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BCLA CLEAR Presbyopia: Management with corneal techniques

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ABSTRACT

Corneal techniques for enhancing near and intermediate vision to correct presbyopia include surgical and contact lens treatment modalities. Broad approaches used independently or in combination include correcting one eye for distant and the other for near or intermediate vision, (termed monovision or mini-monovision depending on the degree of anisometropia) and/or extending the eye's depth of focus [1]. This report provides an overview of the evidence for the treatment profile, safety, and efficacy of the range of corneal techniques currently available for managing presbyopia.

The visual needs and expectations of the patient, their ocular characteristics, and prior history of surgery are critical considerations for patient selection and preoperative evaluation. Contraindications to refractive surgery include unstable refraction, corneal abnormalities, inadequate corneal thickness for the proposed ablation depth, ocular and systemic co-morbidities, uncontrolled mental health issues and unrealistic patient expectations.

Laser refractive options for monovision include surface/stromal ablation techniques and keratorefractive lenticule extraction. Alteration of spherical aberration and multifocal ablation profiles are the primary means for increasing ocular depth of focus, using surface and non-surface laser refractive techniques. Corneal inlays use either small aperture optics to increase depth of field or modify the anterior corneal curvature to induce corneal multifocality. Presbyopia correction by conductive keratoplasty involves application of radiofrequency energy to the mid-peripheral corneal stroma which leads to mid-peripheral corneal shrinkage, inducing central corneal steepening. Hyperopic orthokeratology lens fitting can induce spherical aberration and correct some level of presbyopia.

Postoperative management, and consideration of potential complications, varies according to technique applied and the time to restore corneal stability, but a minimum of 3 months of follow-up is recommended after

Abbreviations: CDVA, Corrected distant visual acuity; D, Dioptre; FDA, Food and Drug Administration (United States of America); ERSS, Ectasia Risk Scoring System; KLEx, Keratorefractive lenticular extraction; LASEK, Laser epithelial keratomileusis; LASIK, Laser *in situ* keratomileusis; OCT, Optical coherence tomography; Ortho-k, Orthokeratology; PRK, Photorefractive keratectomy; SMILE®, Small incision lenticule extraction (KLEx performed using Zeiss femtosecond laser); UDVA, Uncorrected distant visual acuity; UNVA, Uncorrected near visual acuity.

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corneal refractive procedures. Ongoing follow-up is important in orthokeratology and longer-term follow-up may be required in the event of late complications following corneal inlay surgery.

1. Overall purpose

Corneal strategies for correcting presbyopia include both surgical and contact lens treatment modalities and aim to enhance near and intermediate vision through achieving monovision and/or the expansion of the ocular depth of focus [2,3]. Monovision is a form of artificial anisometropia whereby one eye is targeted for emmetropia, while the contralateral eye is corrected for near or intermediate distances, and it relies on interocular blur suppression for clear binocular vision to be achieved at both targeted optical vergences [1,4]. Enhancement of depth of focus can be achieved by pinhole apertures, as well as by corneal shape modification techniques, such as excimer laser ablation that work by the induction of controlled spherical aberration or result in the creation of a multifocal corneal surface [2]. The ocular surface sites at which current modalities are targeted are represented schematically in Fig. 1.

The purpose of this report is to provide an overview of the evidence for the treatment profile, safety, and efficacy of currently available corneal techniques for the management of presbyopia, including monovision and multifocal laser vision correction modalities, corneal inlays, conductive keratoplasty, and orthokeratology (ortho-k). In addition, important considerations for preoperative assessment and patient selection, as well as postoperative management and potential complications are also highlighted.

2. Preoperative assessment/patient selection

Preoperative assessment and patient selection are essential in managing presbyopia, particularly when considering surgical intervention. Critical considerations for preoperative evaluation and patient selection include the visual needs and expectations of the patient, ocular characteristics, and prior history of surgery. Contraindications to refractive surgery include unstable refraction, corneal abnormalities (such as keratoconus or other corneal ectasias, thinning, oedema, interstitial or neurotrophic keratitis, or extensive vascularization), insufficient corneal thickness for the proposed ablation depth, visually significant cataract, uncontrolled glaucoma, uncontrolled external disease (e.g., blepharitis, dry eye disease, atopy/allergy), uncontrolled autoimmune or other immune-mediated diseases, diabetes, uncontrolled mental illness, including anxiety or depression, and unrealistic patient expectations [5,6].

2.1. Visual needs

Understanding the visual requirements of the patient in relation to their occupation, hobbies, working distances, and lifestyle is critical for any optical correction. For corneal techniques, this is especially true since some surgical procedures are irreversible. In general, patients with high visual demands (such as those requiring excellent stereoacuity and contrast sensitivity under various lighting conditions, for example, pilots, drivers, or athletes) may be poor candidates for monovision [7,8] or treatments that significantly elevate higher order aberrations [9]. These patients need to be counselled that an optical over-correction may be required to improve vision in some circumstances. Importantly, litigation in relation to unsatisfactory results following corneal refractive surgery is often related to issues with glare, haloes, or night driving difficulties [10], so a complete understanding of the patient's visual needs is paramount.

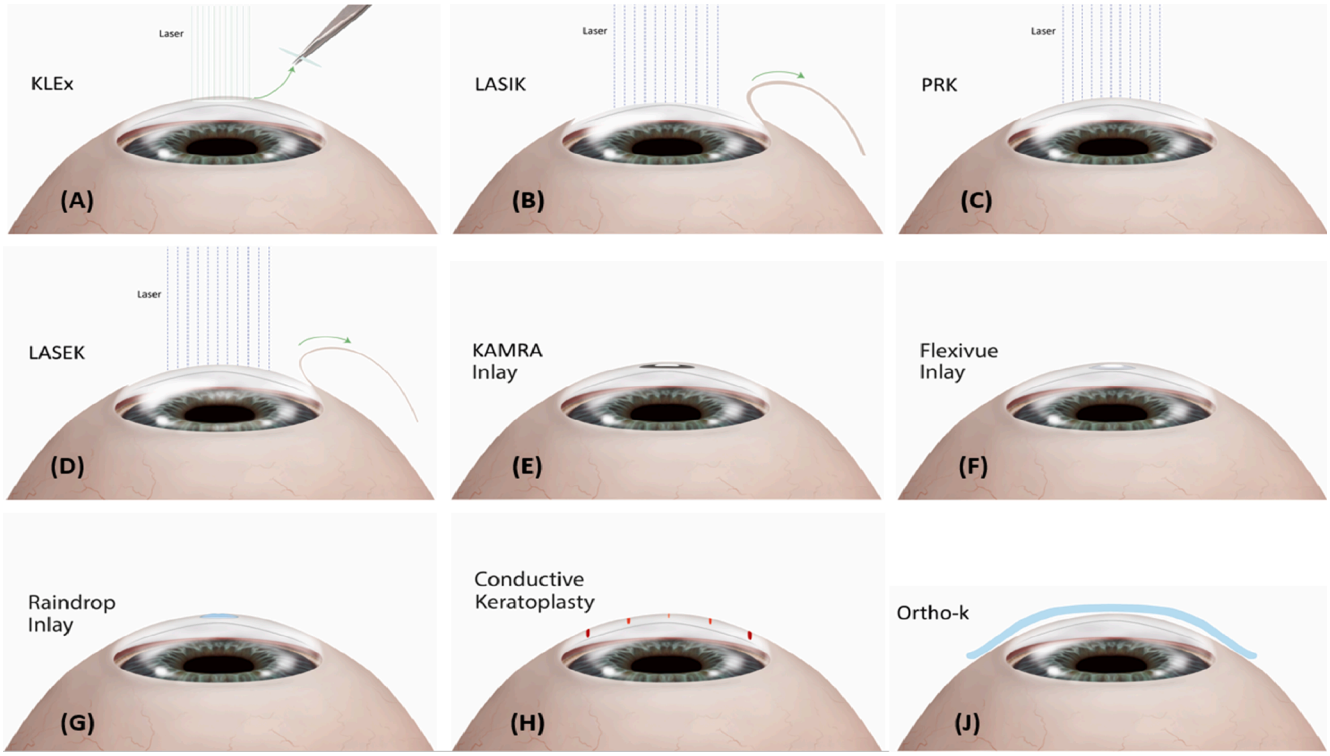

Fig. 1. Corneal techniques for managing presbyopia: (A) Keratorefractive lenticular extraction (KLEx); (B) Laser in situ keratomileusis (LASIK); (C) Photorefractive keratectomy (PRK); (D) Laser epithelial keratomileusis (LASEK); (E) KAMRA™ inlay; (F) Flexivue Microlens™ inlay; (G) Raindrop® Near Vision inlay); (H) Conductive keratoplasty; (J) Orthokeratology (Ortho-k).

2.2. Age

Patients aged approximately 45 to 55 years are potential candidates for presbyopic corneal techniques, since older presbyopes are likely to have lenticular changes and may have better visual outcomes with cataract surgery [11]. Importantly, as the patient continues to age, and their presbyopia continues to naturally progress following a corneal procedure, the treatment efficacy diminishes.

2.3. Refraction

The distant (spherical ametropia and astigmatism) and near (required addition) refractive limits vary for each corneal technique (see Section 3).

2.3.1. Distant refractive error limits

Corneal surgical techniques have been approved for the correction of a wide range of distant refractive errors. Some lasers have Food and Drug Administration (FDA) approval for LASer *In situ* Keratomileusis (LASIK) correction of up to −14.00 dioptres (D) of myopia with up to 6.00D of astigmatism, and up to +6.00D of hyperopia with up to 5.00D of astigmatism) [12]. However, whether an individual's refractive error is suitable for treatment will depend upon the laser available, surgeon preference, and the eye's physical characteristics (such as corneal thickness and estimated residual stromal thickness post-treatment) [13]. Ortho-k can be used to reliably correct a narrower range of refractive errors (up to approximately 6.00D of myopia and 1.75D of astigmatism), with no ortho-k contact lenses currently approved for the treatment of hyperopia [14]. Conversely, conductive keratoplasty which induces corneal steepening, is suitable only for the correction of hyperopic distant refractive errors (original FDA approval for +0.75 to +3.00D with up to 0.75D of astigmatism [15]). Corneal inlays are not intended to alter distant refractive error and therefore are utilised only in the non-dominant eye of emmetropic presbyopes (distant refractive error of up to approximately ± 1D) [16].

2.3.2. Near refractive error limits

The majority of corneal reshaping treatments can provide a near addition correction up to approximately +2.00D, although some can extend up to +3.50D. For monovision corrections using surgical techniques such as LASIK and keratorefractive lenticule extraction (KLEx), (such as SMall Incision Lenticule Extraction (SMILE®))[17], the maximum near addition prescribed is typically less than approximately +2.00D in the non-dominant eye to minimise potential issues related to reduced stereopsis and patient intolerance [18]. For conductive keratoplasty, various nomograms provide up to +2.25D in the non-dominant eye [15]. Currently no studies have described the use of monovision in ortho-k for presbyopic myopes; however, the use of unilateral hyperopic ortho-k to treat presbyopia in emmetropes has produced refractive outcomes often substantially below the target near addition by up to 2.00D [19].

In addition to rendering the non-dominant eye myopic via traditional monovision (approximately +1.50D near addition), Laser Blended Vision (Carl Zeiss Meditec, Jena, Germany) or mini-monovision of up to 1.00D of induced anisometropia, also induces positive spherical aberration in both the distant and near eyes (for example, an average 0.20 μm increase for a 6 mm pupil [20]) to increase the depth of field, inducing a distant centre multifocal effect in the non-dominant eye (see also Section 3.1.1). The Custom-Q nomogram (Alcon Laboratories, Texas, USA) uses a similar approach (an aspheric ablation profile in the non-dominant eye) aiming for approximately −0.40 μm of negative spherical aberration in the near eye over a 6 mm pupil inducing a near centre multifocal effect [21]. This modified monovision approach has the advantage over a standard monovision approach of extending the range of clear vision for intermediate working distances.

The Supracor™ (Bausch & Lomb) and PresbyMAX® (Schwind) platforms (central presbyLASIK) can be used to target mild myopia (−0.50D in each eye) for distant correction, with near additions up to approximately +2.00D (see Section 3.1.3.1)[22]. Synthetic inlays can accommodate a slightly wider range of near additions ranging from approximately +1.00D to +3.50D depending on the specific inlay [23].

2.3.3. Working distance

The working distance required for a particular task is influenced by a number of factors, including the nature of the task (such as target size/detail, office ergonomics, and lighting conditions), the optical correction, pupil size, and depth of field. In a study of the habitual working distances of 59 presbyopes aged 45–63 years, all near/intermediate tasks were undertaken at working distances from 30 to 60 cm (equating to 1.7 to 3.3D in accommodative demand) [24]. Understanding the nature of the visual tasks undertaken by each patient, and their expectations (for example, total spectacle independence) should guide corneal treatment selection in each eye to ensure an appropriate range of clear vision.

2.4. Physical characteristics

(Also see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25].

2.4.1. Tomography/topography

In the pre-surgical workup, anterior topographical data can be used to assess corneal regularity or warpage following the cessation of contact lens wear [26], the habitual level of corneal higher order aberrations can be evaluated, and corneal asphericity (such as the Q-value) can be used to customise surface modifications in some procedures (such as Custom-Q) [27]. Both corneal topography and tomography can screen for pre-existing corneal ectasia which is a contraindication for some corneal surgeries [12].

2.4.2. Pupil size

The entrance pupil size (the pupil imaged through the cornea), and pupil reactivity, directly impact the quality of vision for any technique that aims to induce corneal multifocality (where the refractive power varies across the cornea). For example, in central presbyLASIK the near correction is located within the central approximately 3 mm, and for peripheral presbyLASIK the near addition is located within a mid-peripheral annulus (beyond the central approximately 5 mm) [22]. Centration of the optical correction relative to the entrance pupil/line of sight is also critical, since an offset will generate greater coma and primary spherical aberration compared to a centred treatment [28,29]. Pupil diameter can also influence treatment selection (for example, wavefront-guided ablation or procedures that can provide a larger treatment zone to accommodate larger pupils) [13].

2.4.3. Aberrometry

The measurement of total ocular aberrations (the combination of anterior corneal and internal aberrations) can be used to screen for potential internal optical anomalies not detected by anterior corneal topography. Aberrations vary in keratoconus [30,31] and cortical (root mean square [RMS] coma) and nuclear cataract (RMS spherical aberration) [32], and provide an estimate of pre-treatment quality of vision based on the point spread function. Aberrometry may also be used to plan for customised corneal techniques [33].

2.4.4. Pachymetry

Corneal pachymetry plays an essential role in patient selection for corneal procedures since a minimum residual stromal thickness is required for some surgical procedures to minimise the likelihood of post-operative ectasia (for example, for LASIK, modelling predicts a safe minimum target residual stromal bed thickness of approximately 250 μm, ranging from 220 to 361 μm [34]). Central corneal thickness values

can also play a role in the assessment of intraocular pressure [35] and detection of keratoconus [31].

2.4.5. Visual acuity

Pre-treatment measurements of distant and near visual acuity (such as optimally corrected vision) provide an important baseline measure of visual function. Monocular distant visual acuity (in conjunction with pinhole acuity) can highlight possible pathology of the eye or visual pathway and, in instances where visual acuity is reduced, (for example, mild amblyopia) patients should be advised that any procedure will be unlikely to improve upon this level of acuity.

2.4.6. Contrast sensitivity

Since most corneal corrections elevate anterior corneal higher order aberrations (particularly primary spherical aberration), this can significantly impair contrast sensitivity (such as low contrast acuity/discrimination), and more so under low lighting conditions for larger pupil diameters [36,37]. Therefore, contrast sensitivity testing may form part of a preliminary assessment to exclude patients with pre-existing contrast sensitivity loss (for example, due to elevated corneal aberrations, lenticular changes, retinal or optic nerve pathology). In addition, monovision corrections also reduce contrast sensitivity for higher spatial frequencies [7].

2.5. Previous surgery

Prior ocular surgeries can influence the timing and choice of the corneal technique for correcting presbyopia.

2.5.1. Prior refractive surgery

2.5.1.1. Radial keratotomy. Many techniques can be used to correct residual refractive error after radial keratotomy including excimer laser techniques such as LASIK and PhotoRefractive Keratectomy (PRK), multifocal intraocular lens (IOL) implantation and contact lenses [38–41]. However, following radial keratotomy it can be difficult to predict the postoperative outcome due to refractive instability and the abnormal corneal shape since post- radial keratotomy corneas are relatively proportionally flattened on both the anterior and posterior surfaces of the cornea [42]. Consequently, for post-radial keratotomy eyes, a monovision correction may provide the best possible outcome [8].

2.5.1.2. LASIK and penetrating keratoplasty. Patients who previously underwent LASIK for distant refractive error correction can potentially undergo retreatment for presbyopia (monovision, multifocal LASIK), depending on various factors, primarily the residual stomal tissue thickness [43]. Corneal techniques have also been used to correct residual distant refractive error following penetrating keratoplasty [44–47], and could also be applied to correct for presbyopia.

2.5.2. Prior intraocular surgery

2.5.2.1. Cataract surgery. LASIK or PRK are used in some cases to enhance visual outcomes post-cataract surgery [48]. Patients who have previously undergone cataract surgery and multifocal IOL implantation and are dissatisfied with the visual outcome, may benefit from a corneal technique [49]. In such cases, corneal stability following cataract surgery is essential to ensure a predictable refractive outcome.

2.5.2.2. Glaucoma surgery and scleral buckle. Surgeries that significantly alter the conjunctival anatomy (such as bleb-forming glaucoma surgery or scleral buckle) can impact the placement of the suction ring during LASIK surgery and therefore alternative corneal techniques may need to be considered. Patients undergoing corneal surgery following a scleral buckle should be informed that refractive error may change over time due to axial elongation or changes in corneal curvature related to the buckle [50].

2.6. Contact lens trial of monovision tolerance

'Success' rates reported for monovision with refractive surgery is high (range 80 to 98 %), but this is difficult to compare with other presbyopia management options due to this approach being more challenging to reverse [51]. Patient selection and clinical screening are essential for monovision success. For example, distant esophoria, and a reduction in binocular near visual acuity and stereopsis during monovision indicate a poor prognosis for successful monovision correction [52]. Visual demands should also be considered, such as tasks requiring excellent hand-eye coordination ability, in which depth perception is necessary for both fine-motor and gross-motor skills [53]. Occupations such as construction workers, airline pilots, and bus drivers may also require impeccable depth perception [54]. Prior to undergoing corneal surgery for monovision, it is recommended that patients should trial monovision with contact lenses to assess tolerance and likely visual outcomes [55], but this recommendation is based on limited case studies and a retrospective case evaluation [56–58]. However, patients should be made aware that the actual visual experience following corneal surgery may differ from the contact lens trial due to elevated higher order aberrations induced by surgery [3].

2.7. Binocular function, stereoacuity, motility and ocular dominance

Refractive correction at the corneal plane (surgery or contact lenses) moves with the eyes during convergence which results in different accommodative and convergence demands than those experienced with spectacle correction. For example, a contact lens-wearing myope will have an increased convergence demand at near compared to that with their spectacle correction due to the loss of the base-in prismatic effect [59]. Therefore, a binocular vision screening for near heterophoria is appropriate as corneal-based corrections may be unsuitable for patients with a large near exophoria. Despite a lack of evidence (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25] measurement of ocular dominance is typically used to determine which eye (typically the dominant sighting eye) should be corrected for distant vision (such as driving). However, a crossed monovision approach (where the dominant eye is corrected for near and the non-dominant eye for distant vision) can also be used depending on patient preference as determined by a contact lens trial prior to surgery [7].

2.8. Existing ocular health

A comprehensive assessment of ocular health is an essential part of any patient evaluation. Many ocular conditions (such as ocular surface and lid disease) can be addressed prior to initiating a treatment, while other conditions (such as corneal ectasia) constitute a contraindication for corneal surgery.

2.8.1. Ocular surface disease

Dry eye is a multifactorial disease of the ocular surface characterized by a loss of tear film homeostasis [60]. Moderate-to-severe dry eye may be a contraindication for refractive surgery because post-surgical corneal recovery can be impaired, increasing the risk of chronic dry eye [61]. Other anterior eye conditions such as blepharitis are relative contraindications for refractive procedures and can be managed therapeutically prior to undergoing surgery [62].

2.8.2. Corneal considerations

For some corneal refractive surgeries, such as LASIK, the minimum thickness of the central cornea prior to surgery should be carefully considered [63,64]. The postoperative corneal stromal bed thickness

should be preserved at 250 μm or more, to reduce the risk of post-operative ectasia, with a corneal endothelial density no lower than age-appropriate minimum values of 2000 cells/mm^2 for ages 45–55 years, and 1500 cells/mm^2 for ages 56 years and older [65]. Other absolute contraindications for corneal refractive surgery can include corneal scars or opacities, corneal ectasia, and corneal topographic irregularities [66].

2.8.3. Crystalline lens considerations

Patients with visually significant cataracts usually may achieve more successful visual outcomes through IOL implantation than corneal procedures [11]. Consequently, assessment of the crystalline lens and measures of intraocular scatter are important preoperative assessments. The Objective Scattering Index is a metric that quantifies light scatter as a metric that quantifies light scatter calculated as the ratio between the light in a peripheral annular area (from 12 to 20 min of arc) and the central peak (1 min of arc) [67]. In general, eyes with an Objective Scattering Index value less than 1.0 are unlikely to have visually significant cataracts, while a value between 1.5 and 4 indicates an eye with aberrations or media opacities. An Objective Scattering Index greater than 4 indicates a high likelihood of media opacities such as cataracts [68,69].

2.8.4. Retinal pathology

A detailed, dilated, fundus examination should be performed to identify posterior ocular disease that may impact visual outcomes [70]. LASIK for patients with glaucoma or ocular hypertension is controversial because of the substantial increase in intraocular pressure (up to 53 mmHg has been reported) and potential damage to the optic nerve during the suction forces required for flap creation [71]. In such cases, LASer Epithelial Keratomileusis (LASEK) and PRK, in which a suction ring is not used, are more suitable as a marked rise of intraocular pressure during the procedure, that risks potential damage to the optic nerve during the suction process required for flap creation, is avoided [72].

2.9. Risk assessment

Although elective corneal surgery outcomes have become more reliable over time with the use of improved technology, iris recognition and eye tracking, all corneal surgery carries an element of risk. It is important to consider the risk of adverse events, particularly those that can cause a reduction in visual ability, due to the irreversible nature of most refractive surgery.

Corneal ectasia following LASIK treatment is one of the most feared complications, as it can cause progressive irreversible visual impairment. The rate of occurrence is estimated to be between 0.03 % and 0.66 % of treated eyes [73,74 75], and there has been considerable research into developing a scoring system to identify eyes at risk.

2.9.1. Ectasia risk scoring

The Ectasia Risk Scoring System (ERSS) (Table 1) uses five variables to calculate a cumulative risk score, including corneal topography, expected residual stromal bed thickness, age, preoperative corneal thickness, and preoperative spherical equivalent refraction. Each factor is scored on a risk scale from 0 to 4, with a score of 0 indicating minimal or no risk, and a score of 4 indicating the highest grade of risk. A cumulative score of between 0 and 2 indicates low risk, a score of 3 suggests moderate risk, and scores of 4 or higher indicates high-risk eyes [76]. The ERSS has been reported to be a valid approach for detecting eyes at greater risk of developing corneal ectasia [76–78], although suggestions of including the presence of recent refractive changes has been advocated [79].

2.9.2. Percentage tissue altered

Another proposed approach for assessing post-LASIK ectasia risk is to use the percentage tissue altered formula [80]. This calculation uses the estimated proportion of the cornea that would be removed during surgery – with greater amounts of corneal tissue removed being associated with higher risk – to estimate the risk of corneal ectasia. The formula to calculate percentage (proportion) tissue altered is:

$$\frac{FT + EAD}{CCT} = PercentageTissueAltered$$

Where:
FT = flap thickness.
EAD = estimated ablation depth.
CCT = central corneal thickness.

It has been suggested that a percentage tissue altered of 40% or more is strongly associated with the risk of developing corneal ectasia post-surgery in eyes that have normal corneal topography, correlating more strongly than with other risk factors, including the ERSS [80]. This may suggest that the anterior cornea accounts for the greater impact on the biomechanical properties of the corneal stroma; the anterior stroma has more lamellae and fibril intertwining than the posterior 60 % of the stroma, indicating a greater tensile strength anteriorly [81–83]. However, other studies have not found a greater occurrence of corneal ectasia in cases with a percentage tissue altered of greater than 40 % in the presence of normal corneal topography or tomography [74,84–86]. This may be because of differences in study populations [84] or intrinsic assumptions within the metric as it cannot account for corneal tissue volume [85], rigidity, strength, or curvature. It may be useful to use a combination of the percentage tissue altered and ERSS to more comprehensively assess the risk of post-surgical ectasia.

2.9.3. Corneal biomechanics

With the development of instruments to assess corneal biomechanics, there has been interest in whether this can usefully supplement topographical assessment of the risk of ectasia. The biomechanical behaviour of the cornea has been shown to identify signs of ectasia even before they are apparent on topo/tomographic maps [87–89]. In a retrospective chart review of 128 eyes that developed corneal ectasia despite normal topography compared to 134 healthy controls, combining the tomographic data of the Pentacam with the Corvis (both manufactured by Oculus), using artificial intelligence, demonstrated the best accuracy and the highest effect size for differential diagnosis of normal eyes from the eyes with asymmetric contralateral corneal ectasia with normal

Table 1
The Ectasia Risk Score System for identifying eyes at risk of developing corneal ectasia after LASIK [76].

Factor	*Risk Points*				
	4	*3*	*2*	*1*	*0*
Corneal Topography	Abnormal Topography	Inferior Steeping/Skewed Radial Axis		Asymmetric Bowtie	Normal/Symmetric Bowtie
Residual Stromal Bed Thickness (μm)	<240	240–259	260–279	280–299	≥300
Age (years)		18–21	22–25 yrs	26–29	≥30
Preoperative Corneal Thickness (μm)	<450	451–480	481–510		≥510
Preoperative Spherical Equivalent Manifest Refraction (D)	>−14	>−12 to −14	>−10 to −12	>−8 to −10	−8 or less

topography [90]; the corneal resistance factor had a higher detection ability than corneal hysteresis (Reichert Ocular Response Analyzer).

2.10. Patient expectations, counselling, and psychological aspects

For all potential treatments, it is important to understand patient expectations prior to surgery in seeking the highest level of patient satisfaction [91]. LASIK for distant vision correction has been associated with high patient satisfaction rates, typically over 90 %, and this is linked to setting realistic patient expectations prior to the surgery [92–94]. However, corneal options for presbyopic vision correction tend to have a lower rate of patient satisfaction and lower spectacle independence of 85 % [95], and therefore it is important that patient expectations of the visual outcomes are managed appropriately, according to the presbyopic correction approach.

Good communication and employing a patient-centred approach [96] at all stages is recommended, as it is important to develop and maintain a good clinician-patient relationship throughout the patient journey [97]. Such a relationship may improve patient-perceived outcomes, as the experience with the surgeon and surgical environment has been shown to be an important element of patient-reported satisfaction [98].

Taking time to manage patient expectations by informing patients of the expected result, potential risks, and the expected timeline and process for recovery, is likely to improve patient satisfaction outcomes [99]. This can be conveyed in various formats, including direct discussion between the patient and practitioner, providing further reading materials, and information accessible in other formats such as videos prior to surgery [100]. Providing information in multiple formats, that also allows the patient to take information away, may be of benefit as it reduces reliance solely on patient memory from the consultation or appointment [101]. However, scientific evidence supporting one approach over another, is lacking.

Patients should be advised of commonly reported difficulties after surgery, such as post-LASIK dry eye (see Section 2.8.1)[102]. This is particularly important for patients who appear to be at greater risk pre-surgery; patients who report symptoms of dry eye prior to surgery are more likely to complain of post-LASIK dry eye [103]. Discussing the potential need for further enhancements may also be appropriate for patients with an older preoperative age, greater level of astigmatism, or higher initial refractive error, as there is a higher likelihood in such cases of requiring further surgery or enhancements [104,105]. To avoid this being perceived as failure of the initial surgery, which can result in reduced patient satisfaction [98], it may be beneficial to discuss the possibility of subsequent enhancement prior to the first treatment.

Older patients undergoing refractive surgery have reduced satisfaction outcomes compared to younger patients [106], although this observation has not always been consistent [98]. Providing thorough counselling prior to surgery, including detailed descriptions of the presbyopic options available and how they work (such as monovision or presbyLASIK ablation profiles) might be expected to help reduce the risk of dissatisfaction. Understanding patients' visual habits, such as a strong preference for sighting in one eye may help determine suitability for monovision, and discussion of the expected visual outcomes and risks of the monovision approach, such as loss in contrast sensitivity, binocular visual acuity, or reduced stereopsis is recommended (see Section 2.6).

2.11. Anticipated longevity of treatment effect

The expected longevity of a treatment effect should be discussed clearly with all patients, so that they are able to make an informed decision. Increased use of digital devices at a close working distance, and a greater number of people working to an older age due to later retirement may have contributed to surgical intervention becoming an increasingly attractive option for presbyopic correction [107], but it also means that the expectations regarding the longevity of the treatment effect are likely to increase.

Long-term patient satisfaction rates with corneal laser surgery appears to be high; for example 91 % of patients indicated satisfaction 5 years post-surgery in one study [98], although this report primarily involved participants of non-presbyopic age, for which vision correction for presbyopia was not required. However, reports looking at long-term follow-up in presbyopic patients are limited, as the mean follow-up of published studies is less than 18 months [95]. One study showed a sustained improvement in distant and near vision 5 years after presby-LASIK surgery [108]. Studies investigating the KAMRA™ (AcuFocus, CA, USA) intracorneal inlay have demonstrated longer-term success; one 4 year follow-up study reported improvements in unaided near visual acuity without significant distant vision loss [109], and another found reasonable visual outcomes, at all distances, 60 months post-operation [110]. A further study investigating outcomes for conductive keratoplasty for the treatment of presbyopia after 3 years, found 78 % of participants still had a binocular uncorrected distant visual acuity (UDVA) of 6/6 (20/20) and uncorrected near visual acuity (UNVA) of J3 (Jaeger score) or better, with stable keratometry [111]. Ongoing research examining long-term visual outcomes and patient satisfaction beyond 5 years is required, particularly if surgery is performed in the early stages of presbyopia (before 50 years of age), due to the progressive visual changes expected over at least the ensuing decade.

2.12. Financial implications

Refractive surgery is typically classed as an elective surgical procedure. The financial considerations of refractive surgery may vary depending on the type of procedure selected, surgeon choice, and surgical site. Generally, the cost of refractive surgery can be significant, with supplementary fees for preoperative testing, prescribed medications, and postoperative care. Insurance or national healthcare coverage for refractive surgery is very uncommon, and therefore there is a substantial additional cost consideration for potential patients. Although the initial costs may be considerably expensive, successful refractive surgery has potential to offer long-term cost savings when considered relative to the ongoing expense of spectacles, contact lenses, and associated care over time [112].

3. Corneal treatment options in presbyopia management

3.1. Laser refractive correction presbyopia management options

3.1.1. Monovision laser refractive correction modalities

3.1.1.1. Surface ablation procedures for monovision. Monovision with laser vision correction is the earliest surgical corneal reshaping technique for addressing presbyopia. It involves correcting the distant dominant eye with a target of plano and the non-dominant eye for reading with a target range from −0.25 to −2.25D depending on the level of residual accommodation of the patient [113]. Limited recent research has been published on monovision laser technique outcomes in isolation.

Binocular visual function and patient satisfaction, following monovision induced by PRK has been assessed in 21 myopic presbyopic patients, who all required no reading glasses postoperatively, with all but one maintaining binocular visual acuity of 20/25 or better [114]. All patients maintained binocular fusion, and stereo acuity ranging from 40 to 800 s of arc, and mean patient satisfaction was 86 % (ranging from 40 % to 100 %) [114].

3.1.1.2. LASIK for monovision. In 2007, the FDA approved LASIK treatment for monovision [https://www.ophthalmologytimes.com/view/fda-approves-customized-monovision-lasik-0]. There are reports that the percentage of satisfied patients is greater with LASIK than

with contact lens wear, as high as 98 % [57,115–117]. There may be some element of selection bias given that surgeons may rely on a successful monovision contact lens trial prior to proceeding with monovision LASIK (see Section 2.6). However, the majority of this effect is thought to be due to the induction of small amounts of spherical aberration during laser vision correction which increases the depth of focus and hence the tolerability of monovision with LASIK compared with contact lens wear. Relatively few studies provide detailed data on the visual quality of patients who have undergone LASIK to achieve monovision. Where data are provided, a slight decrease in contrast sensitivity and stereopsis has been observed in the monovision group compared with distant only correction [118]. A retrospective study of 284 consecutively treated LASIK patients, aged 45 years or older, reported that 188 chose monovision [119]; while most chose their dominant eye for distant vision (85 %), those that didn't, had a similar outcome. Of the 172 treated with monovision, 7 % chose to forego monovision and subsequently enhance the near eye to distant vision and 28 % underwent subsequent enhancement of their distant vision eye.

3.1.1.3. Lenticule extraction for monovision. Early laser refractive lenticule extraction procedures were performed with a conventional LASIK flap but since 2007 lenticule extraction has been possible using a femtosecond laser, in a procedure termed Femtosecond Lenticule Extraction (FLEx) [120]. Within a few years a modification of the FLEx procedure, termed SMILE®, was developed [121–123]. This proprietary KLEx procedure obtained FDA clearance in 2016 and rapidly gained popularity around the globe (Fig. 1A). As SMILE offered comparable outcomes to LASIK (Fig. 1B) it was quickly adopted for monovision treatments, although data confirming its efficacy in correcting presbyopia relative to LASIK monovision remains limited. The first published outcomes from SMILE monovision (2018) [124], found postoperatively that 90 % of 49 patients had a binocular UDVA of 20/20 or better and 84 % of those could read J2 or better. Complete spectacle independence was achieved by 84 % of patients and independence from reading glasses was achieved in 92 % of cases. No patient requested refractive enhancement or monovision reversal. The study showed similar safety and efficacy profile for SMILE monovision compared to LASIK monovision and this finding has been corroborated by others [125].

3.1.2. Spherical aberration induction offering multifocality and increased range of focus

Disadvantages of monovision include anisometropia, reduction of stereopsis and, in patients undergoing higher amounts of monovision induction, loss of uncorrected intermediate vision, particularly in those who have lost most of their natural accommodative function. For these reasons, in more recent years, surgeons have started to explore methods of inducing shape alteration using a laser for the purpose of increasing the range of focus in the treated eye(s) through inducing higher-order-aberrations [126]. Some authors describe the different zones of power on the cornea as being multifocal. Either the central portion of the cornea can be targeted for increased near vision with the mid-peripheral cornea targeted more for distant vision or vice versa.

Historically, corneal surgical correction of presbyopia has been associated with some loss of distant vision and contrast perception, leading to reduced quality of vision [127]. This is presumed to be due to corneal aberrations which are induced to increase the range of focus [128]. The detrimental impact is higher for more aggressive presbyopic treatments which aim to provide greater levels of functional vision with an increased range of focus [129]. To mitigate this, newer blended vision approaches have been developed [22], as well as treatments that aim for a different range of focus in the eyes corrected for distant and near vision [130]. These losses seem less evident under binocular than monocular examining conditions [131]. This observation has led to the hypothesis that monocularly treated patients receiving the presbyopic treatment in the eye deemed non-dominant for distant vision may have an advantage for distant vision compared to patients receiving presbyopic treatment binocularly, while retaining most of the gains in near vision [132]. This is a more physiological approach than intraocular multifocality as it has less detrimental impact on distant vision and visual quality. It also allows any residual accommodative function in the crystalline lens to be fully utilised by the patient which allows for a more natural range of vision. Further, it can be reversed (and far less invasively than explantation and replacement of an IOL) and, in the event of perceived night vision difficulties when driving, spectacle use (if needed), represents an easy and straightforward solution.

Better quality of vision has been reported in patients treated with presbyopia-correcting LASIK via controlled spherical aberration induction than with contact lens monovision [133]. A LASIK study where the dominant eye of 25 patients was corrected for distant vision and the non-dominant eye for near vision (by targeting 1.25 D of myopia) found improved functional near vision while distant vision remained good 3 months postoperatively, although contrast sensitivity and stereoacuity were significantly diminished [134]. Another study involving mostly PRK (Fig. 1C) and inducing a lower amount of asphericity in both eyes and lower myopia in the non-dominant eye, showed good functional UNVA with no loss of stereoacuity or contrast sensitivity [135]. Others have demonstrated effectiveness using the same laser platform (Alcon Wavelight EX 500) when simultaneously correcting presbyopia and hyperopia, in which case positive spherical aberration was modified in the dominant eye [133].

3.1.2.1. Laser blended vision. Non-linear aspheric micro-anisometropia LASIK using the PRESBYOND® Laser Blended Vision software (Carl ZEISS Meditech, Jena, Germany), modifies corneal spherical aberrations depending on the existing algebraic sign [20,143,144], resulting in different focal distances for each eye. All PRESYBOND-treated commercial and military pilots achieved Class 1 Medical Certification and reported improved functionality compared to previous vision correction methods [145].

3.1.3. Multifocal laser vision correction modalities

Most of the published literature pertaining to laser vision correction modalities for presbyopia correction in addition to, or combined with, standard or mini-monovision, involves LASIK and is entitled presbyLASIK or multifocal LASIK. However, the same corrections and excimer laser shape alterations possible with LASIK are also possible with surface laser correction using PRK, LASEK or epithelial (epi)-LASEK (Fig. 1D). Indeed, effects of presbyopia have been found to be delayed secondary to inducing corneal aberrations during PRK for myopia [136]. Modification of spherical aberration appears to be one of the key factors in corneal presbyopia correction [137].

Corneal lenticule extraction techniques in use at the time of writing, namely SmartSight (Schwind), CLEAR (Ziemer) and refractive lenticule extraction (branded SMILE®, Zeiss) do not currently have the capability of inducing additional shape change in the cornea beyond refractive correction and thus at present are suitable only as a means of achieving monovision.

3.1.3.1. Central multifocal corneal ablation. Bi-aspheric multifocal ablation techniques create a prolate corneal shape and the controlled induction of negative spherical aberration combined with induction of a low amount of myopia [128], increasing depth of focus [131,138]. The individual (distant) refractive correction is applied over the entire optical zone progressively becoming hyperprolate towards the centre. This shape is influenced by the desired amount of near addition, such that the higher the addition the more powerful the centre becomes [129]. This concept for presbyopia management incorporates residual myopic defocus in the eye intended for near vision ('near eye'), which can be altered to induce more or less myopia combined with lower or higher near additions (via lesser or greater induction of negative spherical

aberration) [130].

The outcomes of this technique, described as simultaneous correction of presbyopia and ametropia using a bi-aspheric cornea modulation technique, have been investigated [128]. The success of the treatment technique is based on the creation of a more positive corneal zone centrally for near vision with the pericentral corneal reserved for far vision.

Different versions of the profile are depicted in Figs. 2 and 3 for an emmetrope. It is seen that for the eyes intended for distant vision, distant-only aspheric optimisation takes place plus a hyperpositive central aspheric region, whereas for near eyes a residual myopic defocus is targeted.

It has been shown that whilst uncorrected intermediate and near vision is improved using either the monovision or hybrid variants of PresbyMAX, corrected distant visual acuity (CDVA) is reduced [127]. For this reason a monocular approach has become more popular in an attempt to maintain optimal distant vision and visual quality, while enhancing unaided intermediate and near vision (in the near eye) through the increased range of focus concept.

The monocular approach of the PresbyMAX profile (Fig. 3) involves correcting one eye fully for distant vision using an aberration-free profile; while correcting the contralateral eye for near with an increased range of focus ablation [139].

After monocular PresbyMAX, UDVA is on average 3 lines better in the distant eye than the near eye, although for the near eye, UDVA averages 20/40 to 20/32, with almost 50 % reaching 20/32 or better. UDVA of 20/20 or better is achieved in almost all of the distant eyes; with an UNVA of J2 or better achieved by 94 % of the patients (binocularly) confirming the hypothesis regarding the potential advantages of monocular presbyopic corneal correction [140].

The Supracor software (Bausch & Lomb) creates a 12 μm elevation beneath a conventional LASIK flap, with negative spherical aberration induced in the central cornea surrounded by an aspheric-optimized midperipheral zone (Fig. 1B). The central hyperprolate area serves to extend the eye's depth of focus by an amount approximately equal to 2.00D of near addition. During the physiological near response the pupil constricts and the central hyperprolate cornea becomes responsible for the visual function, improving near vision. Without the physiological near reaction in place, the larger pupil area results in a mixed image from the central hyperprolate corneal area and the peripheral aspheric, distant vision targeted cornea. A retrospective analysis of 50 eyes of 25 patients reported that the procedure offered a binocular mean UDVA of 0.02 logMAR with 92 % of patients achieving J2 or better binocular UNVA [141]. The authors reported a perceived need for careful patient selection to minimise unanticipated outcomes.

3.1.3.2. Peripheral multifocal corneal ablation. Pseudoaccommodative advanced surface ablation (NIDEK, Gamagori, Japan) has previously been reported to improve UDVA and UNVA in both myopic and hyperopic patients, as well as enhance modulation transfer function [142].

3.2. Corneal inlays

These inserts are placed at various depths in the corneal stroma to improve near vision [146,147].

3.2.1. Synthetic inlays

Synthetic corneal inlays are made from artificial materials, such as acrylic, hydrogel or silicone. These inlays (Fig. 1E–G and Fig. 4) are designed to improve near vision by changing how light enters the eye, helping the eye focus on close-up objects.

3.2.2. Designs

The first corneal inlay to receive FDA approval (KAMRA in 2015), uses small-aperture optics to increase the depth of field of the patient without a change in refractive lens power. Using inlays with small openings effectively blocks the bending of light rays, minimizing refraction and improving near vision [146]. The current model has 8400 laser-etched perforations varying between 5–11 μm that facilitate the passage of nutrients, water, and oxygen through the cornea.

Refractive optic inlays (such as the Presbia Flexivue Microlens™) alter the refractive index of the light path through the cornea. Distant vision is achieved through a central plano zone, and near vision through one or more refractive peripheral zones. Corneal reshaping inlays, such as the Raindrop® Near Vision (ReVision Optics) inlay, modify the anterior corneal curvature to produce a multifocal cornea. Table 2 shows a comparison of three intracorneal inlays.

3.2.2.1. Visual/optical outcomes. Several studies have shown that corneal inlays can significantly improve near and intermediate visual acuity with minimal impact upon distant visual acuity [16,150–154 155 150]. A recent systematic review of 18 studies incorporating 2724 eyes found that 78.5 % of eyes had an UNVA of 20/32 or better and 90.5 % of eyes had an UDVA of 20/25 or better [16].

The initial studies reporting on the efficacy of the Raindrop implant were excellent. A review of FDA clinical data on the shape-changing inlay revealed that 98 % of patients with the inlay achieved near visual acuity of J5 or better, with 67 % achieving J1 or better at 24 months; however the FDA subsequently released 5-year follow-up revealing a corneal haze incidence of 42 % which led to this inlay being withdrawn from the market [155]. Initial studies evaluating the multifocal Icolens (Neoptics, Switzerland) also showed promising results with mean UNVA improving from N18/N24 preoperatively to N8 one year postoperatively in a study of 52 eyes [156].

A 5 year outcome study of KAMRA implantation reported a mean UNVA of J2 or better, and most patients reported high satisfaction with their near vision [157]. Another study reported only a mild reduction in UNVA 5 years after surgery [158]. One study of the KAMRA inlay found that 81 % of patients achieved an UNVA of J2 or better, considered functional for most near tasks [159,160]. Another study of the Raindrop inlay found that 92 % of patients achieved a binocular UNVA of J3 or better [161]. Corneal inlays can effectively improve near vision without

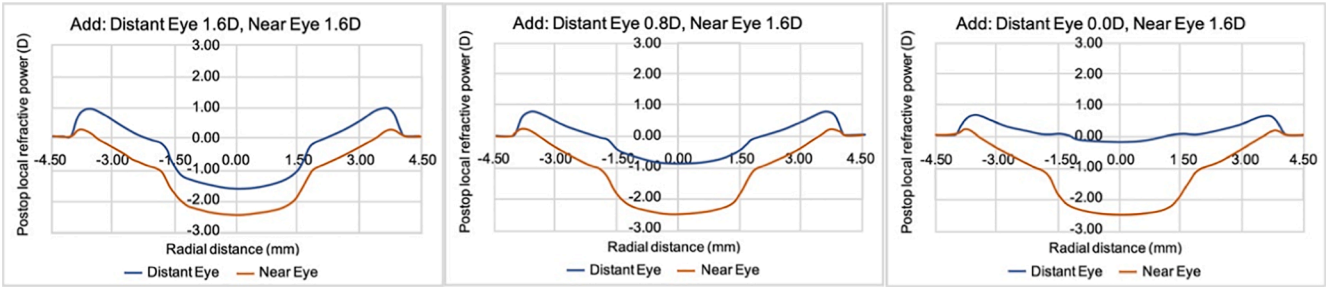

Fig. 2. From left to right, the relative addition in the distant vision eye is reduced from 100% (mini-monovision) to 50% (hybrid) to 0% (monocular) with respect to the near eye.

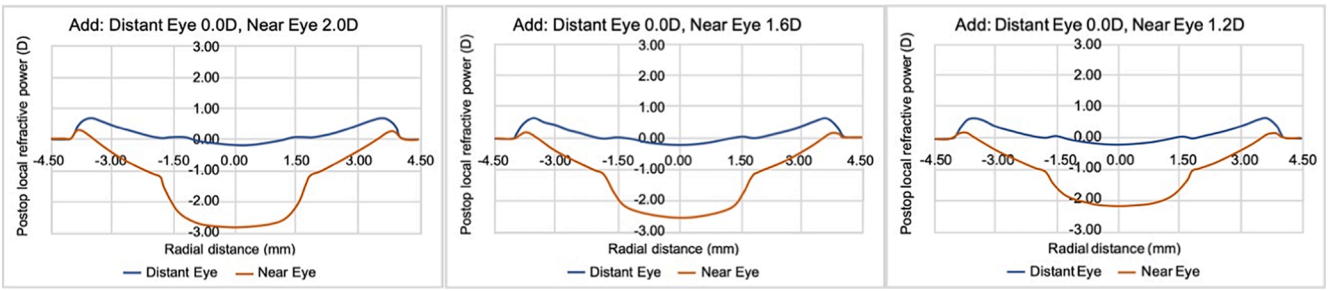

Fig. 3. The presbyopic concept incorporates a residual defocus of −0.89D in the near eye, which can be altered to induce more or less myopia combined with lower or higher near additions (less or more induction of negative spherical aberration). From left to right, the addition is reduced from 2.0D to 1.6D to 1.2D in the near eye.

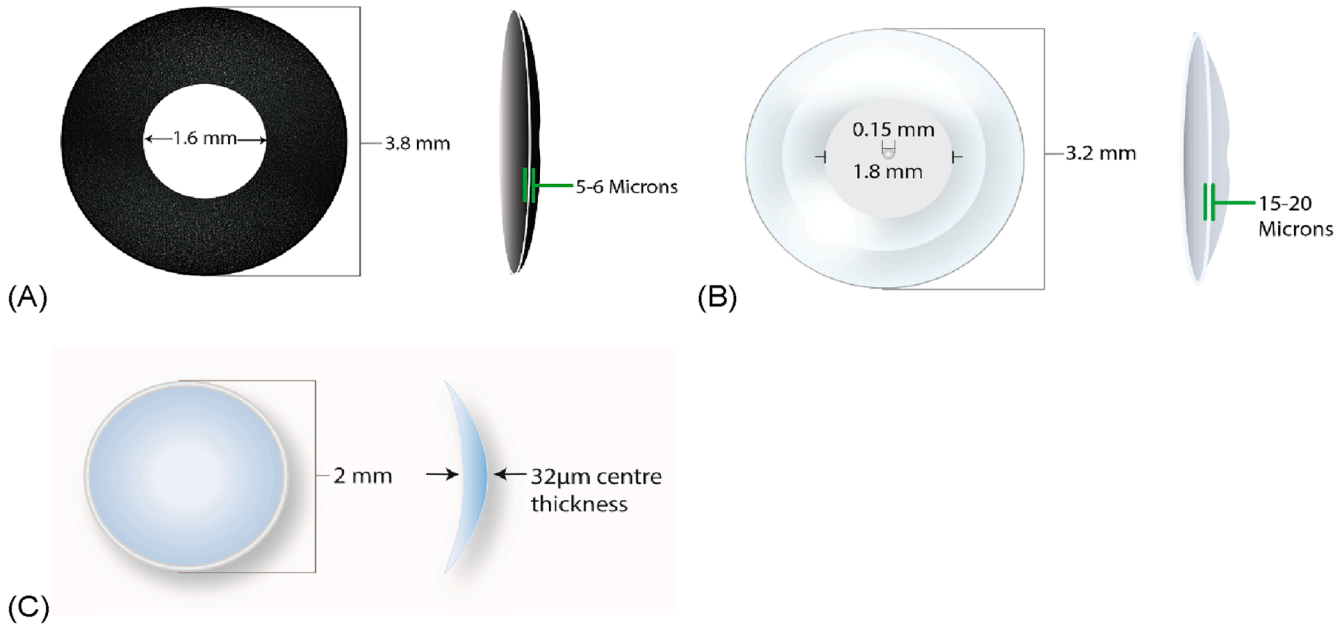

Fig. 4. Schematic representations of the KAMRA™ (A), Flexivue Microlens™ (B) and Raindrop® Near Vision (C) synthetic intracorneal inlays.

significantly impacting distant vision or overall refractive error. However, some patients may experience slight changes in their refraction or require additional correction, particularly for intermediate distances [162]. While some studies have investigated subjective satisfaction with vision after inlay surgery [163], no study has specifically evaluated the impact of corneal inlay implantation on the quality of vision using validated patient-reported outcome measures (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25].

Corneal inlays can reduce contrast sensitivity in some patients, particularly those with larger pupil sizes [164,165]. However, the impact on contrast sensitivity varies depending on the type of inlay used and the individual characteristics of the patient. Investigators have found the monocular contrast sensitivity in inlay-implanted eyes at frequencies of 12 and 18 cycles-per-degree to be lower compared to fellow eyes in mesopic and photopic conditions [166–168], and this effect lasted up to 3 years after surgery.

3.2.2.1.1. Aberrations/complications. Aberrations associated with corneal inlays can be attributed to a number of causes, including the size, shape, and position of the inlay, the quality of the corneal tissue, and the accuracy of the surgical placement. The most common type of induced higher-order aberrations is spherical aberration; other complications of inlays include decentration, refractive instability, epithelial ingrowth, and corneal haze, which can cause visual distortions and reduce visual acuity. [169]. Inlays also pose a risk of keratolysis, infectious keratitis, anterior stromal ulceration, stromal deposits, and interface inflammation [170].

Reported complications of the KAMRA corneal inlay includes a 26 % ≥0.5D hyperopic shift at 3 years [155], a 3.1 % loss of visual acuity of ≥ 2 lines and a 3 % ≥3.5D hyperopic shift at 5 years [158]. Other studies have reported a 1 % rate of inlay repositioning at 1 year and 3.1 % rate of epithelial ingrowth at 5 years [171]. Reported complications of the Raindrop Near Vision Inlay includes a 2 % lost ≥ 2 lines of distant vision duration of 5 years [147], 5 % repositioning rate at 1 year [66], and a 75 % corneal haze rate at 5 years [147]. Reported complications of the Flexivue Microlens inlay includes a 10 % explanation rate due to poor vision at 3 years [154], 37 % loss of 1 line in CDVA at 1 year [172] and 81 % loss of 1 or 2 lines of UDVA after 3 years [153].

3.2.2.1.2. Changes in structural integrity/hysteresis. Despite its reported safety, refractive surgery is known to have a significant impact on corneal biomechanics [157]. Corneal tensile strength has been shown to be depth-dependent with the anterior 40 % of the central stroma reported to be the strongest part of the cornea because of its densely arranged and tightly linked collagen fibres [82,83,173]. The depth of inlay implantation varies between different devices with the KAMRA placed at a depth of 200–220 µm, Flexivue Microlens placed at a depth of 280–300 µm and the Raindrop inlay placed at a depth of 120–150 µm [148,149,174]. No study to date has evaluated the impact of intracorneal inlay implantation on corneal biomechanics *in vivo*.

Corneal inlay implantation can, however, lead to an adherent fibroconnective tissue membrane, suggesting keratocyte-to-

Table 2
Comparison of three intracorneal inlays [148,149].

	KAMRA™	Flexivue Microlens™	Raindrop®
Material	Polyvinylidene fluoride	Copolymer of hydroxyethyl methacrylate and methyl methacrylate, containing an ultraviolet blocker	Hydrogel
Design	5–6 μm thick microperforated artificial aperture, with a total diameter of 3.8 mm and a central aperture of 1.6 mm	The central 1.8 mm diameter is refractively neutral, with a 0.15 mm nutrient port; the annular peripheral zone has an add power of between +1.25 and +3.50D	Positive meniscus-shaped, diameter of 2 mm, and a center thickness of 32 μm
Underlying principle	Increases depth of focus through the pinhole aperture	Corneal multifocality is the basic principle of the Flexivue Microlens inlay by changing the refractive power of the central cornea to improve near vision performance	Alters the eye's refractive power by increasing the central radius of curvature of the cornea overlying the implant
Implantation depth	170–220 μm	280–300 μm	120–150 μm

myofibroblast transdifferentiation and reactive fibroconnective tissue scar formation, that could impact visual potential [175].

3.2.3. Allogeneic inlays

Due to some of the issues with synthetic inlays (such as the increased risk of corneal necrosis and melt due to the potential inability of nutrients to pass through – see Section 3.2.1), allogeneic inlays have been developed, with successful femtosecond laser-assisted corneal small incision allogenic intrastromal lenticule implantation first reported in an *in vivo* primate model in 2015 [176].

The PrEsbyopic Allogenic Refractive Lenticule (PEARL) inlay of thickness 61.5 ± 3.32 mm and 1 mm diameter prepared from another patient undergoing a SMILE procedure (of −2.5 to −3.5D correction) implanted intrastromally in the non-dominant eye of 4 emmetropic presbyopes showed no safety concerns over 6 months follow-up and an improvement in binocular near vision [177]. The TransForm™ Corneal Allograft (Allotex, Boston, Massachusetts, United States) is currently undergoing evaluation in a clinical trial [178]. The 2 to 3.5 mm diameter with centre thickness of 15 to 25 μm acellular lenticules undergo a process of sterilization using electron beam radiation and shaping using an excimer laser. A 6 month unilateral study of 12 presbyopic patients [179], a one-year case series of 28 hyperopic eyes of 16 patients (with an disclosed number of presbyopes) [180] and a three-year unilateral study of 25 patients [181] showed improvement in near vision without significant postoperative complications.

3.3. Conductive keratoplasty

Conductive keratoplasty (Fig. 1H) is a non-invasive procedure in which radiofrequency energy (350–400 kHz) is applied to the mid-peripheral corneal stroma resulting in mid-peripheral corneal shrinkage and central corneal steepening which corrects hyperopia between +0.75 to +3.00D and can correct presbyopia [182,183]. The device (Viewpoint CK system, Refractec, Inc, Irvine, California) comprises a console which generates the radiofrequency energy and a sterile tipped probe measuring 0.45 mm in length and 0.09 mm in diameter. The probe is applied to the desired corneal area, denaturing collagen as the temperature within the stroma rises to 65 °C leaving a 'U' or 'V' shaped footprint approximately 0.15 mm to 0.20 mm wide and 0.50 mm deep [182]. Treatment is performed at 8 cardinal locations at 6 mm, 7 mm and 8 mm and the magnitude of effect is determined by the number of spots treated, the number of rings created and the diameter of the spots from the central cornea. Increasing the number of spots at cardinal locations increases the treatment effect, hence treatments are made in succession of 8, 16, 24 and 32 spots to manage hyperopia ranging from 0.75 to 3.00D [182]. In the management of presbyopia, although multifocality has been reported to occur following conductive keratoplasty, management of presbyopia using this therapy predominantly involves monovision correction. The treatment is applied to the non-dominant eye and the ideal candidate should be near emmetropic bilaterally [111].

3.3.1. Visual/optical outcomes

In the management of low to moderate hyperopia, conductive keratoplasty has been shown to yield 20/40 or better visual acuity in 89 % of eyes at 30 months postoperatively [184]. In a small group of 10 patients, all attained binocular UDVA of at least 20/25 and at least J3 at near [185]. Three years post-conductive keratoplasty, 78 % achieved binocular UDVA of 20/20 and UNVA of J3 [111]. Monovision conductive keratoplasty has also been shown to be effective in the management of presbyopia after implantation of a monofocal intraocular lens, significantly improving unaided near visual acuity from 0.88 ± 0.16 logMAR preoperatively to 0.30 ± 0.13 logMAR [186]. This study also noted an increase in spherical aberration and pseudoaccommodation [186]. Conductive keratoplasty has also demonstrated similar efficacy to LASIK management of presbyopia [187].

In a multicentre clinical trial, a year after conductive keratoplasty, 63 % of subjects were within ± 0.50D of emmetropia, 88 % within ± 1.00D, and 99 % within ± 2.00D. This percentage decreased slightly after 2 years [188]. In a prospective non-randomised controlled trial involving 47 eyes of 37 patients, the mean refractive spherical equivalent was −0.52 ± 0.73D and at 24 months was −0.50 ± 0.77D at 12 months postoperatively [189]. However, beyond 24 months after the procedure, studies show that most patients experience regression; one study reported a mean refractive spherical equivalent of +0.30D, at 23 months postoperatively, and this regressed to +1.39D at 73 months postoperatively, a regression rate of +0.0184D per month after 6 months [190]. A similar trend was reported in another study in patients who underwent conductive keratoplasty without other prior refractive surgery, reporting a regression rate of 0.033D per month [191]. Increased surgically-induced astigmatism has also been reported after conductive keratoplasty, a finding similar to some other forms of refractive surgery, although the increased astigmatism did not necessarily translate to a significant decrease in UDVA [192].

The data regarding the impact of conductive keratoplasty on low contrast sensitivity appears to be limited, however, studies conducted which have explored this parameter indicate no clinically significant difference pre- and postoperatively [183].

3.3.2. Aberrations

An increase in negative spherical aberration and total coma have been reported following conductive keratoplasty compared to hyperopic LASIK [192]. Doubling of the 4th to 6th order aberrations over a 4 mm pupil has been reported [192]. This has been attributed to the more prolate shape of the cornea after the procedure, however, longer-term data regarding changes in ocular or corneal aberration after the procedure is lacking.

3.3.3. Changes in structural integrity/hysteresis

Limited evidence suggests conductive keratoplasty doesn't impact corneal biomechanics, with no change reported in corneal hysteresis or corneal resistance factor following treatment, [193], although a risk of refractive unpredictability and under-correction was identified in those

with higher corneal resistance factors [193].

Little has been reported about the histological impacts of conductive keratoplasty on the cornea. An observational case series involving 6 human corneas scheduled for endothelial keratoplasty, noted a 'U or V shaped' footprint within the stroma along with overlying bullous epithelial oedema or epithelial defects [194]. Increased stromal lamellae, collagen degradation, and decreased keratocytes at the site of the probe application were observed [194].

3.3.4. Impact of conductive keratoplasty on quality of life

Patient satisfaction and visual improvement after conductive keratoplasty has been reportedly quite high even 2 years after the procedure [195]. Highest satisfaction has been associated with the level of improvement in near vision and depth perception [192]. Regarding patient-reported outcomes, 39 % and 38 % reported a marked or extreme improvement in quality of vision after conductive keratoplasty, and 23 % reported either no, mild or moderate improvement [192].

3.4. Orthokeratology

Ortho-k (Fig. 1J) is a process that utilises corneal rigid lenses to temporarily and reversibly modify the anterior corneal shape, especially the epithelial layer [196], using hydraulic forces within the post-lens tear film [14]. In this way, the surface of the cornea can be reshaped to temporarily correct common refractive errors such as astigmatism, myopia and hyperopia [197]. More details on ortho-k lenses and their fitting can be found in the BCLA CLEAR – Orthokeratology report [14]. Presbyopia can also be addressed with ortho-k, either by customising a lens design or by using a monovision approach.

As with other presbyopia treatments, choice of type and mode of presbyopic correction depends on a detailed analysis of the ocular parameters of the patient, ability to suppress blur, visual needs and behaviour [198]. Compared to surgical procedures, ortho-k is fully reversible and less invasive, which may align with the preferences of some presbyopes. While ortho-k is associated with a microbial keratitis rate of 13.9/10,000 patient-years (95 % CI = 1.7 to 50.4) in children, that rate drops to 0/10,000 patient-years (95 % CI = 0 to 31.7) in adults [199], which is considered a safe level in terms of risk, and comparable to other options such as refractive surgery [200].

There are two distinct philosophies for fitting ortho-k lenses for presbyopia. The first uses a continuous aspheric curve, which is designed to create a slightly steeper surface in the central cornea (2–3 mm in diameter) and to exert pressure on the peripheral portion and cause-flattening [201]. The modification of the central area, on the other hand, seems to be more closely related to a moulding effect and, to a lesser extent, to hydraulic pressure [201]. The creation of convex power in the central portion of the cornea does not occur spherically, but rather follows the natural aspheric profile of the cornea [202]; This leads to the generation of a significant amount of higher order aberrations that adversely affect the quality of vision in a majority of patients. The second philosophy is to fit a more common reverse geometry ortho-k lens, offering the flexibility to use a distant-centered or near-centered lens [197].

3.4.1. Physiological impact of orthokeratology lenses

It is understood that the majority of structural changes related to ortho-k primarily affect the corneal epithelium [203]. Physiologically, the hydraulic pressure of the post-lens tear layer can cause epithelial cells to flatten (more negative optical corneal power) if the force applied is positive (correcting myopia or astigmatism), whereas the same cells can swell if the pressure applied is negative (correcting hypermetropia or presbyopia) [204]. There is no identified loss or migration of the cells.

Applied to correct myopia, ortho-k lenses cause mid-peripheral epithelial cells to become larger and more oval in shape; the cells of the mid-peripheral cornea (under the reservoir) are characterized by a delayed surface cell exfoliation and there is no change in the corneal permeability secondary to these changes [205]. There are no significant changes in the stroma or deeper layers [206], although oedema or a microcystic response may be present when lenses with lower oxygen permeability are worn [207,208].

3.4.2. Visual/optical outcomes

Only one published study has examined ortho-k in presbyopia. A contralateral study of 13 emmetropic presbyopic subjects fitted with hyperopic ortho-k lenses targeted to correct +2.00D in one eye only for a week found approximately a −1.00D shift in mean spherical equivalent refraction improving BNVA (monocular) from J10.8 ± 2.4 at baseline to between J3.2 ± 2.3 (morning) and J3.9 ± 3.0 (evening) with no change in binocular UDVA induced by central corneal steepening and paracentral corneal flattening [19].

It has been shown that the switch from spectacles to ortho-k, in a myopic individual, generates a shift towards exophoria [209], especially at near. Depending on the original phoria, this effect can be more or less favorable [210]. Ortho-k is also associated with a closer near point of convergence. In a non-presbyopic population, the accommodative lag, the amplitude of accommodation and the AC/A gradient are reduced in ortho-k relative to the standard condition of spectacle wear [210].

There are several differences between the optimum design of an ortho-k lens in children and adults, at least for myopia. In young myopes, the increased positive spherical aberration is associated with less axial length progression [211], whereas in the case of adults, to minimize halos, the optical zone size is maximised [212] and the transition to the reverse geometry zone, which provides the most convex power, should be gradual.

Despite these efforts, ortho-k lenses reduce contrast sensitivity more in myopic adults than in children, while the level of aberrations does not seem to be different for the same optical zone size [213]. It is suggested that children have greater neural adaptation to elevated aberrations than adults [214], which may be relevant in presbyopia correction.

3.4.3. Changes in structural integrity/hysteresis

There is some evidence that the Ortho-K effect is more rapid and pronounced for stiffer corneas [215]. In adults, corneal biomechanical indices do not appear to change over time during ortho-k treatment [216], with the exception of a few parameters, most likely due to variations in the epithelial layer [217].

As with ortho-k applied to a myopic cornea, corneal changes associated with the correction of presbyopia or hyperopia occur within the first few hours of wear [218]. Over longer-term wear, the central horizontal diameter of corneal steepening tends to reduce, without compromising the level of visual correction. Ortho-k correction for low hyperopia is relatively stable over time, plateauing after a few days of lens wear, however, variable results have been reported for higher refractive errors [218].

3.4.4. Impact of orthokeratology on quality of life

Ortho-k typically improves quality of life for adults by reducing the need for optical correction during the day [219]. While this is true for myopia, there are no studies extrapolating these benefits to presbyopia. However, the presence of halos and glare, especially in low light or when driving at night, can reduce quality of vision and therefore quality of life associated with ortho-k lenses.

4. Postoperative management

4.1. Routine management

4.1.1. Follow up timing and duration

Intervals and duration of routine follow-up will vary according to procedure type. A minimum follow-up period of three months is usually recommended following corneal refractive procedures, to allow sufficient time for epithelial remodelling and refractive stabilisation [220].

Upon discharge, patients should be advised to continue with lifelong optometric surveillance for other ocular pathology.

4.1.2. Postoperative history-taking and patient-reported outcomes

Routine management after corneal-based presbyopia correction should include a targeted history enquiring about symptoms, concerns and satisfaction. This can be achieved with direct face-to-face questioning, or via standardised questionnaires.

Patient-reported symptoms vary according to the procedure and may be related to discomfort (such as foreign body sensation, dryness, pain) or visual disturbance (such as blurring, halos, glare, starburst, night vision difficulties, double vision). There may also be symptoms or problems related to postoperative eyedrops (such as stinging; transient blurring; difficulty with instillation) (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25]. After the initial period of healing and stabilisation, more detailed enquiries should be undertaken to explore outcomes in terms of freedom from spectacles, quality of life and overall satisfaction with the treatment.

4.1.3. Clinical evaluation

4.1.3.1. Routine functional evaluation. Clinical assessment following corneal-based presbyopia treatment usually includes measurements of distant, intermediate and near unaided visual acuity, an updated manifest refraction, and corrected visual acuity measurements at each of the distances. Binocular visual acuities are relevant particularly in the context of approaches that may be affected by binocular summation or inhibition.

4.1.3.2. Additional functional evaluation. Some clinical tests have more of a role in research settings, or in the investigation of specific patient-reported symptoms, rather than in routine evaluation. These include the plotting of defocus curves, measurement of contrast sensitivity, assessment of reading speed and documentation of stereopsis and ocular motility (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25].

Contrast sensitivity is reduced with multifocal corneal ablation profiles [22]. Using optical simulations, image brightness on the retina may be reduced by up to 60 % following small aperture corneal inlay implantation, which is likely to translate into reduced contrast sensitivity [221].

A small-angle esophoric shift and reduction in stereopsis are associated with monovision [222], with an esophoric shift <0.6 prism dioptres, and reduction in stereoacuity of $<50''$ of arc from baseline, being associated with improved patient outcomes [223].

4.1.3.3. Routine physical evaluation. Routine physical evaluation includes a targeted slit-lamp biomicroscopic examination of the eye and adnexal structures, according to the nature of the procedure performed.

Older presbyopic patients exhibit a greater prevalence of both evaporative and aqueous deficient dry eye as well as meibomian gland dysfunction [224], and slower wound healing [22] compared with younger refractive patients. Examination should follow a similar, systematic approach to that recommended by the latest Tear Film and Ocular Surface Society Dry Eye Workshop [225].

Assessment of other specific features is undertaken according to the procedure type and patient-reported symptoms. A full description is beyond the scope of this report, but important clinical features associated with LASIK (flap folds and striae; diffuse lamellar keratitis; central toxic keratopathy; epithelial ingrowth; interface debris; pressure-induced stromal keratopathy), PRK (epithelial closure; haze), KLEx (interface oedema; diffuse lamellar keratitis; interface debris) and inlays (depth of implantation; foreign body reaction; allogeneic graft rejection; oedema; extrusion; iron deposition; epithelial ingrowth as well as signs of haze or infection) should all be sought and managed appropriately [226–229]. Intraocular pressure should be measured to establish a new post-procedure baseline, due to the potential influence of changes in corneal thickness and rigidity.

4.1.3.4. Additional physical evaluation. Additional postoperative investigations may include anterior segment optical coherence tomography (OCT), very high-frequency ultrasound, corneal topography, tomography, aberrometry and specular microscopy. Anterior segment OCT and very high-frequency ultrasound are useful in evaluating epithelial thickness and regularity, interface debris and epithelial ingrowth after LASIK and KLEx, and pocket depth and pachymetry after corneal inlay implantation, as well as signs of haze or infection [230]. Scheimpflug imaging has been used to quantify interface opacity [231].

Corneal endothelial cell density has been shown to reduce slightly following initial implantation with the KAMRA device, after which time, no further loss was detected [227]. Nonetheless, corneal endothelial cell count remains a relevant safety parameter to consider after corneal inlay implantation.

While rarely performed in routine practice, *in vivo* confocal microscopy has demonstrated increased keratocyte activation (a marker of inflammation) after corneal inlay surgery, which correlated with reduced UNVA and CDVA [232]. Other confocal microscopic findings after corneal inlay surgery include reduced anterior stromal keratocyte density and loss of the sub-basal nerve plexus, neither of which resulted in visual complications [232].

4.2. Management of the unhappy patient

4.2.1. Physical complications

4.2.1.1. Neuropathic pain. Corneal neuropathic pain is a rare but debilitating condition that can follow refractive surgery [233]. It can present as a burning sensation, stinging, or severe dryness after unremarkable refractive surgery in the absence of abnormal tear production [234]. Neuropathic pain after refractive surgery may be a form of hyperalgesia to noxious stimuli or allodynia to non-noxious stimuli, as a result of abnormal nerve regeneration despite decreased sensitivity of the nerve being confirmed by esthesiometry [234]. In a cross-sectional survey of patients who had undergone refractive surgery, 46 % reported ocular pain beginning one month post-refractive surgery and reported the pain being triggered by wind, light and temperature [235]. In a systematic review, the impact of refractive surgery on corneal nerves varied depending on the depth and diameter of the ablated cornea for LASIK or PRK, the flap size, the diameter of the lenticule in the case of SMILE [236] and the magnitude of the refractive error [237]. Patients undergoing hyperopic LASIK are expected to have more nerve plexus damage due to the peripheral ablation [238] compared to myopic LASIK [239]. While some degree of corneal nerve regeneration does occur during the healing period post-refractive surgery, *in vivo* confocal microscopy revealed significantly decreased sub-basal corneal nerve plexus density compared to controls as long as 10 years after LASIK refractive surgery [240].

Although older age is associated with an increased risk for dry eye disease [241] and decreased corneal sensation [242], it is not known if corneal neuropathic pain is worse in patients seeking refractive surgery for presbyopia compared to that reported by younger individuals. However, studies indicate a lack of age-related changes in the sub-basal nerve plexus, as assessed by confocal microscopy [243,244]. In terms of procedural contribution to cornea neuropathic pain, PRK has been shown to have faster recovery of corneal sensations and corneal nerve density compared to LASIK, and in a *meta*-analysis of five clinical trials, SMILE showed faster recovery of corneal sensations and corneal nerve density on *in vivo* confocal microscopy compared to LASIK [245,246]. Studies also have shown better corneal sensations with SMILE at 3 months after surgery compared to femtosecond-LASIK, however, this

difference was not significant at 6 months postoperatively [247].

For the management of neuropathic cornea pain after refractive surgery, lubricating drops, the use of punctal plugs or other dry eye disease management strategies can be employed, especially when these diseases co-exist. Nerve regenerative therapies include autologous serum drops, platelet-rich plasma, and topical nerve growth factors [248]. Several studies and systematic reviews report improved corneal sub-basal nerve plexus, decreased nerve tortuosity and reflectivity with the use of these agents [248]. Chronic inflammation has been shown to play a significant role in causing nerve damage, but excessive dampening of inflammation with topical anti-inflammatory agents such as corticosteroids or cyclosporine may prove counterproductive, as an element of inflammation may be valuable in facilitating nerve regeneration [249]. A short, tapered course of low-penetration steroids, such as loteprednol 0.5%, followed by steroid-sparing anti-inflammatory agents such as cyclosporine A 0.005 % (2 to 4 times daily) as well as topical tacrolimus 0.03 % (3 times daily) have been used for the management of neuropathic corneal pain [248]. Newer therapies which show promise in the management of neurotrophic keratopathy include topical cenegermin (Dompé), a recombinant human nerve growth factor [250].

The use of amniotic membranes due to their anti-inflammatory, anti-scarring, anti-fibrotic and neurotrophic properties has been shown to be an effective option in the management of neuropathic cornea pain [248,251]. Contact lens options for management of neurotrophic cornea pain include bandage contact lenses [252], and scleral lenses [253]. These lenses provide symptomatic relief from dryness and also decrease environmental nociceptive stimuli [249,255], though *in vivo* confocal microscopy failed to show any increase in corneal nerve density or tortuosity [255].

In patients with neuropathic corneal pain after refractive surgery, in terms of quality of life, the level of pain and *in vivo* confocal microscopy corneal nerve findings are similar to those seen in post-herpetic neuralgia [256]. Hence some management options applied for post-herpetic neuralgia and other bodily neuropathic pain may be useful in the management of corneal neuropathic pain after refractive surgery. There are reports that the use of oral medications (such as tricyclic antidepressants, carbamazepine, naltrexone), opioid agonists (such as tramadol), calcium channel ligands (such as pregabalin), sodium channel blockers (such as mexiletine), and serotonin-norepinephrine inhibitors (such as venlafaxine) is effective in the management of neuropathic pain [248].

4.2.1.2. Ocular surface dysfunction. All corneal laser vision correction results in temporary disturbance of the ocular surface [257] which risks dryness symptom development postoperatively, however, it does so to varying degrees; this differs from the more prolonged ocular surface dysfunction with dry eye disease [60]. As seen in the case of corneal neuropathic pain, dryness symptoms after refractive surgery are widely attributed to, and correlate with, nerve damage following refractive surgery [258]. Studies have shown worsened tear film stability, tear secretion, dryness symptoms, osmolarity, and corneal sensitivity after laser vision correction [102]. There is also decreased mucin production attributed to damage of the conjunctival goblet cells by the suction device used during the surgical procedure, and also decreased blink rate post refractive surgery [259]. The dryness symptoms and ocular surface signs after laser vision correction can be increased for several months after the procedure and for most patients decrease after 6 months; however, this may last up to a year or more in some cases [103]. Several factors such as high refractive error, ablation depth, and preoperative dry eye disease have been reported as risk factors associated with post-laser vision correction dryness symptoms [247,259]. Other identified risk factors include female gender, intraoperative use of mitomycin C, previous contact lens wear, Asian ethnicity, and a narrow LASIK flap hinge [260]. Considering dry eye and ocular surface disease are more prevalent in the elderly (and hence in those who are presbyopic), it is important to note that post refractive surgery dryness symptoms may be more prevalent in those undergoing refractive surgery for presbyopia.

Overall, it appears that LASIK refractive surgery leads to a significantly greater decrease in tear production and tear stability compared to KLEx and PRK [237,261,263]. Management options for dryness symptoms after laser refractive surgery include lubricating drops, preferably preservative-free, topical steroids and steroid sparing agents such as cyclosporine A [259], autologous serum drops [263], platelet rich plasma drops [264], punctal plugs [265], and scleral lenses [266]. Although the use of newer topical agents such as lifitegrast for the management of dry eye is established [267], their use in relieving dryness symptoms post-laser vision correction has not been well-studied.

4.2.1.3. Dysphotopsia. Dysphotopsia is an unwanted visual phenomenon as a result of external light source interaction with optical boundaries, distorting the retinal image [268]. Dysphotopsia after refractive surgery includes starbursts, haloes, disability glare, and image degradation. There are few studies which explore dysphotopsia after laser refractive surgery with most studies dedicated to dysphotopsia after intraocular lens surgery. Irregular and residual astigmatism have been implicated as causes of starbursts and night glare after LASIK surgery [269]. Patients with flatter preoperative corneal curvature or refractive surgery enhancements are also more likely to experience starbursts and haloes [270]; other factors associated with dysphotopsia after refractive surgery include high refractive error correction, increased ablation depth, and small ablation diameter [271]. Dysphotopsia after refractive surgery does not appear to vary with the type of refractive surgery performed [272].

Several strategies have been recommended for the management of dysphotopsia after refractive surgery. Increasing the treatment zone in patients with small ablation zones preoperatively has been shown to decrease haloes in patients experiencing haloes after PRK [273]. The use of pharmaceutical miotic agents has also been shown to be effective in improving image quality in post-LASIK and in keratoconic eyes [274]. Wavefront or topography-guided zonal ablation has also been advocated as a means of addressing dysphotopsia due to irregular astigmatism after LASIK [269].

4.2.2. Optical complications

4.2.2.1. Surgical complications. Surgical complications after refractive surgery for presbyopia are similar to those seen in other forms of refractive surgery for correction of other refractive errors. These complications may be intraoperative and postoperative. Intraoperative complications reported to occur in SMILE and LASIK includes suction loss, and decentered ablation [275,276]. Intraoperative complications observed in SMILE include irregular bubble layer, cap perforation, issues related to lenticular dissection and/or extraction and complications at the incision site [275]. Intraoperative complications associated with LASIK include flap-related issues such as buttonhole flap, free cap, LASIK flap tear, central island, and debris within the flap and residual stromal bed interface [276]. Treatment area decentration may also occur in PRK [277]. Suction loss may occur in up to 4.4 % of cases in SMILE and LASIK and some risk factors include Bell's phenomenon, deep-set eyes, sudden eye movement, anxiety, improper suction ring or device placement, and surgeon experience [275,276]. Management of suction loss during SMILE depends on the stage at which the suction loss occurs; if the loss of suction occurs prior to laser application or before $<$10 % of the posterior lenticule creation, management is carried out by retreating with the same parameters [278]. However, converting to femtosecond LASIK or retreatment using decreased cap thickness is recommended when $>$10 % of the posterior lenticule has been created [275]. The management of suction loss can also vary depending on whether it occurs during creation of the lenticule side cut, and creation

of the anterior cap surface [279]. It is important to note that such retreatments may affect the refractive outcome and the level of induced higher order aberrations [275]. Proper patient counselling, and drying the anterior surface prior to application, are important preoperative steps that may help prevent suction loss. Transepithelial PRK may also be a means for retreatment after KLEx, with outcomes similar to KLEx retreatment [280]. Other complications might include incision tears, incision bleeding and sub-conjunctival hemorrhage. Bandage contact lenses, lubricating drops, applying pressure to the site of bleeding with sterile cotton swabs, and vasoconstrictive drops are methods which have been advocated for managing these complications [275]. The management of KLEx-related dissection issues includes identification and removal of lenticule remnant using OCT-guided extraction when the remnant is minimal, but in cases of complete retained lenticule, LASIK or PRK may be performed. Excessive manipulation of the anterior cap may lead to perforation of the cap which can be managed conservatively and would be expected to heal with minimal scarring [275].

Adequate suction is important to prevent LASIK flap decentration and if this becomes difficult to achieve, rescheduling the procedure may be a better option [276]. Intraoperative flap tears during LASIK may be addressed by carefully dissecting the flap from the area of tear and switching to surface ablation. This complication can be prevented by ensuring proper suction and decreasing flap diameter in patients with corneal pannus, and scars [276]. Other flap-related complications include buttonhole flap, thin flap, corneal perforation and these may be addressed by proper suctioning, flap replacement, bandage contact lenses over the cornea for protection and surface ablation at least 3 months after corneal healing [276].

Postoperative complications after corneal laser vision correction for presbyopia may include lamellar keratitis, interface haze, epithelial ingrowth, infectious keratitis, corneal ectasia, corneal haze, and interface debris [275–278]. Management of these complications ranges from topical pharmacologic agents and enhancement procedures to flap revisits.

4.2.2.1.1. Refractive surprise after surgery. Refractive surprise may take the form of unplanned over-correction, or under-correction or residual refractive error after laser vision correction for presbyopia. This complication in monovision laser vision correction would not be expected to differ from that seen in the correction of ametropia. Under-correction after KLEx has been reported for SMILE especially in high refractive errors and when cylinder correction exceeds 0.75D [276,282], from data entry errors [282], and when cyclotorsion occurs during the procedure [249]. Ensuring data entered are double-checked [282] and the use of an image-guided system [281] during laser vision correction have been suggested as means to mitigate these issues.

While the use of a monovision contact lens trial prior to monovision refractive surgery for presbyopia is a well-known practice to simulate vision after surgery (see Section 2.6), changes in topography due to contact lens wear and improper refraction are recognised factors associated with refractive surprise in LASIK [276]. Operating room environmental conditions such as temperature and humidity may also affect the refractive outcomes [283]. Discontinuing soft contact lens wear at least 2 weeks prior to assessment for refractive surgery and ensuring optimal operating room conditions have been suggested as a preventive measures; however, enhancement procedures, flap lifts and surface ablation have been suggested as methods to address refractive surprise after laser vision correction. The data regarding the efficacy of chosen strategies and non-surgical management of refractive surprise is limited. In patients undergoing presbyopic LASIK, laser retreatment has been shown to improve visual outcomes in cases with unplanned refractive outcomes [283].

4.2.2.2. Late complications from inlays. Late complications seen after corneal inlays include refractive changes, change in corneal topography over time, migration and extrusion of the implant, corneal stroma haze and decentration of the inlay [284]. Repositioning of the inlay can help recenter a decentered inlay. Extrusion of the inlay has been seen with polymethylmethacrylate (PMMA) materials due to keratolysis and anterior stromal atrophy; use of modern hydrogel inlays, due to their improved water content has decreased the rate of this complication. Stromal haze after corneal inlays occurs due to scar formation and inflammation and may be addressed using topical steroids, mitomycin C and eye ointments [284]. In cases of significant scarring refractory to conservative treatment, explantation of the inlay is recommended [285].

4.2.3. Causes of dissatisfaction

Understanding possible causes of dissatisfaction is essential for counselling patients preoperatively, addressing patient postoperative complaints and improving overall patient satisfaction.

4.2.3.1. Age. Age is a significant factor that affects the success of corneal surgery for presbyopia correction. There are two types of age-related changes affecting the crystalline lens: presbyopia and the development of cataract. Changes in lens clarity result in an increase in internal higher-order aberrations and ocular forward-scattering, with a potentially significant impact on clinical measures, including visual acuity and contrast sensitivity [11]. Patients undergoing presbyopia surgery need a careful assessment of the crystalline lens and, if the lens demonstrates evidence of opacification, the patient should be counselled about lens surgery as an option.

Any refractive procedure, including corneal surgery for presbyopia, requires a period of neural adaptation. Neuroplasticity is the ability of the brain to be shaped by experience and, in turn, for this newly rewired brain to facilitate adaptation to new experiences. Although plastic changes in the brain can occur at any time point in the life cycle, they occur with varying degrees of success at different ages and this should be considered in the preoperative counselling [286–288].

4.2.3.2. Occupation. The occupation of the patient can impact the satisfaction levels following corneal surgery for presbyopia correction. Patients who require high levels of visual acuity for computer work or reading small print may find that the surgery does not provide adequate correction and consequently may be less satisfied with the results of the surgery.

Most presbyLASIK procedures are performed as a hybrid method, combining a certain degree of monovision with a multifocal ablation profile. A meticulous preoperative evaluation assessing patient needs and customising the treatment based on their tolerance of monovision is of utmost importance. A binocular UDVA of 20/25 or better and a UNVA of J3 or better can be expected if the patient and procedure selection are meticulous [286]. Glare, haloes, reduction of contrast sensitivity and a decrease in UDVA may cause dissatisfaction and may require retreatment. Most of these symptoms decrease over time however the patient needs to be aware that reversal can be offered at least 3 months after surgery [22].

4.2.3.3. Personality. Psychologically high-functioning people do not tolerate blur well, whereas traits of “low self-confidence” and “disorganization” correlated positively with blur tolerance [289,290]. Another study demonstrated that patients with neuroticism as the dominant personality trait were the least happy with the postoperative outcomes; whereas patients with conscientiousness and agreeableness as dominant personality traits demonstrated the highest satisfaction with the postoperative outcomes following multifocal intraocular lens implantation [290].

4.2.3.4. Amplitude of accommodation. With presbyopia being a physiological age-related loss in near visual function, associated with a progressive reduction in accommodation [1], patients should be educated

to expect a dynamic progressive condition culminating in the development of cataract and the need for further surgery [22,292].

4.2.3.5. Refractive status. The refractive status of the patient can impact the success of corneal surgery for presbyopia correction. Patients with a high degree of myopia or hyperopia, may not be good candidates for the surgery and will need correction of the distant refractive error at the time of presbyopia correction [292].

As described in Section 2, monovision LASIK or PRK create a low degree of myopia in the nondominant eye to aid near vision so that one eye is utilised for distant vision and the other for near vision [115,117]. Higher degrees of monovision present limitations such as loss of fusion and stereo acuity and is not suitable for patients requiring good stereoacuity like professional drivers, pilots and those undertaking activities requiring good intermediate vision [293]. Myopes tend to be more satisfied with monovision LASIK/PRK than hyperopes, but many surgeons continue to use monovision for the treatment of presbyopia regardless of a patient's refractive error [294]. Techniques such as presbyLASIK and PRESBYOND laser blended vision require good patient selection and preoperative evaluation similar to that of LASIK. The creation of a multifocal profile in the cornea is associated with a decrease in contrast and the assessment of lenticular changes is essential to prevent early postoperative refractive instability [22]. The implantation of small-aperture corneal inlays [109] demonstrated increased depth of focus, better near and intermediate vision, but decreased distant visual acuity and refractive instability in emmetropic presbyopic patients [110,295–297].

4.2.3.6. Pupil size. The size of the patient's pupils can affect the outcomes of corneal surgery for presbyopia correction. In the human eye, pupil diameter ranges between approximately 2 and 8 mm, it changes with luminance, age, monocular adaptation, and field size [298]. The pupil size changes the optical transfer function of the eye, the depth of field, retinal illuminance and contrast sensitivity [298]. The centration of implants, either small-aperture implants or shape-changing corneal inlays, has a critical impact on visual function after surgery [229]. The size of the pupil in relation to the treatment area and transition zone, in corneal reshaping techniques that use laser vision correction, have a direct effect on quality of vision after surgery, particularly for night vision and reading [229]. Preoperative pupillography is very important in central presbyLASIK as the distant vision is obtained from mid-peripheral cornea and therefore patients with poor or sluggish pupil dilation are poor candidates for central or peripheral presbyLASIK [22]. Significant increases in higher-order aberrations were found after conductive keratoplasty and composite fourth- to sixth-order aberrations through a 4.0 mm pupil more than doubled [298]. Total corneal aberrations have been reported to increase, on average, 1.7-fold with a 3 mm pupil and up to 3.7-fold using a 6.5 mm pupil [299,300]. Patients with larger pupils may experience more glare and halos following the surgery which can impact satisfaction levels with the procedure [301].

4.2.3.7. Topography. The corneal topography of a patient can impact the results of corneal surgery for presbyopia correction, therefore a preoperative irregular topography and corneal abnormalities are criteria for exclusion. Topographic and keratometric changes have been reported following small-aperture intracorneal inlays, which can be associated with unsatisfactory UDVA [162,303]. A systematic review of outcomes following 2724 KAMRA implants found that 3.7 % required explantation due to blurred vision, development of epithelial microcysts, incorrect implant placement or hyperopic shift changes secondary to stromal thickening overlying the implant and topographic changes [148,155,303].

4.2.3.8. Comorbidities. Patients with comorbidities may not achieve optimal results due to increased discomfort or unsatisfactory visual outcomes following corneal surgery for presbyopia correction. Therefore, it is important to identify and manage comorbidities before considering the surgery. As previously noted, patients in the presbyopia age group tend to have greater prevalence of both evaporative and aqueous deficiency dry eyes, as well as meibomian gland dysfunction [224]. A careful assessment of the ocular surface is necessary as poor quality of tear film can affect the quality of vision postoperatively (see Section 4.2.1.2) [304]. It is best to avoid presbyLASIK in patients with conditions like age-related macular degeneration, diabetic retinopathy, and optic nerve pathologies where the contrast is poor and visual prognosis is guarded as well as patients with a preoperative history of strabismus or use of prisms [22].

In conclusion, understanding the causes of dissatisfaction among patients who have undergone corneal surgery for presbyopia correction is essential for improving patient outcomes. The management of presbyopia requires a careful judgement of patient expectations and willingness to adapt. Factors such as age, occupation, personality, amplitude of accommodation, refractive status, pupil size, corneal topography, and comorbidities can all impact the perceived success of the surgery.

4.3. Options to improve visual outcomes

4.3.1. Surgical enhancement procedures

The need for laser enhancement following refractive surgery is decreasing due to improved laser nomograms, and improvement in laser technology, however, in some cases, corrective enhancement surgery is still required. Following comprehensive examination including manifest refraction and cycloplegic refraction, refraction stability, tomography/topography, dilated fundus examination, and assessment of the ocular surface, the surgeon must consider the options for retreatment [305].

Post primary LASIK, there are various options, including flap re-lift, re-cut, surface ablation, side cut, mini-flap posterior surface ablation, conductive keratoplasty, and arcuate keratotomy [305]. Important considerations include the time from primary surgery, residual stromal bed thickness, and refractive error. It has been reported that surface ablation and flap lift are equally safe and effective [306], while others suggest flap lift to be more accurate despite a greater risk of epithelium ingrowth [277,308]. The risk of epithelial ingrowth significantly increased when enhancement was performed more than 5 years after primary surgery [229].

The options for enhancement following KLEx include topography-guided PRK, thin-flap LASIK, secondary KLEx, sub-cap-lenticule extraction or femtosecond laser cut patterns (Circle software, Carl Zeiss Meditech, Jena, Germany) [308]. Prior to enhancement after primary KLEx, the surgeon must consider the anterior cap depth, residual stromal bed thickness and the level of refractive error to be corrected [308]. It has been suggested that cap thickness can be used as a guide to choose between 'Circle' and thin-flap LASIK, with thicker caps suited to thin-flap LASIK [309]. Thorough patient counselling is vital in all enhancement cases.

In the presence of residual postoperative ametropia or reading deficit, when a patient is either unsuitable or doesn't want further surgical enhancement, spectacles or contact lenses can often be utilised to improve functional visual results. In some cases with induced irregular astigmatism, where adequate spectacle acuity is not achievable, improvement through rigid contact lens wear may also be required. All post-laser cases requiring ongoing spectacle use will need varying levels of careful postoperative counselling.

4.3.2. Impact on future biometry calculations

The surgical reshaping of the cornea through laser vision correction can result in some unintended changes to ocular biometric parameters, which can alter refractive outcomes [310–313]. Both the intended and unintended changes caused by laser vision correction, as well as their potential impact on the ocular structures pose challenges to current formulae for refractive power calculation [314]. The reduction of

corneal power after myopic refractive surgery results in various compounding sources of error that can lead to the miscalculation of IOL power. The most significant errors include error in the corneal radius of curvature, error from the keratometric index, and formula error for estimation of the effective lens position.

Various approaches and adjustments have been proposed to mitigate such errors. The double-K approach consists of using the corneal power pre-refractive surgery to estimate the effective lens position, while using the post-refractive surgery corneal power in the vergence formula to calculate IOL power [315]. The Double-K versions of SRK/T, Hoffer Q, and Holladay II formulae have also been introduced [315,317]. The Haigis-L model [313] established the correlation between the erroneous measured corneal radii and the effective equivalent corneal powers [316,317] and as the formula does not use the corneal power directly in the estimation of effective lens position it is isolated from the aforementioned errors [316,317]. Regression models have been proposed [318] to derive the effective corneal power from post-refractive corneal topography central power [319]. Barrett True-K formula, which is a variant of the Barrett Universal II formula for post-refractive cornea has also been shown to perform well [320]. The ultimate solution, to address the error introduced by the corneal radius of curvature and the error from the keratometric index as well as their impact on the effective lens power, is to leverage corneal thickness and posterior corneal surface measurements from modern ocular biometers [321–323]. Embedding such measurements into the thick lens variants of IOL power calculation formulae will unlock their potential to address the challenges posed by both intended and unintended changes following laser vision correction.

4.3.3. Combination therapy

Patient lifestyle may demand different forms of refractive correction in different environments [324]. Hence the combination of corneal techniques and adjunct optical approaches (see BCLA CLEAR Presbyopia: Management with contact lenses and spectacles report) [53] and pharmacological approaches (see BCLA CLEAR Presbyopia: Management with scleral techniques, lens softening, pharmaceutical and nutritional therapies report) [325] might enhance the amelioration of presbyopia for some individuals.

4.3.4. Dry eye therapy

Dry eye can impact postoperative outcomes following lens-based or corneal surgery and also impact the ability of a patient to successfully wear contact lenses, and therefore promoting a healthy tear film and managing ocular surface disease is important for comfort and visual clarity (see Section 4.2.1.2) [326].

4.4. Psychological aspects

The prevalence of mental health problems has increased in the wake of the COVID-19 pandemic, with higher levels of anxiety relating to health, employment, finances and social isolation [327,328]. There is some non-peer reviewed evidence that pandemic-related psychological issues may influence how patients cope with the consequences of surgery [22].

4.4.1. Understanding and managing patient dissatisfaction

Patient dissatisfaction after presbyopia surgery may stem from tangible conditions that can be rectified, or conversely may relate to problems that are more difficult to manage, such as failure to meet preoperative expectations of spectacle freedom or visual quality, or complications causing a permanent reduction in corrected visual acuity. There may be unanticipated effects on a patient's ability to perform their occupation or activities of daily living, which can lead to financial or social difficulties. The regret associated with an expensive purchase (the phenomenon of "buyer's remorse") is a threat to a patient's perception of refractive surgery, especially if expectations are not fully realised. There is evidence that purchasing experiences results in less regret than material purchases [329], so encouraging patients to concentrate on the ongoing lifestyle and financial benefits of increased spectacle freedom may help mitigate this factor.

In a study of 294 patients undergoing LASIK monovision, there were no consistently identified preoperative predictors of patient dissatisfaction [330]. Early visual outcomes should be assessed and explained to patients. Some degradation in binocular distant visual performance and contrast sensitivity is expected with most corneal presbyopic strategies [331], and it is useful to remind patients of the reasons why this occurs and emphasise the positive features of their treatment. This is particularly important for patients with good baseline UDVA (such as emmetropic presbyopes). If the eye care practitioner fails to acknowledge and help the patient understand these optical compromises, the patient may lose confidence or feel disappointed in the outcome. Comparison of pre- and post-operative visual function questionnaires may help patients realise the improvement they have experienced (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [25]. Patients should be reminded that neural adaptation over time is likely to result in further improvements in vision (see Section 4.2.3.1). Temporary spectacles should be offered to patients whose binocular distant and/or near vision is unsatisfactory, pending full stabilisation, adaptation and/or subsequent enhancement.

It is useful to reassure patients in the early postoperative period that remedial treatment will be possible if it becomes necessary, rather than denying the issue or allowing patients to feel that problems are permanent. For example, dysphotopsia after LASIK typically reduces between three and six months postoperatively [332], so patients can be advised to expect improvement if initial visual quality is poor.

Monovision can be adjusted or reduced if the patient remains dissatisfied, or encounters problems with stereopsis or diplopia due to loss of fusion. Occupations requiring a high degree of stereoacuity are particularly vulnerable to these issues [22]. Patients with asymmetric treatment strategies should also be advised to avoid comparing the eyes monocularly as this can delay the neural adaptation process [22]. Multifocal corneal ablation profiles can be regularised with further wavefront or topography guided treatment in the event of poor visual quality [333].

4.4.2. Non-permanence of corneal based presbyopic treatments

At discharge, patients should be reminded of the non-permanent nature of corneal presbyopia surgery, with natural changes in corneal and lenticular anatomy leading to a gradual loss of effect over time [58,223], which may necessitate the renewed use of visual aids, or consideration of further treatment. This discussion can help prevent the subsequent perception of treatment failure.

5. Recommendations and future directions

This report has considered currently available evidence for the treatment profile, safety, and efficacy for a variety of corneal techniques for the management of presbyopia, including surgical and contact lens treatment modalities. Although the evidence available demonstrates relatively promising outcomes for monovision and multifocal laser vision correction modalities, corneal inlays, and conductive keratoplasty, the studies were predominantly retrospective in design with modest sample sizes for multifocal laser vision correction modalities. Future comparative prospective studies with larger sample sizes are required to confirm these preliminary findings. However, these findings must also be considered in balance with the potential degradation and compromise in binocular distant visual performance and contrast sensitivity, as well as the intrinsically non-permanent nature and gradual loss of treatment effect associated with natural changes in corneal and lenticular anatomy, which would be expected with most corneal presbyopic treatment strategies. Moreover, further research is also required to characterise preoperative predictors of treatment efficacy, satisfaction, and/or potential complications, that include

neuropathic pain, ocular surface disease, dysphotopsia, and refractive surprise, to inform optimal patient selection to minimise unanticipated outcomes. To date, there have been limited dedicated studies evaluating the effects of ortho-k in patients with presbyopia, although its use could be considered in the subgroup of patients where surgical intervention would not be indicated due to an unacceptably high-risk profile or previous treatment inefficacy.

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