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REVIEW ARTICLE

Clinical outcomes of presbyopia correction with the latest techniques of presbyLASIK: a systematic review

Joaquin Fernández[1], Ainhoa Molina-Martín[2], Carlos Rocha-de-Lossada[1,3,4], Manuel Rodríguez-Vallejo[1] and David P. Piñero[2,5]✉

The aim of this study was to collect the scientific literature on the correction of presbyopia with laser in situ keratomileusis (presbyLASIK) in last years and to analyse the quality of such scientific evidence using a validated methodology for conducting a systematic review. A total of 42 articles were initially identified, but after applying the selection criteria and an additional manual search a total of 23 articles were finally included: 2 non-randomized controlled clinical trials (NRCT) and 21 case series. Quality assessment of NRCTs and case series was performed with the ROBINS-I and the 20-criterion quality appraisal checklist defined by Moga et al. (IHE Publ 2012), respectively. For NRCT, the risk of bias was moderate in one study and serious in the other NRCT, being the main sources of risk, the domains related to confounding, selection of participants and measurement of outcomes. For case series studies, the main source of risk of bias was subjects not entering the study at the same point of the conditions (different levels of presbyopia). Likewise, a significant level of uncertainty was detected for the following items: consecutive recruitment of patients, blinding of outcome assessors to the intervention that the patient received, and conclusions of the study not supported by the results. Research on presbyLASIK to this date is mainly focused on case series generating a limited level of scientific evidence. The two NRCTs identified only demonstrated the potential benefit of combining the multiaspheric profile with some level of monovision in the non-dominant eye.

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INTRODUCTION

A definitive presbyopia correction technique is one of the main challenges for refractive surgeons nowadays, which must deal with patients with increasingly demanding visual requirements. A large proportion of myopic and hyperopic subjects, with or without astigmatism and with or without cataract, search for spectacle independence at any age, and accordingly, different types of techniques have been developed to overcome the near and intermediate visual difficulties associated to each age range. Presbyopia-correcting IOLs are increasing its visibility on clinical practice in the case of pseudophakic subjects in which the accommodative ability has been reduced or is absent, but in the case of young presbyopes with a remaining accommodative function, other techniques seem to be more appropriate than removing a functional and clear lens [1].

PresbyLASIK is a refractive technique in which the corneal shape is ablated with a multifocal profile, that is with a multiaspheric ablation to provide acceptable focus for distance, intermediate and near vision [2]. Different laser manufacturers have developed their own algorithms to create this multifocal profile, and accordingly different trade names have been assigned depending on the manufacturer: Supracor (Technolas Perfect Vision GmbH), Presbyond (Carl Zeiss Meditec GmbH), PresbyMax (SCHWIND eye-tech-solutions GmbH), or Custom Q (Alcon Laboratories Inc.) (Fig. 1) [3]. Some of these algorithms are programmed based on the target near addition or planned according to the subject's age, but the effective change on refraction comes from the controlled change in the corneal asphericity from the center to the periphery, depending not only on the magnitude of near addition but also on the distance vision ablation profile (if myopic or hyperopic). Additionally, two more variants have to be considered since presbyLASIK can be central when the near vision profile is applied in the central cornea, or peripheral, when it is applied peripherally [4]. All these combinations provide a wide range of refractive options for presbyopic patients, with the additional possibility of combining a multiaspheric profile in one eye and a conventional profile in the fellow eye, generating some level of myopia and consequently some level of monovision. This wide range of options makes difficult to know the real impact of a specific multiaspheric ablation profile without the interference of factors such as the induction of micro-monovision. The aim of the current investigation was to review the scientific literature about the efficacy of presbyLASIK in myopic and hyperopic presbyopes, analysing the quality of the scientific evidence associated to this technique, the bias sources of the studies revised and to determine the requirements of future studies evaluating the clinical outcomes of this surgical option of correction of presbyopia.

[1]Department of Ophthalmology (Qvision), VITHAS Hospital, Almería, Spain. [2]Department of Optics, Pharmacology and Anatomy, University of Alicante, Alicante, Spain. [3]Department of Ophthalmology, Hospital Virgen de las Nieves, Granada, Spain. [4]Department of Surgery, Area of Ophthalmology, University of Seville, Seville, Spain. [5]Department of Ophthalmology (IMQO-Oftalmar), Vithas Medimar International Hospital, Alicante, Spain. ✉email: david.pinyero@ua.es

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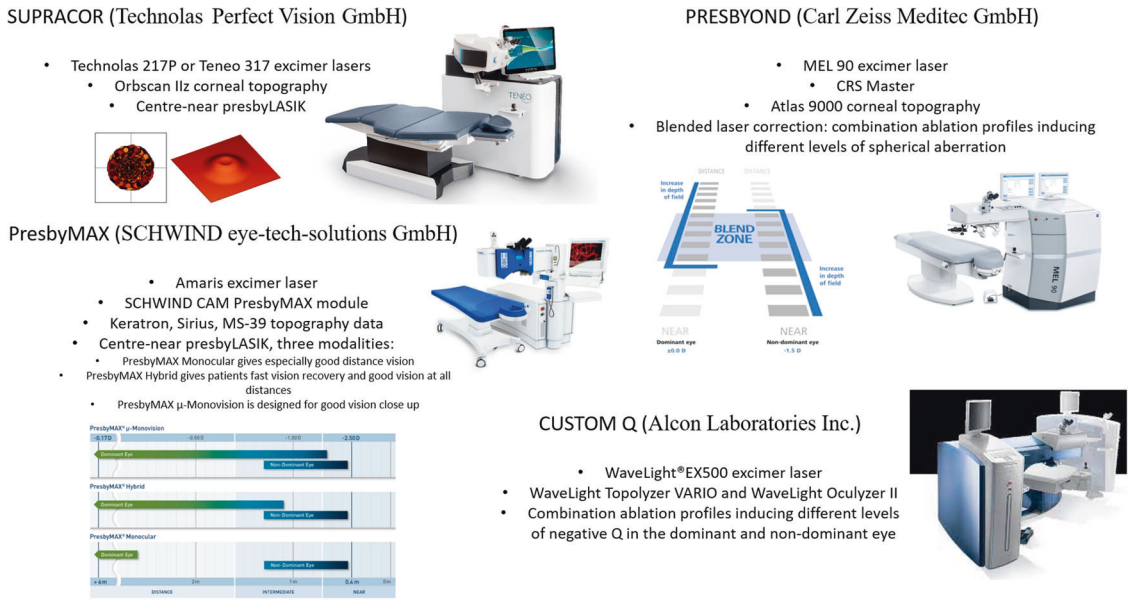

Fig. 1 Main characteristics of the four main platforms of presbyLASIK that are commercially available.

METHODS

A search equation including the following terms was conducted in PubMed database: PresbyLASIK OR PresbyMax OR Presbyond OR Presbyone OR Custom Q. Additionally, the following specific selection criteria were applied as a search filter:

(i) Original articles.
(ii) Articles in English.
(iii) Articles since 2010.

Titles and abstracts were reviewed from this first search, and only those articles whose aim was to evaluate the visual outcomes of presbyLASIK technique in presbyopic subjects were considered. Optical simulations or case reports were excluded. Duplicates were also excluded. In a second step, complete texts were reviewed to confirm the selection criteria applied. Manual search brought us back an additional article that was included afterwards.

Quality assessment of publications was performed by two methods depending on the type of study [5, 6]. The higher level of scientific evidence was represented by non-randomized clinical trials, that is prospective interventional studies, using for this type of studies the tool ROBINS-I to assess the risk of bias, as recommended [7]. At protocol stage, the review question was to evaluate presbyopic subjects (participants) operated on with presbyLASIK (experimental intervention) in comparison to monovision (comparator) for visual acuity (VA), refraction, quality of vision, spectacle independence, aberrations, or contrast sensitivity (outcomes). The aim for these studies was to assess the effect of assignment to intervention. The ROBINS-I is a tool developed to assess risk of bias in the results of non-randomized studies that compare health effects of two or more interventions. Specifically, the following bias domains are evaluated:

- Pre-intervention: bias due to confounding and bias in selection of participants into the study.
- At intervention: bias in classification of interventions.
- Post-intervention: bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result.

After answering the different questions used to evaluate these domains, an overall evaluation is provided as follows: low risk of bias (the study is judged to be at low risk of bias for all domains), moderate risk of bias (he study is judged to be at low or moderate risk of bias for all domains), serious risk of bias (the study is judged to be at serious risk of bias in at least one domain, but not at critical risk of bias in any domain), and critical risk of bias (the study is judged to be at critical risk of bias in at least one domain).

The main body of the scientific evidence recruited in this search was represented by case series, that is prospective or retrospective observational studies with limited groups of participants in most of cases. For these studies, the 20-criterion quality appraisal checklist described by Moga et al. [8] was applied to evaluate this type of evidence. This tool examines different items evaluating the execution of the study (aim, recruitment, description of characteristics of subjects, inclusion criteria, definition of the intervention, blinding of assessors, follow-up, methodology, adverse events, conclusions, or competing interests) but also the quality of the reporting (clear definition of main outcomes measures and statistical tests) [9]. Depending on the number of positive responses (YES in front of PARTIAL/UNCLEAR or NO), a score is assigned. Before using the checklist, the relevant aspects should be addressed by the assessors. Summary of the applied criteria in this study is represented in Fig. 2.

RESULTS

The search was conducted on 13th of May, 2021. Following the search equation described, a total of 42 articles were identified, including four articles in other languages that were excluded. After applying the selection criteria, 22 articles were selected for a more comprehensive evaluation with the selected tools. A manual search included an additional article, and therefore 23 articles were finally included: 2 non-randomized controlled clinical trials (NRCT) [10, 11] and 21 case series studies [12–32]. Figure 3 shows the flow chart followed during the search. The main causes of exclusion were nine articles that were reviews of the previous literature, and eight articles with no access to full text. Main characteristics of the articles finally included in the systematic analysis are summarized in Tables 1, 2. As shown in Table 2, different types of ablation profiles of different excimer laser platforms have been used in the articles revised.

The quality and risk of bias of the revised articles was obtained and summarized following the guidelines of each evaluation tool in Table 3 (for ROBINS-I) and Table 4 (for Moga tool). For NRCT, the

1. Is the hypothesis/aim/objective of the study clearly stated?
May include: outcomes, type of intervention and type of patients.
**Most of the studies fail describing the type of subjects (presbyopia is supposed but not clear, also fail describing if myopes or hypermetropes, if the lens is transparent or not).*

2. Was the study conducted prospectively?
May include the word "prospective".

3. Were the cases collected in more than one centre?
May include the word "multicentric" or mention of various settings.

4. Were participants recruited consecutively?
May include the word "consecutive".

5. Are the characteristics of the participants included in the study described?
May include: number of subjects, age, refraction and addition.
**Most of the studies fail describing the preoperative addition.*

6. Are the eligibility criteria for entry into the study clearly stated?
May include both inclusion and exclusion criteria.

7. Did participants enter the study at a similar point in the disease?
Similar point of the disease was considered when:
- *Age range of subjects < 10 years or a mean value with SD ± 5 years*
- *Addition range < 1.50D or a mean value with SD ± 0.50D*

8. Was the intervention of interest clearly described?
May include: type of laser, algorithm, if unilateral or binocular, and symmetry.

10. Are the outcome measures established a priori?
All relevant outcomes are described in introduction and/or methods.

11. Were outcome assessors blinded to the intervention that patients received?

12. Were the relevant outcomes measured with appropriate objective and/or subjective methods?
Main outcomes may be measured with standard techniques.

13. Were the relevant outcomes measured before and after the intervention?
May appear preoperative and postoperative data of the main outcomes.

14. Were the statistical tests used to assess the relevant outcomes appropriate?
May include the statistical methods used for the analysis of the main outcomes.

15. Was follow-up long enough for important events and outcomes to occur?
May have a follow up period at least of 6 months.

16. Was the loss to follow-up reported?
May include: losses of follow-up or they can be deduced by the information in tables or only patients which complete the follow-up were included.

17. Does the study provide estimates of the random variability in the data analysis of relevant outcomes?
May include mean and SD or median and ICR at least.

18. Are the adverse events related with the intervention reported?
May include: complications or adverse events, and also re-interventions or enhancements (both).
**Most of studies described the re-interventions, but only few specify the complications or its absence.*

19. Are the conclusions of the study supported by results?
May include statements well supported by the evidence.
**Some studies conclude that the intervention is satisfactory, but only few analyse the patient reports by validated questionnaires.*

20. Are both competing interests and sources of support for the study reported?
May include any source of support (funding) and the competing interests, or specify nothing to declare in both funding and interests.
**Most of studies fail in declaring the funding, possibly because no funding was received, but this should be also specified.*

Fig. 2 Criteria used for quality assessment with the 20-criterion quality appraisal checklist defined by Moga et al. [8]. Studies may provide this specific information to receive the positive rating (YES).

risk of bias was moderate in one study [10] and serious in the other NRCT [11], being the main source of risk the domains related to confounding, selection of participants and measurement of outcomes (Table 3). For case series studies [12–32], the main sources of risk of bias was subjects not entering the study at the same point of the conditions (different levels of presbyopia) (14 "No" answers from the 21 articles evaluated) (Table 4), and the inclusion of cases collected from different centers (17 "No" answers from the 21 articles evaluated). The answer "Partial" was reported for half of the articles revised or more in the following items: establishment a priori of relevant outcome measures (10/21) and report of both competing interests and sources of support of the study (13/21). Likewise, there was a significant level of uncertainty for a large proportion of the studies revised for the following items: consecutive recruitment of patients (12 unclear answers/21), blinding of outcome assessors to the intervention that the patient received (21 unclear answers/21), and conclusions of the study not supported by the results (6 unclear answers/21).

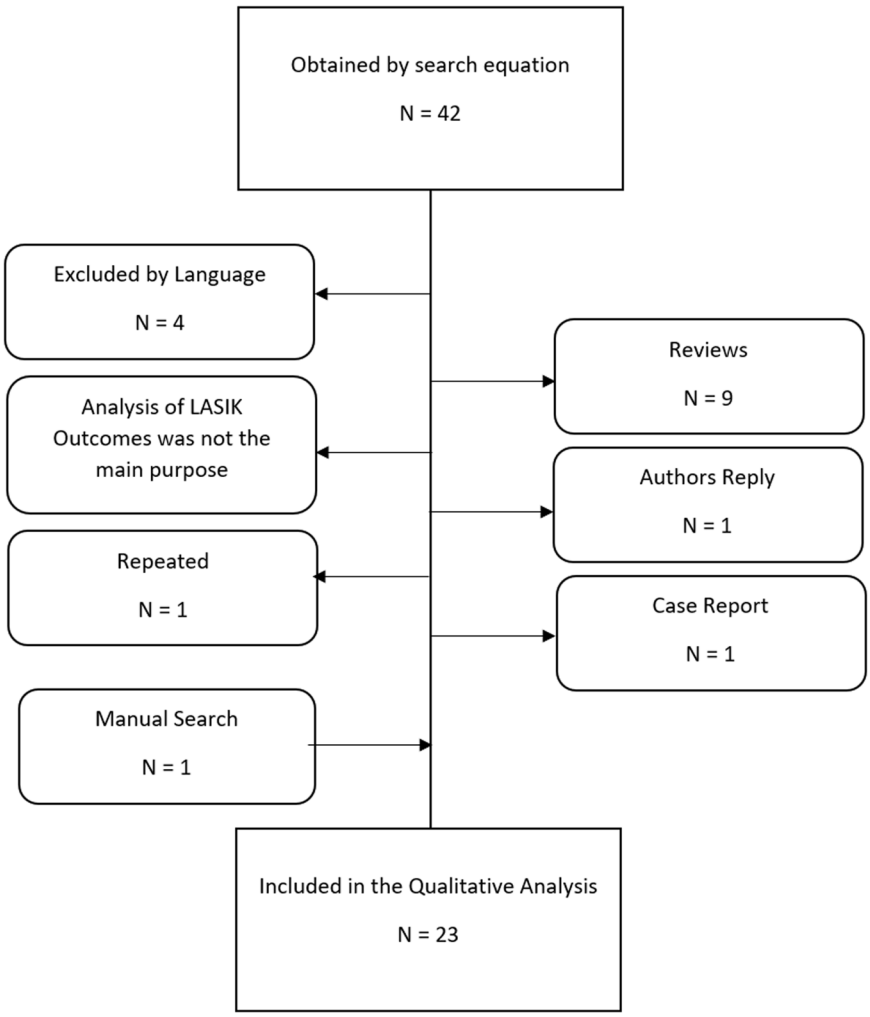

Fig. 3 Flow chart of the selection process of relevant articles that were included in the current systematic review.

DISCUSSION

The induction of controlled amounts of primary spherical aberration has been shown to be an effective option to expand the depth of focus (DOF) of the eye and consequently to provide a functional correction of vision across different distances for presbyopes [33]. Likewise, the induction of some level of other types of high order aberrations (HOAs), such as secondary spherical aberration or primary coma, has also shown a positive impact on the enlargement of the DOF [34, 35]. This aberrometric induction can be generated at the corneal plane by means of an excimer laser which was the initial concept of presbyLASIK [4]. However, this technique has been modified continuously with aim of maximizing the level of DOF achieved and minimizing the level of spectacle independence [5]. This evolution has led to the combination of a multiaspheric profile inducing a controlled amount of HOAs with the concept of micro-monovision, which consists of leaving a small myopic residual refraction in the non-dominant eye. The question is if this procedure can be still considered or called presbyLASIK or if it is modified version of the monovision concept. Likewise, there are several combinations that have been proposed but their real clinical benefit is still unclear: multiaspheric profile in both eyes (classical or symmetric presbyLASIK), multiaspheric profile in both eyes with additional micro-monovision in the non-dominant eye (bilateral presbyLASIK combined with μ-monovision), different multiaspheric profiles (different addition) in both eyes (asymmetric bilateral hybrid presbyLASIK), a conventional monofocal ablation profile in the dominant eye and multiaspheric profile in the non-dominant eye (asymmetric monocular mode presbyLASIK). The aim of the current study was to revise systematically the published research on presbyLASIK to know the real evidence associated to this technique, its risk of bias, if there are sufficient evidence of the benefit of one specific combination over the other ones, and how the scientific evidence on this technique can be consistently improved.

In the bibliographic search performed, only two NRCTs were found in which central presbyLASIK was applied. Kohnen et al. [10] performed a comparison of two types of presbyLASIK techniques: 15 patients treated with bilateral presbyLASIK combined with μ-monovision and 15 patients treated with asymmetric bilateral hybrid presbyLASIK. These authors found that the hybrid and μ-monovision groups did not differ significantly except for distance-corrected near visual acuity, with a better outcome in those eyes treated with presbyLASIK combined with μ-monovision (0.21 ± 0.15 logMAR vs. 0.34 ± 0.17 logMAR). This trial showed a moderate bias due to selection of participants and measurement of outcomes, with no inclusion of a control group using a conventional ablation profile with or without monovision approach. The second NRCT included in the current systematic review was conducted by Leray et al. [11] in which the dominant eye was operated using a conventional profile and the non-dominant eye was programmed with an aspheric ablation profile and −0.75 D of residual refractive error. These authors concluded that aspheric hyperopic LASIK could increase the DOF without

Table 1. Summary of main studies characteristics.

Study	Type of Study	Prospective/retrospective	Subjects
Kohnen et al. [10]	NRCT	Prospective	Group hybrid: 14 Group μ-monovision: 15
Leray et al. [11]	NRCT	Prospective	76
Avila and Vivas [14]	Case Series	¿?	15
Rahmania et al. [12]	Case Series	Prospective	28
Boucenna et al. [13]	Case Series	Retrospective	23
Fu et al. [17]	Case Series	Prospective	18
Fu et al. [18]	Case Series	Prospective	22
Ganesh et al. [15]	Case Series	Retrospective	101
Liu et al. [16]	Case Series	Prospective	37
Luger et al. [19]	Case Series	Retrospective	19
Villanueva et al. [20]	Case Series	Retrospective	12
Chan et al. [22]	Case Series	Retrospective	36
Pajic et al. [21]	Case Series	Prospective	36
Courtin et al. [24]	Case Series	Prospective	65
Vastardis et al. [23]	Case Series	¿?	19
Wang et al. [25]	Case Series	Prospective	69
Luger et al. [28]	Case Series	Retrospective	32
Saib et al. [26]	Case Series	Retrospective	37
Soler et al. [27]	Case Series	Prospective	Group symmetrical: 16 Group asymmetrical: 14
Gifford et al. [29]	Case Series	Retrospective	31
Baudu et al. [31]	Case Series	Retrospective	358
Luger et al. [30]	Case Series	¿?	33
Uthoff et al. [32]	Case Series	Prospective	30

impairing far vision, but this conclusion should be taken with care as the increase of DOF cannot be attributed exclusively to the induction of spherical aberration because a myopic residual refractive error was present in all patients. This leads to a serious level of bias due to confounding variables.

Concerning the case series, as shown in Table 4, all studies showed one or more sources of bias, being subjects not entering the study at the same point of the conditions (different levels of presbyopia) and no inclusion of cases collected from different centers among the most detected. Likewise, some conditions to avoid bias was partially accomplished in most of the case series revised, especially in terms of establishment a priori of relevant outcome measures and report of both competing interests and sources of support of the study. Furthermore, some conditions leading to bias were not clearly identified in these case series, such as a non-consecutive recruitment of patients, not blinding of outcome assessors to the intervention that the patient received, and the description of some conclusions not fully supported by the results. It should be considered that all these series reported an improvement in intermediate and near visual performance after the laser intervention, but without a control group to compare.

Most of articles on presbyLASIK are focused on reporting the outcomes of central presbyLASIK [10–32], with very limited research on peripheral presbyLASIK [36, 37]. As most of articles on this technique were published several years ago and the current research on this issue is focused on central presbyLASIK, it can be hypothesized that some limitations could be present in peripheral presbyLASIK. However, there are no comparative studies of both techniques confirming this issue. Pinelli et al. [36] reported a mean binocular uncorrected decimal visual acuity of 1.06 ± 0.13 for distance and 0.84 ± 0.14 for near at 6 months after peripheral presbyLASIK, with a decrease of contrast sensitivity for the spatial frequencies of 3, 6, 12, and 18 cycles/degree. Epstein and Gurgos [37] investigated the outcomes of monocular peripheral presbyLASIK on the non-dominant eye with distance-directed monofocal refractive surgery on the dominant eye, reporting the achievement of complete spectacle independence in 89% of hyperopes and 92% of myopes. However, these authors did not measure the defocus curve to assess the level of visual functionality achieved and the impact on visual quality was not fully investigated.

The research on presbyLASIK shows significant weaknesses and biases that should be avoided in future trials. First, more controlled comparative studies are needed to obtain consistent conclusions about the real clinical benefit of this technique over the use of a conventional ablation profile to correct the refractive error inducing a specific level of monovision. Second, as is commonly performed in articles reporting the outcomes of presbyopia-correcting IOLs, some results and analyses should be mandatory for reporting the outcomes of any type of presbyLASIK technique, including the defocus curve, the measurement on uncorrected and distance-corrected intermediate and near visual acuity and the analysis of contrast sensitivity to confirm the real impact on visual quality. Furthermore, the evaluation of the binocular vision, with specific analysis of the impact on sensorial fusion and stereopsis, must be performed in any study evaluating the results of an asymmetric presbyLASIK approach with different types of correction in each eye. Likewise, comparative studies of the results of presbyLASIK and the outcomes with different types of presbyopia-correcting IOLs, including trifocal or extended depth of focus IOLs, should be also performed in the near future to understand better the role of this therapeutic option on presbyopia.

In conclusion, research on presbyLASIK to this date is mainly focused on case series generating a limited level of scientific

Table 2. Characteristics of the laser ablation profile or mode used in the different studies revised in the current systematic review.

Study	Laser	Algorithm	Uni/bilateral	Symmetry	Design
Kohnen et al. [10]	Schwind	PresbyMax Multifocal mode	Bilateral	Asymmetrical	Group Hybrid: DE Multifocal profile A; NDE Multifocal profile B/Group μ-monovision: DE Multifocal profile target Neutro; NDE Multifocal profile target μ-monovision
Leray et al. [11]	Allegretto	Custom Q	Unilateral	Asymmetrical	DE: Monofocal profile; NDE: Multifocal profile target μ-monovision
Avila and Vivas [14]	Wave Light EX 500	Custom Q	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Rahmania et al. [12]	Wave Light EX 500	Custom Q	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target Monovision
Boucenna et al. [13]	Technolas Teneo TM 317	Supracor	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Fu et al. [17]	Amaris Schwind 1050RS	PresbyMax Schwind monocular mode	Unilateral		DE: Monofocal profile target Neutro/NDE: Multifocal profile target Neutro
Fu et al. [18]	Amaris Schwind 1050RS	PresbyMax Schwind monocular mode	Unilateral		DE: Monofocal profile target Neutro/NDE: Multifocal profile target Neutro
Ganesh et al. [15]	MEL 90 platform	CRS Master	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target Monovision
Liu et al. [16]	Amaris Schwind 750S	PresbyMax Schwind Hybrid mode	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Luger et al. [19]	Amaris Schwind 500	PresbyMax Schwind Aspheric mode	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Villanueva et al. [20]	Amaris Schwind 500	PresbyMax Schwind v3.01			No information
Chan et al. [22]	Amaris Schwind 500	PresbyMax Schwind Aspheric mode	Unilateral		DE: Monofocal profile target Neutro/NDE: Multifocal profile target Neutro
Pajic et al. [21]	Technolas 217P	Supracor	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Courtin et al. [24]	Wave Light EX 500	Custom Q	Unilateral		DE: Monofocal profile target Neutro/NDE: Multifocal profile target Neutro
Vastardis et al. [23]	Technolas 217Z	European Conformity marked	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Wang et al [25]	Wave Light EX 500	Custom Q	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Luger et al. [28]	Amaris Schwind 500	PresbyMax Schwind Aspheric mode	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Saib et al. [26]	Technolas 217P	Supracor	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Soler et al. [27]	Technolas 217P	Supracor Zyoptix Tissue Saving Algorithm	Bilateral	Symmetrical Asymmetrical	Group Symmetrical: Multifocal profile target μ-monovision in both eyes; Group Asymmetrical: DE: Multifocal profile target Neutro/NDE: Multifocal profile target μ-monovision
Gifford et al. [29]	MEL 80 platform	CRS Master	Bilateral	Asymmetrical	DE: Multifocal profile target Neutro/NDE: Multifocal profile target Monovision
Baudu et al. [31]	Amaris Schwind 500	PresbyMax Schwind Aspheric mode	Bilateral	Symmetrical	Multifocal profile target Neutro in both eyes

Table 2. continued

Study	Laser	Algorithm	Uni/bilateral	Symmetry	Design
Luger et al. [30]	Amaris Schwind 500	PresbyMax Schwind Aberration-Free mode	Bilateral	Symmetrical	Multifocal profile target Neutro in both eyes
Uthoff et al. [32]	Amaris Schwind 500	PresbyMax Schwind Aberration-Free mode	Bilateral	Symmetrical	Multifocal profile target μ-monovision in both eyes

Table 3. Summary of the results obtained by ROBINS-I tool for risk of bias assessment for non-randomized clinical trials.

Author, ref.	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reportedresults	Overall bias
Kohnen et al. [10]	Low	Moderate	Low	Low	Low	Moderate	Low	Moderate
Leray et al. [11]	Serious	Low	Low	Low	Low	Low	Low	Serious

Table 4. Summary of the results of 20-criterion quality appraisal checklist tool for case series assessment developed by Mogaetal.

	Was the aim of the study clearly stated?	Was the study conducted prospectively?	Were the cases collected in more than one center?	Were the patients recruited consecutively?	Were the characteristics of the subjects included in the study described?	Were the eligibility criteria for entry into the study clearly stated?	Did patients enter the study at a similar point in the disease?	Was the intervention of interest clearly described?	Were relevant outcome measures established a priori?	Were outcome assessors blinded to the intervention that patients received?	Were the relevant outcomes measured using appropriate objective/ subjective methods?	Were the relevant outcome measures made before and after the intervention?	Were the statistical tests used to assess the relevant outcomes appropriate?	Was follow-up long enough for important events and outcomes tooccur?	Were losses to follow-up reported?	Did the study provide estimates of random variability in the data analysis of relevant outcomes?	Were the adverse events reported?	Were the conclusions of the study supported by the results?	Were both competing interests and sources of support for the study reported?
Avila and Vivas [14]	Yes	Unclear	No	Unclear	Partial	Partial	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Unclear	Yes
Baudu et al. [31]	Yes	No	No	Unclear	Yes	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	No	Yes	Partial	Unclear	Partial
Boucenna et al. [13]	Yes	No	Yes	Unclear	Partial	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Partial
Chan et al. [22]	Yes	No	No	Yes	Partial	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Unclear	Partial
Courtin et al. [24]	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial
Fu et al. [17]	Partial	Yes	No	Unclear	Yes	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fu et al. [18]	Partial	Yes	No	Yes	Yes	Yes	No	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Partial
Ganesh et al. [15]	Partial	No	No	Unclear	Partial	Partial	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Partial
Gifford et al. [29]	Partial	No	No	Unclear	Partial	Partial	No	Yes	Yes	Unclear	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes
Liu et al. [16]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial
Luger et al. [28]	Partial	No	No	Yes	Yes	Yes	Yes	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Yes
Luger et al. 2013 [30]	Yes	Unclear	Unclear	Unclear	Yes	Yes	No	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	No	Unclear	Yes
Luger et al. [19]	Partial	No	No	Yes	Yes	Partial	Yes	No	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Yes
Pajic et al. [21]	Yes	Yes	Unclear	Unclear	No	No	Unclear	Yes	Partial	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Partial	Yes	Yes
Rahmania et al. [12]	Yes	Yes	No	Yes	Partial	Yes	No	Yes	Partial	Unclear	Partial	No	Yes	Yes	Yes	Partial	Yes	Unclear	Partial
Saib et al. [26]	Yes	No	No	Yes	Yes	Yes	No	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial
Soler et al. [27]	Yes	Yes	No	Unclear	Yes	Partial	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Yes
Uthoff et al. [32]	Yes	Yes	No	Unclear	Yes	Yes	No	Yes	Yes	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	No	Unclear	Partial
Vastardis et al. [23]	Partial	Unclear	No	Unclear	Partial	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Partial
Villanueva et al. [20]	Partial	No	Unclear	Yes	Yes	Partial	Yes	Partial	Yes	Unclear	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Partial
Wang et al. [25]	Partial	Yes	No	Unclear	Partial	Partial	No	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial

Question 9 of the tool about co-interventions was not considered in the analysis.

evidence. The two non-randomized clinical trials identified only demonstrated the potential benefit of combining the multiaspheric profile with some level of monovision in the non-dominant eye for inducing an enhanced near visual performance. Future controlled clinical trials are needed to provide more consistent evidence of the benefit or equivalence of this therapeutic option over other options for compensation of presbyopia.

SUMMARY

What was known before

- PresbyLASIK is a refractive technique in which the corneal shape is ablated with a multifocal profile, that is with a multiaspheric ablation to provide acceptable focus for distance, intermediate and near vision in presbyopia.
- Different laser manufacturers have developed their own algorithms to create their own presbyLASIK multifocal profile.
- Different studies have been conducted to show the results of this option of presbyopia correction with different laser platforms.

What this study adds

- Research on presbyLASIK to this date is provided a limited level of scientific evidence as it is mainly focused on case series.
- Two non-randomized clinical trials have been performed that have demonstrated the combination of the multiaspheric profile with some level of monovision in the non-dominant eye generates a satisfactory outcomes.
- More controlled comparative studies are needed to obtain consistent conclusions about the real clinical benefit of this technique over a monofocal ablation as well as about the real differences between the different presbyLASIK options that are currently available.

REFERENCES

1. Balgos MD, Vargas V, Alió J. Correction of presbyopia: an integrated update for the practical surgeon. Taiwan J Ophthalmol. 2018;8:121–40.
2. Vargas-Fragoso V, Alió JL. Corneal compensation of presbyopia: PresbyLASIK: an updated review. Eye Vis. 2017;4:11.
3. Shetty R, Brar S, Sharma M, Dadachanji Z, Lalgudi VG. PresbyLASIK: a review of PresbyMAX, Supracor, and laser blended vision: Principles, planning, and outcomes. Indian J Ophthalmol. 2020;68:2723–31.
4. Alió JL, Amparo F, Ortiz D, Moreno L. Corneal multifocality with excimer laser for presbyopia correction. Curr Opin Ophthalmol. 2009;20:264–71.
5. Zeng X, Zhang Y, Kwong JSW, Zhang C, Li S, Sun F, et al. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review. J Evid Based Med. 2015;8:2–10.
6. Kelly RE. Biliary problems in infancy and childhood. Probl Gen Surg. 1999;16:101–7.
7. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non- randomised studies of interventions. BMJ. 2016;355:i4919.
8. Moga C, Guo B, Harstall C. Development of a quality appraisal tool for case series studies using a modified delphi technique. IHE Publ. 2012:1–71. https://www.ihe.ca/advanced-search/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique. Accessed 2 June 2021.
9. Guo B, Moga C, Harstall C, Schopflocher D. A principal component analysis is conducted for a case series quality appraisal checklist. J Clin Epidemiol. 2016;69:199–207.e2.
10. Kohnen T, Böhm M, Herzog M, Hemkeppler E, Petermann K, Lwowski C. Near visual acuity and patient-reported outcomes in presbyopic patients after bilateral multifocal aspheric laser in situ keratomileusis excimer laser surgery. J Cataract Refract Surg. 2020;46:944–52.
11. Leray B, Cassagne M, Soler V, Villegas EA, Triozon C, Perez GM, et al. Relationship between induced spherical aberration and depth of focus after hyperopic LASIK in presbyopic patients. Ophthalmology. 2015;122:233–43.
12. Rahmania N, Salah I, Rampat R, Gatinel D. Clinical effectiveness of laser-induced increased depth of field for the simultaneous correction of hyperopia and presbyopia. J Refract Surg. 2021;37:16–24.
13. Boucenna W, Hagège A, Lussato M, Morfeq H, Kochbati E, Jany B, et al. PresbyPRK vs presbyLASIK using the SUPRACOR algorithm and micromonovision in presbyopic hyperopic patients: visual and refractive results at 12 months. J Cataract Refract Surg. 2021;47:878–85.
14. Avila MY, Vivas PR. Visual outcomes in hyperopic myopic and emmetropic patients with customized aspheric ablation (Q factor) and micro-monovision. Int Ophthalmol. 2021;41:2179–85.
15. Ganesh S, Brar S, Gautam M, Sriprakash K. Visual and refractive outcomes following laser blended vision using non-linear aspheric micro-monovision. J Refract Surg. 2020;36:300–7.
16. Liu F, Zhang T, Liu Q. One-year results of presbyLASIK using hybrid bi-aspheric micro-monovision ablation profile in correction of presbyopia and myopic astigmatism. Int J Ophthalmol. 2020;13:271–7.
17. Fu D, Zhao J, Zhou XT. Objective optical quality and visual outcomes after the PresbyMAX monocular ablation profile. Int J Ophthalmol. 2020;13:1060–5.
18. Fu D, Zhao J, Zeng L, Zhou X. One year outcome and satisfaction of presbyopia correction using the PresbyMAX® monocular ablation profile. Front Med. 2020;7:589275.
19. Luger MHA, McAlinden C, Buckhurst PJ, Wolffsohn JS, Verma S, Arba-Mosquera S. Long-term outcomes after LASIK using a hybrid bi-aspheric micro-monovision ablation profile for presbyopia correction. J Refract Surg. 2020;36:89–96.
20. Villanueva A, Vargas V, Mas D, Torky M, Alió JL. Long-term corneal multifocal stability following a presbyLASIK technique analysed by a light propagation algorithm. Clin Exp Optom. 2019;102:496–500.
21. Pajic B, Pajic-Eggspuehler B, Mueller J, Cvejic Z, Studer H. A Novel laser refractive surgical treatment for presbyopia: optics-based customization for improved clinical outcome. Sensors. 2017;17:1367.
22. Chan TCY, Kwok PSK, Jhanji V, Woo VCP, Ng ALK. Presbyopic correction using monocular bi-aspheric ablation profile (PresbyMAX) in hyperopic eyes: 1-year outcomes. J Refract Surg. 2017;33:37–43.
23. Vastardis I, Pajic-Eggspühler B, Müller J, Cvejic Z, Pajic B. Femtosecond laser-assisted in situ keratomileusis multifocal ablation profile using a mini-monovision approach for presbyopic patients with hyperopia. Clin Ophthalmol. 2016;10:1245–56.
24. Courtin R, Saad A, Grise-Dulac A, Guilbert E, Gatinel D. Changes to corneal aberrations and vision after monovision in patients with hyperopia after using a customized aspheric ablation profile to increase corneal asphericity (Q-factor). J Refract Surg. 2016;32:734–41.
25. Wang Yin GH, McAlinden C, Pieri E, Giulardi C, Holweck G, Hoffart L. Surgical treatment of presbyopia with central presbyopic keratomileusis: one-year results. J Cataract Refract Surg. 2016;42:1415–23.
26. Saib N, Abrieu-Lacaille M, Berguiga M, Rambaud C, Froussart-Maille F, Rigal-Sastourne JC. Central presbyLASIK for hyperopia and presbyopia using micromonovision with the Technolas 217P platform and SUPRACOR algorithm. J Refract Surg. 2015;31:540–6.
27. Soler Tomás JR, Fuentes-Páez G, Burillo S. Symmetrical versus asymmetrical presbyLASIK: results after 18 months and patient satisfaction. Cornea. 2015;34:651–7.
28. Luger MHA, McAlinden C, Buckhurst PJ, Wolffsohn JS, Verma S, Arba Mosquera S. Presbyopic LASIK using hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Am J Ophthalmol. 2015;160:493–505.
29. Gifford P, Kang P, Swarbrick H, Versace P. Changes to corneal aberrations and vision after Presbylasik refractive surgery using the MEL 80 platform. J Refract Surg. 2014;30:598–603.
30. Luger MH, Ewering T, Arba-Mosquera S. One-year experience in presbyopia correction with biaspheric multifocal central presbyopia laser in situ keratomileusis. Cornea. 2013;32:644–52.
31. Baudu P, Penin F, Arba, Mosquera S. Uncorrected binocular performance after biaspheric ablation profile for presbyopic corneal treatment using AMARIS with the PresbyMAX module. Am J Ophthalmol. 2013;155:636–47. 47.e1
32. Uthoff D, Pölzl M, Hepper D, Holland D. A new method of cornea modulation with excimer laser for simultaneous correction of presbyopia and ametropia. Graefes Arch Clin Exp Ophthalmol. 2012;250:1649–61.
33. Fernández J, Rodríguez-Vallejo M, Burguera N, Rocha-de-Lossada C, Piñero DP. Spherical aberration for expanding the depth of focus: a review for the anterior segment surgeon. J Cataract Refract Surg. 2021;47:1587–95.
34. Legras R, Benard Y, Lopez-Gil N. Effect of coma and spherical aberration on depth-of-focus measured using adaptive optics and computationally blurred images. J Cataract Refract Surg. 2012;38:458–69.

35. Benard Y, Lopez-Gil N, Legras R. Optimizing the subjective depth-of-focus with combinations of fourth- and sixth-order spherical aberration. Vis Res. 2011;51:2471–7.
36. Pinelli R, Ortiz D, Simonetto A, Bacchi C, Sala E, Alió JL. Correction of presbyopia in hyperopia with a center-distance, paracentral-near technique using the Technolas 217z platform. J Refract Surg. 2008;24:494–500.
37. Epstein RL, Gurgos MA. Presbyopia treatment by monocular peripheral presby-LASIK. J Refract Surg. 2009;25:516–23.

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COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

Correspondence and requests for materials should be addressed to David P. Piñero.