# Intraocular lenses for presbyopia correction: past, present, and future

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**Purpose of review**
To discuss the development of presbyopia-correcting intraocular lenses (IOLs), what we have learned since their introduction a few decades ago, what are the options currently on the market, and where the technology is heading in the future.

**Recent findings**
Multifocal and accommodating IOLs have gone through several modifications to improve distance, intermediate and near vision compared to their predecessors. These modifications have also targeted unwanted side-effects such as glare and halos in the multifocal lenses and inconsistent near-vision results in the accommodating IOLs and although the results have improved, they are far from perfect. Therefore, careful patient selection for each of these technologies is crucial for success and patient satisfaction.

**Summary**
Presbyopia correction remains a great challenge in cataract and refractive surgery. In this article, we review the development of presbyopia-correcting IOLs, starting from the simple, two-zone, multifocal, refractive models introduced 2 decades ago, the current Food and Drug Administration (FDA) approved multifocal and accommodating lenses as well as those undergoing FDA trials and take a look into developing technologies that may be available to us in the future.

**Keywords**
accommodative intraocular lens, cataract surgery, multifocal intraocular lens, presbyopia, refractive surgery

## INTRODUCTION

Advances in phacoemulsification and intraocular lens (IOL) technology have enabled cataract surgery to evolve into a more refined procedure. The goal is no longer only removal of the cloudy lens with a close approximation of the refraction, but also the achievement of the best possible refractive outcome with restoration of vision for near and distance without spectacles. As patients' expectations increase, the management of the refractive component, including presbyopia, has become more important.

Accommodation is an active fluid dioptric change in the refractive power of the eye and has a multifactorial mechanism [1]. Presbyopia occurs when there is a decrease in the amplitude of accommodation caused in part by the hardening of the crystalline lens [2], which results in a decrease near vision that can significantly affect the quality of life [3–5]. Discussion of the theoretical basis of accommodation and presbyopia is beyond the scope of this review.

Accommodation implies an increase in power as a response to the contraction of the ciliary muscle which releases tension on the zonules, allowing the lens to change shape. This change needs to be differentiated from pseudoaccommodation which is an increased depth of focus in a pseudophakic eye beyond that predicted by the optical properties of the IOL and is attributed to the static optical properties of the pseudophakic eye independent of ciliary muscle actions [6,7▪]. Another term that needs to be differentiated is pseudophakic accommodation, which describes the dynamic change in the refractive state of the eye caused by the forward movement of the IOL/bag complex [7•]. For the purpose of this review, we will group under accommodating IOLs, those that are theoretically designed to either flex forward or change the distance between optics

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## KEY POINTS

- Presbyopia correction remains one of the great challenges in cataract and refractive surgery.
- Advances in the last 2 decades have improved visual outcomes and decreased side effects in both multifocal and accommodating intraocular lens (IOL) designs, but none has proven, so far to be problem free.
- Innovative designs in the accommodating IOLs arena are at different developmental stages and some will probably be available in the next few years.
- New technologies are emerging that will allow not only to improve intermediate and near-visual acuities, but also to personalize the IOL to the patients pupil size, visual axis, corneal aberrations, and visual needs.

(for dual-optic lenses) when ciliary muscle contraction is stimulated.

Presbyopia remains one of the most challenging and last frontiers in cataract and refractive surgery; different approaches to treat presbyopia have been studied in recent years such as remodeling of the sclera (scleral expansion and sclerotomy techniques) [8–10], corneal procedures (presbyLASIK [11–13], corneal inlays [14–16], and conductive keratoplasty) [17,18], monovision techniques [18], and replacement of the crystalline lens with either multifocal or accommodating lenses. Each of the techniques has advantages and disadvantages and none has proven, so far to be problem free.

This chapter looks into the evolution of presbyopia-correcting IOLs, from the initial models, our current options, and what lies ahead for the future.

## PAST: MULTIFOCAL LENSES–REFRACTIVE LENSES

The first multifocal lens to be granted Food and Drug Administration (FDA) investigational status was the 'bull's eye' lens manufactured by Precision-Cosmet, later acquired by IOLAB and marketed as the NuVue lens (acquired by Bausch & Lomb Surgical, Rochester, New York, USA), which was a simple, two-zone, refractive lens with center near dominance optic. Next, Storz (Bausch & Lomb) developed the True Vista lens, which was a more complex center distance dominant, three-zone lens [19].

The first presbyopia-correcting IOL to be FDA approved was the Array (Advanced Medical Optics, Santa Ana, California, USA) in 1997. In some of the first studies, 72% of the eyes implanted with the Array could see both 20/40 for distance and J3 for near compared with 48% with a monofocal lens [20]. Other authors reported that in comparison with monofocal lenses, the Array demonstrated a high level of uncorrected and corrected distance vision, improved uncorrected and distance-corrected near vision, reduced spectacle dependency, and a high level of patient satisfaction despite some loss of low-contrast visual acuity and increased reports of halos and glare [21–25]. This zonal progressive refractive design was the predecessor of the ReZoom (Advanced Medical Optics, acquired by Abbott), approved in 2005 for the combined treatment of cataract and presbyopia. The upgrades from the Array to the ReZoom included a change from silicone to a three-piece, 6 mm optic, hydrophobic acrylic platform and a center distance dominant lens that achieves its two primary focus points by five alternating concentric zones. Zones 1, 3, and 5 are distance dominant, whereas zones 2 and 4 are near dominant. The design of the optic differs from that of the Array in that its second and third zones have been enlarged, and the fourth and fifth zones have been reduced in size. An aspheric transition between the zones provides balanced intermediate vision. These changes lead to a reduction in nighttime glare and improved uncorrected near vision (UCNVA) when compared with its predecessor [26]. This type of lens gives a better uncorrected distance visual acuity (UCDVA) and uncorrected intermediate visual acuity (UCIVA) than UCNVA, with data from the manufacturer claiming spectacle independence for distance intermediate and near vision in 93, 92, and 81% of patients [available at www.rezoomiol.com/files/PackageInsert.pdf (accessed 3 July 2011)]. The modifications in the ReZoom lens significantly decreased the complains of moderate glare and halos, with one study demonstrating a reduction of these symptoms to less than 10% of the number of implanted eyes 2 years postoperatively. In this same study, mean uncorrected distance, intermediate and near vision at final visit were 0.04 LogMAR, 0.07 LogMAR and J2.3, respectively [27].

### Diffractive lenses

The first diffractive lenses were the Pharmacia 811E (Advanced Medical Optics Santa Ana, California, acquired by Abbott) and the 3M 815LE (3M Corp, St Paul, Minnesota, USA) [19]. The 3M diffractive lens was purchased by Alcon laboratories and named the ReSTOR (Alcon, Forth Worth, Texas, USA), which was the first diffractive IOL to be FDA approved in 2005; a center near dominant 6 mm optic, single-piece hydrophobic acrylic lens with a central 3.6 mm optic zone with 12 concentric

diffractive rings, in which the height of each diffractive step decreases with increasing distance from the lens center (1.3–0.2 μm), this is called apodization. The refractive region surrounds the apodized area. The ReSTOR had a +4.0 D add for near vision at the lens plane (approximately +3.2 D of at the spectacle plane) [28]. This lens demonstrated very good UCDVA and UCNVA with high rates of spectacle freedom [29–31]. In a study by Chiam *et al.* [32], this lens delivered an UCDVA of 20/30 or better in 93.8% eyes and an UCNVA of 20/30 or better in 75.0% of eyes. Moderate glare was reported by 21.3% of the patients. Glare and halos have been reported as the main complication of this type of lens [33].

In 2007, the FDA approved the aspheric version of the ReSTOR (AcrySof IQ, ReSTOR), which has 10 μm of negative asphericity, while maintaining its apodization, diffractive and refractive components, this negative aberration compensated for the positive corneal aberrations. In a postmarketing study, 3-month data showed that patients implanted bilaterally with the aspheric model were all 20/30 or better UCDVA compared with only 65% in the original ReSTOR group [26]. In another study by Cochener *et al.* [34], bilateral implantation of the ReSTOR IQ resulted in vision of 0.8 in 93.3% of patients for near and in 88.6% for distance. After surgery, 87.2% of the patients were spectacles free and 93.1% thought that surgery resulted in a positive change. Dysphotic phenomena continue to be the major draw back of multifocal lenses as shown in a study by Petermeier and Szurman [35], in which dysphotic phenomena were noted by 66% of patients implanted with the ReSTOR, although they were mild and of no consequence in 59% of them.

## ACCOMMODATING LENSES

The only accommodating IOL to be approved by the FDA is the Crystalens (Eyeonics, Inc., Aliso Viejo, California, USA, acquired by Bausch & Lomb in 2008) in 2003 for the treatment of aphakia and in 2004 to correct presbyopia in patients with cataracts. The original model (AT-45) had a 4.5-mm silicone optic and two flexible, hinged plate haptics. The FDA trial found at 1-year follow-up monocular near and intermediate visions of 20/40 or better in 90.1 and 99.6% of the cases [36]. Seven-year data on the initial FDA trial indicate that UCNVA was better at 7 years than at 1 year postoperatively [available at http://www.bauschsurgical.com/cataract/crystalens/features-and-benefits.aspx (accessed 2 July 2011)]. Since then, the Crystalens has had several modifications including a new 5 mm optic for its Five-o model, which was then carried to their next model the HD which was approved in 2008 and features a 1.5-mm blended bispheric optical zone in the center to enhance near vision by increasing depth of focus. According to the manufacturer's data, UCNVA was J3 or better in 100% of the patients [www.bauschsurgical.com/cataract/crystalens/crystalens-hd.aspx (accessed 2 July 2011)]. A more recent case series comparing the Crystalens HD with a monofocal IOL found that the distance-corrected near-visual acuity improved significantly in both groups ($P \leq 0.03$) and the difference between groups was at the limit of statistical significance ($P = 0.05$). The uncorrected near-visual acuity was significantly better in the accommodating IOL group (J5 versus J3; $P = 0.01$) [37]. Major issues reported with the Crystalens include its inconsistent results for UCNVA [28] and problems with capsular contraction causing lens tilt resulting in astigmatism and reduced quality of vision (Z syndrome) [38,39].

## PRESENT

Improvements on previous platforms and recently FDA approved presbyopia-correcting IOLs have increased patient satisfaction and quality of life [40].

### Multifocal lenses: refractive lenses

The ReZoom lens is still available and provides good distance and spectacle-independent intermediate vision; the downsides of this lens continue to be its dependence on spectacles for near tasks and the increased incidence of photic phenomena compared to other multifocal lenses [41].

The Lentis M Plus (Oculentis, Berlin, Germany) is a bifocal lens available in Europe that consists of an aspheric, asymmetric, far-vision zone combined with a sector-shaped, near-vision segment of +3.0 diopters, instead of the usual zones of other multifocal models, one of the theoretical advantages of its design is the decrease in glare and halos associated with the refractive rings [42▪].

The M-Flex 630F +3 (Rayner, East Sussex, UK) which is also available in Europe, is a center distance dominant, 6.25 mm optic, aspheric, hydrophilic, acrylic lens with five refractive zones that alternate between two powers, the distance base power and the +3.00 add power which is equivalent to +2.25 D at the spectacle plane. In a recent study, this lens delivered a 12-month follow-up mean UCDVA of 20/25, UCIVA 20/32, and UCNVA of 20/40, whereas the BCDVA (best corrected distance visual acuity) was 20/20, the CIVA (corrected intermediate visual acuity) was 20/32, and the DCNVA (distance corrected near visual acuity) was 20/40 [43]. The reported incidence of glare and halos with this lens seems to be very low, with no patient reporting any

disturbance by the 12-month follow-up in two different series [43,44].

## Diffractive lenses

The AcrySof IQ ReSTOR +3.00 D was introduced recently. The previous +4.0 D lens delivered excellent UCDVA and UCNVA near with high patient satisfaction, but with a suboptimal UCIVA, because of the fact that the design offers two focal planes (near and distance), compromising intermediate vision [32,45,46]. This finding is consistent with reports of lower satisfaction for intermediate vision among patients implanted with the ReSTOR +4 [47]. The +3.0 D model was designed to improve intermediate vision while maintaining near- and distance-visual acuity. The new model incorporates a +3.0 diopter correction at the lenticular plane (approximately +2.5 D at the spectacle plane), it also has three fewer steps and wider step spacing to increase intermediate vision [www.acrysofrestor.ca/professional/apodized-diffractive-optics.asp (accessed 4 July 2011)]. Recent studies have compared the +4.0 D and +3.0 D models, demonstrating better intermediate visual acuity under high and low contrast and a more comfortable reading distance with the +3.0 D model without compromising UCDVA or UCNVA [48,49]. One of the main advantages of the +3.0 D lens is the difference in the mean patient-preferred near distance which changes from approximately 31.6 cm to the more comfortable distance of 40 cm [50,51]; Furthermore, a study by Alfonso *et al.* [52▪▪] found better intermediate visual acuity at 50, 60, and 70 cm with the +3.0 D lens than with the +4.0 D. The farther reading distance and better UCIVA achieved with the +3.0 D model have been associated with improved patient-reported outcomes and satisfaction [53,54].

Glare and halos continue to be an issue with the ReSTOR +3. A study by Petermeier *et al.* [54], comparing the +3 D and +4 D models, found that the +3 D group noticed more glare and flare and the +4 D group noticed more halos. The reason for less perception of halos in the +3 D group might be that the halo size, which is the size of the out-of-focus image on the retina, depends on the add power of the near focus, making the halo of the +3 D model smaller [55]. In contrast, the halo would be smaller but with higher intensity and might be experienced more as a glare/flare than as a halo. This situation might be the reason for the increased perception of glare/flare in the +3 D group [54].

Although not in the United States market yet, the ReSTOR Toric is the newest addition to the line, this lens has been available in Europe since 2010 and it is also available in Canada. This lens combines the technology of the ReSTOR +3.0 D with the astigmatic correction of the AcrySof IQ Toric to provide a single platform to correct astigmatism and improve near and intermediate vision. This lens is expected to enter the United States market in 2012 [www.alconsurgical.com/ACRYSOF-Iq-Restor-Multifocal-Toric-Iol.aspx (accessed 4 July 2011)].

The Abbot Tecnis multifocal IOL was first available only as a three-piece silicone lens (ZM900), it later became available as a three-piece acrylic (ZMA00) or a single-piece acrylic (ZMB00), which were the models approved by the FDA in 2010.

The Tecnis multifocal IOL is a center distance dominant, 6-mm optic, aspheric hydrophobic acrylic lens with a +4.0 D near add (+3.0 D at the spectacle plane), it has an aspheric anterior surface and a fully diffractive posterior surface. This design splits the light among near and distance focus regardless of pupil size [56]. A retrospective study on the earlier version of this IOL found an UCDVA of 20/30 in 85% of eyes and an UCNVA of J1 in 93.7% of 2500 eyes 3 years postoperatively [57]. One-year results of the FDA trial demonstrated that mean UCDVA with the new aspheric version was statistically and clinically equivalent compared to a monofocal group, whereas mean binocular and monocular UCNVA and distance-corrected near vision were significantly better with the multifocal lens ($P < 0.001$). Overall, 84.2% of the patients implanted with the Tecnis multifocal lens achieved binocular UCDVA of 20/25 and near vision of 20/32 or better [58]. One of the advantages of this lens is the relative 'pupil independence' derived from the full posterior diffractive surface [59]. As with other multifocal lenses, photic phenomena continue to be an issue. In a prospective study, Palomino Bautista *et al.* [60] reported glare and halos in 22.4% of patients implanted with the Tecnis multifocal (ZM900), although symptoms tended to improve over time with no patient rating them as severe at the 6-month visit. On a large retrospective series of 2500 eyes implanted with the Tecnis ZM900, glare and halos were reported as severe by only 6.1 and 2.12% of patients, respectively [57]. These results are concordant with others in the literature that demonstrate a low incidence of severe glare and halos complaints with this lens [61].

A few examples of other diffractive lenses not available in the United States market include The OptiVis (Aaren Scientific Inc., Ontario, California, USA) which combines a refractive zone of progressive power in its central 1.5 mm diameter and a diffractive zone that occupies the area between 1.5 and 3.8 mm diameters and the Acri Lisa 366D (Carl Zeiss Meditec, Hennigsdorf, Germany), which is a single-piece, aspheric, biconvex, refractive–diffractive, bifocal

IOL with a 6-mm optic. The surface is divided into main zones and phase zones; the phase zones assume the function of steps of diffractive IOLs and have a mean refractive power corresponding to the zero diffractive power of the main zones. The IOL power responsible for distance vision is thus refractive and diffractive at the same type. The near add at the IOL plane is +3.75 D [62▪].

### Accommodative lenses

The Crystalens is still the only accommodating IOL approved by the FDA, the latest addition to the line is the Crystalens AO, Approved in 2009. The AO has an aspheric optic that enhances the depth of field, eliminates spherical aberration and has a uniform power center to edge that improves performance in cases of mild decentration [63]. Initial reports by the company show that 100% of patients implanted with the Crystalens AO had binocular UCDVA, UCIVA, and UCNVA of 20/40 and J3 or better [www.bausch.com/en/ECP/Clinical-Resources-and-Education/Crystalens-AO (accessed 4 July 2011)]. Most of the peer-reviewed literature was done with the previous models of the Crystalens (AT-45, Five-O, and HD). Several studies have been unable to demonstrate the expected accommodative shift with the Crystalens. Studies with high-frequency ultrasound [64] and pharmacologic accommodation [65] have shown changes that correspond with only 0.25–0.75 diopters of accommodation, which is less than ideal; this limited accommodating effect of the Crystalens has inclined many surgeons to aim for −0.50 D to −0.75 D of myopia in the nondominant eye for their bilateral Crystalens patients [66]. The other downside of the Crystalens has been issues with tilting and decentration of the lens caused by capsular contraction and fibrosis [38,39,67].

Unlike multifocal lenses, the Crystalens does not distribute light energy through multiple images; it has a single focus point, making it a good option for patients with a low threshold for photic phenomena who are willing to accept certain compromise in near vision.

## FUTURE

Presbyopia is the refractive condition with the widest range of treatment options. However, none of these options are ideal, and all entail varying degrees of visual compromise. Therefore, the quest for better presbyopia IOLs continues.

Some of the interesting developments are taking place in the accommodating IOLs arena, in which some new lenses are being used in Europe and currently undergoing FDA trials. One of these lenses is the Synchrony accommodating IOL (Visiogen Inc., Irvine, California, EUA, a subsidiary of Abbot Medical Optics) which consists of a foldable, single-piece, dual-optic system that features a high plus-powered anterior optic joined by a spring haptic to a minus-powered posterior optic [68,69]. When the two optics are close together, the eye is set for distance, when the ciliary body contracts on attempted accommodation, capsular bag and zonular tension are released, and the front optic moves forward, changing the eye's focus to intermediate or near vision [70]. This lens has been marketed in Europe since 2006 and is the next lens most likely to gain FDA approval. In a prospective study, presented at the 2009 ASCRS symposium, 100 patients were randomly assigned to receive binocularly either Synchrony or ReSTOR lenses. UCDVA was 20/20 or better in 90% of the patients in both groups, UCNVA was equivalent with the two lenses, but the Synchrony lens provided better UCIVA and less halos and glare compared to the ReSTOR [71]. Long-term improvement in reading performance up to 2 years postimplantation of the Synchrony IOL has been shown, suggesting that accommodation is still present at this time [72▪▪].

The Tetraflex (Lenstec Inc., St. Petersburg, Florida, USA) is an acrylic, 5.75 mm, single optic lens that has two haptics and an anterior vault, designed to move anteriorly with both vitreous pressure and ciliary swelling [www.thetetraflex.com/tetraflex3.html (accessed 10 July 2011)]. This lens is available in Europe since 2004.

A very interesting lens with an innovative design is the NuLens (NuLens, Herzlyia-Pituach, Israel), this accommodating lens is designed to actually change power during accommodation through the alteration of lens curvature. The system consists of a small rigid chamber containing a silicone gel that is pressurized by a piston, actuated by the capsular diaphragm. The collapsed capsular bag, zonules, and ciliary processes form the moving diaphragm that transfers force to the device that is fixed to the ciliary sulcus. The pressurized gel is displaced through a round hole to form a lens-shaped bulge continuously changing its curvature in correlation with the ciliary muscle movements [73]. Initial results with this technology are encouraging [74].

Other accommodating lenses under development include the 1CU (HumanOptics, Erlangen, Germany), which is a single-piece, acrylic IOL with four haptics, the FlexOptic (Quest Vision, Austin, Texas, USA) and the SmartLens (Medenium, Irvine, California, USA).

Another promising technology is the Light Adjustable Lens (Calhoun Vision Inc., Pasadena,

California, USA), which can be adjusted postoperatively to correct myopia [75], hypermetropia [76], and astigmatism [77–79] to an initial emmetropic state; subsequently, a small near zone can be added during a subsequent adjustment, allowing the size and location of the add zone to be customized to the patient's visual axis and pupil diameter. Preliminary results from a pilot study demonstrated UCDVA of 20/25 in 83.3% of the eyes and UCNVA of J2 in 87.5% of the eyes [80]. A different approach using the same technology consists on increasing the asphericity of the lens with the UV-light irradiation, thus increasing depth of focus and improving UCIVA [81].

Refractive index shaping is another new technology in which in-situ IOL power customization is performed by using focused 500-mW femtosecond laser pulses to alter the refractive index of the lens, this technology is still in the early development stages [82].

One of the long sought dreams in presbyopia management has been to refill the capsular bag with a flexible polymer of the right optical properties and capable of responding to movements of the ciliary body. Some studies have shown promise with some materials in animal and in-vitro studies; however, this technology is still in developmental stages [83–85].

## CONCLUSION

Presbyopia correction remains a great challenge in refractive surgery. Developments in lens-based technologies have improved dramatically over the last decade with both multifocal and accommodating lenses achieving good outcomes with careful patient selection. In the next few years, we will witness the introduction of many of these lenses to the market as well as the development of new technologies to provide our patients with great vision at every distance.

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### Conflicts of interest

*The authors have no financial or conflicting interests to disclose.*

## REFERENCES AND RECOMMENDED READING

Papers of particular interest, published within the annual period of review, have been highlighted as:

- ■ of special interest
- ■■ of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 75–76).

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