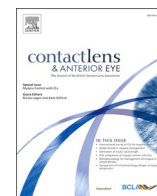




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## BCLA CLEAR presbyopia: Management with intraocular lenses

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## ABSTRACT

Cataract surgery including intraocular lens (IOL) insertion, has been refined extensively since the first such procedure by Sir Harold Ridley in 1949. The intentional creation of monovision with IOLs using monofocal IOL designs has been reported since 1984. The first reported implantation of multifocal IOLs was published in 1987. Since then, various refractive and or diffractive multifocal IOLs have been commercialised. Most are concentric, but segmented IOLs are also available. The most popular are trifocal designs (overlying two diffractive patterns to achieve additional focal planes at intermediate and near distances) and extended depth of focus designs which leave the patient largely spectacle independent with the reduced risk of bothersome contrast reduction and glare. As well as mini-monovision, surgical strategies to minimise the impact of presbyopia with IOLs includes mixing and matching lenses between the eyes and using IOLs whose power can be adjusted post-implantation. Various IOL designs to mimic the accommodative process have been tried including hinge optics, dual optics, lateral shifts lenses with cubic-type surfaces, lens refilling and curvature changing approaches, but issues in maintaining the active mechanism with post-surgical fibrosis, without causing ocular inflammation, remain a challenge. With careful patient selection, satisfaction rates with IOLs to manage presbyopia are high and anatomical or physiological complications rates are no higher than with monofocal IOLs.

## 1. Overall purpose

Sir Harold Ridley pioneered intraocular lens (IOL) insertion as part of cataract surgery from 1949, which has been refined extensively in the decade since the first such procedure. Modern surgical methods of phacoemulsification reduce the induced post-operative refractive error. Advanced instrumentation allows improved ocular biometry to the extent that surgeons can make good predictions for desired refractive outcomes. As well as the ability to select the power of the IOLs to induce monovision, refractive IOL designs for presbyopia have been introduced

with optical properties similar to contact lenses (see BCLA CLEAR Presbyopia: Management with contact lenses and spectacles report) [1]. Other novel designs specific to IOLs, such as diffractive and 'accommodative' optics have also been developed. This has led to the introduction of clear lens extraction as a refractive surgery procedure, involving the same surgery as phacoemulsification, but on an eye without a cataract.

*Abbreviations:* IOLs, Intraocular lenses; EDOF, Extended depth of focus.

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## 2. History and market trends

The use of monovision for the management of presbyopia using contact lenses has been utilised since the early 1960s and in refractive surgery since the mid-1990s [2,3]. The first published report of intentional use with monofocal IOL designs was in 1984 [4]. They presented a retrospective review of 100 patients with bilateral posterior chamber IOLs who were corrected to leave one eye myopic and found a reduction by half in the number of patients who required the use of spectacles after surgery. A recent review of the IRIS® Registry (Intelligent Research In Sight) revealed that pseudophakic monovision for presbyopia correction remains a prevalent form of correction in the United States of America, with approximately 34 % of patients in the registry receiving bilateral monofocal IOLs with some degree of myopic offset in one eye [5].

The first reported implantation of multifocal IOLs was published in 1987, detailing results from 46 eyes of 38 patients [6]. Other bifocal IOL designs from that period that were commercially marketed included both refractive and diffractive designs [7,8] made from polymethyl methacrylate. Key limitations of this material were the need for very large incisions for insertion as well as the surgical technique associated with extracapsular cataract extraction which often resulted in induced large amounts of corneal astigmatism associated with suturing [9], affecting the effectiveness of multifocal IOLs.

The introduction of foldable IOLs beginning in the mid 1980's paralleled the rise in the adoption of phacoemulsification, developed by Charles Kelman in the late 1960's [10], allowing much smaller incisions and more predictable ocular healing [11]. Foldable IOLs were initially made of a silicone elastomer; however, silicone had limitations including a relatively low refractive index necessitating thicker lens profiles and being subject to fouling, bacterial adhesion and posterior capsular opacification [11]. The development of acrylic materials, both hydrophobic and hydrophilic, allowed further innovation in the foldable IOL space which has continued to the present day [12]. The acrylic lenses have higher refractive indices resulting in thinner lenses an unfold more slowly than silicone lenses, allowing better control of lens implantation.

The first multifocal to receive approval by the United States Food & Drug Administration in 1997 was the Array lens (AMO, Irvine, CA), a foldable IOL made of silicone with five alternating distance and near refractive zones with the centre zone being for distance [13]. It was later replaced by the ReZoom (AMO, Santa Ana, CA) hydrophobic acrylic IOL, again with a concentric ring design [14]. The first mixed apodized diffractive and refractive design was approved in 2005 as the AcrySof ReSTOR multifocal IOL (Alcon, Fort Worth, TX), with later modifications to alter the near addition powers [15].

The pace of innovation in both materials and designs accelerated greatly over the next 20 years, leading to the development of foldable IOLs in multiple designs and materials including extended depth of focus (EDOF) [16], trifocal [17], light adjustable [18] and multiple attempts at 'accommodative' IOLs [19]. Despite the availability of around 100 different intraocular lenses designed for the management of presbyopia by 2020 [20], estimates are that only around 10 % of current cataract procedures involve implantation of an IOL with multifocal effect [21]. Within that small percentage of surgeries, there has been a shift away from bifocal IOLs toward EDOF and trifocal designs among surgeons implanting multifocal IOLs [21].

## 3. Patient selection and pre-operative evaluation

Presbyopia presents unique challenges for patients and eye care professionals. The restoration of accommodative ability in some form remains the largest frontier of untreated refractive error and there is still no established consensus on a single treatment paradigm that suits all [22]. Addressing the visual needs of patients, age-related factors, refraction considerations, physical characteristics, and ocular health are crucial in achieving optimal outcomes for presbyopic individuals. This

section explores various factors influencing presbyopia management using intraocular lenses and outlines potential treatment options to meet individual patient needs.

### 3.1. Patient needs & expectations

#### 3.1.1. Patient communication

When having the conversation about options for presbyopic correction at any stage of the process, it pays to be proactive in explaining the natural ageing process of the crystalline lens and the progressive nature of presbyopia with time. Some authors have advocated for "dysfunctional lens syndrome" nomenclature to cover the concepts of presbyopia (stage 1), early visual changes related to cataract (stage 2) and the later stages of cataract development that commonly lead to lens extraction and replacement with an intraocular lens (stage 3) [23]. Though not all agree that the details within the schema are well supported by rigorous scientific support [24], the framework it provides facilitates conversation with a patient approaching their 40's and beyond to explain the many visual changes they can expect in the ensuing decades. The framework can also help explain what the cataract patient may be experiencing prior to and following surgery and provides clinical testing recommendations for the eye care professional managing their care over this time frame.

Prior to offering any intervention, it is essential to have a conversation about the likelihood of experiencing dysphotopsia with many of the advanced IOL designs [25]. It has been suggested that patients of all ages should be reminded that there are some naturally occurring photic phenomenon due to native higher-order aberrations, spectacles, contact lenses or even the cataracts themselves [26] and reassurance offered regarding the likelihood of adaptation with time. Another topic to approach upfront is the discussion of what the patient can control in their environment to improve performance: task lighting, working distance and use of adjunct spectacles can provide a boost in some difficult task specific areas.

It is also worth noting that providing the information in a simple, straightforward in-person conversation is important. A recent review of websites for patient-oriented online information for cataract surgery revealed that the information available may not be comprehensible to the general public [27]. The study found that readability and accessibility aspects were not optimised in the majority of sites accessed.

#### 3.1.2. Visual history

Practically, in modern day life, three visual domains of the patient need to be addressed: the ability to read "up close (near)", the ability to see at "working" distance (intermediate), and the ability to drive (far) [28]. However, individual patients may prioritise each of these needs in a unique way, making it imperative to undertake a thorough review of their needs and expectations prior to selecting a surgical approach. Understanding the dynamic balance of needs and critically evaluating the mix of distance, intermediate and near tasks in daily life will facilitate a better match to available IOL options. Thorough assessment of each patient's prior experiences with different forms of refractive correction they may have used can also be helpful. Standardised questionnaires for evaluating the impact of cataracts may be helpful in setting patient expectations of how removal and implantation of an IOL may be expected to benefit them [29–34]. The history and symptoms should explore any issues with patient stability as peripheral vestibular disorders such as Meniere's disease impair retinocortical processing of visual information and so such patients are not good candidates for multifocal or monovision IOL implantation [35].

#### 3.1.2.1. Satisfaction with prior modes of correction

3.1.2.1.1. *Spectacle lenses.* A factor often used as a motivator for patients to consider multifocal IOLs and as a measure of success is spectacle independence is the ability to do daily activities without the

need for spectacles [36]. Issues with spectacles for the correction of presbyopia can include functionality, convenience and cosmesis (see BCLA CLEAR Presbyopia: Management with contact lenses and spectacles report) [1]. However, there are some interesting caveats to consider when exploring this area with patients. Patients who found spectacles bothersome (for reasons such as condensation on lenses, a need for cleaning, feeling heavy or slipping down the nose) or who preferred their appearance without spectacles are three times more likely not to wear them postoperatively [37]. In an effort to develop a questionnaire quantifying spectacle independence following cataract surgery, researchers noted in the qualitative research phase that patients often considered themselves spectacle-independent, yet, when queried, they actually wore correction for certain activities [31]. It is worth probing to understand if there are situations where spectacle wear would be acceptable to improve task-specific vision activities. For example, if a patient had a hobby that required very close work or work under conditions of poor contrast that usually occurred in a predictable location, they may be willing to use a pair of reading spectacles for that purpose. Or having a pair of spectacles for distant vision to be left in the car for use while driving at night may be acceptable.

**3.1.2.1.2. Contact lens history.** If a patient has worn multifocal or monovision contact lenses successfully in the past, they may be more inclined to consider a multifocal option in an IOL and are possibly better equipped to deal with the photic phenomena encountered with multifocal IOLs. One trial showed that reductions in stereoacuity and binocular visual acuity were less in patients who were successful contact lens monovision patients and that laterality of sighting dominance had less of an effect on the successful outcome with monovision [38]. Conversely, another review of contact lens studies found the success in monovision correlated with distant correction on dominant eye, and less than 50 s of arc stereoacuity reduction; this review also suggested that monovision resulted in significant reduction of binocular contrast sensitivity function, but resulted in minimal reduction of binocular visual acuity, peripheral vision, visual field width and binocular depth of focus compared to a monofocal, but these were not predictors of successful outcomes [2]. Patients with a history of unsuccessful monovision do better with a more balanced approach in IOLs such as multifocal or EDOF designs [39]. A slightly more challenging history is when a patient reports a history of problems with contact lens wear. In that case it's important to attempt to uncover the underlying reason. Both comfort and vision complaints in contact lenses can be caused by ocular surface issues [40] that should be addressed prior to surgery. Vision issues related to intolerance to haloes and glare could be a sign of poor adaptation to the complex optics of multifocal or EDOF IOLs.

### 3.1.3. Prior ocular or refractive surgery

Increasingly, cataract surgery is being performed on patients who have previously undergone a corneal refractive procedure. These patients, accustomed to functioning without glasses before the onset of presbyopia, have high expectations for uncorrected visual acuity and spectacle independence after cataract surgery [41]. After prior myopic refractive surgery, a hyperopic outcome may occur following cataract surgery or refractive lens exchange due to an underestimation of the effective corneal power and an overestimation of the effective lens position during IOL power calculations. The reverse situation occurs with prior hyperopic refractive surgery. Special considerations with respect to IOL power calculations and lens selection is necessary for these cases [42–45], but they can achieve moderately satisfactory results [46,41].

Prior radial keratotomy can present unique challenges and considerations during intraocular surgery. The effects of radial keratotomy on the cornea and the changes in corneal curvature can influence preoperative counselling, IOL power calculations, incision planning, intraoperative and postoperative management [47,45]. Patients with phakic IOLs present another challenge for biometry, but newer formulas such as the Kane and traditional formulas with Wang-Kock axial length have been shown to result in good outcomes [48].

## 3.2. Visual and ocular assessment

### 3.2.1. Refraction and visual acuity

Since IOL power calculation does not utilise any refractive data, distant refraction prior to surgery is mainly for purposes of legal documentation. However, careful evaluation of preferred working distance for daily activities is essential in the pre-surgical evaluation, as this directly impacts selection of IOL design and power and will determine where the optimal zones or points of clear vision will occur. As noted previously, along with the assessment of typical and critical near and intermediate tasks, understanding when and where spectacle lenses might be acceptable can aid in the discussion of which combination of refractive options might best suit the patient's lifestyle.

### 3.2.2. Angle kappa ( $\kappa$ )

Angle kappa ( $\kappa$ ) is defined as the difference between the pupillary axis and the line of sight. Some studies have indicated that it can be important in centration considerations for multifocal IOLs [49,50], while others have found no effect on visual outcomes of multifocal IOL implantation [51–53]. The actual measurement requires use of Purkinje images but can be estimated using a topographer display of the corneal apex and the entrance pupil centre.

### 3.2.3. Ocular health assessment

**3.2.3.1. Anterior segment.** Corneal topography is useful not only for deriving precise corneal curvature values needed for IOL power calculations, but also to detect corneal astigmatism and irregularities that can influence refractive outcomes. Patients with both presbyopia and astigmatism of more than 0.50–0.75 D are less likely to achieve an optimal post-operative visual outcome, and in these cases astigmatism should be addressed with surgical treatment with keratorefractive or toric IOL options [54]. Corneal astigmatism should be quantified and minimised when using premium IOLs [36], with generally a cut-off of  $\pm 0.50$  D for non-toric designs [55]. In cases of higher corneal astigmatism, a toric IOL and / or corneal refractive procedures should be considered.

Corneal topographers can also be useful for assessing tear film disturbances which can cause reduced or unstable vision. Dry eye is a major cause of dissatisfaction after multifocal IOL implantation, [56–58] and this is not impacted by patient age [59]. Particular care needs to be taken of patients with ocular surface disease when conducting pre-operative biometry as this can impact refractive targeting accuracy [60].

Tomography provides a more in-depth assessment, including corneal shape, curvature, and thickness. Undiagnosed corneal warpings arising from conditions such as keratoconus or pellucid marginal degeneration are not uncommon in older age groups and will influence the choice of surgical options [61]. Aberrations in corneal structure such as thinning and irregular astigmatism associated with these conditions are challenging to manage, due to the inability of IOLs to neutralise irregular astigmatism. Such patients are not suitable candidates for multifocal technologies to manage presbyopia, but options such as monovision or pinhole lenses may work well in select cases. Undiagnosed basement membrane dystrophy and dry eye disease can also impact visual outcomes [62] and are best diagnosed and treated pre-operatively.

**3.2.3.2. Posterior segment.** Retinal integrity plays a crucial role in the success of premium IOL technologies for presbyopia correction. Poor retinal or macular function can significantly impact visual outcomes, limiting the effectiveness of technologies such as multifocal or EDOF IOLs. While it has been considered that conditions affecting the macula, such as age-related macular degeneration or diabetic retinopathy, can lead to reduced contrast sensitivity, decreased visual acuity and compromised visual performance with multifocal IOLs, there is no evidence that patients with retinal disease should be advised against having multifocal IOLs implanted [63]. Studies demonstrated good

postoperative visual acuity, contrast sensitivity and spectacle independence for distance along with high patient satisfaction in glaucomatous eyes implanted with multifocal IOLs [64]. Considerations in patient selection include anatomical factors (such as the type and severity of glaucomatous visual field defects, glaucoma subtype and presence of ocular surface disease) and functional factors (such as the reliability of disease monitoring) [64]. Eyes with macular or retinal pathology, as detected with the use of optical coherence tomography, are best suited for monofocal lenses and the adoption of monovision may be useful to provide some presbyopic correction [65,66]. However, EDOF IOLs may also give good outcomes in patients with low-grade retinal changes [67].

## 4. Lens designs

### 4.1. Monofocal

#### 4.1.1. Symmetrical correction

Standard single focus (monofocal) IOLs are currently the most widely implanted IOL type due to their relatively low cost, good outcomes and low incidence of photic phenomena [68]. They do not allow for complete spectacle independence as they provide good uncorrected vision at a single focal point only, typically for distant vision [69]. Thus, patients usually require corrective lenses for near and intermediate tasks. However, the range of clear focus will depend on neural and optical factors, which, depending on the typical task demand of the presbyopic individual, may be sufficient with minimal or even no additional optical power [70]. Surprisingly, some patients report being spectacle-independent with monofocal IOL implantation [71], particularly those with smaller pupils or low amounts of residual astigmatism [72]. Still, contrast sensitivity has been reported to be a better predictor of patient satisfaction [73].

#### 4.1.2. Aspheric

Aspheric optics can be incorporated within an IOL to provide an increased depth of focus and thus a wider range of vision; however the benefits to near vision remain unclear, and require confirmation through larger scale studies [74].

### 4.2. Refractive multifocals

#### 4.2.1. Symmetrical correction

Refractive multifocal IOLs often include a concentric design, with zones of higher optical power to focus rays of light passing through the pupil to nearer distances, overlaid on the optic powers for optical distant vision.

#### 4.2.2. Asymmetrical designs

More recently, segmented lenses have been developed which feature the near portion in a specific area of the IOL, much like in a bifocal spectacle lens. Segmented IOLs are rotationally asymmetric IOLs which rely on good centration, as the distribution of light to the near segment depends upon the proportion of the near segment within the pupil. They have been found to be more prone to optical quality degradation when decentred [75], but otherwise have a low incidence of glare and halo [25,76,77] and are somewhat comparable with monofocal IOLs in this regard [78]. They have been reported to give good levels of vision and patient satisfaction [79,80].

### 4.3. Diffractive designs

Diffractive designs use diffraction of light at a boundary to create multiple focal points, with the separation between ring edges determining the effective near addition power of the IOL [81]. In fully diffractive MIOLs the concentric rings covers the entire central IOL optic and so the splitting of light is not affected by pupil size. Partially diffractive multifocal IOLs only incorporate this diffractive pattern over a

specific area of the optic, and so are more affected by pupil size.

### 4.4. Extended depth of focus (EDOF) IOLs

By definition, an extended depth of focus (EDOF) IOL is a single, contiguous, elongated focal point that enhances depth of focus [82]. This approach can reduce the adverse effects of a reduction in contrast and increased dysphotopsia due to spreading the light entering the pupil into different refractive planes [83], while providing superior intermediate and near performance compared to a monofocal [84]. The EDOF effect can be achieved via low powered additions in the form of wavefront shaping [85], aspheric induced spherical aberrations with [71] or without [86] diffractive optics and pinhole [87] lens designs [20,88]. These designs are generally ideal for patients with less intensive or prolonged close distance tasks to be performed, with a pair of adjunct spectacles recommended for fine near tasks. As with other multifocal intraocular lens designs, logistic regression has identified postoperative dry eye symptoms, binocular near and distance visual acuity, and glare symptoms as significant independent factors affecting patient satisfaction [89].

### 4.5. 'Accommodative' IOLs

Accommodative IOLs should, by definition, demonstrate anatomically measurable changes in dioptric power. Current designs rely on the contractility of the ciliary muscles remaining throughout life, while the force of the lens capsule from the reduced tension on the lens zonules (see BCLA CLEAR Presbyopia: Mechanism and optics report) [90], leading to a change in lens position or shape (Fig. 1).

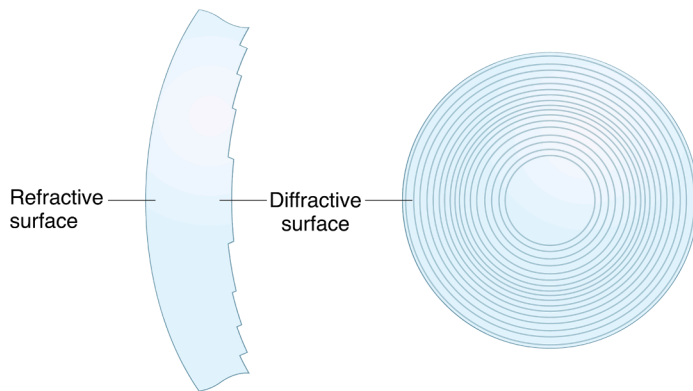
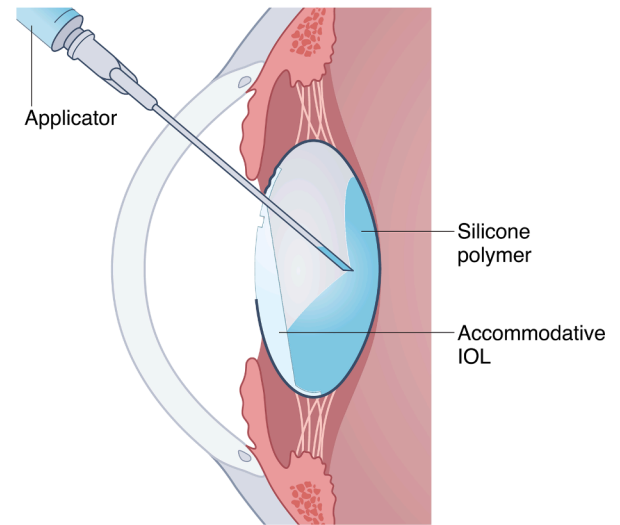
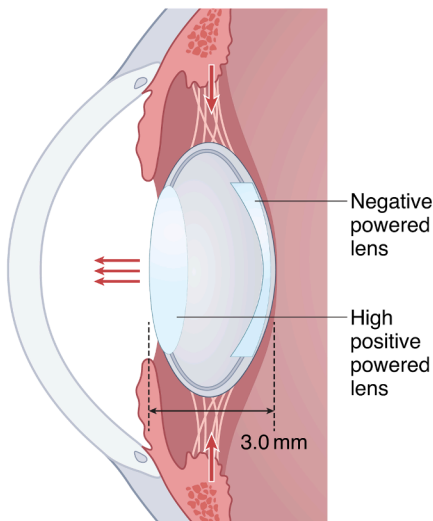
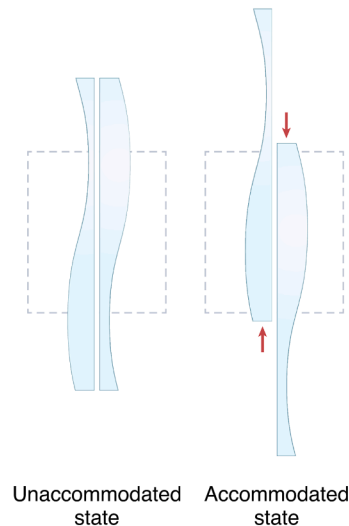
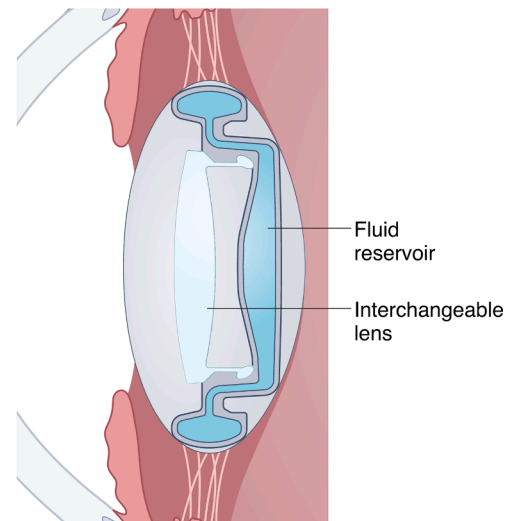
Much research and development has been dedicated to softening the lens cortex to allow the restoration of accommodation. This has included the development of injectable materials and refinement of surgical techniques. However, fundamental problems still occur in the form of leakage of refilling materials, insufficient accommodation and secondary capsule opacification [91].

Flexible haptic IOLs have been tested with the proposed mechanism being an increase in optical power induced by a forward movement induced by lens capsule constriction. While initial benefits for near vision were reported in patients' near visual acuity [92–97], the objectively measured accommodative range was minimal [98–100]. These effects and the near distance benefits in vision, in at least some studies, declined with time due to lens fibrosis [99–101]. While there is one FDA-approved 'accommodative' IOL [102], it is questionable whether the dioptric power does change [103] and while it was enhanced to include an aspheric optic, 40 to 70 % of patients still required reading spectacles after implantation, with satisfaction rates ranging from 10 to 80 % [104,105]. However, a systematic review suggested an improvement in distant-corrected near visual acuity and greater spectacle independence over monofocal IOLs, while contract sensitivity and distant vision remained similar [106]. This may result from changes in aberrations increasing the depth of focus to create pseudoaccommodation [107,108].

A dual optic design allows for a larger accommodative range (approximately 2.5 D/mm movement compared to < 2 D/mm with a mono-optic IOL) [109] from separation of the high plus-powered anterior and negative posterior optics [110], and was found to give stable reading performance [111] and an average range of focus of approximately 3.5 D [112], slightly outperforming a hinge optic IOL [113]. Variable focus IOLs based on lateral shifts of two lenses with cubic-type surfaces (such as the Alvarez design) have also been conceived [114] and tested [115,116].

Changes in curvature using contraction of the lens capsule that displaces fluid within a fluid-filled optic [117,118], or soft and rigid haptic parts [119] have also been developed. A modular design with an optic detachable from a base-lens can make such designs easier to remove and adjust [120]. Another approach has involved creating a change in



**a Diffractive IOL****b Lens refilling accommodative IOL design****c Dual optic accommodative IOL design****d Lateral shifting cubic-type surfaces accommodative IOL design****e Modular curvature changing accommodative IOL design**

**Fig. 1.** Examples of advanced IOL optical designs for the correction of presbyopia. (A) diffractive, (B) lens refilling accommodative, (C) dual optic accommodative; (D) accommodative lateral shifts of lens elements with cubic-type surfaces, (E) fluid displacing change of curvature accommodative modular design.

curvature of a flexible optical membrane pushed through a rigid hole in a diaphragm; this transfers forces via a silicone gel in a piston from forward movements of the capsular diaphragm and is depressurised by backward movements of the diaphragm; this causes a power increase in the reverse direction (decreases with accommodative effort) and the proposed 10 D of accommodation achieved was implied from an average 0.09 mm displacement of the membrane rather than confirmed by any optical measurement [121].

While a truly 'accommodative' IOL could be considered the holy grail for presbyopia and these have been in development for over two decades, there is little evidence that demonstrates the current designs cause a change in optical power, that can be sustained in the presence of lens fibrosis following surgery.

#### 4.6. Comparison between presbyopic lens designs

A number of systematic reviews focusing on randomised controlled

trials of presbyopia-correcting IOL designs have been published. These reviews differ as to whether trifocal IOLs outperform bifocal designs [122,123], but with both optical profiles, near vision is better than with monofocal IOLs [124–127,123,128]. A comparison of refractive and diffractive IOLs suggested that eyes implanted with refractive MIOL showed better uncorrected distance and intermediate visual acuity, while eyes implanted with diffractive MIOL had better uncorrected near visual acuity with less photic phenomenon [129]. While one review found no statistical differences between multifocal and monofocal IOLs regarding contrast sensitivity, glare or halos [125], others have found the opposite [124,126,127].

EDOF IOLs provided better intermediate visual acuity than monofocal IOLs [127]. Trifocal IOLs generally offered better near vision, but poorer intermediate vision and more halo photopic effects than EDOF IOLs [130–132,128]. However, EDOF IOLs still increase the risk of contrast reduction and halos over monofocal IOLs [133]. Studies on 'accommodative IOLs are less common and any near vision benefits and

spectacle independence [106] may come from other factors such as multifocality and lens flexure, so comparisons with monofocal IOLs have a low level of certainty [69].

## 5. Surgical approaches

An alternative to new IOL designs is modification of the implantation approach to achieve a wider range of functional vision (Fig. 2).

### 5.1. Monovision

Pseudophakic monovision usually involved the dominant eye being corrected for distance vision and the non-dominant eye corrected for near to mid-range vision using traditional monofocal IOLs. It is possible to modify the amount of intended myopia from ‘full’ monovision of around  $-2.50$  dioptres or more (with one eye corrected for distant vision and the other for a distance  $\leq 40$  cm, to modified or ‘mini-monovision’ in which there is a smaller interocular power difference [134]. Several studies have reported an improvement in spectacle independence with mini-monovision [135–140]. However, it is worth noting that the patient will be required to undergo neuroadaptation with this option, so it is recommended only in those with good tolerance [141]. As with laser refractive surgery (see BCLA CLEAR Presbyopia: Management with corneal techniques report – section 2.6 [142]), a contact lens monovision trial is recommended prior to surgery to assess adaptation and tolerance, but there appears to be limited research on the effectiveness of this approach [8]. Other limitations of monovision include a reduction in stereoacuity [143], which is not affected by multifocal IOL designs [144].

### 5.2. “Mix and Match”

Particularly as cataract surgery is often conducted in one eye before the other, surgeons can choose to implant a different IOL design or power (relative to the refractive prescription for distant vision) in the second eye to expand the range of vision (referred to as a mix-and-match or blended approach) [145].

Combining bifocal IOLs with different add powers in each eye has not been found to significantly improve distance visual acuity, contrast sensitivity, or spectacle independence versus binocular implantation of a bifocal diffractive [146] or trifocal IOL; in fact a better range of visual acuities at near and intermediate distances were reported with the trifocal option [147,148]. Combining different multifocal IOL near addition powers has been shown to give a wide range of vision and excellent patient satisfaction [149–151]. Mixing-and-matching bifocal

IOLs with lenses of a different design, however, can help to lower the incidence of photic phenomena while maintaining excellent visual outcomes [152,153]. One common approach for reducing the photic phenomena is to combine a multifocal IOL in one eye with an IOL of a different design in the other eye, such as a segmented bifocal IOL; this has been shown to give excellent visual performance at far and intermediate distances, and functional visual acuity at near while minimising glare and halos [152].

### 5.3. Light-adjustable IOL

The light adjustable IOL is implanted in a semi-polymerised state, so that it can be adjusted after surgery, allowing IOL position and ocular aberrations of the eye post-surgery to be taken into account. This approach has been used to optimise a near correction power in one eye for a monovision approach [154] and, in theory, the posterior surface of the lens can be adjusted to create both refractive multifocality and diffractive bifocality [155].

### 5.4. Phakic IOLs for presbyopia

The IOL designs discussed in this review so far have been those used to replace the crystalline lens. These are typically introduced after phacoemulsification of the clear crystalline lens (hence the term ‘clear lens extraction’) to exchange the powerful crystalline lens with one that allows the far distance refraction to be close to emmetropia (hence the term ‘refractive lens exchange’). In patients with presbyopia, this IOL may have a design that allows near vision also, as discussed above. An alternative type of IOL is one that does not require removal of the crystalline lens. In this case, the lens may be introduced into the cornea, such as corneal inlays (see BCLA CLEAR Presbyopia: Management with corneal techniques report) [142]. Another option is to introduce the IOL in front of or behind the iris. Collectively these are commonly termed phakic IOLs. However, lenses placed in front of the iris are also known as anterior phakic IOLs or anterior chamber lenses. The term ‘posterior’ phakic IOLs is sometimes used to denote IOLs that are placed behind the iris but using the term ‘posterior chamber lenses’ is incorrect since they sit anterior to the crystalline lens. Anterior chamber lenses are not a recent development and were used in the past after intra capsular cataract extraction. This type of cataract extraction involved removal of the crystalline lens and the supporting lens capsule, meaning that there was no remaining lens capsule where an intraocular lens could be placed. These patients would typically be left aphakic at the time of surgery and require optical correction with a high-powered positive lens in either spectacles or contact lenses. These aphakic patients could be

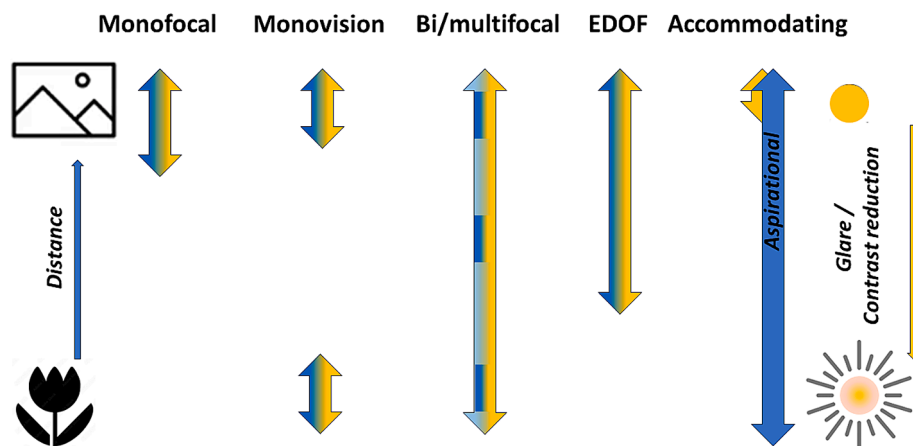


Fig. 2. Depiction of the range of clear focus (blue) compared to the risk of contrast reduction and glare (yellow) from the different categories of presbyopia correction IOLs. Multifocality increases the range of clear focus, but generally increases the risk of contrast reduction (from spreading the light entering the pupil over a wider focal range) and glare (from the interface between the optical elements).

corrected with an anterior chamber lens too. The aphakic IOL could be implanted at the time of the intra capsular cataract extraction or in a separate surgical procedure at a later date. Typically, anterior chamber lenses would be designs such as an iris clip or an iris peg lens (Fig. 3). These patients would often not undergo dilated fundus examination at future eye care appointments since mydriasis could dislodge the iris-attached lens.

Anterior chamber lenses made a resurgence as an option in refractive surgery, and this coincided with the introduction of new posterior phakic IOLs [156], especially for cases of higher refractive errors that were outside the usual range for laser refractive surgery [157,158]. Initially, these IOLs were monofocal, but as the need for presbyopia correction became more apparent, multifocal designs became available [159], as well as toric designs for astigmatism [160]. Monovision remains an option with phakic IOLs but is not discussed here as the principles remain the same as monovision with other options such as contact lenses, corneal surgery or other types of intraocular lenses (see Section 4.1). Another use for phakic intraocular lenses have been to use them alongside other treatments, such as laser refractive surgery, although the biometry must be performed with care since the assumptions made in ocular biometry calculations are altered after laser refractive surgery [161]. A patient with a high refractive error could have a phakic IOL implanted and then have any residual ametropia corrected by laser refractive surgery, requiring less laser reshaping of the cornea so the result would be more predictable. Again, the phakic IOL could be a design that corrects presbyopia. However, phakic IOLs have not made a major impact in the refractive surgery arena nor have many designs been developed as options. There seem to be more options available for presbyopia where the IOL is placed in the crystalline lens capsular bag. Potential complications may deter use of phakic IOLs. For lenses placed in the anterior chamber, in addition to the potential to damage endothelial cells there may be a risk of causing damage to the anterior chamber angle and causing secondary glaucoma; often a peripheral iridotomy is performed to negate this problem [162]. Phakic IOLs placed behind the iris have been reported to cause traumatic cataract and this may be an issue, especially in less experienced hands [156]. If the phakic IOL is made from a foldable material then it can be inserted through a small incision, but non-foldable phakic IOLs require larger incisions, which can be made further away from the cornea, but risk introducing unwanted surgically-induced astigmatism.

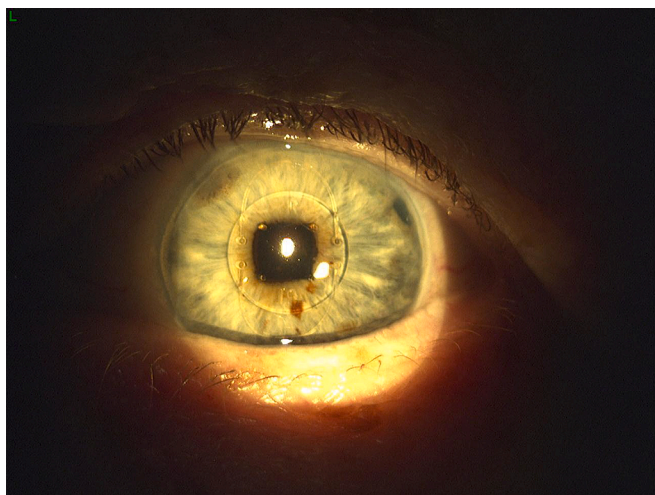


Fig. 3. An iris peg IOL with an iris clip. Note the square-looking pupil resulting from the four pegs along with the wiry haptic that clip onto the iris.

## 6. Postoperative management specific to presbyopia correction IOLs

When assessing the outcome of patients who have undergone implantation of presbyopia correction IOLs it is important to review their visual acuity. It is useful to know the monocular visual acuity, but it is more important to establish binocular visual acuity and level of visual comfort with unaided vision. Patient-reported outcome measures could be assessed using validated questionnaires [163] and these are useful when comparing different procedures. Various studies have reported improved near vision only with specific near charts and since often different near charts are used it is difficult to compare (see BCLA CLEAR Presbyopia: Evaluation and diagnosis report) [164]. Small residual refractive errors may be tolerated by the patient but larger uncorrected astigmatism or other ametropia may need to be addressed. The remedial treatment may involve using corneal refractive surgery vision correction to remove any residual ametropia [165–169]. As stated above, some IOL designs will reduce contrast sensitivity function, so this is a useful measure to take post-operatively [164]. Visual field examination is not specifically performed to examine patients who have undergone implantation of presbyopia correction IOLs, but the optic zone of an IOL may theoretically cause scotoma effects for the patients [170] although this has not been shown with single vision or multifocal IOLs.

Multifocal IOLs are more prone to photic phenomena such as glare and halos than monofocal IOLs as a result of the numerous optical transitions present within the pupil area [171] and this remains one of their main drawbacks. This can occur with all optical designs, but less so with EDOF IOLs. Dysphotopsia can affect quality of vision, resulting in patient dissatisfaction; other drawbacks compared to monofocal IOLs include higher relative cost, reduced contrast sensitivity and a need for neural adaptation [172]. Patient dissatisfaction with the outcome of multifocal IOL implantation due to a failure to neuroadapt can be managed by an IOL exchange with an alternative optical design of presbyopia-correcting or monofocal IOL. One study demonstrated better results exchanging the lens for an alternative multifocal IOL design but acknowledged that both options are feasible solutions [173]. While explantation of an IOL is not a desired outcome, it has been identified that this can be done safely to relieve unsatisfactory visual outcomes in several case series [174–176]. Screening for the impact of photic phenomenon prior to surgery and using this to inform IOL choice can help to reduce dissatisfaction post-implantation [177].

Anatomical and physiological complication rates do not seem to differ between different multifocal IOLs [123,178] and there is no evidence to suggest a higher rate of complications compared to monofocal implantation with the same surgical technique. Likewise, IOL material and design related issues such as glistening and posterior subcapsular opacification rates are not related to multifocal optics. More cases of posterior capsule opacification and the need for laser capsulotomy were seen in patients implanted with early accommodative IOLs [69]. The outcome for laser retinopexy for retinal tears and epiretinal membrane surgery was not adversely impacted by multifocal compared to monofocal IOL implants [179,180], but more time may be necessary for the procedure.

## 7. Recommendations and future directions

There continue to be innovations in the field of IOL materials and design. Some newer approaches include the use of a new material called crosslinked polyisobutylene [181] and a light-controlled refractive index material [182]. Adjustable IOL power technology has been in development for over a decade [183] in which modular optics allow a replaceable lens (such as a toric or multifocal, to be added to a stable base unit, which is in contact with the lens capsule to transmit forces from changes in the ciliary muscle, via the zonules, in an attempt to restore accommodation [118]. Furthermore, femtosecond sculpted lens technology has been developed to alter the refractive index of an



implanted IOL by adding water to a selected area, giving the potential to induce and reverse individualised multifocal optics [184].

Mechano-optoelectronic implants with their own energy supply are currently being researched, with the end goal of offering a totally automated and on-demand treatment for presbyopia. Innovations include solar-powered autofocus to be controlled with a smartphone application and optical power change delivered without a change in lens shape through activation of an electroactive liquid crystal optic (powered by a solid-state hermetically sealed rechargeable power cell) encapsulated within an aspheric monofocal IOL. It has been proposed that a photovoltaic cell with photosensors that monitor the patient's pupillary dynamics, can enable patient-specific programming so that the lens can adjust the eyes' focus based on the patient's individual and specific needs.

A major finding from this review is the paucity of evidence underpinning many of the decisions which are made around the clinical management of presbyopia with intraocular lenses and the prediction of which will give an individual the best outcomes. With the ageing population and increasing number of lens replacements required to replace cataracts, the need for innovative IOLs that decrease the impact of presbyopia is paramount.

### Declaration of competing interest

Cristina Schnider is a retiree, stockholder and paid consultant for Johnson & Johnson Vision and a paid consultant for Lentechs and Lenz therapeutics. Dagny Zhu has had research grants and is an advisor and paid consultant for Alcon, and a paid consultant for Lenstec and Johnson & Johnson Vision. James S. Wolffsohn has received grant funding from Alcon and Rayner, is a paid consultant for Alcon, Atia Vision and Bausch + Lomb, and has stock ownership in Wolffsohn Research Ltd. Shehzad A. Naroo has received unrestricted grant funding from Lenstec, Teleon Surgical and Topcon Europe. Leonard Yuen, Radhika Rampat, Sandeep Dhallu, Tanya Trinh, Bharat Gurnani, Ahmed Abdelmaksoud and Gurpreet Bhogal-Bhamra have declared no financial interests.

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