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Refractive Laser Surgery for Vision Conditions

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Rapid Review

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Abbreviations

AMSTAR2	A Measurement Tool to Assess Systematic Reviews 2
AXIS	Appraisal tool for Cross-Sectional Studies
CDVA	corrected distance visual acuity
CI	confidence interval
CRT	corneal refractive therapy
LASIK	laser-assisted in situ keratomileusis
MA	meta-analysis
MCID	minimal clinically important difference
NEI RQL-42	National Eye Institute Refractive Error Quality of Life Instrument
PRK	photorefractive keratectomy
QIRC	Quality of Life Impact of Refraction Correction
QoL	quality of life
SD	standard deviation
SE	spherical equivalent
SR	systematic review
RCT	randomized clinical trial
UDVA	uncorrected distance visual acuity

Key Messages

- None of the identified studies were of sufficient quality to formulate conclusions on the clinical effectiveness of refractive laser surgeries compared to conventional vision correction for people with vision conditions.
  - The identified evidence for the clinical effectiveness of photorefractive keratotomy (PRK) was limited to 1 low-quality study that did not detect a visual acuity difference between participants who had PRK and participants who wore contact lenses.
  - Low-quality evidence from 1 study found participants who had undergone PRK had greater vision-related quality of life (QoL) than participants who had not had PRK. Another low-quality study found that participants who wore contact lenses had greater vision-related QoL than participants who had undergone a laser-assisted in situ keratomileusis (LASIK) procedure.
  - Low-quality evidence suggested that contact lenses resulted in fewer incidences of vision loss events than LASIK.
- No evidence-based guidelines on best practices for refractive laser surgeries met the criteria for this review.

Context and Policy Issues

What Is the Condition?

Unsatisfactory visual acuity as a result of uncorrected refractive errors is the single largest contributor to the global burden of vision conditions and has an adverse impact on the QoL of individuals around the world who are affected by it.[1,2] The vast majority of refractive errors are addressed in the developed world, including Canada. Conventional vision technologies, such as eyeglasses and contact lenses, are a readily available, simple, and safe means of refractive error correction.

A variety of vision conditions are caused by refractive error and are candidates for correction with laser surgical interventions. Refractive error is a result of anatomic imperfection in the shape of the eyeball or 1 or more of its constituent parts. The cornea is on the outer surface of the eyeball. Precise reshaping of this transparent structure can correct refraction errors caused by a variety of anatomic imperfections. Vision conditions, such as myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (uneven focus), can be corrected by different approaches using a laser to reshape the cornea to compensate for the different anatomic imperfections that incorrectly refract and focus light on the retina. Presbyopia is commonly the result of an age-related hardening of the lens of the eyeball and a decreasing ability to dynamically change the shape of the lens to optimize near visual acuity. More sophisticated laser surgical strategies can be applied to offer monovision to people with presbyopia through corneal reshaping, effectively creating a different focus in each eye or in different fields of view: 1 optimized for distance visual acuity and 1 optimized for near visual acuity.[3,4] This results in a sacrifice in uncorrected distance stereoacuity.[5] Keratoconus, another common eye condition resulting in refractive error, is a degenerative asymmetric

thinning and deformation of the cornea resulting in astigmatism.[6] A role for refractive laser surgery for people with keratoconus is less well established.[7] Its relevance to refractive laser surgeries is more often cited as a contraindication due to the thinning cornea.[8] For some very common vision conditions, refractive laser surgery has the potential to offer people an increased QoL by eliminating reliance on conventional vision technologies.

What Is the Technology?

Refractive laser surgeries use an excimer laser, which was approved in Canada for PRK in 1991. Subsequently, LASIK has become the most commonly performed procedure.[9] PRK and LASIK use a different surgical approach to access corneal tissue before reshaping it with the excimer laser. Additional variations on these procedures include Epi-LASIK and laser epithelial keratomileusis (LASEK).[5]

Why Is It Important to Do This Review?

Conventional vision technologies, including contact lenses and eyeglasses, can eliminate refractive error with a very familiar and minimal risk profile and QoL impact. Evidence regarding the comparative clinical effectiveness, associated risk, and QoL benefits of refractive laser surgeries is required for both patients and health care decision-makers. The objective of this report was to retrieve and review the evidence regarding the clinical effectiveness of refractive laser surgery for people with vision conditions and to also retrieve and review evidence-based guidelines regarding the use of refractive laser surgery for this population.

Research Questions

1. What is the clinical effectiveness of refractive laser surgery for people with vision conditions?
2. What are the evidence-based guidelines regarding the use of refractive laser surgery for people with vision conditions?

Methods

Literature Search Methods

An information specialist conducted a literature search on key resources, including MEDLINE, the Cochrane Database of Systematic Reviews, the International Health Technology Assessment (HTA) Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were refractive laser surgery and visual acuity. CADTH-developed search filters were applied to limit retrieval to health technology assessments, systematic reviews (SRs), meta-analyses (MAs), or indirect treatment

comparisons; randomized controlled trials (RCTs), controlled clinical trials, or any other type of clinical trial; and guidelines. The search was completed on September 1, 2023, and limited to English-language documents published since January 1, 2018.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Criteria	Description
Population	People with vision conditions (e.g., myopia, hyperopia, astigmatism, presbyopia, keratoconus)
Intervention	Refractive laser surgery (e.g., LASIK, photorefractive keratectomy, radial keratotomy, astigmatic keratotomy, automated lamellar keratoplasty, laser thermal keratoplasty, conductive keratoplasty)
Comparator	Q1: Conventional vision correction technologies (i.e., prescription glasses, contact lenses) Q2: Not applicable
Outcomes	Q1: Clinical benefits (e.g., visual acuity, quality of life, patient satisfaction) and harms (e.g., adverse events) Q2: Recommendations regarding best practices (e.g., appropriate patient populations, treatment protocols, contraindications)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, nonrandomized studies, evidence-based guidelines

LASIK = laser-assisted in situ keratomileusis.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1 or were published before 2018.

Critical Appraisal of Individual Studies

The included publications were critically appraised by 1 reviewer using the following tools as a guide: A Measurement Tool to Assess Systematic Reviews 2 (AMSTAR 2)[10] for SRs, and the Appraisal tool for Cross-Sectional Studies (AXIS) for cross-sectional studies.[11] Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 276 citations were identified in the literature search. Following screening of titles and abstracts, 273 citations were excluded, and 3 potentially relevant reports from the electronic search were retrieved for full-text review. From the grey literature search, 1 potentially relevant report was retrieved for full-text review.

Of these potentially relevant articles, 1 set of guidelines were excluded for lack of sufficient evidence-based development methods and 3 publications met the inclusion criteria and were included in this report. These comprised 1 SR and 2 nonrandomized studies. Appendix 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[12] flow chart of the study selection.

The identified guidelines may be of interest, despite unreported methodology and ungraded recommendations. This reference is provided in Appendix 5.

Summary of Study Characteristics

Additional details regarding the characteristics of included publications are provided in Appendix 2.

Study Design

The SR included in this report by Wu et al.[13] was published in 2020. It included all 19 relevant RCTs on LASIK in the US FDA's database that were published between 2003 and 2019 as well as 2 previously published Australian population studies. One study counted all new cases of contact lens–related microbial keratitis in Australia through surveillance of all ophthalmic practitioners[14] and the other was a survey study used to estimate the fraction of the Australian population that used contact lenses.[15]

The nonrandomized studies included in this report consisted of 2 cross-sectional studies: Bokhary et al. (2022)[16] and González-Pérez et al. (2019).[17]

No guidelines that formulated evidence-based recommendations for refractive laser surgery were identified.

Country of Origin

The SR by Wu et al. (2020)[13] was conducted in Australia. It included a population-based estimate of the percentage of contact lens users and associated safety in Australia; LASIK safety data were obtained from the US FDA database of RCTs. The countries where the RCTs were conducted were not reported.

The study by Bokhary et al. (2022)[16] was conducted in Saudi Arabia. The cross-sectional study by González-Pérez et al. (2019)[17] was conducted in 1 university and 1 ophthalmology clinic in Spain.

Patient Population

The SR[13] included data from 4,882 eyes from participants in LASIK RCTs, representing an unreported number of individuals older than either 18 or 21 years depending on the study with a wide range of refractive errors ranging from 6 diopters (D) to −15 D. Of the 19 included RCTs, 10 studies included participants with astigmatism up to 8 D.[13] Additional data were obtained from an Australian surveillance study, published in 2008, of all contact lens–related vision loss cases over the course of 12 months in people aged between 15 and 64 years who wore contact lenses[14] as well as from a telephone survey study published in 2014 on the proportion of contact lens users among the general Australian population.[15]

The 2 nonrandomized studies included in this report were cross-sectional studies in which participants were examined at a single time point in a hospital setting. The study by Bokhary et al. (2022)[16] included participants aged between 19 and 40 years with a myopia spherical equivalent (SE) of 10.5 D or less, hyperopia SE of 4.50 D or less, and astigmatism of 6.00 D or less. Participants with ocular pathology, prior

ocular surgery, pre-presbyopia, or who were taking medication were excluded; however, the latter criteria were not further defined. In this study, 51 participants were not planning to undergo PRK, 50 participants were going to undergo PRK and had stable refraction for at least 1 year (pre-PRK group), and 44 participants had received PRK within the past 5 years (post-PRK group). The participants in the post-PRK group were further stratified by how long it had been since they received PRK: 1 week (n = 13), 1 week to less than or equal to 6 months (n = 16), or greater than 6 months (n = 15). The groups of participants were similar with regard to sex but significantly different in age and uncorrected distance visual acuity. The majority of the study participants living in Saudi Arabia used spectacles alone (control group: 86.3%; pre-PRK group: 78.0%) for vision correction as opposed to contact lens or spectacles and contact lens. Of all participants, 98.6% had myopia.[16] González-Pérez et al. (2019)[17] examined 4 groups of 24 participants each: participants with eyes that were emmetropic, participants with myopia and had undergone LASIK surgery 12 months prior, participants who used continuous wear silicone-hydrogel (Si-H) contact lenses for 12 months, and patients who had worn corneal refractive therapy (CRT) lenses for 12 months. The mean SE ranged from −2.04 D to −2.91 D; all participants who wore contact lenses had myopia. The groups participated at 1 university and 1 ophthalmology clinic. Any differences in mean age, sex, and SE were not statistically significant.[17]

Interventions and Comparators

The intervention arm of the SR comprised an MA of RCTs on various LASIK systems for the correction of refractive errors. The primary control of the RCT data was reported as the preoperative state of the treated eye. Wu et al. (2020)[13] did not provide more details about the study design of the RCTs and did not use the control arm data from the RCTs. The comparators examined were any contact lens type, daily wear contact lenses, overnight soft contact lenses, and overnight wear Si-H contact lens. The rates of contact lens usage and associated vision loss were obtained from published Australian epidemiological surveys.[13-15]

The intervention of interest in the cross-sectional study by Bokhary et al. (2022)[16] was PRK for the correction of refractive error. Two control groups were enrolled in this study; 1 group who intended to correct their refractive error by PRK (pre-PRK) and another group who used conventional vision correction technologies (prescription glasses and/or contact lenses) and did not intend to correct their refractive error by any refractive surgical intervention. The study by González-Pérez et al. (2019)[17] included participant groups whose refractive error had been successfully corrected with LASIK with the Wavelight Allegretto Wave Eye-Q (Wavelight GmbH, Germany), CRT orthokeratology lenses (Paragon, AZ), or continuous wear (30 nights during 12 months) lotrafilcon A Si-H contact lenses (Alcon Pharmaceuticals Ltd., Switzerland). A participant group with eyes that were emmetropic and who had never used visual correction was also included as a control group.

Outcomes

The SR[13] estimated the frequency of vision loss events per eye associated with vision correction by LASIK compared with contact lens use. Loss of vision from LASIK was all-cause vision loss at 6-month follow-up, whereas all incidents from Australia of vision loss over the course of 12 months related to contact lens use was from participants after contact lens–related microbial keratitis. In both cases, vision loss was defined as a loss of 2 or more lines of best spectacle-corrected visual acuity and these rates were stratified by contact

lens type and duration of wear. The results were also used to derive the number of years of contact lens wear equivalent to the one-off risk associated with LASIK. The authors suggested this vision loss outcome provided better context than prior studies in which vision loss following a LASIK procedure was reported only as a result of microbial keratitis. The authors did not provide data on causes of vision loss captured in the RCTs. Although only vision loss following microbial keratitis was included for the contact lens use group, the authors acknowledged this limitation and suggested that other causes of contact lens–related vision loss are very rare with supporting references.[13]

Bokhary et al. (2022)[16] reported uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), as measured by a Snellen chart in which 0 D represented perfect vision. SE, as measured by autorefractometer, and central corneal thickness, as measured by Scheimpflug imaging (Pentacam HR, Oculus Inc., WA), were also reported.

Results from the Quality of Life Impact of Refractive Correction (QIRC) administered at a single time point were also reported by Bokhary et al. (2022).[18] This subjective patient-reported outcome measure used a response scale in 5 categories and a "not applicable" response and was linearly converted to a score from 0 to 100 with higher numbers indicating higher QoL. The QIRC used by Bokhary et al. (2022)[18] was translated into Arabic from the English version and validated using Rasch analysis. An overall QIRC score was reported for each participant group, although a minimal clinically important difference (MCID) was not reported. Results for each of the 20 questions, and results for the 6 domains of the QIRC were also reported.[16] The study by González-Pérez et al. (2019)[17] reported the overall score and domain subscore means of the National Eye Institute Refractive Error Quality of Life Instrument (NEI RQL-42) administered to participants at a single time point. This instrument is a validated survey that consists of 42 questions to assess 13 different vision-related QoL domains. Each question is scored from 1 to 100, with higher numbers reflecting greater QoL. These numbers were reported without the context of a MCID.

Summary of Critical Appraisal

Systematic Review

The SR[13] included in this report provided an MA of RCTs on LASIK systems identified in the FDA database, although it did not analyze comparative findings of the included RCTs. The SR extracted the incidence of vision loss from the identified literature; however, this narrow objective was not well suited to conduct a methodologically comprehensive SR. The SR lacked critical domains of the AMSTAR 2 criteria and, consequently, critically low confidence was associated with the findings in Wu et al. (2020).[13] The AMSTAR 2 criteria that were lacking or absent from the SR were a clearly formulated research question, prior establishment of review methods, a comprehensive literature search, literature selection criteria, duplicate literature selection and data extraction, justification for only using RCTs, information on excluded studies, critical appraisal of included studies, justification for combining trial data, assessment of publication bias, and a discussion of study limitations. The study did report a potential conflict of interest. The most obvious methodological concern that increased the potential for bias was the potential differences between populations that participated in the RCTs and the populations from which the incidence of vision loss associated with contact lens use was estimated. The SR did not provide any comparison between these 2

populations. Similarly, the outcome for vision loss for LASIK participants was all-cause, whereas the vision loss for contact lens users was as a result of microbial keratitis. The SR did report limited methodology for a systematic literature search and selection, data extraction, a summary of included studies, the funding source of included studies, and a defined follow-up period; however, based upon the aforementioned limitations, the SR could not be relied upon to provide an accurate and comprehensive summary of the risk of vision loss identified by the included LASIK studies. The confidence in conclusions regarding the risk of vision loss associated with LASIK compared with contact lens use included additional low-quality evidence and therefore was also rated as critically low.[13]

Nonrandomized Studies

The nonrandomized studies[16,17] included in this report used a cross-sectional, observational design. These studies had all the limitations associated with this approach, the most significant of which was difficulty in determining the degree of causality between the intervention and observed outcomes. Furthermore, neither study provided justification for the sample size; therefore, findings that lacked a statistical difference between groups did not support any conclusions. Neither study reported any findings with respect to a MCID that made a statistically significant difference of unknown clinical relevance.[16,17] Bokhary et al. (2022)[16] did not report 1 visual acuity outcome (SE) for all groups of participants; it was only reported for subgroups of 1 participant group. Bokhary et al. (2022)[16] used a Kruskal-Wallis test for statistical significance for the QoL questionnaire, which did not identify which individual group differences were statistically significant. This made interpretation challenging because this study had 2 untreated participant groups.

Despite these limitations, both studies[16,17] had methodological strengths, as described in AXIS.[11] Neither study was a broadly disseminated survey with a large percentage of nonrespondents, as is typical for cross-sectional studies, and both recruited participants with defined inclusion and exclusion criteria. Both studies examined objective outcomes using validated patient-reported outcomes, had a clear study objective, reported patient characteristics, statistical methodology was reported, conclusions were justified, a discussion of limitations was provided, ethics approval was obtained, and both had a statement that the study had no potential conflict of interest.[16,17] Both studies[16,17] reported statistically significant age differences between groups, and Bokhary et al. (2022)[16] identified differences in UDVA between the participant groups. Bokhary et al. (2022)[16] did not report relevant methodology but did provide some limited longitudinal CDVA data for post-PRK participants.[16] Overall, the strengths of these studies remained limited by the cross-sectional study design and the findings were at high risk of bias.

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Summary of Findings

Appendix 4 presents the main study findings.

Clinical Effectiveness of Refractive Laser Surgeries

Visual Acuity

Bokhary et al. 2022[16] reported UDVA and CDVA in 3 groups of participants: a control group that used conventional vision correction with no intention of undergoing refractive surgery, a group planning on

undergoing PRK (pre-PRK), and a group that had undergone PRK (post-PRK). Without refractive correction, including before correction for the post-PRK group, there was a statistical difference in visual acuity among the 3 groups. The control group had the highest visual acuity followed by the pre-PRK group; the post-PRK had the lowest visual acuity. When the participants used conventional vision correction, or after PRK in the post-PRK group, there was no statistical difference in visual acuity. The subgroups of participants in the post-PRK group had statistically significant differences in CDVA and those participants who had PRK more than 6 months prior had greater visual acuity. The authors stated that PRK requires a longer recovery than LASIK, and the corneal epithelial layer can take as long as 2 weeks to heal, which could explain the differences among the post-PRK subgroups.[16]

Spherical Equivalent

The measure of astigmatism, SE of manifest refraction, was obtained from all 145 participants but was only reported for the 44 post-PRK participants. Participants at 1 week (n = 13), at less than or equal to 6 months (n = 16), and greater than 6 months following PRK (n = 15) demonstrated statistically significant differences with the participant groups examined at later intervals having less refractive error due to astigmatism.[16]

Quality of Life

The 2 cross-sectional studies[16,17] reported results of QoL self-assessments from different groups of study participants. Bokhary et al. (2022)[16] found a statistically significant difference in the overall QIRC score between groups. Participants who had undergone PRK had the highest QIRC score (mean = 53.84; standard deviation [SD] = 7.14), while the scores of the control group and the pre-PRK group were 45.79 (SD = 7.15) and 43.68 (SD = 5.69), respectively.[16] Individual scores within the convenience, well-being, and health concern domains of the QIRC were statistically significantly higher for participants in the post-PRK group than those for participants in the control and pre-PRK group. No statistically significant differences were identified among the post-PRK subgroups of 1 week, 1 week to 6 months, and greater than 6 months.[16] Individual QoL scores of the QIRC are summarized in Table 7 of Appendix 4.

González-Pérez et al. (2019)[17] found a statistically significant difference in the NEI RQL-42 overall score for participants who wore Si-H contact lenses of (mean = 87.1; SD = 6.4) compared with participants who had undergone LASIK 12 months prior (mean = 80.0; SD = 10.2). The authors attributed this overall difference as a summation of differences in subscores that evaluated diurnal fluctuations, glare, expectations, and worry aspects of QoL. However, only differences in worry, symptoms, and expectation QoL subscores were statistically significant in isolation. No other statistically significant differences were identified between the participant groups that had undergone refractive surgery and those who used conventional vision correction. The authors interpreted their findings as continuous wear Si-H contact lenses were associated with the highest global QoL scores and LASIK was associated with the lowest scores.[17]

Neither study provided context for the identified differences with respect to a MCID.[16,17]

Adverse Events: Vision Loss

The SR[13] reported the incidence of all causes of vision loss, defined as the loss of 2 or more lines of best spectacle-corrected visual acuity, associated with LASIK procedures and contact lens use. The MA of 19

RCTs identified the rate of vision loss at 6 months after LASIK as 66 events per 10,000 eyes (95% confidence interval [CI], 34 to 108 events per 10,000 eyes). The authors also extracted data from a previously published Australian surveillance study by Stapleton et al. (2008)[14] that identified an annualized incidence of vision loss of 0.28 per 10,000 eyes (95% CI, 0.28 to 0.31 per 10,000 eyes) associated with contact lens use.[13] The extracted data were used to calculate the number of years of contact lens use that presented an equivalent risk of vision loss associated with the single 6-month risk following LASIK. Across all contact lens types, 218 years (95% CI, 103 to 391 years) of wear presented the same risk of vision loss as LASIK. Overnight soft contact lenses presented 31 risk-equivalent years (95% CI, 16 to 51 risk-equivalent years), overnight wear Si-H contact lens presented 48 risk-equivalent years (95% CI, 25 to 79 risk-equivalent years), and daily wear soft contact lenses presented 320 risk-equivalent years (95% CI, 165 to 525 risk-equivalent years). The authors formulated cautious comparative conclusions based on the data, including that individual risk is low with either LASIK or contact lenses.[13]

Limitations

The comparative evidence identified in this report consisted of 1 SR and 2 cross-sectional studies that were evaluated as at high risk of bias. The critical appraisal of the SR was limited by the less conventional objective of the included SR, in which additional low-quality data were combined with the MA data for the comparative outcome analysis. Although addressed narratively in this report, the standard criteria of the AMSTAR2 critical appraisal tool did not account for the addition of other unsystematically selected low-quality data. The studies included in this report consisted of undefined populations from RCTs in Australia, Saudi Arabia, and Spain, and the relevance of this evidence for patients with vision conditions in a Canadian setting is therefore unclear. Additionally, the participants examined for visual acuity and QoL outcomes in the identified evidence almost exclusively had myopia, and the relevance to people with related refractive errors, including hyperopia and astigmatism, is unknown. This report did not identify any evidence of sufficient quality to inform decision- or policy-making. It is unknown if any high-quality studies that compared refractive laser surgeries to conventional vision correction technologies are forthcoming. In addition, this report did not identify any evidence-based guidelines that provided recommendations for best practices when considering refractive laser surgery for people with vision conditions.

Conclusions and Implications for Decision- or Policy-Making

This report identified 1 SR and 2 cross-sectional studies published since 2018 that examined the clinical effectiveness of refractive laser surgery compared with conventional vision correction technologies for people with vision conditions.[13,16,17]

As reported by Bokhary et al. (2022),[16] statistically significant differences in corrected visual acuity outcomes were not identified between participants who did not intend to have PRK, participants who had not yet undergone PRK, and participants who had undergone PRK within the past 5 years. This study had significant

limitations inherent to the cross-sectional design, may have been insufficiently powered to detect differences between groups, and uncorrected visual acuity and age differed between participant groups. This study found participants at later follow-up times after PRK had increased visual acuity; however, no baseline data were provided for these subgroups of fewer study participants. Inferences for comparative visual acuity outcomes for PRK compared with conventional vision correction technologies were not apparent based on this evidence.

A prior relevant CADTH report[19] including QoL outcomes identified 1 prospective, longitudinal, parallel-group, multicenter survey study of 1,800 adults that compared clinical effectiveness of laser eye surgery to eyeglasses, in a literature search that spanned from January 1, 2013, to May 27, 2018. This survey study, appraised at high risk of bias, found LASIK patients reported higher overall patient satisfaction compared with those who wore contact lenses. This study also found that a greater proportion of participants who wore contact lenses reported night-driving and night visual disturbances than participants who had undergone LASIK, whereas outcomes such as dry eye, small print reading, depression, eye infection, eye ulcer, and eye abrasion did not differ longitudinally or between participant groups.[19]

This current report identified 1 cross-sectional study, appraised at high risk of bias, that found participants who had undergone PRK reported higher overall vision-related QoL, better driving in glare conditions, and better QoL in domains of convenience, health concerns, and well-being compared with participants who were using conventional corrective lenses.[16] In contrast, the other cross-sectional study identified in this report,[17] also appraised at high risk of bias, did not identify any significant difference in a satisfaction subscore of a QoL questionnaire between participants who had a LASIK procedure and those who wore contact lenses. Furthermore, this study found that participants who wore conventional contact lenses reported greater overall QoL, reported as a summation of statistically significant differences in QoL subscores of worry, symptoms, and expections.[17] An interpretation of the conflicting QoL findings between these studies was not possible. Although different vision-related QoL questionnaires were used in each study, all conclusions were associated with very low confidence based on the appraised risk of bias.[16,17,19]

The SR by Wu et al. (2020)[13] reported on vision loss outcomes, and it was also appraised at a high risk of bias for this report. Although the findings of risk associated with LASIK and contact lenses were based upon different populations of unknown clinical comparison, the magnitude of the findings suggested there is a greater risk of vision loss with LASIK in the setting of a clinical trial compared with contact lens use in the general population. The authors suggested that the results support a low risk of vision loss to an individual with either LASIK or contact lens use.[13] Any interpretation of the evidence identified in this report should be made with caution due to a lack of high-quality evidence. The literature screening process suggested the current literature is primarily focused on comparisons between different refractive laser surgery procedures without direct comparisons with conventional vision correction technologies, and it is unclear if relevant high-quality comparative evidence is forthcoming.

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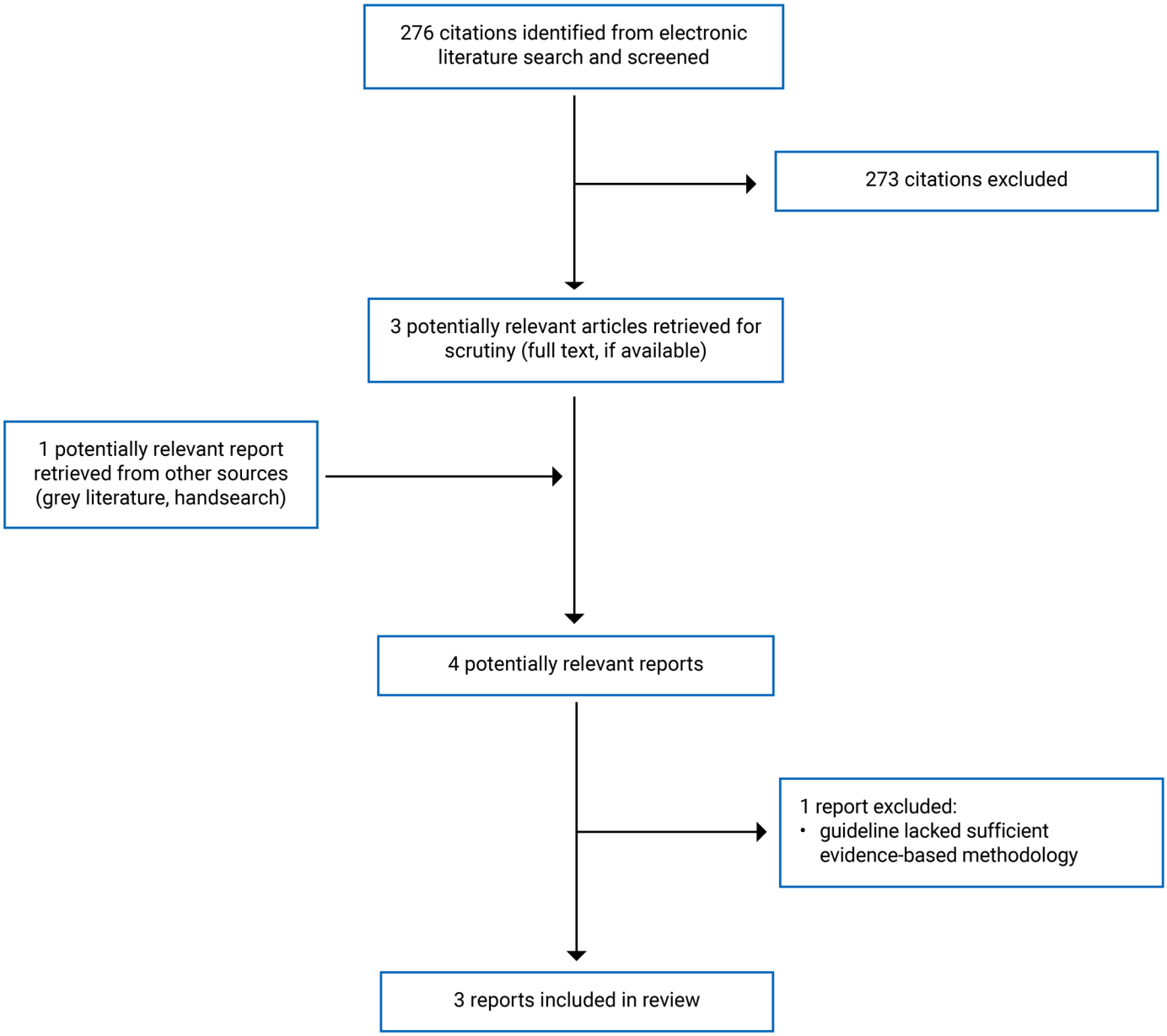
Appendix 1: Selection of Included Studies

Figure 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Note that this appendix has not been copy-edited.

Table 2: Characteristics of Included Systematic Review

Study citation, country, funding source	Study designs and numbers of primary studies included	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Wu et al. (2020)[13] Australia **Funding sources:** Brien Holden Vision Institute, Australia; UNSW, Australia; Vision Cooperative Research Centre, Australia; CIBA Vision, US; National Health and Medical Research Council, Australia.	SR with MA. Intervention: 19 RCTs published within the FDA database. Comparator: 1 prospective surveillance study in combination with a published survey study.	Intervention: older than 18 or 21 years with a wide range of preoperative refractive error with 10 of 19 RCTs including astigmatism up to 8 D. Comparator: Age 15 to 64 years.	**Intervention:** LASIK (various manufacturers and models of LASIK systems) **Comparator**: contact lens	Outcomes: Vision loss defined as ≥ 2 lines loss of BSCVA at 6 months. Contact lens wear year equivalent to the one-off risk associated with LASIK. Follow-up: 6 months for LASIK patients

BSCVA = best spectacle-corrected visual acuity; LASIK = laser-assisted in situ keratomileusis; RCT = randomized controlled trial; UNSW = University of New South Wales.

Table 3: Characteristics of Included Primary Clinical Study

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Bokhary et al. (2022)[16] Saudi Arabia **Funding source:** None	Cross-sectional study and questionnaire	Participants with refractive errors (myopia [≤ 10.5 D], hypermetria [≤ 4.50 D], or astigmatism [≤ 6.00 D]) Age: 19 to 40 years Sex: 80.7% female Number of participants = 145 Settings: 1 hospital in Saudi Arabia Exclusions: ocular disease, diabetes, medication	**Intervention:** PRK (n = 94) consisting of preoperative participants (n = 50) and postoperative participants (n = 44) **Comparator:** Conventional vision correction technologies (n = 51)	Outcomes: UDVA, CDVA (Snellen chart), SE (autorefractometer), corneal topography (Oculus Pentacam HR), QIRC[a] (Arabic version) Follow-up: postoperative 1 week (n = 13), ≤ 6 months (n = 16), > 6 months (n = 15)
González-Pérez et al. (2019)[17] Spain **Funding source:** NR	Cross-sectional questionnaire	Myopic patients: −6.00 to −0.75 D, ≤ −1.75 D astigmatism all successfully corrected with 1 of 3 study interventions Emmetropic	**Intervention:** • LASIK - Wavelight Allegretto Wave Eye-Q (Wavelight GmbH, Germany) (n = 24) • CRT orthokeratology	**Outcomes:** • Overall NEI RQL-42[b] Questionnaire average scores • NEI RQL-42 subscales: clarity, expectations, near

Study citation, country, funding source	Study design	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
		participants: refractive error < ± 0.50 D to serve as uncorrected controls Age: > 18 years Sex: 60.4% female Number of participants = 96 Settings: 2 Spanish centres	lenses (Paragon, AZ) (n = 24) • Continuous wear (30 nights during 12 months) lotrafilcon A Si-H CL (Alcon Pharmaceuticals Ltd., Switzerland) (n = 24) **Comparator:** Emmetropic subjects (n = 24)	vision, far vision, diurnal fluctuations, activity limitations, glare, symptoms, dependence, worry, suboptimal correction, appearance, and satisfaction. Follow-up: 1 year

AZ = Arizona; CDVA = corrected distance visual acuity; CL = contact lens; CRT = Corneal Refractive Therapy; LASIK = laser-assisted in situ keratomileusis; NEI RQL = National Eye Institute Refractive Error Quality of Life Instrument; NR = not reported; PRK = photorefractive keratectomy; QIRC = Quality of Life Impact of Refractive Correction; SD = standard deviation; SE = spherical equivalent; Si-H CL = silicone-hydrogel contact lens; UDVA = uncorrected distance visual acuity.

[a]The QIRC consists of 20 vision-related quality of life questions with a 5-category response scale.

[b]The NEI RQL-42 consists of 42 multiple choice ratings of 0 to 100 of 13 different vision qualities.

Appendix 3: Critical Appraisal of Included Publications

Note that this appendix has not been copy-edited.

Table 4: Strengths and Limitations of Systematic Review Using AMSTAR 2[10]

Strengths	Limitations
Wu et al. (2020)[13]	
• The follow-up period of the source data were defined • Data extraction methodology described • Summary description of included studies provided • Funding of studies listed • Statistical methodology for MA provided	• Research question addressed indirectly from different study types with 1 population-based surveillance study serving as source for control data and 19 RCTs for intervention data • Age inclusion criteria differed for intervention and control • Research question not clearly formulated • Review methods not established before review • Literature from a single database • Selection criteria unclear and not done in duplicate • Data extraction not done in duplicate • No justification provided for using only RCT data • No information on excluded studies • No critical appraisal of included studies • Statement of potential COI • No assessment of statistical heterogeneity of combined trial results • Insufficient discussion of study limitations • No assessment or discussion of possible publication bias

AMSTAR 2 = A Measurement Tool to Assess systematic Reviews 2; COI = conflict of interest; MA = meta-analysis; RCT = randomized controlled trial.

Table 5: Strengths and Limitations of Clinical Studies Using the AXIS Checklist[11]

Strengths	Limitations
Bokhary et al. (2022)[16]	
• Clear study objective • Study design appropriate • Provides some baseline patient data despite cross-sectional study design • Clear and appropriate study populations • Objective outcomes appropriately measured • Validated questionnaire for subjective data • Outcomes clearly reported with statistical significance and precision estimates • Statistical methods reported • Adequate reporting of all quantitative results • Conclusions justified by the findings • Limitations discussed	• No sample size justification • Acknowledged small sample size • Unclear response rate • Unclear methods for calculating mean outcome measure

Strengths	Limitations
• Ethics approval obtained • A statement of no COIs	
González-Pérez et al. (2019)[17]	
• Clear study objective • Study design appropriate • Clear and appropriate study populations • No nonresponders • Validated questionnaire for subjective data • Outcomes clearly reported with statistical significance and precision estimates • Statistical methods reported • Adequate reporting of all quantitative results • Conclusions justified by the findings • Limitations discussed • Ethics approval obtained • A statement of no COIs	• Post hoc sample size justification • Study populations not statistically matched

AXIS = Appraisal tool for Cross-Sectional Studies; COI = conflict of interest.

Appendix 4: Main Study Findings

Note that this appendix has not been copy-edited.

Table 6: Summary of Findings by Outcome — Visual Acuity

Visual acuity	Bokhary et al. (2022)[16] Cross-sectional study		
	Control (n = 51)	Pre-PRK (n = 50)	Post-PRK (n = 44)[a]
UDVA n (%)[a]			
0 to 0.1 D[b]	4 (7.8%)	0 (0%)	0 (0%)
0.2 to 0.3 D	7 (13.7%)	0 (0%)	0 (0%)
0.4 to 0.6 D	10 (19.6%)	7 (14.0%)	3 (6.8%)
≥ 0.7 D	30 (58.8%)	43 (86.0%)	41 (93.2%)
CDVA n (%)			
0 to 0.1 D	50 (98.0%)	48 (96.0%)	44 (100%)
0.2 to 0.3 D	1 (2.0%)	2 (4.0%)	0 (0%)
CCT (mcg), mean ± SD	554.78 ± 44.346	556.02 ± 37.874	557.98 ± 37.504
Post-PRK subgroups	**1 week (n = 13)**	**≤ 6 months (n = 16)**	**> 6 months (n = 15)**
CDVA (D), mean (SD)	0.169 (0.138)[c]	0.031 (0.060)[c]	0.013 (0.035)[c]
SE (D), mean (SD)	−0.654 (0.451)[c]	−0.0781 (0.405)[c]	−0.083 (0.323)[c]

CCT = central corneal thickness; CI = confidence interval; CL = contact lens; LASIK = laser-assisted in situ keratomileusis; SD = standard deviation; SE = spherical equivalent.

[a]For the Post-PRK participants VA without correction (UDVA) refers to VA before PRK.

[b]Absolute value of D

[c]VA and SE differed significantly (P < 0.05) between all Post-PRK subgroups.

Table 7: Summary of Findings by Outcome — QIRC Scores

Scores Mean ± SD	Bokhary et al. (2022)[16] Cross-sectional Questionnaire (QIRC)			
	Control (n = 51)	Pre-PRK (n = 50)	Post-PRK (n = 44)	P
Visual Function Domain				
Driving in glare conditions	45.79 ± 7.15	43.68 ± 5.69	53.84 ± 7.14	< 0.0001
Visual Symptom Domain				
Feeling tired or strained	43.00 ± 14.14	38.69 ± 11.00	45.06 ± 6.90	0.256
Convenience Domain				
Unable to use sunglasses	45.03 ± 9.99	45.25 ± 11.80	49.30 ± 8.59	0.054
Planning before activities	43.42 ± 13.31	43.84 ± 14.84	52.56 ± 9.79	0.002
Vision upon waking	45.28 ± 12.73	38.04 ± 11.85	52.43 ± 12.25	< 0.0001

Scores Mean ± SD	Bokhary et al. (2022)[16] Cross-sectional Questionnaire (QIRC)			
	Control (n = 51)	Pre-PRK (n = 50)	Post-PRK (n = 44)	P
Unaided vision for swimming	46.72 ± 12.56	41.08 ± 11.62	56.19 ± 10.92	< 0.0001
Trouble with correction for gym	42.53 ± 12.14	34.71 ± 13.16	49.61 ± 9.85	< 0.0001
Cost Domain				
Associated costs of correction	51.32 ± 12.87	49.16 ± 12.49	55.94 ± 10.39	0.034
Maintenance costs of correction	45.49 ± 13.05	41.16 ± 12.79	50.21 ± 11.54	0.004
Health Concerns Domain				
Reliability concerns	45.18 ± 12.81	38.97 ± 8.92	55.80 ± 12.87	< 0.0001
Concern about worse vision	42.27 ± 11.78	37.02 ± 6.76	47.93 ± 11.65	< 0.0001
Concern about complications	39.86 ± 12.64	36.32 ± 11.04	46.85 ± 11.19	< 0.0001
Concern about UV protection	47.22 ± 13.09	47.74 ± 12.28	45.52 ± 11.33	0.722
Well-being Domain				
Appearance	49.15 ± 19.71	41.30 ± 13.88	59.97 ± 18.52	< 0.0001
Appearance to others	46.12 ± 16.66	52.18 ± 16.90	56.91 ± 14.68	0.013
Felt complimented	49.89 ± 15.06	52.70 ± 16.39	64.64 ± 14.54	< 0.0001
Felt confident	50.25 ± 18.33	54.34 ± 16.52	62.88 ± 15.52	0.002
Felt happy	45.67 ± 16.82	47.77 ± 16.41	59.62 ± 15.73	< 0.0001
Felt able to do things	37.33 ± 18.67	39.15 ± 16.42	52.08 ± 15.16	< 0.0001
Felt eager to try new things	48.64 ± 19.77	48.31 ± 15.98	56.21 ± 15.93	0.07
Overall				
Appearance	45.79 ± 7.15	43.68 ± 5.69	53.84 ± 7.14	< 0.0001

CRT = corneal refractive therapy; LASIK = laser-assisted in situ keratomileusis; NEI RQL-42 = National Eye Institute Refractive Error Quality of Life Instrument; SD = standard deviation; Si-H CL = silicone-hydrogel contact lenses.

Table 8: Summary of Findings by Outcome — NEI RQL-42 Scores

Subscore domain Mean ± SD	González-Pérez et al. (2019)[17] Cross-sectional Questionnaire (NEI RQL-42)			
	Emmetropes (n = 24)	LASIK (n = 24)	Si-H CL (n = 24)	CRT (n = 24)
Clarity of vision	95.8 ± 7.5[d]	81.6 ± 22.7	93.9 ± 8.0	85.8 ± 16.4
Expectations	91.7 ± 19.5[b]	62.5 ± 33.1[c]	91.7 ± 28.9	79.5 ± 36.8
Near Vision	88.7 ± 20.4	91.8 ± 12.2	96.7 ± 6.2	97.0 ± 8.0
Far Vision	86.9 ± 9.6	82.6 ± 19.4	86.4 ± 8.9	86.6 ± 20.9
Diurnal Fluctuations	83.0 ± 22.6	76.0 ± 23.2	89.2 ± 16.2	84.0 ± 20.2

Subscore domain Mean ± SD	González-Pérez et al. (2019)[17] Cross-sectional Questionnaire (NEI RQL-42)			
	Emmetropes (n = 24)	LASIK (n = 24)	Si-H CL (n = 24)	CRT (n = 24)
Activity limitations	99.5 ± 1.8	99.5 ± 1.8	100.0 ± 0.0	96.8 ± 10.8
Glare	93.7 ± 8.4[b, c]	69.8 ± 25.2	86.4 ± 3.6	85.4 ± 3.6
Symptoms	78.9 ± 15.4	80.1 ± 14.1	93.1 ± 6.0[a, b]	88.4 ± 12.6
Dependence	92.0 ± 16.5[c]	82.3 ± 30.7[c]	23.3 ± 15.8	74.3 ± 26.5c
Worry	60.4 ± 28.6b	36.5 ± 22.3	80.2 ± 10.0[a, b, d]	37.5 ± 33.7
Suboptimal correction	97.9 ± 7.2	98.9 ± 3.6	100.0 ± 0.0	94.8 ± 8.4
Appearance	82.9 ± 26.1	92.2 ± 20.9	93.3 ± 9.8[a]	85.0 ± 17.3
Satisfaction	60.0 ± 40.0	83.3 ± 28.1	93.3 ± 9.8	85.0 ± 17.3
OVERALL	85.5 ± 12.8	80.0 ± 10.2	87.1 ± 6.4[b]	83.5 ± 6.4

CRT = corneal refractive therapy; LASIK = laser-assisted in situ keratomileusis; NEI RQL-42 = National Eye Institute Refractive Error Quality of Life Instrument; SD = standard deviation; Si-H CL = silicone-hydrogel contact lenses.

[a]Significantly (P < 0.05) greater than emmetrope participant mean.

[b]Significantly (P < 0.05) greater than LASIK participant mean

[c]Significantly (P < 0.05) greater than Si-H CL participant mean

[d]Significantly (P < 0.05) greater than CRT participant mean

Table 9: Summary of Findings by Outcome — Vision Loss

Vision Loss[a]	Wu et al. (2020)[13] Systematic Review	
	n/N	Incidence (95% CI)
Vision Loss		
LASIK (6 months follow-up incidence)	38 cases of vision loss per 4,882 eyes	66/10,000 (34 to 108)*
CL (annualized incidence)	285 cases of vision loss per population survey	0.28/10,000 (0.25 to 0.31)
Years of CL use with equivalent risk compared to the one-off LASIK procedure risk		
All CL types	285 cases of vision loss	218 (103 to 391)
Daily wear soft CL	64 cases of vision loss	320 (165 to 525)
Overnight soft CL	23 cases of vision loss	31 (16 to 51)
Overnight wear Si-H CL	92 cases of vision loss	48 (25 to 79)

CI = confidence interval; CL = contact lens; LASIK = laser-assisted in situ keratomileusis; Si-H CL = silicone-hydrogel contact lens

[a]Authors report this as a conservative estimate that takes into account heterogeneities among studies using a random-effects model.

Appendix 5: References of Potential Interest

Note that this appendix has not been copy-edited.

Guidelines and Recommendations: Unclear Methods

American Academy of Ophthalmology. Refractive Surgery Preferred Practice Pattern. 2022: https://www.aao.org/education/preferred-practice-pattern/new-preferredpracticepatternguideline-3. Accessed 2023 Aug 30.

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