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# BCLA CLEAR Presbyopia: Evaluation and diagnosis

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## ABSTRACT

It is important to be able to measure the range of clear focus in clinical practice to advise on presbyopia correction techniques and to optimise the correction power. Both subjective and objective techniques are necessary: subjective techniques (such as patient reported outcome questionnaires and defocus curves) assess the impact of presbyopia on a patient and how the combination of residual objective accommodation and their natural DoF work for them; objective techniques (such as autorefraction, corneal topography and lens imaging) allow the clinician to understand how well a technique is working optically and whether it is the right choice or how adjustments can be made to optimise performance. Techniques to assess visual performance and adverse effects must be carefully conducted to gain a reliable end-point, considering the target size, contrast and illumination. Objective techniques are generally more reliable, can help to explain unexpected subjective results and imaging can be a powerful communication tool with patients. A clear diagnosis, excluding factors such as binocular vision issues or digital eye strain that can also cause similar symptoms, is critical for the patient to understand and adapt to presbyopia. Some corrective options are more permanent, such as implanted inlays / intraocular lenses or laser refractive surgery, so the optics can be trialled with contact lenses in advance (including differences between the eyes) to better communicate with the patient how the optics will work for them so they can make an informed choice.

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*Abbreviations*: ADVS, Activities of Daily Vision Scale; CAT, Computerised Adaptive Testing; CLIQ, Contact Lens Impact on Quality of Life; CLUE, Contact Lens User Experience; FDA, Food Drug Administration; FGVS, Freedom from Glasses Value Scale; IOLs, Intraocular Lenses; LASIK, Laser in Situ Keratomileusis; MAS-2EV, Multifocal Acceptance Score to Evaluate Vision; NAVQ, Near Activity Visual Questionnaire; NEI-RQL, NEI Refractive Error Quality of Life instrument; NEI-VFQ, National Eye Institute Function Questionnaire; NVPTQ, Near Vision Presbyopia Task-based Questionnaire; NVQL, Near Vision-Related Quality of Life; OCT, Optical Coherence Tomography; PAL, Progressive Addition Lenses; PICQ, Presbyopia Impact and Coping questionnaire; PRK, Photo Refractive Keratectomy; PROMs, Patient Reported Outcome Measures; PRSIQ, Patient Reported Spectacle Independence Questionnaire; QIRC, Quality of Life Impact of Refractive Correction; QoV, Quality of Vision; RSVP, Refractive Status and Vision Profile; VF-14, Visual Function-14.

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# 1. Overall purpose

This report aims to consolidate the evidence-base on what techniques can be used to detect and monitor the progression of presbyopia, assess the impact of amelioration techniques, and establish how the techniques are best performed. It also explores how presbyopia should be diagnosed to ensure consistent communication with patients, uniformity between health care professionals and robust epidemiological information for authorities to enable them to allocate appropriate resources.

## 2. Techniques related to presbyopia diagnosis and evaluation

## 2.1. Psychometric techniques

### 2.1.1. Patient reporting

Almost everyone older than their mid-40 s has objective presbyopia, and symptoms are usually noticed before seeking clinical care. To compensate for near vision loss, people adopt different mechanisms in their daily activities, such as using larger font sizes, extra lighting and a longer working distance, before resorting to reading spectacles [1] or other methods of near refractive correction.

Eye care practitioners rely on patients' reporting symptomatology during case history evaluation to understand the impact of presbyopia and its refractive correction on their quality of life. Clearly understanding the impact of presbyopia is critical to managing a presbyope (see section 4.3). To further explore symptomatology more systematically, patient reported outcome measures (PROMs) should be administered, although non-validated questionnaires might occasionally be used depending on the clinical need. For instance, the performance of personalised progressive addition lenses was compared to a conventional fixed design using subjective gradings such as zone widths, blur gradient smoothness, and amount of distortion [2], as these measures are not currently captured in any PROMs.

PROMs are increasingly used in ophthalmic research and clinical practice to quantify subjective outcome measures systematically, allowing for the measurement of the impact of presbyopia or its correction from the patient's perspective, including physical, social, and emotional domains. Thus, PROMs shift the focus from clinician-driven to patient-driven outcomes in clinical practice, research, and policy settings [3]. Refractive errors have been shown to negatively impact on people's quality of life [4]. For example, spectacle wearers may have concerns around cosmetic appearance despite achieving excellent near vision [4].

PROMs (also known as 'instruments') are useful in evaluating the effectiveness of treatments and interventions by comparing pretreatment and post-treatment scores, and can also be used to compare different treatments or interventions. Alternatively, item banking administered using computerised adaptive testing has shown promise given their unique ability to accurately and efficiently measure refractive error-specific quality of life [5,6]. When item banking is fully developed, it will offer clinicians and researchers the possibility to select relevant items according to their measurement needs (refractive surgery, contact lenses, spectacle correction). Thus, improving the understanding and monitoring of refractive error upon quality of life. In the field of contact lenses, the development of the Contact Lens User Experience (CLUE) item banks (377 items (questions) in 4 domains: comfort (128 items), vision (194 items), handling (43 items) and packaging (12 items)) have shown excellent psychometric properties using item response theory [7].

# 2.1.2. Patient reported outcome measures

Several PROMs currently exist to assess refractive error (see BCLA CLEAR Presbyopia: Epidemiology and Impact report)[8], but when selecting the appropriate instrument, it is important to note that only a limited number were developed for use in presbyopic populations. Similarly, as illustrated in Table 1, it is also important to establish if the

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instrument was developed using a broad range of patients that included different refractive errors and a full range of refractive error management options (spectacles, contact lenses, refractive surgery). Finally, some questionnaires have been developed to assess quality of life implications resulting from refractive errors, whereas others focus on other latent traits such as quality of vision/symptoms or independence from spectacles after multifocal intraocular lens (IOL) surgery (Table 1).

Self-reported questionnaires rely on patient recall of visual experiences experienced at present, in general, or over past few weeks [20]. Therefore, when responding, patients are not exposed to the same visual environments. To overcome this limitation, the Multifocal Acceptance Score to Evaluate Vision (MAS-2EV) [21] combines a representation of natural images representing scenes encountered in daily life together with a measurement of near stereoacuity and self-reported judgement of the quality of vision relevant to their daily visual tasks. This measurement has the potential to evaluate and compare multiple presbyopic corrections, but further work is needed to compare the value of this metric with validated questionnaires.

2.1.2.1. Near activity visual questionnaire (NAVQ). This presbyopiaspecific questionnaire enables the measurement of difficulties in nearvision ability and satisfaction with a variety of presbyopia-correction techniques. The questionnaire includes 10 questions about near-vision tasks and one on overall satisfaction with near-vision [14]. The NAVQ was developed and validated using Rasch analysis in a sample of presbyopic patients that included a range of corrections (monofocal IOLs, multifocal IOLs, accommodating IOLs, multifocal contact lens wearers and varifocal spectacle wearers). A critical evaluation of the NAVO has identified that the wording used in the instructions could be interpreted differently by respondents having presbyopia corrected surgically or with contact lenses, given that instructions specifically ask respondents to answer all questions if/when you do the described activity without extra reading spectacles [20]. In addition, it has also been noted that instructions do not include a specific timeframe for recollection, although this would be advantageous [20]. The NAVQ is undergoing an update to reflect the increase in activities associated with the use of technology (such as smartphones and tablets) since its development and validation among an entirely phakic cohort [22].

2.1.2.2. Presbyopia impact and coping questionnaire (PICQ). The PICQ is a newly developed questionnaire that measures the impact of presbyopia and coping strategies in patients with presbyopia [17]. It was developed in accordance with the standards described in the United States Food Drug Administration (FDA) PRO Guidance [23]. The psychometric properties of the questionnaire were evaluated using item response theory, which produced an 8-item coping domain and a 6-item impact domain. However, one of the limitations of the questionnaire is that its comprehension and comprehensiveness were only evaluated with presbyopes that were either emmetropes or surgery-corrected emmetropes. Further independent evaluation of the questionnaire is needed before it can be used to evaluate the effectiveness of new treatments for presbyopia in clinical trials and/or to assess interventions aimed at improving the quality of life of patients with presbyopia.

2.1.2.3. Near vision presbyopia task-based questionnaire (NVPTQ). To avoid recall difficulties, the novelty of the NVPTQ is that it captures patient's self-report after completing four paper-based reading tasks (excerpts from a book, newspaper article, nutrition label and menu) in standardised lighting conditions (mesopic and photopic) and distances from the reading materials. Patients are asked to evaluate their ability to perform the near vision tasks, use of coping behaviours and satisfaction with their reading performance [16]. Similar to the PICQ, the questionnaire was also developed in accordance with FDA's PRO guidance [23]. Although the authors attempted to include electronic tasks, they were finally excluded as participant's feedback indicated that they were

## Table 1

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Summary of Patient Reported Outcome Measurement instruments available in adult populations indicating the population used during initial validation and constructs measured (adapted from [5]).

		Construct measured with the instrument				
Adult population targeted during initial validation	Methods of correction of refractive error during initial validation	Quality of life	Quality of vision/ symptoms	Impact/ coping strategies/ satisfaction	Spectacle independence after multifocal IOL surgery	
Age range: 18–81 years	Spectacles	NEI-RQL [9]				
	Contact lenses					
Emmetropes	Refractive surgery					
Myopes						
Hyperopes						
Presbyopes						
Age range: 18–71 years	Spectacles	RSVP [10]				
	Contact lenses					
Emmetropes	Refractive surgery					
Myopes						
Hyperopes						
Presbyopes						
Age range: 16–35 years	Spectacles	QIRC [11]				
	Contact lenses					
Myopes	Refractive surgery					
Hyperopes						
Astigmatism						
Age range: 21–78 years	Spectacles		QoV [12]			
	Contact lenses					
Emmetropes	Refractive surgery					
Ametropes	Intraocular refractive surgery (including monofocal, multifocal &					
Cataract	pseudoacommodative IOLs)					
Age range: 16–35 years	Contact lenses	CLIQ [13]				
Contact lens wearers						
Age range: 40–91 years	Uncorrected presbyopia	NVOL [1]				
Presbyopia	Spectacles					
	Monofocal, multifocal & accommodating IOLs		NAVO / NAVO-P			
Age range: 30–82 years	Multifocal contact lenses		[14,15]			
0	Varifocal spectacles					
	•					
Presbyopes						
Age range: 41–59 years	Not described			NVPTQ [16]		
Drosbyonos						
Ago rongoj 41 EQ vooro	Not described			<b>PICO</b> [17]		
Age lange. 41–59 years	Not described					
Presbyopes						
Age range: 57–73 years	Multifocal IOLs				FGVS [18]	
0 0 0						
Cataract or presbyopia with refractive						
surgery						
Age range: 41–90 years	Accommodating, monofocal, multifocal, extended range of vision				PRSIQ [19]	
	IOLs					
Presbyopia with refractive surgery						

IOLs – intraocular Lenses; CLIQ – Contact Lens Impact on Quality of Life; FGVS – Freedom from Glasses Value Scale; NAVQ-P – Near Activity Visual Questionnaire (Presbyopia); NEI-RQL – NEI Refractive Error Quality of Life instrument; NVPTQ – Near Vision Presbyopia Task-based Questionnaire; NVQL – Near Vision-Related Quality of Life; PICQ – Presbyopia Impact and Coping questionnaire; PRSIQ – Patient-Reported Spectacle Independence Questionnaire; QIRC – Quality of Life Impact of Refractive Correction; QoV – Quality of Vision; RSVP – Refractive Status and Vision Profile.

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not capturing how they interacted with devices in daily activities. Moreover, other non-reading tasks that presbyopes may encounter difficulties with are also not included (such as sewing, doing manual repairs, applying make-up) as part of this near vision task-based evaluation. Similar to the PICQ questionnaire, further evaluation of the NVPTQ is needed and in the meantime, to provide a comprehensive evaluation, it will need to be used alongside other presbyopia-specific PROMs.

2.1.2.4. National eye Institute refractive error quality of life instrument (NEI-RQL). The NEI-RQL questionnaire was created specifically to measure the impact of refractive error and its correction on daily activities, addressing limitations of other tools such as the National Eye Institute - Visual Function Questionnaire (NEI-VFQ) [9], the Activities of Daily Vision Scale (ADVS) [24], and the 14-item questionnaire that assesses visual function (VF-14) [25], which were not designed to distinguish between individuals with corrected refractive error and those with normal vision. The NEI-RQL was developed for patients with 20/30 or better ( $\leq$ 0.18 logMAR) distant visual acuity, with or without correction or refractive surgery [26]. The NEI-RQL comprises 42 items across 13 sub-scales [9]. Although initial validation using traditional validation methods supported the reliability and validity of the NEI-RQL, a later evaluation using Rasch analysis showed serious deficiencies [27]. The availability of six response options for some items was discovered to be problematic as respondents tend to use only four or five, leading to poor performance of response categories and increased respondent burden. Moreover, the questionnaire demonstrated multi-dimensionality in six sub-scales and inadequate measurement precision due to poorly targeted items.

2.1.2.5. The refractive status and vision profile (RSVP). The RSVP measures self-reported quality of life (symptoms, functioning, expectations concerns) associated with refractive error and its correction [10]. The 42-item questionnaire was originally developed to capture patients' perceptions following refractive surgery, and as a result, 92 % of the participants had undergone refractive surgery. For this reason, it is only valid when evaluating the quality of life following refractive surgery [11]. Rasch analysis was used to evaluate the psychometric properties of the RSVP questionnaire and identified several problems [28], which improved using a shortened 20-item Rasch-scaled RSVP. In spite of this, it has later been found that none of the eight subscales included within the RSVP are valid for assessment of quality of life in patients with refractive error (lack appropriate and adequate items to address concepts captured within scales) [29].

2.1.2.6. Quality of life impact of refractive correction (QIRC). The QIRC questionnaire is a widely used questionnaire [30,31] that measures the quality of life impact of spectacles, contact lenses and refractive surgery [11]. The QIRC has been recommended as a preferred option to the RSVP for use in refractive outcomes research [28,29]. It was developed and validated in the UK population using Rasch analysis [11]. However, the questionnaire was developed with pre-presbyopic individuals only, thus limiting its applicability to presbyopes by not fully exploring presbyopic-specific issues.

2.1.2.7. Contact lens impact on quality of life (CLIQ). The CLIQ measures the impact of contact lenses on quality of life [13]. Although this questionnaire was targeted at adults, it was confined to the prepresbyopic population. This means that although it could be used clinically in presbyopes, it will not address presbyopia-specific issues that might be experienced in this population. For example, issues relating to the use of multifocal contact lenses, monovision or the use of distant vision contact lenses and reading spectacles. 2.1.2.8. Quality of vision (QoV). QoV is an instrument that measures the quality of vision by asking respondents to rate how frequent, severe, and bothersome 10 symptoms (glare, haloes, starbursts, hazy vision, blurred vision, distortion, double vision, fluctuation in vision, focusing difficulties and depth perception issues) have been over the past week using a 4-point scale [12]. The intended population includes patients with and without refractive correction (spectacles, contact lenses, refractive surgery, and intraocular refractive surgery with various types of IOLs) and patients who have eye diseases such as cataracts. Although the presbyopic population was included in its development, the questionnaire does not explore quality of life and/or specific activity limitations associated with presbyopia. Thus, it might need to be used alongside other questionnaires for a more comprehensive evaluation of presbyopia-specific issues.

2.1.2.9. Near vision-related quality of life (NVQL). In developing countries, little is known about the impact of presbyopia on quality of life, and there is a lack of correction of presbyopia, even with simple strategies such as the use of reading spectacles [32]. A study evaluating the impact of uncorrected presbyopia on the quality of life in subjects aged 40 and over in rural Tanzania demonstrated a significant impact on this rural setting [1]. Participants were asked to complete an unvalidated questionnaire that included tasks of everyday living in rural Tanzania that require near vision, for example, cooking food, sorting rice or grain, writing letters, or cutting fingernails and toenails. Similar findings were found in adult residents of Calabar (Nigeria) [33], but further research using superior psychometric models (Rasch analysis) is needed to further develop and evaluate the impact of vision-related quality of life with uncorrected presbyopia in developing countries.

2.1.2.10. Freedom from glasses value scale (FGVS) and the Patient-Reported spectacle independence questionnaire (PRSIQ). The FGVS is an instrument developed using classical test theory that measures patient's perceived value of being independent from spectacles after multifocal IOL surgery [18]. The scale solely focuses on the benefits of living without spectacles and includes items covering convenience, health concerns and emotional well-being. Limitations of this scale include the fact that content development was based on a small sample size of patients and the lack of construct validity and reliability of the scale [18].

## 2.1.2.11. Patient-reported spectacle independence questionnaire (PRSIQ).

The PRSIQ is used to quantify spectacle and/or contact lens independence at various distances (distant, intermediate and near) following cataract surgery with IOL implantation [19]. The questionnaire was initially developed with input from clinicians and patients following bilateral IOL implantation and was later evaluated using item response theory modelling to evaluate the psychometric properties. Three concepts of spectacle independence are evaluated as part of the survey: need, wear and ability to function without correction. Since its development, PRSIQ has used to evaluate spectacle independence outcomes following IOL implantation [34,35].

## 2.2. Psychophysical techniques

## 2.2.1. Acuity

2.2.1.1. Static. Measures of static visual acuity (that is the target and observer are stationary) are key in the clinical assessment of individuals with presbyopia, and in trials of surgical and therapeutic treatment approaches. As highlighted in BCLA CLEAR Presbyopia: Definitions report [36], acuity assessment is undertaken at a range of viewing distances corresponding to far (or distant), intermediate, and near vision. Charts based on logMAR progression have the advantage of a regular

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progression of letter sizes and spacings, which also allows changes in the distance of the chart to be easily scaled. Measuring static acuity for distant, intermediate and near distances is covered in the BCLA CLEAR Presbyopia: Definitions [36].

2.2.1.1.1. Defocus curves. By testing visual acuity at varying levels of dioptric defocus, an understanding of visual performance across a range of distances can be achieved; this can be particularly useful when evaluating and comparing the performance of presbyopia-correcting strategies [37]. In theory, the assessment of a defocus curve can replace the measurement of distant-corrected visual acuity at different testing chart distances and provides a greater level of detail than, for example, 2–3 discrete acuity measures [38].

Defocus curves may be plotted monocularly or binocularly and require the patient's distant refractive error to be corrected. A series of negative and positive power spherical lenses are placed in front of the eye(s) and the logMAR acuity is assessed at each level of defocus. The basic optical formula for focal length (f = 1/D) can be used to determine the physical distance that each level of defocus represents, for example, viewing through -2.50 D lenses corresponds to 40 cm [39]. The dioptric range of defocus tested is usually in the range + 2.00 D to -5.00 D, with measurements taken in 0.50 D steps [38,40,41], even though some authors have proposed 0.25 D intervals within the + 0.50 to -0.50 D region to obtain greater granularity regarding visual acuity for distant viewing vergences [39]. Although defocus curve assessment is a timeconsuming procedure and can be challenging for patients to maintain concentration [42], attempting to speed up data collection by using larger step sizes than 0.50 D is not recommended as the detail obtained from the defocus curve is reduced and common analyses such as range of clear focus and area under the curve are distorted [40].

During defocus curve testing, either the order of presentation of defocus lenses or the test chart letters should be randomised to minimise bias from memorisation and/ or a desire from patients to demonstrate good vision, for example, following presbyopia correction [43,44]. An alternative to using spherical lenses to introduce defocus is to move the test chart in real space and take measurements at a range of distances; this approach is more complex and rarely performed as accurate results would require resizing the chart at each distance along with careful control of illumination levels [38,42].

Prior to analysis of defocus curve data, acuities should be corrected

for spectacle magnification/minification induced by the trial lenses [44,45]. Approaches to analysis include direct comparisons of visual acuity at specific dioptric steps, the DoF method, and area under the defocus curve (Fig. 1). The direct comparison approach is commonly used to compare performance of different IOLs and involves statistical evaluation of visual acuity at discrete levels of dioptric defocus; whilst it is straightforward to make a direct comparison for a single dioptric step, the linked repeated measurements acquired for a whole defocus curve must be taken into account during statistical testing to reduce the possibility of a type I error [38,45,46]. Direct comparison is most useful to highlight differences in visual acuity at a specific distance, rather than more global performance [39].

DoF analysis interprets visual acuity over a range of distances and describes the dioptric defocus range over which a participant can maintain an absolute level of acuity (such as 0.30 logMAR is often used as this represents the visual standard for driving in many countries), independent of the best corrected VA, or a relative level of acuity compared to best corrected visual acuity (such as + 0.04 logMAR worse than best visual acuity). Cut-off limits are often arbitrary and vary between studies - an American Academy of Ophthalmology task force has advocated for 0.20 logMAR as the visual acuity threshold for evaluation of extended DoF IOLs [47]. Furthermore, in a single defocus curve, the criterion acuity may be passed through several times, for example with multifocal IOLs. Thus, area under the defocus curve (either area of focus or acuity reserve) can be useful for determining relative performance, by splitting the defocus curve into far (-0.50 to + 0.50 D), intermediate (-2.00 to > -0.50 D) and near (-4.00 to > -2.00 D) sections (Fig. 1); this approach has been shown to be sufficiently sensitive to differentiate between designs of multifocal IOLs [45]. More recently, a methodology based on acuity reserve has been described for the interpretation of defocus curves [48]. Acuity reserve represents the difference between print size (that is visual acuity demand) and the measured visual acuity at a particular distance (visual acuity threshold) [39]. Targets can be resolved when the visual acuity demand is lower than the visual acuity threshold, but when the demand is greater than the visual acuity threshold, the target cannot be resolved. To calculate an area under-thecurve metric using acuity reserve, an acuity demand curve is plotted on the defocus curve; the region below the target acuity and above the defocus curve equates to the acuity reserve. Over a range of distances, or



Fig. 1. Methods to quantify the DoF from a defocus curve. <u>Relative</u> to the best visual acuity allowing for the variability in acuity measurement; <u>Absolute</u> (at fixed level such as + 0.30 logMAR; true <u>subjective range of clear focus</u> (just on negative section of the X-axis; <u>DoF</u> (range on clear vision without accommodation or a multifocal correction; area metric with DISTant, INTermediate and NEAR regions.

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object vergences, the area under-the-curve metric can provide a single value describing performance. The acuity reserve approach has been used to compare trifocal IOL designs with regard to intermediate and near performance [48]. Area under-the-curve approaches to defocus curve analysis can provide a closer correlation to functional and subjective outcomes than a direct comparison at specific dioptric steps [39].

2.2.1.2. Dynamic visual acuity. Dynamic visual acuity has been described as "the ability to visually resolve subtle spatial details of an object when the object, the observer, or both, are moving" [49]. For purposes of comparison, static visual acuity distinguishes details of the images of static objects falling on the retina when the observer is stationary. Dynamic visual acuity evaluates the ability of the eye to actively look for information [50], resembling real-world tasks such as driving and flying. As the target speed increases the observer's acuity decreases. In such cases the static acuity is not indicative of the acuity when observing moving objects [51]. Hence this is an important aspect of visual function for a presbyope.

There are a number of factors that influence dynamic visual acuity, for example age, contrast, target size, target speed size, trajectory, exposure time and colour [52]. Dynamic visual acuity declines with age under all levels of illuminance, object speed and target size, with illumination being the most important factor in a dynamic setting [51].

In a study that measured dynamic visual acuity in 826 individuals ages 5 to 92 years, dynamic discrimination reached its highest level at the age of 15 years, becoming slower from the age of 20 years and older [53]; the ability to discriminate moving objects was greater amongst males compared to females.

There are several devices available to measure dynamic visual acuity, but they are mostly used for research or therapy [52]. They can have static optotypes (observed during head motion) or moving optotypes (presented either mechanically or by using a digital display). Head mounted virtual reality devices are becoming more popular and they can be programmed to measure dynamic visual acuity [54]. Dynamic visual acuity tests are mainly conducted to assess vestibular function in otolaryngology, sport activities and other diseases for example cataracts, optic neuritis, glaucoma and dizziness [55].

*2.2.1.3. Measurement conditions.* Visual acuity would normally be measured in near optimal conditions, normally high background luminance, high contrast targets and good room lighting. However, visual acuity measures may be significantly affected by changes in measurement conditions, so for research purposes, careful specification, control and consistency of conditions is required [56,57].

2.2.1.3.1. Targets. The type and presentation of optotypes can impact measured visual acuity. In individuals of all ages, isolated single line acuity measures achieve higher scores than those from a full chart in normal and amblyopic eyes, as the crowding effect is reduced [56]. Using single line or single letter acuity could therefore over-estimate visual acuity. Types of targets include *sans serif* letters, or for those who are not able to recognise and/ or report letters, tumbling E's. Landolt C's, or pictures. Ideally, all optotypes on a chart should be of equal legibility, although this is not truly possible with letter targets [58]. If more than one acuity measure is to be taken, randomisation or additional charts are required to avoid memorisation effects, which may be particularly pronounced when multiple measurements are made during a single examination [59].

2.2.1.3.2. Lighting levels. Illumination refers to the intensity of light falling upon an object. The Early Treatment Diabetic Retinopathy Study (ETDRS) protocol specified that for distant visual acuity assessment, an illumination level between 807 lx and 1345 lx should be used [60]. Significant worsening of distant visual acuity measures (even from illuminated charts) has been reported when measurements are taken in low room illumination, by as up to 0.13 logMAR [57,61,62]. The impact of low illumination on visual acuity measurements may be exacerbated

by the presence of refractive error [61,63,64], which may reflect reduced retinal blur under higher illumination levels due to pupil constriction.

2.2.1.3.3. Time of day. Small diurnal variations in visual acuity have been reported, with individuals typically demonstrating poorer uncorrected and spectacle-corrected acuities later in the day [65,66]. Physiological factors including changes in intraocular pressure, varying corneal hydration and curvature, as well as external factors such as variable testing conditions, participant effort and concentration have been suggested to contribute to slightly worse visual acuity measures in the evenings [66,67]. In environments where room illumination may vary significantly depending on the time of day, such as those with windows and natural light, an illuminance meter has been recommended to ensure consistency in measurement conditions [57].

## 2.2.2. Reading performance

The act of sustained reading is made almost exclusively at a near distance. Therefore, its performance is strongly impacted by presbyopia arising. Measuring reading performance can be used to assess the strength of presbyopia's impact on this ability or a way to evaluate the benefit of any device to "restore" accommodation.

Reading performance is affected by many features of the stimuli utilized to measure it, such as the font and size of the text, the length, frequency and lexicality of words, the type of the text (meaningful passages, unrelated words, non-words), the layout of the text, the intraword and inter-word spacing, and the line spacing [68-72]. Therefore, in the last decades, standardised clinical tests to evaluate reading performance have been developed to be used in clinical and research settings [73–75]. The majority of these tests display the reading materials with a logarithmic progression of the print sizes such as the Sloan Continuous Text Read Cards [76], the Bailey-Lovie Near Reading Card [77], the Colenbrander English Continuous Text Near Vision Cards [74], the SKread Charts [78], the Balsam Alabdulkader-Leat Chart [79], the MNREAD test [80], the Radner reading chart [81]. However, mainly the MNRead and Radner tests have been extensively used in the presbyopia field because validated versions are available in many languages [82]. MNREAD test was introduced in 1989 as a computerised test [80], and then moved to printed cards [83,84]. It comprises short sentences of 60 characters including spaces arranged in three lines, which decrease in size with a 0.1 logMAR-step. The Radner reading chart comprises short sentences of 14 words arranged in three lines. The different sentences were generated to be comparable to each other, being of the same word length, the number of syllables per word, the lexical difficulty, and linguistic aspects such as grammar and syntax [81,85].

The main parameters that can describe reading performance achievable with the mentioned standardised reading charts are the reading acuity, the mean and the maximum reading speed, and the critical print size. There are slight differences in the way those parameters are calculated. However, the reading acuity can be generally defined as the smallest text of the chart that can be read entirely, the maximum reading speed (measured in words per minute) as the reading speed that can be achieved when print size is not a limiting factor, and the critical print size is the smallest print that can be read at the maximum reading speed (Fig. 2)[74,75]. Digital versions of these reading performance tests offer more standardisation [86] and automation of reading distance, timing and data analysis [87].

The International Reading Speed Texts [88], designed for low vision research, provides long paragraphs of 141 words, controlled for syntactic difficulty to measure reading fluency [89]. It allows for the measurement of reading speed, and it is available in versions for 17 languages. The Wilkins Rate of Reading Test was designed to require only very basic reading skills and maximise visual demand [90]. It is made of 10 lines of the same 15 words arranged in pseudo-random order to achieve meaningless passages. This layout can allow the construction of many equivalent passages useful for investigating the effect of different visual conditions in cross-over studies [91].

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Fig. 2. Reading speed curve: relationship between reading speed as a function of print size. Dashed lines represent the two-limbed fit for the data.

## 2.2.3. Contrast sensitivity

Contrast sensitivity (1/contrast threshold) is an important factor affecting the quality of vision. It refers to the ability to differentiate an object from its background [92] and is measured across a range of spatial frequencies to determine the contrast sensitivity function, which describes the pattern detection ability of individuals. Contrast sensitivity is better associated with real world performance than traditional high contrast visual acuity measures and therefore provides a measure of functional vision [93], even when traditional acuity measures are normal [94]. Decreased contrast sensitivity is one of the significant visual changes that occurs with aging [95–98]. The loss of spatial contrast sensitivity at scotopic and mesopic conditions is more prominent than in the well-lit environment [99–101]. However, the sensitivity for lower spatial frequency decreases under rapid temporal modulation [96,100,102]. Contrast sensitivity assessment is particularly important to assess the performance of pseudo-accommodative optical devices to correct presbyopia since they increase spherical aberration that can compromise the modulation transfer function of that optical system, reducing contrast sensitivity [103]. Increasing the wavefront variance decreases visual performance in a pupil size dependent way [104]. For this reason, contrast sensitivity has been extensively investigated in studies on presbyopia correction with multifocal contact lenses [105-112], multifocal IOLs [111,113-118], multifocal corneal laser ablation [119-122] and corneal inlays [123,124]. The optical features of multifocal devices affects the contrast sensitivity function in different ways [109,116,117], with contrast sensitivity generally reduced compared to monofocal contact lenses, IOLs or spectacles [116,117].

Contrast sensitivity tests utilise different types of stimuli (gratings or letters), psychophysical methods and mediums (paper-based or computer) [125]. One of the most widely used clinical tests is the Pelli-Robson chart [126] which presents triplets of Sloan letters of a fixed size (49 mm; subtending 0.9c/deg in height at 1 m) of decreasing contrast in 0.15 log unit steps. The test is useful to identifying low spatial frequency loss and has demonstrated good repeatability [127–129]. A 'by-letter' scoring method, allowing for confusion between 'C' and 'O', has also been recommended to improve repeatability and address issues with the legibility of the letters [125]. Computer-generated versions of the Pelli-Robson chart provide less accurate and repeatable results compared to classic printed version, possibly due to the monitor affecting the contrast rendering on the screen [130,131]. Hence care is

needed when comparing results as they are not interchangeable. The Mars contrast sensitivity chart is similar to the Pelli-Robson chart, but was developed for near testing (50 cm) so uses a smaller letter size and contrast decrements (0.04 log unit) [132]. It has been shown to have good repeatability [129] and excellent agreement with the Pelli-Robson chart in young and older adults [130,133].

Other contrast sensitivity tests include the Vistech Vision Contrast Test System (VCTS) [134], and its newer version, the Functional Acuity Contrast Test (FACT) [135]. Both tests utilise sine-wave gratings at three orientations with five spatial frequencies at nine contrast levels (FACT has smaller step sizes than VCTS, of 0.15 log units). However, the FACT uses "blurred" grating patch edges smoothed into a grey background. The test uses a three-alternative force-choice method. Both tests have been reported to have poor repeatability for contrast sensitivity measurement in normal patients [128,136] and in cataract and refractive surgery outcomes [137]. An alternative to these tests is the VectorVision chart (such as CSV-1000) which also uses sine gratings, but it is a retroilluminated chart and only tests four spatial frequencies [125]. Although the test is clinically reliable in monitoring glaucoma therapy [138], low reliability has been reported in normal adult and children [139] because the two-alternative force-choice method of the test can cause error due to guessing.

Paper-based contrast sensitivity tests are easy to use in a clinical setting, however only broad discrete spatial contrast sensitivity can be assessed, limiting their flexibility [140]. Contrast sensitivity tests are not interchangeable and are strictly dependent on the different lighting conditions [128].

Computerised contrast sensitivity tests allow measurement of contrast sensitivity across a range of spatial frequencies and contrast, with the use of more sophisticated psychophysical methods being less dependent upon environmental lighting [141,142]. A Bayesian adaptive algorithm has been developed to estimate the contrast thresholds across a range of spatial frequencies [143]. This method allows high precision and efficiency rapid contrast sensitivity function measurement with excellent agreement with contrast sensitivity function measured by conventional method [144].

Since smartphone and tablet devices have become more easily accessible, new applications have been introduced to measure contrast sensitivity function [145–149]. The Aston mobile contrast sensitivity app which displays the complete contrast sensitivity function (a sine

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grating from low to high spatial frequency in the X-axis and from low to high contrast in the Y-axis), can be completed in less than one minute and shows good repeatability, though it showed higher contrast threshold than conventional tests [148]. An app to measure contrast sensitivity function with tablet devices (iPad) was compared against the FACT and no significant differences were found when the same contrast sensitivity steps were used [147]. Another app using tumbling E can also be completed in less than one minute and has shown good repeatability and agreement with a tumbling E version of the Pelli-Robson test [149]. However, both mobile contrast sensitivity apps were tested in normal young adults or specific group of individuals, so their reliability in measuring contrast sensitivity in older adults are not known.

The psychophysical methods to measure contrast sensitivity vary between different tests [150]. Pelli-Robson test uses the descending limits procedure that present super threshold contrast stimuli initially and the contrast level is reduced until a negative response is obtained. The descending limits method tends to underestimate the threshold while the ascending limits method tends to overestimate the threshold [151]. Staircase methods, or more sophisticated adaptive staircases methods available in computerised devices to measure contrast sensitivity, can provide more accurate results of the contrast threshold [125].

## 2.2.4. Measuring the AoA

2.2.4.1. Push-up / down and minus lens techniques. The 'push-up / down technique' is a method that can be used to determine a patient's AoA. The AoA is the maximum increase in optical power that an eye can achieve when adjusting its focus from far to near [152]. Knowledge of the AoA is useful when determining whether a near addition is required to manage presbyopia and, if it is, the value of the AoA helps determine what power of reading addition is needed.

2.2.4.2. Push-up technique. The patient performs this technique while looking though their fully corrected distant refraction, which should be balanced to provide the maximum plus power [153,154]. A target of text 1 log unit larger than threshold reading size [155] is presented at a dioptric distance of two (that is at 50 cm) from the patient's spectacle plane [153,156] and the patient is asked if they can focus on the text clearly. If they can, the target is slowly brought closer while the patient is asked to report when they can no longer keep the text completely clear. The dioptric distance from the spectacle plane to target at the first report of sustained blur is the subject's AoA. If the distance is measured in metres, then the inverse of this distance is the patient's AoA [154,155].

There is alignment in the literature that at least three measurements of AoA should be made and averaged to reach the final value [156,157]. Additionally, most authors recommend measuring accommodation monocularly and averaging between the eyes, because binocular measures over-estimate the value [154,157] due to the influence of convergence demands [158]. There is some variability in the literature regarding the optimal target with early reports recommending a single vertical line [159] while more recent guidelines seem to favour either a single letter [154,157], a single line of letters [154,155] or a paragraph of text [156,160]. It has been suggested that the target should be changed to a smaller size as it gets closer to provide more accuracy [155]. For those patients with difficulty focusing on the near target without any assistance, +1.00D may be placed over their distant refraction for the purposes of conducting the push-up technique (subtracted from the result) [161]. Accommodation measured by push-up technique has been shown to overestimate accommodation compared to more objective methods [155,162,163], presumed to be due to confounding effects of depth of field and poor blur detection [154].

2.2.4.3. Push-down technique. The push-down technique is similar to the push-up technique, but the object is moved away from the patient until it can first be clearly seen. It will tend to under-estimate the AoA and lacks standardisation of nomenclature and technique [164]. To minimise errors during clinical measurement of the AoA, it has been suggested that clinicians slide the visual object slowly whilst holding the rule in primary position of gaze and use the end-point criterion of sharp focus [165]. Using the average of the push-up and push-down techniques would further minimise any measurement errors associated with over and under-estimating effects.

2.2.4.4. Minus lens technique. The minus lens or negative lens to blur technique is conducted with the patient looking monocularly through their optimal distant refraction at an illuminated distant letter chart placed at 6 m. The accommodative demand is increased by adding minus lenses in 0.25 D steps until the patient reports it is impossible to hold the threshold acuity line in clear focus by making a conscious accommodative effort [154]. The minus power added over the distant correction is recorded as the AoA [154,166]. This method should be conducted under monocular conditions because it results in an excess of accommodative convergence which would be likely to disrupt binocularity [152]. Accommodation measured using the 'negative lens to blur' method has been shown to underestimate accommodation in younger adults and overestimate in older adults compared to more objective methods [154].

2.2.4.5. *Retinoscopy*. Retinoscopy has the advantage of not requiring judgement from the patient, but does require clinical expertise and skill. It can be used for measurement of AoA, with the practitioner determining the endpoint when accommodation is relaxed compared to maximally stimulated [167]. However, glare from the retinoscope beam can be an issue [165].

2.2.4.6. Calculating the near addition from the AoA. The near addition will depend on the dioptric working distance that the patient requires. It has been recommended that a person should not be expected to use more than half or two-thirds [166] of their AoA when conducting sustained close work. As a guide, if the patient's required working distance is declared or demonstrated to be 40 cm (2.50 D) or greater, the magnitude of near addition required can be calculated as:

### Dioptric working distance - 1/2 AoA

where AoA is the mean push up/down AoA between both eyes [165,166,168]. If the working distance is less than 40 cm, it may be acceptable to only leave one third of accommodation in reserve, and therefore the amount of near addition required can be calculated as [166,168]:

# Dioptric working distance - 1/3 AoA

However, it has been shown objectively that the mean proportion of accommodation exerted throughout an intense near task was 81 % (range 45 to 97 %), which increased with the individual's age, being robust to fatigue [169].

## 2.2.5. Dysphotopsia

A photopic phenomenon, termed dysphotopsia, can be induced by multifocal optics [170] and refractive surgery, the extent of which may be related to the ablation profile and pupil size [171,172], corneal and crystalline lens opacities [173], and is one of the few clinical tests correlated with night driving performance [174]. This is a major cause of multifocal dissatisfaction [175] and is a key factor in multifocal IOL explants [176,177]. It can be described by terms such as halo, starbursts and glare.

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Subjective assessment of dysphotopsia has been assessed by basic questions [178] and unvalidated questions/questionnaires (such as the 10 item Pseudophakic Dysphotopsia Questionnaire; 10 item visual symptoms questionnaire) on dysphotopsia [179–183]. Another approach has been the use of images such as the EyeVisPod illustrations [184] and a validated questionnaire based on standardised photographic images of ten photic phenomena (PIPP) being bright/dark/serrated arc, night/day halos, night/day starburst, central flash, ripple or streams [185] to represent the severity and types of dysphotopsia.

One digital approach has been software displaying customisable luminous peripheral stimuli that the patient is asked whether they can detect around a more luminous central one (the glare source) at 3 positions along 12 axes in a low light environment to calculate a visualdisturbance index. It has been shown to be sensitive to retinal disease [186], cataract [187], age [187] and myopic LASIK [188], but repeatability studies have not been published.

To measure the retinal blur circle or halo, several instruments, often referred to as halometers, have been created. These devices quantify the size of a photopic scotoma created by a central glare source, assessing forward light wide angle scatter rather than the narrower straylight [175], which has a stronger association with subjectively reported dysphotopsia, [184]. Early methods to assess halos required patients to draw the outline of the perceived halo produced by a candle at a set distance [189]. Others involve visually 'bracketing' the edges of the halo with the examiner's hands [190], comparison of their halo with objects of known diameter [191], or mechanical movement of a target towards or away from the light source in limited meridians [192]. Perimetry around a central glare source has also been applied [171,193]. However, few of these techniques have been validated [190,191], had their repeatability assessed [171,190,191] or are able to identify differences between multifocal and monofocal IOLs [190,193]. Early digital halometers consisted of a central light glare source, requiring the patient to circle the perceived photopic phenomenon [194-196]. These halometers have been used to examine dysphotopsia following multifocal IOL implantation [196] and post LASIK under physiological [194] and pharmacological (with a miotic agent) conditions [195]. The lightdistortion analyzer (Agilent Technologies), consisting of a central white light-emitting diode (LED) surrounded by 240 small, white LEDs distributed in 24 meridians 15 degrees apart, has been developed [197] and is able to differentiate between IOL optical designs [198,199] Another instrument that allow the area of obscuration of a target due to a glare source to be measured in multiple meridians (the Aston halometer) has been validated [200] and shown to differentiate between IOL optical designs [184].

Impact of glare on acuity or contract sensitivity [179], such as with the Brightness Acuity Tester, has also been used to assess presbyopia corrections such as contact lenses [201] and multifocal IOLs [202,203]. Such an approach can be reliable and discriminative [127], but is rarely used in routine clinical practice.

### 2.2.6. Eye dominance

Eye (or ocular) dominance is the superiority of one eye whose visual function predominates over the other eye [204]. As extensively recognized in the last century, this superiority depends on the visual skill examined, and therefore on the test used for this purpose [205]. It should be considered that the ocular dominance has multiple dimensions rather than one [206]. Several main types of ocular dominance have been broadly defined: acuity, sensory, sighting and motor [205,207]. However, in the last three decades, mainly sensory [208–215] and sighting [214,216–230] ocular dominance have been considered in studies involving presbyopes. Sensory dominance refers to the eye that dominates during retinal rivalry conditions; the sensory dominant eye can be determined by assessing which visual percept provides the most uncomfortable blurred vision during distant viewing with optimal correction and an additional plus lens (+1.00 or + 1.50 D) is introduced in front of either eye[214]. The sighting dominance implies a preference

in a task in which one eye has to be used, for example when a subject has to choose which of the physiologically diplopic images is lined up, or closest to being lined up, with the other object [231].

Traditionally, the evaluation of ocular dominance has been considered extremely important in the correction of presbyopia using multifocal optics and monovision with contact lenses, IOL and surgical techniques [221,231-234]. Especially in monovision, mini-monovision, or modified monovision (see BCLA CLEAR Presbyopia Definitions report)[36], which are forms of imposed anisometropia for which it is required that the eyes of presbyopes are corrected for different distances, the decision as to which eye should be corrected for far and which for intermediate or near might be of some importance [231,235]. Generally, for this purpose, the dominant eye is corrected for the most used distance, which is usually the far distance [234–237]. The rationale behind this choice was based on the assumption that it should be easier to suppress blur (which is an important mechanism in monovision adaptation) in the non-dominant eye than in the dominant eye [237]. The magnitude of eye dominance has an impact on the success of monovision [232]. However, it is still not clear, which kind of eye dominance between sighting and sensory (which are not strongly correlated with each other [238]) should be considered to make the best choice in monovision to achieve the best results in presbyopia correction [212.239].

This debate is fed by the different reliability of the two measurements and the relationship between the measurements and the suppression mechanism that could favour monovision success. One good feature of the sighting dominance measure is its consistency [206,220] when the test is repeated under the same conditions, although it has been found that the measure can be affected by changes in viewing distance and angle of gaze [240,241]. Measures of sensory dominance are less reliable [220]. Concerning the possible link between eye dominance and blur suppression, there is scarce evidence relating sighting dominance with blur suppression [242–244], but when the same eye demonstrated both sensory and sighting dominance, it was easier to suppress blur [245].

Regardless of the debate of the type of dominance, the importance of ocular dominance in monovision correction can be determined by comparing the performance of presbyopic people corrected with conventional versus crossed monovision (in which the non-dominant eye is corrected for the most used distance) [233]. Interestingly, many studies have indicated that crossed monovision can provide a good rate of success in some surgical monovision treatments [221,246], and also good visual outcomes [229,243] compared to conventional monovision.

Hence, no clear and reliable predictors of the success of presbyopia strategies such as multifocal or monovision corrections, in both in the contact lens [247] or surgical [248] field have been identified. Very commonly, clinicians use to correct the dominant eye for the most used distance which is usually the far distance [234–237]. However, the advantage of this clinical choice is not supported by clear scientific evidence [216,234]. The lack of this link might be due to the subjective nature of the dominance assessment, but no objective tools to assess eye dominance are available [249].

## 3. Objective techniques

## 3.1. Optical power

In a normal cornea, standard keratometry and corneal topography are sufficient in measuring four sample points to determine the steepest and flattest meridians of the cornea, thus yielding accurate values for central corneal power [250]. In a cornea that has undergone keratorefractive surgery, such as photorefractive keratectomy (PRK) or laser in situ keratomileusis (LASIK), these four points are insufficient to provide an accurate estimate of the corneal refractive power [251]. Inaccurate calculation of corneal refractive power from the anterior corneal curvature thus occurs, as the device assumes the standardized

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value for refractive index of the cornea (1.3375 in most cases), which is based on the assumption that there is a stable anterior corneal curvature/posterior corneal curvature ratio [250]. Removal of corneal tissue changes the relationship between the curvatures of the front and back surfaces of the cornea, thus invalidating the use of the standardized refractive index [250,252].

Many different lens equations and strategies exist for post-refractive surgery eyes. Some equations use historical data (pre-operative refraction readings and central keratometry), while others do not [250,253–259]. Some strategies involve using Scheimpflug tomography or anterior segment optical coherence tomography (OCT) to measure additional corneal parameters that could be helpful in achieving a more accurate lens power calculation.

A number of methods now exist to correct presbyopia by manipulation of the cornea alone [38,260–267]. These include insertion of inlays to reshape the corneal surface, thereby creating negative spherical aberration [266,268–270], an inlay to extend DoF via a pinhole design [262,271] or LASIK to create a multifocal ablation on the anterior corneal surface [119,261,264,272,273] These, and other methods, are covered in greater detail in BCLA CLEAR Presbyopia: Management with Corneal Techniques report)[274]. Given that many of these patients will subsequently require cataract extraction, it is vitally important to assess baseline corneal curvature, thickness and topography for such values to be used for accurate calculation of any IOL.

## 3.1.1. Corneal topography

Corneal topography plays an essential role in the management of presbyopia for two main reasons. Firstly, topography is used to determine the power of the cornea, and a precise assessment of this is required to accurately determine the power of any IOL implanted postcataract surgery [275]. Secondly, an accurate method to determine corneal shape and its impact on IOL calculation is required in patients who have previously undergone keratorefractive surgery [255,257]. Corneal power forms one of the three most important measures for IOL calculation, along with anterior chamber depth and axial length [275,276]. If the calculation of corneal power is inaccurate, it will have profound consequences on the remaining steps in the calculations of IOL power, regardless of the nomogram used [276,277]. The same holds true for axial length measures, with previous studies determining that appropriate IOL power calculation will vary depending upon the formula used, and that the formula selected will depend upon the axial length of the eye [278].

The optics of the eye has been extensively studied [279,280]. Assuming a refractive index of 1.376, the power of the cornea is slightly above 43 dioptres (D), thus accounting for approximately two-thirds of the eye's total optical power [279]. The human lens thus contributes about one-third to the total power of the eye during relaxed accommodation [279]. Crystalline lens power increases with accommodation from about 21-22D in the unaccommodated state to above 30D for the fully accommodated lens [279,281]. Corneal shape, and subsequently its power, can be determined via a variety of instruments:

3.1.1.1. Reflection techniques. Measurement of the curvature of the anterior surface of the cornea was initially undertaken using the keratometer, which was invented by von Helmholtz in 1851 to assess the magnitude and orientation of corneal astigmatism [282]. The reflection of a target of known size of a known distance is viewed using a shortfocus telescope, and a relatively simple equation allows the corneal front surface radius of curvature to be determined. The corneal power associated with the measured radius can also be calculated using an assumed refractive index for the corneal tissue. The actual region over which a standard keratometer measures corneal radius is that of two small areas approximately 1.5 mm on either side of the central fixation point. Most modern keratometers are automated, using infrared devices that rapidly and automatically determine central keratometery and

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refractive error simultaneously. In addition to determining central radius of curvature, it is useful to measure peripheral radius values, particularly in complicated conditions such as post-penetrating keratoplasty and post-refractive surgery. Standard keratometers cannot determine corneal curvature accurately if the surface being measured does not have a constant radius of curvature or is not radially symmetrical. For this reason, dedicated instruments using other technologies have been developed to measure 'corneal topography' over a larger portion of the cornea. The target is a series of concentric rings (a Placido disc image), permitting both central and peripheral curvature to be determined. The image is captured electronically, and image-processing software provides analysis of the reflected image. As the reflection of the mires occurs at the change of refractive index from air to the tear film on the ocular surface, the quality of the tear film is critical to accurate measurement. The curvature, height and power distribution of the corneal surface is presented using colour-coded maps, in which greens and yellows represent powers characteristic of those found in normal corneas, blues or cooler colours represent flatter areas (low powers) and reds or hotter colours represent steep areas (high powers). The history and detailed description of topographers are described elsewhere [283,284].

3.1.1.2. Optical section techniques. Reflective devices are limited to determining the shape of the anterior corneal surface only. A range of instruments are available that allow tomographic imaging, a process whereby a series of two-dimensional images are reconstructed into three-dimensional (3D) images using technology such as slit-scanning, Scheimpflug imaging and OCT.

3.1.1.2.1. Slit-scanning devices. The Orbscan 3 (Bausch & Lomb, Rochester, NY) combines slit-scanning technology with a Placido disc system to obtain topographic measurements of both anterior and posterior corneal surfaces, full corneal pachymetry or anterior chamber depth, but at a higher resolution of 23,000 points compared to the previous Orbscan IIz's 9,000 points [285]. The instrument scans across the anterior corneal surface, obtaining sequential slit images, whilst simultaneously recording reflection data from a Placido disc device. The data are then reassembled into a 3D reconstruction of the anterior and posterior corneal surface [286–288].

3.1.1.2.2. Scheimpflug imaging devices. The Scheimpflug Principle involves the rotation of a lens about its horizontal or vertical axis to adjust the plane of focus, extending the DoF. The original Pentacam (Oculus, Wetzlar, Germany) was the first instrument to use a rotational Scheimpflug camera, permitting imaging from the anterior corneal surface to the posterior lens surface to provide 3D, non-contact imaging of the anterior segment [289]. The instrument uses a 475 nm blue light source and two camera systems to capture an image. The rotational Scheimpflug camera takes up to 50 cross-sectional images on an angle from 0 to 180 degrees in a single scan, acquiring 25,000 data (elevation) points in approximately two seconds. As the instrument uses a rotating camera, accurate measurements can be obtained from highly irregular corneas that reflective Placido-based systems struggle to image accurately. It has been followed by several newer iterations, including the Pentacam HR (which has 138,000 elevation values), Pentacam AXL and the newest Pentacam AXL Wave, that provide additional information, such as axial length, wavefront aberration measurements and retroillumination imaging capabilities [290].

3.1.1.2.3. Anterior segment optical coherence tomography (OCT). OCT is a non-contact optical imaging technique that is capable of high-resolution cross-sectional imaging of biological tissue using infrared light [291,292]. Lateral resolution of the image is a function of the optics of the device. The coherence length of the light source dictates the axial resolution. Conventional interferometry (laser) has a long coherence length (in the order of a meter), so to image the eye at high resolution, broadband (covering a range of frequencies) light sources are used to shorten the coherence length to micrometers. These broadband light

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sources are typically super-luminescent diodes (bright light-emitting diodes) and lasers with extremely short pulses (femtosecond lasers). An interference pattern occurs if light from the reference arm (reflected from a mirror) and the measurement arm (reflected from ocular surfaces) travel the 'same' optical distance (that is a difference of less than a coherence length) before being recombined. Any light that is outside the short coherence length will not contribute to the coherence pattern. The technique uses Michelson interferometry to compare a partially coherent reference beam to one reflected from tissue. The two beams are combined and interference between the two light signals occurs only when their path lengths match to within the coherence length of light. The magnitude and distance within the tissue of the reflected or back-scattered light at a single point are determined using a mirror system to form a reflectivity profile (or an A-scan, analogous to ultrasound) [293].

A tomographic image, a B-scan, is generated by assembling multiple A-scans. Reflections occur at boundaries between materials of differing refractive indices, and the greater the difference in index the greater the amplitude of the reflected signal. The B-scan represents a cross-sectional view of the structure under investigation, similar in appearance to a histological section.

OCT was initially used to image retinal complications, in which tissues had become separated or changed in structure. Commercially available OCTs with anterior segment imaging capabilities are now commonplace. With resolutions between 2 and 20 µm, anterior segment OCT is increasingly used to examine the cornea [294] and has proven useful in determining epithelial and total corneal thickness changes following refractive surgery [295,296], assessing corneal central and average thickness in cases of ocular hypertension and glaucoma [297], in patients with corneal oedema [298] and in the examination of patients with dry eye disease [299]. Anterior segment OCT imaging modules also incorporate anterior and posterior corneal topography, permitting shape and power calculations of the cornea. New technology provides multiple simultaneous beams (hyperparallel OCT) rather than scanning of a single beam, to rapidly capture three-dimensional biometry of the ocular structures [300]. Three main types of OCTs are available for anterior segment imaging: time domain, spectral domain and swept source scanning [301].

## • Time domain OCT

In time-domain OCT, a movable reference mirror is used to reflect the light source to generate a series of images. By taking a series of 500–2,000 A-scans per second, a reflectivity profile is generated, and the depth of ocular tissues is determined [292]. However, the low A-scan rate of time domain OCTs negatively impact the resolution and sensitivity of the images obtained [302].

## • Spectral-domain (Fourier-domain) OCT

Where time domain OCT uses a moving reference mirror, spectraldomain OCT (also known as Fourier-domain OCT) uses a fixed reference mirror. The interference between the ocular tissue and the reference reflections is detected by a spectrometer which is Fourier transformed to generate an A-scan [302,303]. Spectral domain OCTs use wavelengths of 820–879 nm, with the spectral bandwidth setting the axial resolution of images (3–5  $\mu$ m compared to 17  $\mu$ m) and the signalto-noise ratio is proportional to the number of detector pixels. However, the longer wavelength used in time domain OCTs allows deeper tissue penetration, to better image anterior segment structures [292,302,303]. The speed of image acquisition with spectral domain OCTs is faster than time domain OCT, acquiring 25,000 to 50,000 A-scans per second [302].

### • Swept-source OCT

Swept-source OCT is another form of Fourier domain OCT, which uses longer wavelengths of 1050 to 1300 nm, permitting deeper penetration into tissues and allowing imaging with enhanced visualisation of the anterior segment [304]. This technology uses a tunable laser that scans through a range of wavelengths of the light source to generate an interferogram. The interferogram is Fourier transformed to produce an A-scan, and several A-scans are assembled to form the cross-sectional Bscan. The scans are of high resolution, with photodetectors replacing charge couple device cameras to further increase resolution to 1  $\mu$ m and overall scan acquisition time is faster than spectral domain OCT (up to 108,000 scans per second), which reduces any artifacts arising from eye movements [292,305]. The reduction in signal-to-noise ratio with penetration depth in spectral dispersive OCT is overcome by swept source OCT; however, it has been suggested there are non-linearities with wavelength, especially at high scanning frequencies [306]. A recent report demonstrated that use of a SS-OCT was very useful in determining IOL powers in eyes with posterior subcapsular cataracts [307].

## 3.1.2. Autorefraction / aberrometry

Refraction measures the power of the eye relative to the viewing distance, so by comparing autorefraction or aberrometry refraction when an individual is focusing at a distant object and at near, any objective accommodation will cause a negative shift in power. Hence autorefraction is a key objective measure of the main mechanism of presbyopia (a loss of accommodation) and can also be used to quantify attempts to restore eye focus. Targets which can be optically varied in accommodative demand can be located within the visual path of instrumentation, but the accommodative state can be influenced by the 'closed' nature of the instrument (termed instrument myopia) [308]. Hence open-field instruments, where the patient views targets in the open environment through a beam-splitter, are preferred in accommodation research. Accommodation is considered to be uniform across all meridians, so a mean spherical equivalent is traditionally used or only one axis is assessed (compared to three to determine a sphero-cylindrical refraction [309]). The principal methods of autorefraction / aberrometry include:

*3.1.2.1. Purkinje images.* Attempts have been made to measure changes in refractive error by photographing the Purkinje images. However, the 3rd Purkinje image is very dim and the glare of the light source obscures the target [310].

3.1.2.2. Automated retinoscopy. Some autorefractors use a technique that is an adaptation of retinoscopy whereby the speed or the direction of movement of an image is detected by photodetectors and computed to determine the patient's refraction. However, the speed of measurement is limited, especially if multiple meridians are to be assessed [311].

3.1.2.3. Intensity of the fundus reflected image. Optometers (a term coined by Porterfield in 1759 to describe an instrument for "measuring the limits of distinct vision, and determining with great exactness the strength and weakness of sight") encompass a Badal optical system, placing a convex lens at its focal length in front of the eye, creating a linear relationship between the distance of the Badal lens to the eye and the ocular refraction within the meridian being measured (Fig. 3).

Light reflected from the retina has an optimum intensity along its axis at the point in which it is focused, so moving the lens along the axis to identify the maximum can be related to the optical power of the eye [312]. As the refractive power was not calculated from the magnitude of

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Fig. 3. Badal optometer principle.



Fig. 4. Scheiner disc optometer principle.

the signals, it was unaffected by the pupil size above a threshold diameter (around 3 mm with static measurements and 4 mm in dynamic configuration [309]). However, this requires a movable lens carriage so is relatively slow and it requires good fixation for accurate measurement [313]. If the carriage is disabled and set manually to the linear portion of the voltage output/time curve, the change in intensity quantifies dynamic accommodation over a limited range of about 3.0D [314]. The waveform amplitude produced varied substantially between individuals, presumably because of individual differences in media characteristics or retinal reflectance, so universal calibration was not possible.

*3.1.2.4. Scheiner principle.* The Scheiner disc principle is based on a double pinhole being placed in front of the patient's eye to determine the level of ametropia present (Fig. 4). A myopic eye will see the image viewed through the two holes as crossed, whereas the hyperopic eye will see the images uncrossed, with the pinholes occluded in turn to identify

whether the image is crossed or not. In autorefractor form, two infrared lights are used (to have minimal impact on pupil size and visual distraction), imaged in the plane of the pupil (acting as virtual pinholes), with a photodetector observing the degree of coincidence between the two images on the fundus. The focus is adjusted by axial displacement of the illumination and detection systems until the fixation target is focused and aligned on the retina. As the separation between the lights varies with refractive error, researchers [310,315] were able to measure accommodation continuously by rotating a wheel, obscuring each slit in turn at 300 Hz. Modulation of the signal in phase with the rotation of the disc occurred with eye defocus, with the ratio of light between the photocells indicating the direction of the defocus. No modulation occurs if the eye is focused on the filament image. Although the temporal resolution was high, calibration assumed that the accommodative response to a dioptric stimulus was accurate, the measurement range was small (about 3.0D), pupil dilation and precise fixation was required (with the participant's head stabilised using a bite bar).



**Fig. 5.** Photoretinoscopy (eccentric) optometer principle. When the eye is focused in the plane of the camera, the reflection from the pupil is evenly illuminated (top image). When the eye is focused in front of the camera plane, the reflection from the pupil is brighter in the direction of the light source (middle image). When the eye is focused further than the camera plane, the reflection from the pupil is brighter in the direction away from the light source (bottom image).

3.1.2.5. Size of projected image. The size of an image reflected off the retina is altered by the optics and length of the eye. This principle has been used to reduce the need for adjustment of a lens position for precise focus and instead an infrared ring or parallel line target imaged on a digital camera sensor is image processed to determine its reflected dimensions [316]. The open-field Shin-Nippon / Grand Seiko branded autorefractors have been found to be highly valid (accurate) compared to subjective refraction and repeatable in both adults [317] and children [318], with pupil sizes as small as 2.3 mm. The instrument can be converted to give dynamic measurements of accommodation up to 60 Hz by continuous display of the measurement ring and image analysis of the video output of the instrument [319].

3.1.2.6. Photorefraction. Photorefraction allows the remote (at about 1 m) measurement of refractive error by analysing the vergence of light reflected from the fundus (Howland and Howland, 1974). In early designs, the light source was centred on the camera lens and surrounded by four-cylinder lens segments (orthogonal photorefraction). The lens segments focused the light creating a cross-shape pattern, with the length of the 'arms' being correlated to refractive error in each meridian. The sign of the refractive error could only be determined by the bluish arm fringes, caused by chromatic aberration if the eye was hyperopic, or reddish if the eye was myopic. Some screening studies used isotropy photorefraction (such as [320]) which involved 3 images, one focused on the pupils, one 0.50D in front and one 0.50D behind the pupil plane [321]; the greater the degree of defocus of the eye relative to the camera, the greater the radius of the imaged blur circle of the pupil, with the sign of the error being determined from a comparison of the images.

Eccentric photorefraction typically involves light entering the pupil from infrared sources positioned just below the centre of the camera lens on a mask (creating a 'knife-edge') obscuring the lower half of the camera lens [322-324]. Original versions analysed the height of the light crescent in the pupil, but the analysis of the intensity gradient of the pupil light crescent is more robust and is currently utilised (Fig. 5). If the eye is focused at the distance of the camera lens, no reflected rays enter the camera aperture, and the pupil is evenly and diffusely illuminated. In an eye focused closer than the camera (that is relative myopia), the reflected light is divergent and only rays emerging from the lower part of the pupil can enter the camera aperture (due to the camera mask). A luminance gradient is generated in the pupil with most light in the bottom of the pupil. In contrast, if the eye is focused more distant than the camera (that is relative hyperopia), only rays emerging from the upper part of the pupil can enter the camera aperture. If multiple light sources are placed below the knife edge, the accommodative range over which no light crescent is visible (dead-zone) is compressed and the brightness gradient is more linear [325]. Astigmatism can be measured in static mode by placing knife edges in multiple meridians 60° apart and measuring the perpendicular gradient profile of light [326,327].



Fig. 6. Hartmann-Shack aberrometry principle which uses a lenslet array to evaluate the visual disturbances of the wavefront exiting the eye from a laser pointsource input. The deviation of the light spot from each lenslet from that of a perfect wavefront is measured with a charge-coupled device (CCD) digital camera.



Fig. 7. Pyramidal aberrometry principle. The pyramid dissects the light exiting the eye into four images of the pupil with different intensities onto the same digital sensor; the local wavefront tilt can be computed from the relative point-to-point intensity differences between the four pupil images, allowing much higher resolution than the other aberrometer types. CCD = chare coupled device. L = lens.

This approach continues to be used in commercial instruments [328], including improving image interpretation accuracy with deep learning [329] and in attempts to measure refraction with smartphones [330].

3.1.2.7. Aberrometry. An aberrometer is an advanced form of autorefraction that examines light refraction from multiple sites on the eye. The most common sensor is the Hartmann-Shack which uses a lenslet array to evaluate the visual disturbances of the wavefront exiting the eye from a laser point-source input (Fig. 6). The deviation of the light spot from each lenslet from that of a perfect wavefront is measured with a digital camera [331]. Tscherning aberrometers shine a fine bundle of laser beams into the eye and the pattern on the retina, having traversed through the eye's optical system, are imaged with a digital camera to determine the wavefront induced distortions [332]. Ray tracing aberrometry involves scanning a single laser beam, parallel to the line of sight, across the optics of the eve and imaging the projection on the retina at each point in the scan to construct a map of the wavefront distortion [333]. More recently pyramid aberrometers [334] dissect the light exiting the eye into four images of the pupil with different intensities onto the same digital sensor; the local wavefront tilt can be computed from the relative point-to-point intensity differences between the four pupil images, allowing much higher resolution than the other aberrometer types (Fig. 7). Other aberrometry principals have also been developed, but are not yet widely used [334].

While the waveform can be used to mathematically derive Zernike coefficients of higher order aberrations or point spread functions [335], it is the lower order spherical aberrations that can be used as with autorefractors, to assess objective accommodation. Transitions between different refractive zones (such as with diffractive lens optics) can create distortions in localised laser light deviation, compromising the optical quality measurements derived by aberrometer [336,337].

3.2. DoF

The DoF is the perceptual tolerance of the human eye to retinal defocus [338] and can be defined as "the distance in front and behind the focal point (or retina), for a given setting of an optical system (or a steady state of accommodation of the eye), over which the image may be focused without causing a sharpness reduction beyond a certain tolerable amount" [339]. DoF is the relationship between the DoF measured as dioptric distance (D) between the points behind and in front of the retina conjugated with the vergence range in the object plane that does not result in objectionable deterioration in retinal image quality (Fig. 8) [340].

The DoF is important in ameliorating presbyopia symptoms because it can partially compensate for the loss of accommodation (also known as pseudo-accommodation [36], allowing presbyopes to still see in focus over a range of distances [341]. For example, an emmetropic presbyope 60-year-old with an objective accommodation close to zero, and a DoF of 1.00 D, who is viewing at infinity, has a hyperfocal distance of 1 m. The contribution of DoF explains also why the AoA curve measured with subjective methods without appropriate compensation for the DoF (such as push-up or negative lenses to blur; see Section 2.2.4), shows a residual accommodation over 55 years when objective accommodation is practically null (Fig. 9). The difference between the subjective (greater) and objective AoA has been widely shown [342].

To determine the DoF, according to its definition, a criteria should be established for a "certain tolerable amount of sharpness reduction" that can be determined both with subjective and objective measures [343]. The most widely subjective criteria used to measure DoF is the perception of just detectable target blur [344]. In other subjective methods, DoF is described as the dioptric range of defocus over which the observer can sustain a specific level of visual acuity (absolute criteria) or does not exceed a specific reduction of visual acuity or contrast sensitivity compared to the best level of that functionality (relative criteria) [38,343]. For example, the latter criteria to detect the DoF can be adopted with the defocus curve paradigm (see paragraphs 2.2.1.1.1) as the horizontal distance on the curve (D) for a threshold level of + 0.1 logMAR from the maximum visual acuity [345].

Objective ways to define the DoF are, for example: the focusing range for which no change in accommodation is detected [346,347] - in this case, the retinal defocus error would not exceed the requisite neurosensory threshold to ignite accommodation [348]; or for which some parameters (directly measured or calculated) of the quality of the retinal image (such as the point spread function) does not exceed a certain value [343,349].

The subjective DoF increases with age [346], and it is always greater than the objective counterpart which is instead more stable over the same period [346]. Considering the different methods and criteria to identify the blur to measure the DoF, the value of human total DoF (the sum of the proximal and distal halves of the DoF) was found to range from 0.04 D to 3.50 D [344].



Fig. 8. Sketch of the relationship between depth of field and DoF.



**Fig. 9.** Example of accommodative and pupillary response in a 54-year-old male elicited by a stimulus with two cycles of 0–3 D accommodation demand. Despite the absence of accommodation response (blue line), the accommodation stimulus ignites a pupillary constriction (the pecks down in the green line after the onset of accommodation demand). The first peck down (about at 4 sec) is the response due to due switching on of the stimulus (light response). (Redraw from the output of Osiris Aberrometer; CSO, Florence Italy).

DoF depends on several factors mainly linked to the stimulus properties (such as luminance [350,351], contrast [343,350], wavelength [350], spatial details [343,351,352]), the optical properties of the eye (such as pupil size [343,352], retinal eccentricity [353–355], refractive state [356,357], monochromatic and chromatic aberrations [358], diffraction [359]), retinal and neural factors [342], visual acuity [359,360], Stiles-Crawford effect [349], and also the instruction and training in any measurement involving subjective judgment [343].

Measuring the DoF is important in presbyopia examination and correction because it can influence the needs of presbyopes, and therefore the precision of correction that should be provided by corrective lenses and surgical treatment [344]. It is also important to understand how the DoF of the eye is actually gained by pseudo-accommodative strategies that work on increasing spherical aberration of the eye (with multifocal contact lens [361,362], multifocal orthokeratology treatment [363], multifocal IOLs [248,364], multifocal corneal refractive surgery [248]) or by pinhole DoF expansion (with IOLs, corneal inlays and pharmaceuticals – see BCLA CLEAR Presbyopia: Management with reports) [38,274,365–367]. Therefore, one way to assess how effective a presbyopia correction method can be, especially in the case of multifocal modalities, is to measure the DoF directly, or the magnitude of spherical aberration induced by the correction (see section 3.1.2.7 on aberrometry).

## 3.2.1. Pupil size

In presbyopes, investigating pupil size, position and dynamics can provide useful information about the residual near visual functionality and the quality of vision with different correction strategies, especially multifocal optical designs displayed by contact lenses, IOLs, corneal refractive surgery and corneal inlays [106,214,248,364,368-375]. Pupil size controls the amount of light entering the eye and affects the DoF of the eye, the diffraction and the magnitude of specific aberrations [343,344,349,352,376,377]. The total DoF decreases by about 0.12 D per millimetre increase in pupil diameter over the range from 2.5 to 8.0 mm [352]. Besides the level of illumination which is the most important factor affecting pupil size [378], and also the pupil centre location [379], age is another important factor that affects both pupil size and its dynamics [340]. Pupil size decreases with age [380] and this can help in reducing the defocus blur and increasing DoF of the system to cope with accommodative decline [381], although this is not apparent in early presbyopes [382]. This mechanism represents the pillar behind several proposals to correct presbyopia such as the pharmacological reduction of pupil size, or the use of small aperture optics embedded in corneal

inlays, IOLs or contact lenses [274,365–367,383–390]. Pupil size can also be influenced by refractive errors [391–393], though not all studies have found the same findings [380,394,395], and can be reduced under binocular compared to monocular conditions [396,397]. The pupillary near response is still elicited in presbyopes unable to accommodate [325,382,398](Fig. 9).

It is not simple to measure pupil size accurately since the many factors reported above which can affect its size [399]. The pupil diameter can be measured by rulers [400], comparison methods (patient's pupil is compared with a reference card as for the Rosenbaum card) [401], light-amplification pupillometers [400,402–404], digital infrared video pupillometers [399,402,404–408] (these devices can be either handheld or more often, integrated with digital videokeratography) [405] and aberrometers (that assess the pupil diameter from the outgoing ocular wavefront) [402]. Some of these new techniques allow dynamic and binocular measurement [402]. Infrared pupillometry instruments provide reliable results [402,407], however, dark adaptation is critical for accurate pupil measurement [409].

Pupil size can impact the area of the lens optics exposed and therefore influence the visual performance [214,248,364,375]. For example, the contraction of the pupil in near vision can allow better functioning of multifocal devices (IOLs and contact lenses) that employ a centre-near design, because this contraction enhances the contribution of the near area in the centre of the lens and reduces the contribution of the annular periphery with correction for distant vision [369,375,382] However, the impact of the pupil on multifocal devices can be very different depending on the optical design of the device [375] and studies have found no association with patient preference or performance between designs [214,223]. For some multifocal contact lenses and IOLs, pupil diameter affects visual performance (termed pupil-dependence) [410-412], with an individual's loss of contrast (which is a potential factor leading to dropout in presbyopic contact lens wearers) [413] and dysphotopsia symptoms [414]. Other optical designs, such as nonsymmetrical and diffractive bifocals or multifocal may be less affected by pupil diameter (termed pupil independence) [375,415].

Optical device centration relative to the pupil has been explored to aid the understanding of the visual performance with multifocal contact lenses (including orthokeratology), IOLs and corneal laser-based approaches, which is generally assessed through a slit lamp or with topographical techniques [364,373,416–419]. Decentration of diffractive and bifocal IOLs have a negative impact on optical quality [420], whereas no effect of pupil centration was found to be associated to wearers preference or performance of different multifocal contact lenses

#### [214].

## 3.2.2. Neural factors

Adaptation can affect the actual perception of image focus [421,422] and can therefore ameliorate the symptom of presbyopia, interacting with the pseudo-accommodative strategies of correction. For example, the increased DoF in presbyopia, which is an increased tolerance to defocus related to the gradual onset of presbyopia [346], not explainable only with the reduction of pupil size occurring at that age [423], has been suggested to result from a blur-adaptive phenomenon [422,424,425]. It has also been proposed that forms of neuroadaptation might overcome the visual drawbacks (such as a contrast sensitivity drop) induced by spherical aberration used in multifocal contact lenses, IOLs and corneal inlays, to enhance the DoF in presbyopes [426]. This idea is supported by the fact that the visual system can remove aberrations from the perceptual experience [427]. Understanding these forms of neuroadaptation are important for optimising presbyopia correction [428,429]. Different techniques of neuroimaging and electrophysiology have been utilized to study neuroadaptation mechanisms in presbyopia correction: functional magnetic resonance imaging to explore brain correlates of adaptation to multifocal IOLs [430,431]; the use of visual evoked potential to explore brain correlates of adaptation to monovision [228] and multifocal IOLs [432]; and multifocal electroretinography to explore early retinal correlates of adaptation to multifocal IOLs [433]. Interestingly, these methods found that several sites from the retina to the visual cortex and frontoparietal areas may play a role in the neuroadaptation to optical devices for presbyopia correction [228,430,431,433]. However, the understanding of these adaptation mechanisms is still limited.

## 3.3. Lens shape / position

The change in shape of the crystalline lens has been used as an indirect measure of the change in lens power with accommodation [434]. However, it requires assumptions of the refractive index of the crystalline lens, which has a changing gradient with age [435]. Imaging can also be useful for assessing the *in-vivo* mechanics of IOLs designed to restore accommodation [436].

# 3.3.1. Scheimpflug imaging

The Scheimpflug principle images the anterior eye with a camera perpendicular to a slit-beam, create an optic section of the cornea and lens (see Section 3.1.1.2.2). Most modern devices rotate the camera around the visual axis capturing multiple images to create a threedimensional image of the anterior chamber. However, due to the refracting surfaces the light passes through and the tilt of the camera, the unprocessed Scheimpflug image is distorted. The image is decreased in size perpendicular to the direction of the optical axis so the curvature radii of subsequent radii are reduced, such as the posterior corneal surface and both the lens surfaces [437] and the anterior chamber depth underestimated in pseudophakic eyes [438]. The material of the IOL will also affect the measured light scatter, limiting the usefulness of Scheimpflug imaging in absolute quantification of posterior capsule opacification [439]. As well as lens positioning [440], the technique had been used to examine changes in the human lens thickness with age [441] and transparency after femtosecond laser attempts to soften the lens [442].

#### 3.3.2. Ultrasound biomicroscopy

Ultrasonography involves the measurement of the time taken for high (radio) frequency audio mechanical pulses, usually generated by piezo-electric components, to be reflected by tissue interfaces (A-scan). The probe can be scanned across the eye to create a section (B-scan) or moved in a raster pattern to extract three-dimensional structure [443]. As the technique uses high frequency pulses rather than light waves, it can penetrate opaque corneas and the iris to examine the peripheral lens

/ IOL, ciliary body and surrounding structures. The resolution and depth of penetration of ultrasonography are affected by transducer frequency. Traditional ultrasonography of the whole eye uses a 10-20 MHz transducer, with approximately 100 µm resolution achieving 25 mm penetration. High-frequency ultrasound biomicroscopy with a transducer of approximately 50 MHz increases the tissue resolution as small as 30 µm, but reduces tissue penetration depth to 4-5 mm. Higher frequency ultrasound (such as 75 MHz) can be utilized improving lateral resolution and increasing the sensitivity to backscattered light from the corneal stroma. This very high frequency ultrasound still allows the iris and body to be visualized through the sclera despite the increased effects of absorption of the ocular tissues and fluid media [444]. Ultrasound biomicroscopy has been used to show that accommodative ciliary muscle function is preserved in older humans [445] and to investigate the mechanism of action of accommodation [446]. The velocity of sound transmittance through the lens with age doesn't seem to change, so image warping is avoided [447].

# 3.3.3. Optical coherence tomography (OCT)

Optical Coherence Tomography (OCT) quantifies the distances of objects within an organ by the reflection of light [448]. However, because the speed of light is so much faster than sound (approximately 872,000 times; 299,792,458 m/s compared to 344 m/s), interference is used rather than the time between light pulse emission and detection of reflections. The different forms of OCT are described in Section 3.1.1.2.3.

As with any image reconstruction technique where a wave such as light or sound passes through curved media of differing refractive indices, the image needs to be de-warped to allow spatially accurate presentation and measurement [449]. If the cornea is imaged, this can be detected using edge detection algorithms, and fitted to correct the image of the deeper surfaces. However, the corneal surfaces are usually outside the field of view if the crystalline lens or IOL is imaged, and none of the optical surfaces are analysed when observing the retina.

A longer wavelength (around 1310 nm compared to 840 nm for posterior eye OCTs) has been used for some dedicated anterior eye OCTs due to penetration and tissue absorption light characteristics, although imaging is restricted by the iris which is designed to block light entering the eye [301]. Instead, the ciliary muscle can be imaged through the sclera [450,451]. OCT has been used extensively to image the crystalline lens during accommodation [452] and to locate the position of implanted IOLs [453], scleral expansion band [454] and inlays for presbyopia [455].

A similar A-scan technique has been adopted for ocular biometry, which has an order of magnitude higher resolution than ultrasonography (approximately 0.01 mm versus 0.1 mm). It has been termed partial coherence tomography (with a laser light source) or optical low coherence reflectometry (using a light-emitting diode) [456]. A limited angle B-scan OCT has also been adopted to visualise the macular area for ensuring appropriate fixation [457]. This is used to measure axial length for IOL optical power calculation, although in dense cataracts, ultrasonography has better penetration. In the future, hyperparallel OCT will allow axial length of a region of the retina to be mapped simultaneously, allowing for the mitigation of inaccurate fixation [300].

### 3.3.4. Magnetic resonance imaging

Magnetic resonance imaging uses the principal of nuclear magnetic resonance in which nuclei spins resonate at radio frequencies to give a recorded signal that contains information about the chemical and physical structure of molecules containing hydrogen or, less commonly, other nuclei with non-integer spins [458]. When the object to be imaged is placed in a powerful, uniform, magnetic field the nuclear spins within the tissue are more likely to align either parallel or anti-parallel to the magnetic field. If a radio-frequency pulse at the correct resonant frequency is then applied, these spins will be knocked off axis and as they return to alignment will radiate a radio-frequency echo, of the same

#### Table 2

Presbyopia definitions relevant to diagnosis [36].

Term	Definition
Presbyopia	Occurs when the physiologically normal age-related reduction
	in the eye's focusing range reaches a point that, when optimally
	corrected for far vision, the clarity of vision at near is
	insufficient to satisfy an individual's requirements
Accommodation	The change in optical power of the eye due to a change in
	crystalline lens shape and position
Far/distant vision	Far vision at a distance at which the accommodative demand
	(incident vergence) is less than 0.25 dioptres.
Intermediate	Intermediate vision at a distance at which the accommodative
vision	demand (incident vergence) is between 0.5 and 2.0 dioptres.
Near vision	Near vision at a distance at which the accommodative demand
	(incident vergence) is more than 2.0 dioptres.

frequency, that can be detected. The magnitude of the signal and its decay will depend on the density of the nuclei and their local structural environment making it a useful measure of tissue characteristics. The resonant frequency of the spins depends on the local magnetic field strength and so, by applying a spatially varying magnetic field gradient, a spatial image of the organ tissue can be produced [301]. A series of 2D tomographic slices allows 3D volume imaging, with increasing strength (typically 1 to 7 Teslas in clinical scanners) improving spatial resolution and signal-to-noise ratio [459].

Magnetic resonance imaging avoids health risks associated with ionising radiation found in routine X-rays (high energy, short-wavelength radiation which is able to pass through tissue) and computerised tomography (simultaneous X-rays from different angles) scans, but retains the ability to penetrate and image the whole human body without optical distortions. Magnetic resonance imaging has been utilised to quantify *in vivo* accommodative changes in the aging human ciliary muscle diameter in phakic and pseudophakic eyes [460–462].

## 4. Diagnosis

#### 4.1. Key definitions

The following definitions apply to the terminology used in the following sections (see BCLA CLEAR Presbyopia: Definitions report)[36] (Table 2).

## 4.1.1. Transition to presbyopia

Presbyopia is diagnosed when the accommodative function of the eye is insufficient to satisfy an individual's requirements for near vision when they are optimally corrected for far vision (see BCLA CLEAR Presbyopia: Definitions report)[36]. The diagnosis of presbyopia is therefore dependent on how close an individual needs to focus for their tasks and it follows that a person will be diagnosed with presbyopia earlier if they need to focus at 20 cm compared to 45 cm. AoA at different ages has been studied for more than a century and all confirm that in healthy children and young adults accommodation has a large range and facilitates good near vision at very close distances [153,463-466]. While early data was reported as showing a linear negative relationship between age and accommodation [464], work that followed suggested that a sigmoidal curve fitted the data better [465]. More recently, accommodation measured objectively across a wide age span confirmed the sigmoidal data curve [466-468], despite measuring lower amplitudes compared to the earlier methodologies [469] (Fig. 10).

Accommodative amplitudes remain high and stable until the age of about 20; by age 30 the amplitude is already in a steep decline before stabilising again close to age 50 at levels less than one dioptre (Fig. 10) [466]. The scatter of data points illustrates that exact accommodation loss for an individual cannot be predicted purely based on biological age (Fig. 10). Additionally, variability in the age of onset of presbyopia has been reported across different regions of the world with indications that younger presbyopia onset may be attributed to one or more of factors such as higher exposure to UV, higher temperatures, lower socioeconomics and worse hygiene conditions [470].

Research is divided on how much of their total accommodation an individual can use to support sustained symptom-free near vision. Earlier reports recommended only engaging half or two thirds of the total accommodation in order to prevent asthenopia [471,472], whereas more recent research has shown that using 70–80 % accommodation for extended periods is feasible [169,473].

### 4.1.2. Adaptation

When people with presbyopia experience a gradual loss of near visual acuity, they often develop coping mechanisms to manage their condition before seeking treatment. Mild presbyopes may need to hold objects further away to see them clearly and they may struggle to focus in low light conditions, experience eye fatigue/asthenopia or develop



Fig. 10. Maximum accommodation amplitudes for subjects pooled from four studies [466–469].

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headaches. Moderate presbyopes may require larger font sizes, brighter lighting, and some reading aid in most settings, such as taking pictures with their phones and magnifying them to see more clearly. Advanced presbyopes cannot read at close or intermediate distances without a reading aid and may have difficulty identifying objects, such as food on their plates [474].

Myopic contact lens wearers typically experience symptoms earlier compared to myopes corrected with spectacles due to the additional accommodative demands they face when wearing contact lenses (with the reverse being true for hypermetropes) [475]. Additionally, myopes often cope by removing their spectacles when reading, whilst holding the reading material at their far point, but contact lens wearers do not have this option whilst wearing their contact lenses. Therefore, when treating patients with presbyopia, it is crucial to thoroughly discuss treatment options and provide reassurance that although there will be a steady decline in near vision over time when using a distant correction, reading corrections can compensate to still provide them with excellent near visual acuity.

In a large-scale survey of 2000 presbyopes in Japan, symptoms such as difficulty seeing small letters up close and improved vision at a distance were first experienced between the ages of 43.9 and 46.7, with males exhibiting symptoms at a younger age and experiencing a greater burden on near vision compared to females [476]; on average, patients obtained their first reading spectacles around the age of 48 years old. Clinical data from contact lens wearers revealed that females were more likely to tolerate early presbyopia through under-correction of myopic refractive errors, while males preferred full myopic correction [476].

## 4.1.3. Influence of working distance / tasks

The non-presbyopic visual system is able to adapt to different working distances in order to maintain clear focus at near. Once accommodation is reduced to the point that an individual struggles to perform a desired task at their preferred working distance, presbyopia becomes evident. The magnitude of the presbyopia correction is typically prescribed based on the required intermediate or near task distances and the measured residual accommodation, or this can be presumed from their age [472]. [477].. It has been shown that smartphone users view their devices at a distance closer than the normal reading distance (<40 cm) used for a typical hardcopy text [478,479]. This working distance places a high demand on accommodation and vergence, thus potentially inducing and exacerbating symptoms of headache, blurred vision, and eve strain [480]. It has been suggested, therefore, that eye care practitioners should consider the closer distance adopted by patients while performing various near tasks when testing and prescribing a correction for near [478].

## 4.1.4. Influence on whether correction can be easily removed

Myopes have the advantage of being able to read when removing their distant-correction spectacles. While objectively they meet the definition of being presbyopic (see BCLA CLEAR Presbyopia: Definitions report) [36], functionally they can overcome the burden of presbyopia in a simple and inexpensive way [481]. The forward shift of spectacles in myopic presbyopes has been shown to affect the awareness of myopes about presbyopia; consequently, myopic patients with higher refractive errors who take advantage of increasing their spectacle vertex distance or removing their spectacles may not realise they have presbyopia until later, causing them to be unaware of the condition [482]. However, whether this option is satisfying for myopic patients in the long term and for both near and distant vision remains questionable. It has been shown that myopic patients who wear only single-vision distant spectacles have a poorer overall quality of life compared to myopic users of progressive addition lenses for both low and high myopia [330]. This finding may suggest that with myopic presbyopes, a proper diagnosis and prescription for far and near vision together are required for a better quality of life and functional vision.

# 4.2. Patient communication and awareness

The results of a prospective study conducted in Japan showed that awareness of presbyopia increased with age, with half of the participants aged between 45 and 49 being aware of the condition, rising to 87.5 % in those aged between 50 and 54, and 100 % in the 55 to 59 age group. Surprisingly, none of the 15 participants aged 44 years and underreported being aware of presbyopia [482]. These findings contrast with another study [476], which found that 38 % of participants experienced difficulties focusing before 40 years of age, although the data was based on historical recall. The prospective study highlighted that patient awareness of presbyopia and difficulty with near tasks significantly increased when binocular near visual acuity with habitual correction reduced to 0.0 logMAR (20/20) [482]. At this level, more than 80 % of patients were aware of presbyopia and experienced difficulty reading a newspaper or a book for an extended period. These findings suggest that a near visual acuity of better than 0.0 logMAR is necessary for comfortable near vision, and this could be a useful threshold for diagnosing presbyopia and analyzing treatment options. Additionally, the COVID-19 pandemic has been shown to lead to an earlier onset of presbyopia in Japanese by approximately 4 years for a 1.0D near addition requirement, which may be due to stress and increased digitalization [483].

A survey of 135 patients, aged 40 years and above, attending an optometry clinic in the UK revealed that 70 % were aware of presbyopia and considered it a normal part of aging [484]. However, only 15 % knew the correct definition of presbyopia, with many believing it was caused by eye strain, stress, or reading in low light.

## 4.3. Protocol

Presbyopia is under-corrected in many countries worldwide, and there is a high prevalence of unmet need for near vision correction, especially among the working-aged population [485]. This is perhaps due to the lack of proper diagnosis and treatment of this condition. The protocol steps for the diagnosis and management for presbyopic patients should be:

# 1. Detailed history

- a. current refractive correction worn (spectacles or contact lenses) including previous refractive surgery
- b. near tasks including visual demands, lighting and working distance the patient is holding near materials for work/hobbies, difficulties experienced and coping mechanisms used
- c. any resulting symptoms such as eye strain or headaches (see Section 2.1)
- d. if relevant, consider the use of presbyopic-specific PROM (see Section 2.1 and BCLA CLEAR Presbyopia: Epidemiology and Impact report)[8]
- 2. Update the distant prescription

a. measure far, intermediate and near acuity with this prescription

- 3. Measurement of pupil size, residual accommodation, binocular vision (to rule out anomalies that might be causing the symptoms) (see Section 2.2 and 3.2.1)
- 4. Determine the magnitude of the required addition [472] refining the reading add using the patient's preferred working distance and/or trial lens methods. Factors that should be considered, including age [486], sex [487], ethnicity [488], distant correction [489], near visual acuity [482], and most importantly, the working distance adopted by the patient to perform different near tasks [478]. Establish eye dominance if the patient is considering using multifocal optics, monovision contact lenses, IOL and surgical techniques (see Section 2.2.6).
- 5. Check the range of distances that provide the patient with the required level of vision for the desired task (ideally with that object) with the addition in place

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- a. demonstrate the benefits of lighting or additional reading spectacles as appropriate
- b. if an addition is not required raise awareness of presbyopia by letting the patient know changes to expect in the coming years and also to return should visual demands change (for example new visual demands in a new job)
- 6. Demonstrate visual effect of presbyopia correction to distant vision and explain when the correction should be worn
- 7. Communicate
  - a. about the need to adapt to the presbyopia correction device
  - b. any expected changes with time such as the need for a higher add
     c. share information about presbyopia prior to its onset to raise awareness

- d. discuss optimal correction to be worn if patient has been identified at high risk of falls (see Section 5.3 on Safety)
- e. discuss alternative options such as the use of contact lenses

Communicating the nature of presbyopia and treatment options is considered vital by patients [484] and therefore should be a component of the presbyopia diagnosis protocol by all eye care practitioners. Patients should expect to develop presbyopia at around 40 years of age [474], and practitioners should begin discussing presbyopia with them before it is experienced. It's important to note that the treatment strategy will vary depending on the patient's visual demands, correction preferences and the severity of their presbyopia. Therefore, prescribing for presbyopia should be tailored to each patient's specific circumstances, keeping in mind that a proper diagnosis and prescription for

# Table 3

Points to consider when comparing the effectiveness and safety of different presbyopia correction strategies that are currently available (see reference to the relevant BCLA CLEAR Presbyopia: Management with reports).

Ease	Туре	Vision correction	Comment on effectiveness	Safety	
Relatively easy access, flexible correction and reversible	Spectacles [366]	<ul> <li>Single vision</li> <li>Bi/trifocal</li> <li>Progressive addition lenses</li> </ul>	Simple, accessible, effective correction of near vision	Can cause peripheral aberrations [532], secondary musculoskeletal symptoms [508,509] and falls [510] in gaze-dependent corrections	
	Contact lenses [366]	<ul><li>Monovision</li><li>Multifocal</li></ul>	Monovision: Good clinical results [223,501] and +1.50 Add considered optimal [533] although reduced contrast sensitivity and stereopsis occurs [223,501,503]	Monovision: Limitation when driving at night [231] All: Includes typical contact lens complications,	
	Pharmaceutical [367]	• Increase DoF via pupil miosis	Multifocal: Can perform as well as progressive addition lenses [500]. Current clinical measures do not help to predict success [214] With AGN-190584 (Vuity®, Allergan, an AbbVie Company) 30.7% and 18.4% of subjects achieved an improvement of 3 or more lines in mesopic distant-corrected near visual acuity on Day 20 hours 2 and 6 reproduktive [515 524]	the majority of which have reduced risk with increased adherence to correct wear and care procedures, or with use of daily disposable compared to reusable soft lenses [514] Side effects of miotics reported as: headaches, dizziness, decrease of light perception, ocular surface dryness [534,535], with caution require in patients with pre-existing retinal disease	
	Corneal inlays [274]	<ul> <li>Extended DoF via pinhole</li> <li>Reshape anterior cornea to create negative aberration</li> </ul>	Pinhole: Good near vision outcomes with minimal distant vision impact [536]	All: Onset regression, haze and loss of distant acuity reported [518,519], and explantation rates, depending on design used of 3.7% to 10% [266,383,518] with haze persisting in some cases	
		Generate corneal multifocality	Good efficacy reported [537]		
	Laser refractive [274]	<ul> <li>Corneal monovision</li> <li>Corneal collagen shrinkage</li> </ul>	Monovision: Can have high success rates [246,520]	Monovision: Mid-range vision impairment, reduced scotopic/mesopic acuity, reduction o contrast sensitivity and stereopsis [246,520]	
		Multifocal corneal laser profile	Laser-based technique show good results for uncorrected near vision, although a reduction of one line of distant acuity [538,539]	Can be a high rate of refractive regression from techniques using radio frequency; use of technique in decline [540]	
			Termed presbyLASIK, with patient refraction relevant in determining which technique to use: central, peripheral or laser blended vision [264]	Possible for distant acuity to be impacted [541]	
More invasive method, less easy to change or remove	Intraocular lenses (IOLs)[365]	<ul><li>Monovision</li><li>Multifocal</li></ul>	Greater spectacle independence and better uncorrected near vision with multifocal IOLs compared to monovision [116,505] Extended DoF designs give functional near	Dysphotopsia possible, variable with optical design and overall lens profile: glare, light streaks, starbursts, light arcs, rings, haloes, or flashes of light [526]	
			vision	All IOL approaches carry the complication risks associated with cataract surgery [542]	

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both far and near vision are necessary for improved quality of life and functional vision [490].

## 5. Evaluating between presbyopia management strategies

There are many different approaches available for the correction of presbyopia. Determining the relative safety, efficacy and patient suitability of those strategies is a key requirement for eye care professionals. This knowledge helps with gathering more targeted information related to patient lifestyle, their visual environment and their expectations; it helps inform which ocular assessments to conduct during the ocular examination and finally leads to an evidence-based conversation with the patient such that they can make an informed choice about their presbyopia correction.

In order to be relevant to current clinical practice, this section focuses on currently available management strategies. There are many additional management approaches that are being explored, either still in development or undergoing clinical trials, the details of which can be found in the specific reports for: management with contact lenses and spectacles, corneal techniques, scleral techniques, pharmaceuticals and IOLs (see BCLA CLEAR Presbyopia: Management with reports) [274,365–367].

Perhaps the two most important areas to consider when weighing up the merits of different presbyopic corrections are their overall efficacy and safety. These are summarised in Table 3. In addition to these outcome measures, there are also other considerations which influence the choice of presbyopic correction, such as access and affordability.

### 5.1. Access and affordability

Some correction strategies are more widely available than others, which will naturally influence how commonly they are used. There is also a widespread view that this presbyopia can be ameliorated fully by the use of low-cost reading spectacles [491]. Affordability clearly impacts recommendation of correction type too. More than 50 % of presbyopes in developing countries are impacted by a lack of awareness, and accessibility to affordable options [492–494], leading to a lack of adequate correction [495]. Cost was not considered a barrier in a group of pre-presbyopes and presbyopes that attended a focus group in the United Kingdom. Instead, comfort and convenience were considered to be more important factors [484]. In some countries, individuals can receive support from their employers if they need a presbyopic correction specifically when using visual display units to the Health an Safety (Display Screen Equipment) Regulations 1992 [496].

# 5.2. Efficacy

It has been noted there is currently no management approach available which restores natural accommodation [38]. In the absence of this desired solution, currently available strategies take a number of different approaches to correct for the gradual loss of near focusing from presbyopia. These strategies can be grouped into spectacles, contact lenses, surgical procedures and pharmaceutical intervention (see BCLA CLEAR Presbyopia: Management with reports)[274,365–367]. Within these different corrections overlap exists in the type of optical correction offered which might be a binocular correction that is gaze-independent or gaze-dependent; monovision; simultaneous retinal images, increased DoF via pinhole or restoring focusing dynamics.

There is a lack of information to help inform eye care professionals in advising patients on the most appropriate management options. A number of factors need to be considered, including patient lifestyle, visual environment, level of presbyopia, refractive error, ocular health, pupil size and ocular aberrations. Even when those are taken into account, predicting patient outcomes and preference of their vision correction strategy remains challenging [214,223,497,498].

Of the available strategies, spectacles, in the form of progressive

addition lenses are often the first recommendation [490]. However, there is good evidence about the performance of modern multifocal contact lenses in new and established presbyopes. They can provide high levels of visual satisfaction and good vision at different distances [499,500], without the loss of stereopsis which occurs with monovision [223,501–503]. Contact lenses also provide a good option for patients to assess different forms of vision correction – monovision, modified monovision, extended DoF or simultaneous vision multifocal - which can be a useful indicator for acceptance of various visual solutions ahead of surgical interventions that use similar approaches. In reality, many patients use multiple modalities to suit the range of activities and environments that make up their daily lives [490].

In terms of reversibility, naturally both spectacles and contact lenses provide flexibility in correction, and there are likely many patients who would benefit from dual correction with both options. The currently available pharmaceutical option of a miotic to increase depth of field generates a temporary effect, and corneal inlays can be removed if required [498].

Few studies have compared the effectiveness of corneal inlays [113] and corneal reshaping techniques [504] compared to other presbyopia correcting options such as multifocal IOLs (see BCLA CLEAR Presbyopia: Management with Corneal Techniques report)[274]. When the effectiveness of different IOLs designs are compared, for example comparing multifocal IOLs to monofocal or accommodating IOL lenses, better uncorrected near vision and a higher frequency of spectacle independence occurs with multifocal IOLs [116,505]. This is balanced by multifocal designs also resulting in a higher risk of dysphotopsia [506,507]; also see BCLA CLEAR Presbyopia: Management with intraocular Lenses report [365].

# 5.3. Safety

It has been noted that the required gaze-relocation through progressive addition lenses can lead to secondary musculoskeletal symptoms [508,509] and falls [510]. Eye care practitioners should familiarize themselves with existing guidelines that focus on the importance on vision in preventing falls [511]. Recommendations include adaptations to the case history to determine which patients have a higher risk of falling and determination of any history of falls in the previous 12 months. Eye care practitioners should also understand the type of spectacles worn by the patients when walking outdoors and whether bifocal/progressive addition lens wearers report any problems negotiating steps and stairs when wearing their spectacles. To minimise the risk of falls for patients identified at high risk of falls, eve care practitioners should avoid large changes in prescription and advise patients about the effects of spectacle magnification during adaptation to new spectacles. They should not prescribe bifocal/progressive addition lenses when patients at high risk of falls wear single vision spectacles [512]. Long-term wearers of bifocal/progressive addition lenses with significant ametropia that participate in frequent outdoor activities should be advised the use of an additional distant single vision spectacles outdoors to reduce the risk of falls [512]. In contrast, long-terms wearers of bifocal/progressive addition lenses with significant ametropia who take part in little outdoor activity should continue to wear their bifocal/ progressive addition lenses for most activities [512]. Older patients at high risk of falling that wear monovision contact lenses should be advised that the loss of stereoacuity increases their risk of falls and should be encouraged to wear a single vision distant correction instead [513]

A 2021 literature review concluded that contact lens-related complications are common and can affect about one-third of wearers [514]. However, the majority of those complications are mild, often with modifiable risk factors and can be easily managed if they occur. Visionrelated changes with contact lens correction for presbyopia include reduced contrast sensitivity and stereopsis with monovision corrections [501–503].

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The most common side effects of the only miotic-based pharmaceutical therapy with an indication for presbyopia are headache and ocular hyperaemia [515]. Blurred vision and ocular irritation have also been reported, and patients are advised to be counselled on changes they may notice with night vision [515,516]. Miotics are suspected to carry an increased risk of retinal detachment, so retinal examination is advised, especially in patients with pre-existing retinal disease [517].

Regression, haze and loss of distant acuity are possible following the implantation of corneal inlays [518,519]. The fact that corneal tissue is not removed during the procedure as with laser refractive approaches does mean that removal of an inlay is possible. Explant rates vary by type of inlay, but have been found to be required in up to 10 % of cases [266,383,518] with haze persisting in some cases.

Refractive laser corneal monovision can result in mid-range vision impairment, reduced scotopic and mesopic acuity, reduced contrast sensitivity and stereopsis [246,520]. PresbyLASIK approaches, whether central or peripheral in type, have both been associated with loss of at least two lines of distant visual acuity, a significant decrease in contrast sensitivity and a need to re-treat over time [521].

Complications associated with cataract surgery and IOL implantation can occur during the procedure, for example posterior capsule rupture [522]; short-term following the operation, for example, retinal detachment [523] and cystoid macular oedema, or long-term, such as IOL dislocation [524] and posterior capsule opacification [525]. Depending on the IOL design used, dysphotopsia is possible which includes glare, light streaks, starbursts, light arcs, rings, haloes, or flashes of light [526].

### 5.4. Cosmetic appearance

Qualitative research exploring the impact of refractive error on quality of life has shown that concerns about cosmetic appearance varies across wearers. Some spectacle wearers are concerned about their cosmetic appearance when wearing spectacles. In contrast, others believe wearing spectacles it's fashionable nowadays and for others concerns about their cosmetic appearance whilst wearing spectacles have reduced with age [4]. In line with this, a study exploring patients' attitudes and beliefs about refractive correction for presbyopia did not report reluctance to wear single distant or reading/varifocal spectacles due to poor cosmetics although participants expressed negative cosmetic concerns about bifocal spectacle lenses [484].

With regards to contact lens wear, it has previously been reported that a larger proportion of females wear contact lenses for presbyopia compared to pre-presbyopic groups, possibly reflecting a stronger desire among presbyopic females of the cosmetic benefits of contact lenses [527]. When exploring the reasons of eye care practitioners towards fitting multifocal contact lens it was found that the primary reason was to address cosmetic concerns of spectacle wearers and also to fit in with active lifestyles [528].

A study exploring reasons for patients to undergo surgical compensation of presbyopia and additional ametropia found that 65 % of the respondents to the survey were female. Reasons for choosing the procedure included feeling self-conscious wearing spectacles, cosmetic reasons and restrictions in outdoor activities [529].

Nowadays, more people are looking for ways to maintain a youthful appearance [530] and beauty-enhancing behaviours are now considered to be universal rather than a female phenomenon [531]. Therefore, eye care practitioners would need to consider concerns relating to cosmetic appearance when recommending corrections for presbyopia.

# 5.5. What affects patient choice?

As outlined in this section, patient choice is affected by several factors. These include accessibility to, and affordability of, correction strategies, plus individual expectations of the most suitable vision correction to meet the needs of their visual demands and lifestyle. The ability to select from flexible correction options that can be easily removed or changed may be important, for example by combining spectacle and contact lens corrections. For others, the desire for a more permanent solution via either laser refractive or surgical options may be preferred.

The eye care professional must incorporate these patient expectations into their ultimate recommendation, whilst also adding in necessary ocular factors such as the patient's refraction, best-corrected acuity, binocular status, anterior ocular health, clarity of the crystalline lens and retinal health. Given the natural progression of presbyopia over time, along with patient visual demands changing during the same period, correction of presbyopia for an individual may ultimately involve use of a number of these different strategies over the years.

## 6. Recommendations and future direction

It is important to be able to measure the range of clear focus in clinical practice to advise on presbyopia correction techniques. A near addition that is too weak will impede task performance and affect productivity and quality of life, whereas a near addition that is too strong will limit the range of clear focus unnecessarily and make adaptation more difficult and/or might result in non-tolerance to the correction. The wrong choice of correction could cause frustration with efficacy or unnecessary safety risks. Both subjective and objective techniques are necessary: subjective techniques assess the impact of presbyopia on a patient and how the combination of residual objective accommodation and their natural DoF work for them; objective techniques allow the clinician to understand how well a technique is working optically and whether it is the right choice or how adjustments can be made to optimise performance. Using a standardised PROM allows comparison of techniques and a practitioner to benchmark their outcomes against other clinicians. They are also useful in considering adopting new techniques based on the results of clinical trials. Techniques must be carefully conducted to gain a reliable end-point, especially the target size, contrast and illumination. Defocus curves allow visual acuity across a range of distances to be considered and are clinically useful to compare across techniques. However, some correction techniques are pupil size dependent so illumination will impact the result. Contrast and dysphotopsia are also critical for optical techniques that overlay images focused at different planes and these tests are now simpler to perform in routine clinical practice. Objective techniques are generally more reliable, can help to explain unexpected subjective results and imaging can be a powerful communication tool with patients.

Presbyopia is a journey with multiple options so it is important to prepare the patient in advance and to try different approaches with them; like footwear, one device is unlikely to suit all their environmental / lifestyle needs [490]. A clear diagnosis, excluding factors such as binocular vision issues or digital eye strain that can also cause similar symptoms, is critical for the patient to understand and adapt to presbyopia, which is often the first impact of ageing they will notice. Surveys and focus groups have demonstrated that there is a lack of patient education on presbyopia and the options available to them [484]. More research is needed into how presbyopia is corrected across the world, what impacts this and how it changes with time. Some corrective options are more permanent, such as implanted inlays / IOLs or laser refractive surgery, so the optics can be trialled with contact lenses in advance (including differences between the eyes) to better communicate with the patient how the optics will work for them so they can make an informed choice. While there are many drawbacks to ageing, visual aspects can be minimised if proactively managed by eyecare practitioners and newer technological solutions offer promise for a more youthful lifelong range of vision in the future.

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James S Wolffsohn: Writing - original draft, Writing - review & editing, Validation. David Berkow: Writing - original draft, Writing review & editing, Validation. Ka Yin Chan: Writing - original draft, Writing - review & editing, Validation. Suraj K Chaurasiya: Writing original draft, Writing - review & editing, Validation. Daddi Fadel: Writing - original draft, Writing - review & editing, Validation. Mera Haddad: Writing - original draft, Writing - review & editing, Validation. Tarib Imane: Writing - original draft, Writing - review & editing, Validation. Lyndon Jones: Writing - original draft, Writing - review & editing, Validation. Amy L. Sheppard: Writing - original draft, Writing - review & editing, Validation. Marta Vianya-Estopa: Writing - original draft, Writing - review & editing, Validation. Karen Walsh: Writing - original draft, Writing - review & editing, Validation. Jill Woods: Writing - original draft, Writing - review & editing, Validation. Fabrizio Zeri: Writing – original draft, Writing – review & editing, Validation. Philip B. Morgan: Writing – original draft, Writing – review & editing, Validation.

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