3 studies performed statistical data analysis and showed no statistical difference in preoperative mean refractive SE [4–6]. 3 studies collected preoperative data but didn't compare [26–28]. Data analysis of 6 studies did not show a difference between PRK and LASIK groups (WMD, -0.24 . CL, -1.01 to 0.53 . $p = 0.54$. $I^2 = 91\%$). A sensitivity analysis was done. After removing [Spadea L 2006] it did alter the above results (WMD, 0.14 . CL, -0.17 to 0.45 . $p = 0.37$. $I^2 = 24\%$) Fig. 4.

Of the 6 studies. All of them reported postoperative mean spherical equivalent. With different follow-up intervals ranging from 1 to 36 months. 4 studies reported postoperative mean SE at 1 month [27, 4–6]. Data analysis was done and showed a statistically significant difference. (WMD, -0.91 . CL, -1.35 to -0.48 . $P < 0.0001$. $I^2 = 71\%$) Fig. 5.

At 6 months 5 studies reported the Post operative spherical equivalent. Data analysis showed no statistical difference. (WMD, -0.10 . CL, -0.33 to 0.14 . $P = 0.42$. $I^2 = 65\%$). Figure 6 At the last follow-up ranging from 9–36 months, all studies collected mean SE. Data were analyzed and were not statistically significant. (WMD, -0.00 . CL, -0.22 to 0.21 . $P = 0.97$. $I^2 = 60\%$) Fig. 7.

Four publications reported the proportion of eyes achieving uncorrected distance visual acuity 20/20 or better at the last follow-up. Examining the forest plot has revealed a difference in the proportion of eyes that had UDVA of 20/20 or better between the PRK and LASIK groups. Analysis of these data has revealed it to be statistically significant (OR, 0.52 CL, 0.33 to 0.83 . $P = 0.006$.

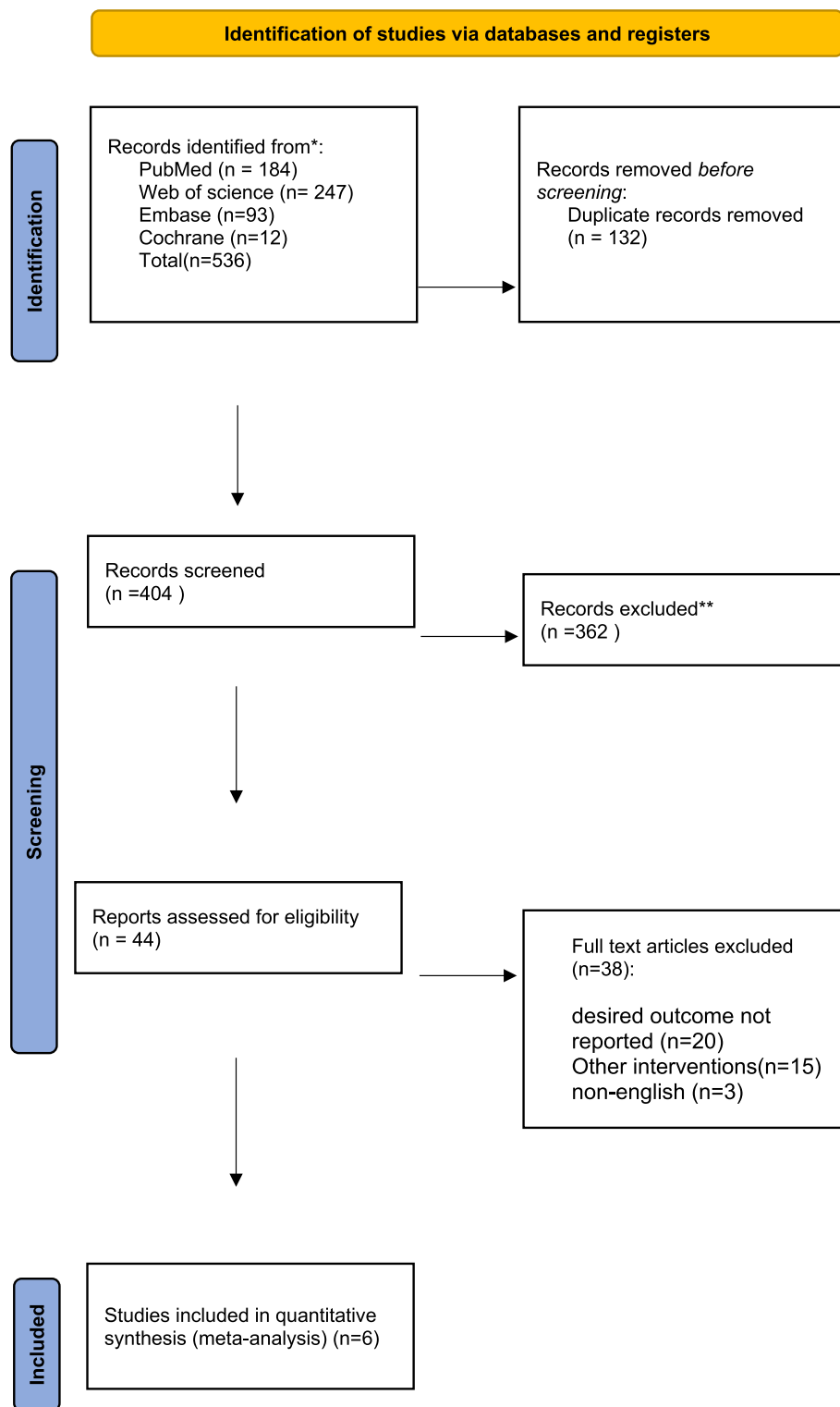


Fig. 1 PRISMA flow diagram of study selection

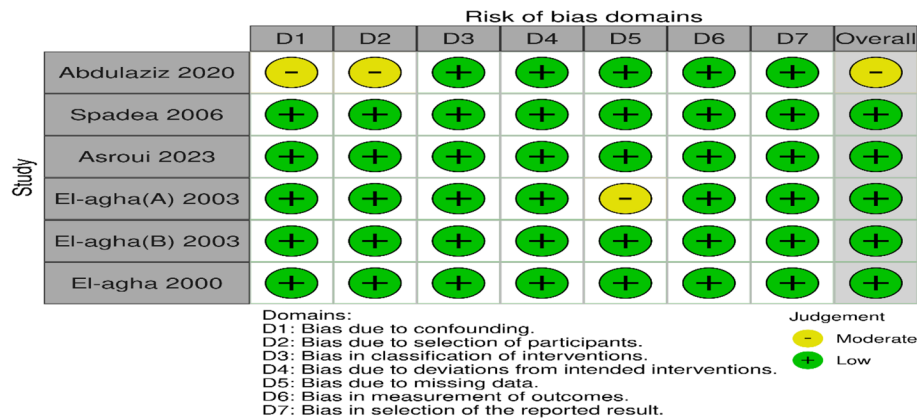


Fig. 2 “Risk of bias summary ”review authors’ judgements about each risk of bias item for each included study

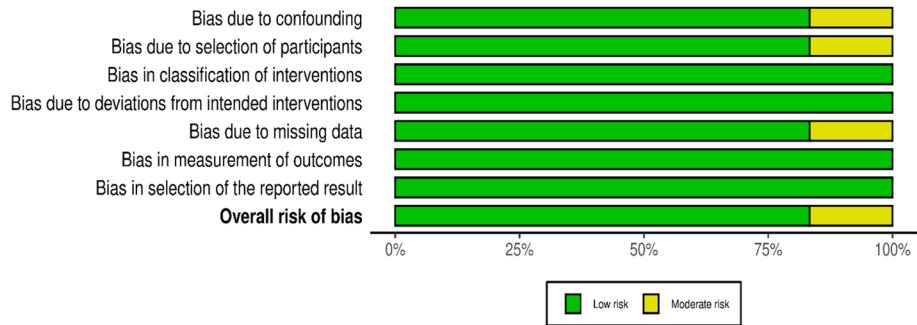


Fig. 3 “Risk of bias graph ”review authors’ judgements about each risk of bias item presented as percentages across all included studies

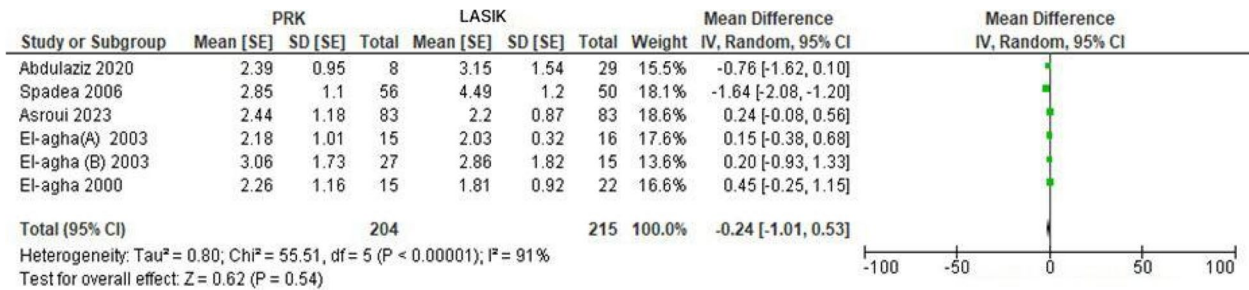


Fig. 4 Forest plot of preoperative mean refractive spherical equivalent between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures

I²=0%) Fig. 8. The same four publications have also reported a UDVA of 20/40 or better and data analysis has shown no statistical difference (OR, 1.53. CL, 0.36 to 0.51. P=0.57 I²=0%) Fig. 9. Refraction within ±0.5D was reported in four studies [27, 3, 4, 6]. Follow-up time ranged from 9 to 36 months. Examining the forest plot revealed significant differences in the percentage of eyes within ±0.5D at the last follow-up. Figure 10 Statistical analysis shows the difference in

the percentage of eyes within ±0.5D between PRK and LASIK. (OR, 0.64. CL, 0.44 to 0.94. P=0.02 I²=86%). Figure 11 Due to high heterogenicity (i=86%) we changed the fixed effect to Random effect, and it shows (OR, 1.10. CL, 0.30 to 4.03. P=0.88 I²=86%). All studies provided data on the proportion of eyes achieving a postoperative refractive accuracy within ±1 Diopters. The duration of follow-up across these studies varied from 9 to 36 months. Inspection of the forest

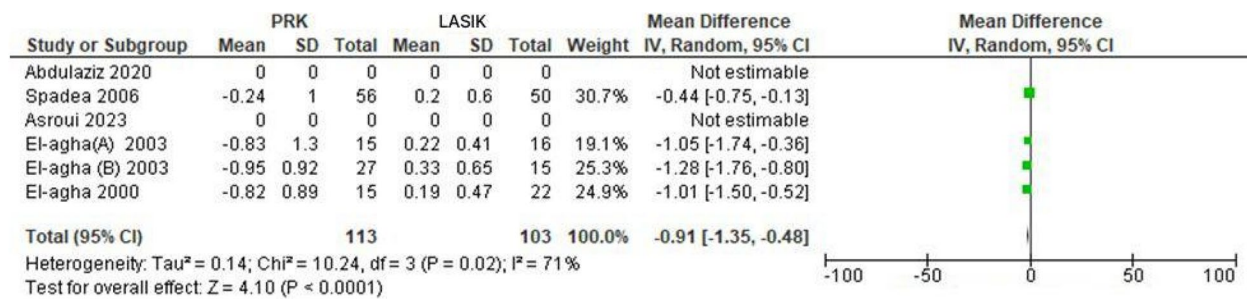


Fig. 5 Forest plot of postoperative mean refractive spherical equivalent between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures at 1 month

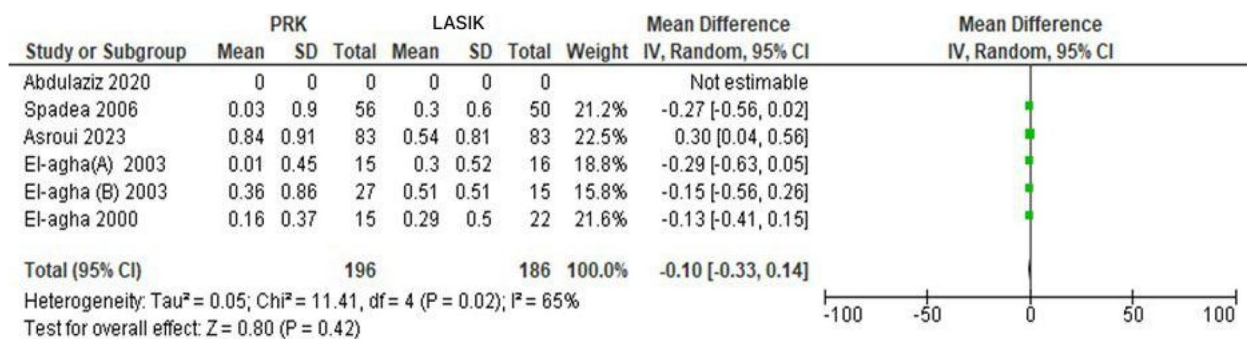


Fig. 6 Forest plot of post operative spherical equivalent between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures at 6 months

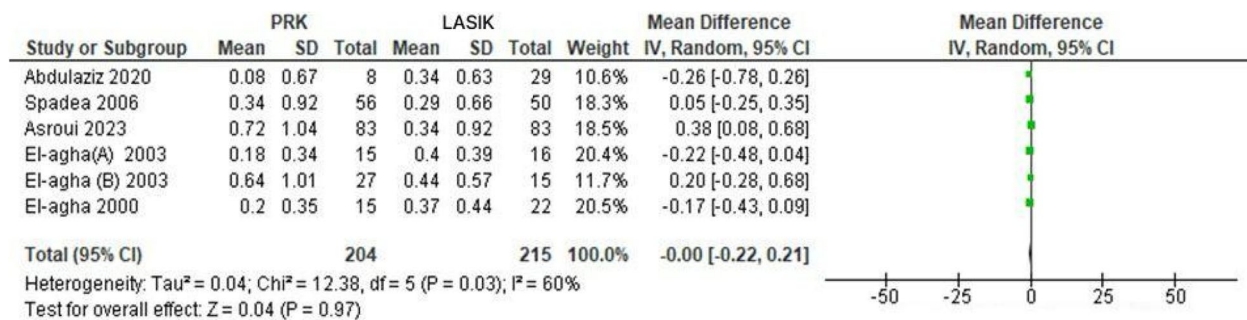


Fig. 7 Forest plot of postoperative mean refractive spherical equivalent between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures at last follow up

plot indicates no difference in the percentage of patients achieving within ± 1 Diopters of target refraction between the PRK and LASIK groups. The data analysis indicated that this result was not statistically significant (OR, 1.13. CL, 0.71 to 1.80. $P = 0.61$ $I^2 = 0\%$) Fig. 12.

Corneal Haze was reported in 5 studies [4–6, 26, 28]. The findings indicated that the severity of corneal haze was greater in eyes that underwent PRK compared to those treated with LASIK. (OR, 7.49. CL, 2.69 to 20.80. $P = 0.0001$ $I^2 = 0\%$) Fig. 13. Loss of spectacle-corrected

visual acuity of two Snellen lines or more was reported in 6 studies and examining the forest plot showed no significant difference (OR, 1.48. CL, 0.44 to 5.00. $P = 0.52$ $I^2 = 0\%$) Fig. 14.

Discussion

No notable differences were found in the outcomes of eyes treated with PRK and those treated with LASIK. The comparison of postoperative mean spherical equivalent (SE) revealed no statistically significant variation between

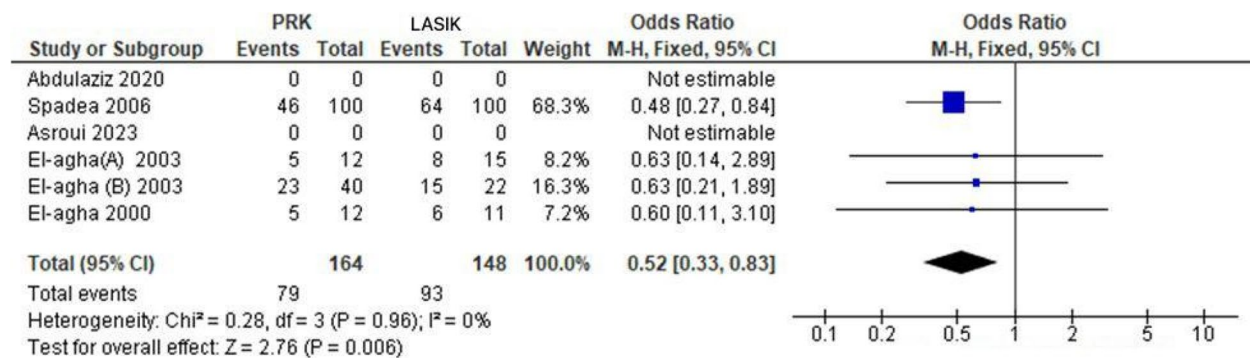


Fig. 8 Forest plot of post operative uncorrected visual acuity (UCVA) 20/20 or better between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) Procedures

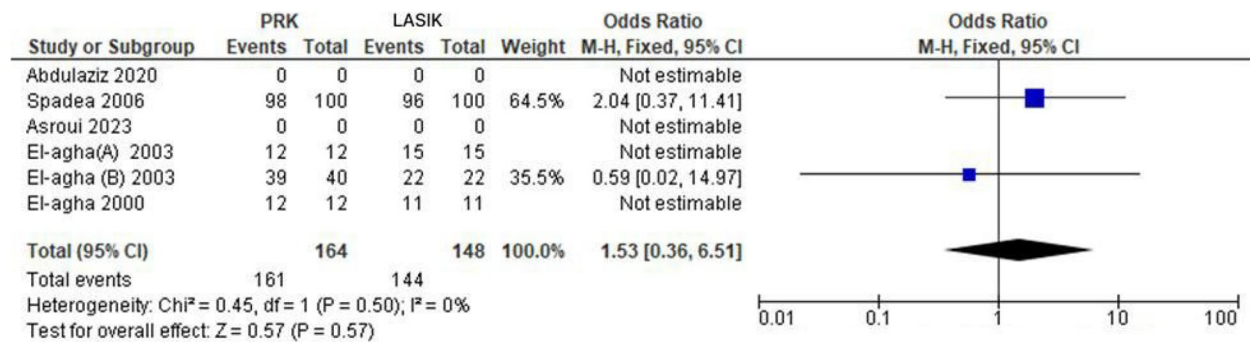


Fig. 9 Forest Plot of Post operative uncorrected visual acuity (UCVA) 20/40 or better between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures

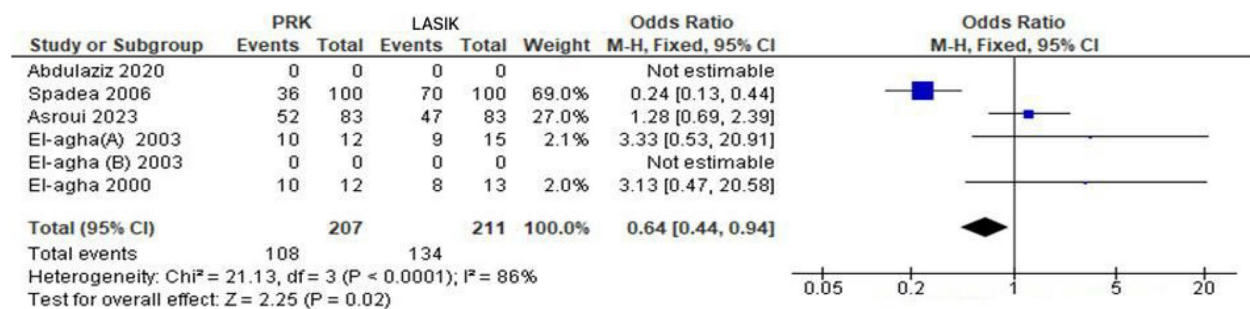


Fig. 10 Forest Plot of post operative fixed Refraction within $\pm 0.5D$ between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures

the two groups, except at the one-month mark. This may be attributed to the initial myopic overshoot aimed during PRK [6]. Beyond this point, at the six-month interval and the final follow-up, the differences did not reach statistical significance.

The aggregated data across studies for postoperative uncorrected distance visual acuity (UDVA) achieving 20/20 or better demonstrated statistically significant discrepancies between the two methods. In the

analysis, 79 (54.11%) out of 146 eyes that underwent PRK, and 93 (62.84%) out of 148 eyes treated with LASIK, attained a UDVA of 20/20 or greater. This suggests that patients who received PRK were less likely to achieve 20/20 vision or better compared to those who received LASIK. Similar rates in both PRK & LASIK were reported in other studies at the end of their follow-up periods [29, 30]. Attaining a UDVA of 20/20 or superior is a criterion for patients to potentially

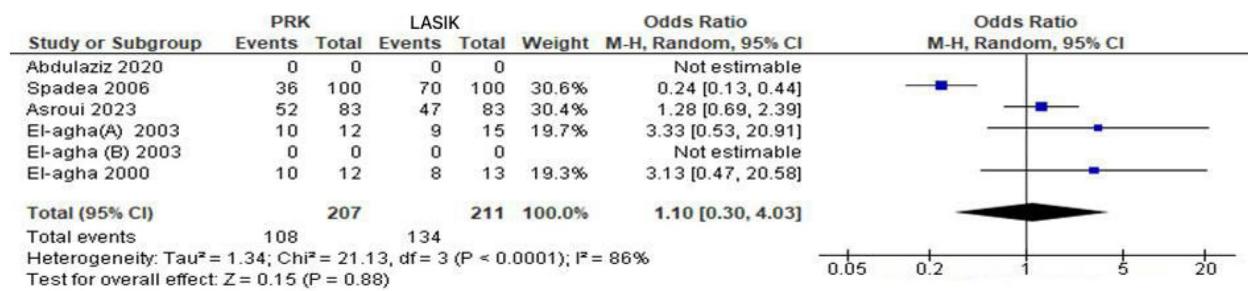


Fig. 11 Forest Plot of post operative random refraction within $\pm 0.5D$ between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) Procedures

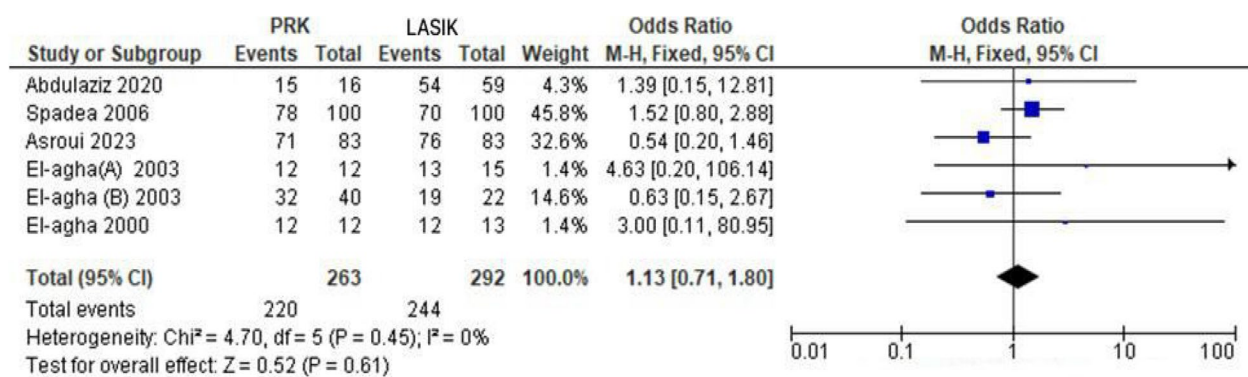


Fig. 12 Forest Plot of post operative refraction within $\pm 1D$ between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures

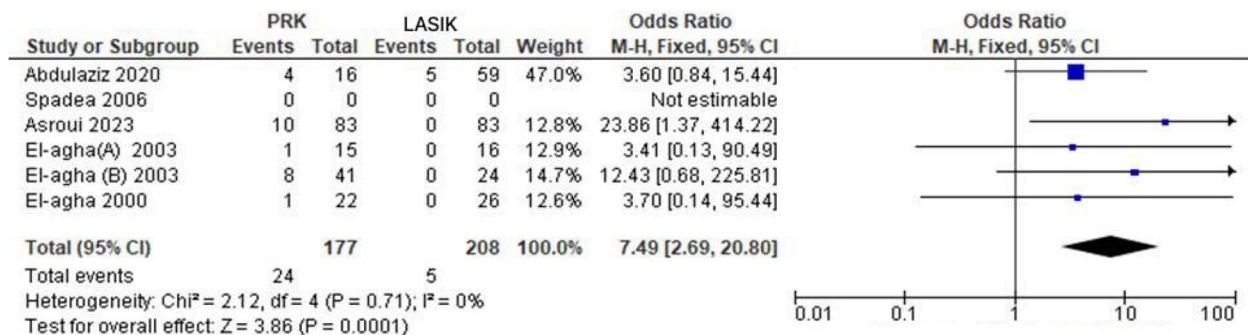


Fig. 13 Forest plot of post operative haze between photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK) procedures

dispense with the need for glasses or contact lenses for vision and is associated with a high level of patient satisfaction following refractive surgery. In those achieving 20/40 or better while the point estimate suggests that PRK could be more likely to result in 20/40 vision or better when compared to LASIK, the lack of statistical significance and the wide confidence interval indicate that no definitive conclusion can be drawn from this data regarding the superiority of one procedure over the other in this regard.

83.6% of the eyes in the PRK group, in comparison with 83.5% of the eyes in the LASIK group, were within $\pm 1.0 D$ of emmetropia, while 52.1% of the eyes in the PRK group, compared with 63.5% of the eyes in the LASIK group, were within $\pm 0.5D$ of emmetropia.

The present analysis indicated that less corneal haze was observed after LASIK (2.4%) than after PRK (13.56%), And it was statistically significance between the 2 groups. Corneal haze is a recognized postoperative complication associated with PRK and LASIK surgeries.

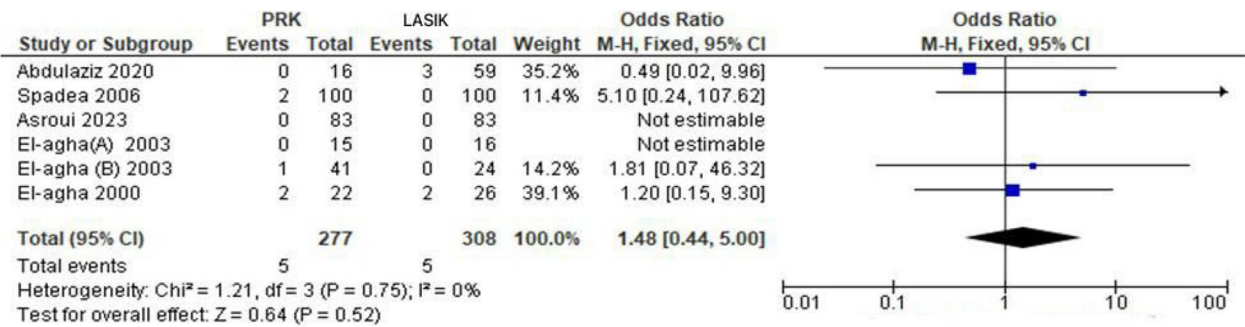


Fig. 14 Forest Plot of the comparison of the loss of two or more lines of best corrected visual acuity (BCVA) between PRK and LASIK procedures

The interaction of laser energy with the corneal epithelium and the underlying stromal tissue can lead to an excessive healing response. This process involves the release of cytokines and the recruitment of myofibroblasts, which can disrupt the normal corneal structure and lead to the development of corneal haze [8]. Abdulaziz AS et al. have noticed haze to be frequent in the PRK group but it was a mild grade, peripheral, and did not affect the central optical area of the cornea ²⁶. Asroui et al. haven't reported flap complication in the LASIK group, and in the PRK group only 13.2% of eyes out of which three eyes had grade 3 and 2 eyes had grade 2 haze 3 years postoperatively [4]. Clinicians and patients considering LASIK versus PRK often weigh the risks of corneal haze against the risks of dry eye syndrome, as these are the most reported complications for each procedure. While our meta-analysis extensively analyzed corneal haze, data on dry eye syndrome were not consistently reported across the included studies. However, it is well-documented in the literature that LASIK is associated with a higher incidence of dry eye compared to PRK, primarily due to disruption of corneal nerves during flap creation, which impacts tear production and corneal sensation [32]. By contrast, PRK does not involve flap creation, potentially leading to a lower risk of chronic dry eye. This omission may unintentionally favor LASIK by not addressing one of its more common complications, and we acknowledge this as a limitation of our study.

An important consideration in hyperopic LASIK outcomes, as noted in Ortega-Usobiaga et al., is the impact of retreatments following undercorrection. Their study demonstrated that efficacy and predictability of retreatment procedures were significantly influenced by the magnitude of diopters corrected in the primary and retreatment procedures. Specifically, higher attempted corrections (> +4.00 D combined or > +1.00 D in retreatment) were associated with reduced safety and predictability, emphasizing the challenges of achieving stable outcomes in higher hyperopic corrections. This aligns

with our findings, as the included studies predominantly focused on corrections within the low-to-moderate hyperopia range ($\leq +5.00$ D), where both LASIK and PRK demonstrated comparable safety and efficacy. However, these results suggest that for higher hyperopic corrections, achieving refractive stability may require cautious planning and a lower threshold for retreatment. The limitations of high diopter corrections may partly explain the regression and variability observed in some studies, as well as the need for more robust nomograms and individualized treatment protocols to improve long-term outcomes [31].

The risk of a loss of 2 or more lines on the Snellen visual acuity chart was compared between patients of the PRK group and the LASIK group. Results from the studies included did not demonstrate a statistically significant difference in the risk of this level of visual acuity loss between the two refractive procedures. The incidence of the event, with only 5 cases reported in each group out of 277 for PRK and 308 for LASIK, respectively. Both procedures seem to have a similar safety profile in terms of this significant visual outcome.

This meta-analysis had several potential limitations. Differences in study designs, patient selection criteria, surgical techniques, and follow-up periods. Since not all studies provided a complete set of data for the specified outcomes, it was impossible to include every study in the analyses of each outcome. One major limitation in assessing predictability in hyperopic corneal surgery is the reliance on manifest refraction rather than cycloplegic refraction, which fails to account for latent hyperopia and may lead to overestimating accuracy. Among the studies included in this analysis, most used manifest refraction for postoperative assessments, with a few studies incorporating cycloplegic refraction for preoperative evaluations. For example, El-Agha (2000, 2003) and Spadea et al. [5, 6, 27, 28]. used cycloplegic refraction preoperatively, but postoperative outcomes were largely based on manifest refraction. This

methodological variability should be considered when interpreting predictability outcomes reported in this meta-analysis. Acknowledging these limitations, we managed to aggregate the data from various studies and conduct a statistical evaluation of their findings. Because no randomized controlled studies matched the inclusion criteria, we were unable to provide definitive answers to certain concerns like long-term efficacy and safety and concluded that more research is required.

Conclusion

In conclusion, our systematic review and meta-analysis provide a comparative evaluation of LASIK and PRK for hyperopia correction. While both procedures are effective, LASIK demonstrates advantages in terms of faster recovery and reduced postoperative discomfort, but with potential flap-related complications. PRK, though associated with higher rates of corneal haze, remains a viable option, especially for patients concerned about flap issues. The findings underscore the need for individualized patient assessments when choosing a refractive procedure. Future studies should focus on long-term outcomes and patient satisfaction to refine these recommendations.

Abbreviations

LASIK	Laser-assisted in situ keratomileusis
PRK	Photorefractive Keratectomy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International prospective register of systematic reviews
SE	Spherical equivalent
UDVA	Uncorrected distance visual acuity
pIOLs	Phakic intraocular lens

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Authors' contributions

All authors contributed equally to the conception, design, data collection, and analysis of the study. Each author also participated in drafting and revising the manuscript critically for important intellectual content and approved the final version to be published.

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Data availability

The data presented in this study are available in article.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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