

## Presbyopia-correcting Intraocular Lenses in Cataract Surgery— A Focus on ReSTOR® Intraocular Lenses

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### Abstract

Correction for presbyopia in cataract patients is a significant challenge for ophthalmologists and cataract surgeons, however, an increasingly diverse array of intraocular lenses (IOLs) that are capable of providing good quality near vision is available. Currently available synthetic lenses use different technologies to correct for presbyopia. The latest iterations of the AcrySof® ReSTOR® IOLs combine an optic with a central apodized diffractive zone, a peripheral refractive zone, an aspheric anterior to combat corneal aberrations, and an ultraviolet (UV)- and blue-light filtering chromophore. The AcrySof® IQ ReSTOR® IOLs provide excellent near vision restoration with increased spectacle independence and minimal severe side effects. As a result, it may represent a significant advance over other presbyopia-correcting technologies. IOLs such as the AcrySof® IQ ReSTOR® are increasingly replicating the full visual capabilities of the crystalline lens and are an important advancement in the treatment of presbyopia in cataract patients.

### Keywords

Accommodation, aspherical, cataract surgery, diffraction, intraocular lenses, multifocal IOL, presbyopia, visual function

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Presbyopia is defined as the inability to focus on near targets, and its correction following cataract surgery remains one of the most significant challenges for ophthalmologists and cataract surgeons.<sup>1,2</sup> According to the World Health Organization (WHO), age-related cataracts are responsible for ~48% of world blindness, equating to ~18 million people,<sup>3</sup> whereas presbyopia is estimated to affect over one billion individuals globally and may be universal in those aged >65 years.<sup>4</sup>

Presbyopia arises due to the age-related loss of crystalline lens accommodation,<sup>1,5,6</sup> but the underlying mechanisms remain enigmatic.<sup>7,8</sup> The replacement of the opaque crystalline lens by simple monofocal intraocular lenses (IOLs) during cataract surgery is capable of restoring good vision, particularly distance vision,<sup>9</sup> but historically, spectacle use was still required to correct for presbyopia. However, new generation IOLs are increasingly able to reproduce the full functional range of the crystalline lens, including correcting for presbyopia, thereby reducing spectacle dependence. Several types of presbyopia-correcting IOLs are available, including accommodative, zonal refractive, full optic diffractive, and apodized diffractive IOLs.<sup>1,5,6,10</sup> This article discusses the different types of presbyopia-correcting IOLs available, describes their clinical performance, advantages and disadvantages, and focuses

specifically on the latest iterations of the apodized diffractive AcrySof® IQ ReSTOR® IOL (Alcon Laboratories, Inc.). New generations of IOLs that replicate the full accommodative range of the crystalline lens and correct for presbyopia will enable ophthalmologists to further improve the range of post-operative visual function in cataract patients.

### Accommodative, Zonal Refractive, and Full Optic Diffractive Intraocular Lenses Accommodative – Crystalens®

The Crystalens® (Bausch & Lomb, Inc.) is described as the first accommodating lens. The first model (AT-45) was approved for the treatment of cataract and presbyopia in 2004.<sup>1,6</sup> The Crystalens® has a silicone monofocal optic with an ultraviolet (UV)-light filter and two flexible, hinged plate haptics. The optic is available in powers of +4 to +33 diopters (D) and its position in the capsular bag is maintained by two polyamide loops across each end of the plate haptics. Correction of presbyopia is provided by pseudophakic accommodation. Rearrangement of the ciliary muscle during constriction causes an increase in vitreous pressure on the lens optic which shifts anteriorly as the haptics flex.<sup>5</sup> More recent versions of the Crystalens® include the AT-50, with a 5mm optic and wider haptics,<sup>11</sup> and the Crystalens® AO®

which combines the accommodating technology with an aspheric optic.<sup>12</sup> The aspheric compensates for the positive spherical aberration of the cornea, a function normally provided by the crystalline lens, further improving the depth of field.<sup>13</sup>

**Zonal Refractive—ReZoom®**

Unlike the Crystalens, the ReZoom® (Abbott Medical Optics, Inc.) is a multifocal IOL and was approved for the treatment of cataracts and presbyopia in 2005.<sup>1</sup> The ReZoom® is a three-piece IOL consisting of two monofilament haptic arms that maintain its position in the capsular bag, and a UV-light filtering acrylic optic comprised of five concentrically arrayed visual zones. Each concentric zone is devoted to a different focal range and/or brightness, with zones two and four devoted to near visions. The ReZoom® therefore generates a continuous, progressive range of foci that provides depth of field dependent on pupil diameter.<sup>14</sup> Optical power ranges from +6 to +30 D, and the two near-dominant zones provide up to +3.5 D addition (add) power for near vision.

**Full Optic Diffractive—Tecnis®**

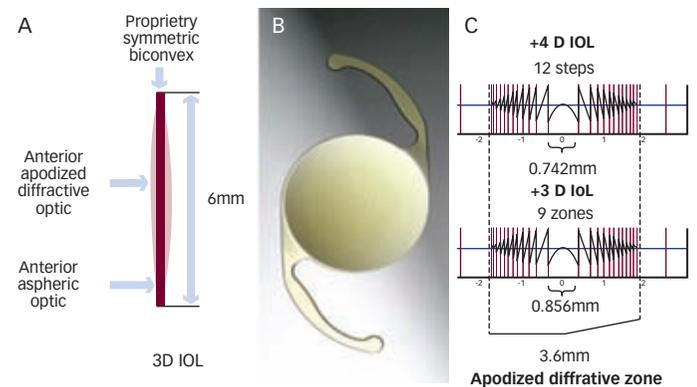
A full optic diffractive IOL, the Tecnis 1-piece (Abbott Medical Optics, Inc.), is an acrylic, single-piece multifocal IOL consisting of a diffractive optic and two haptic arms that maintain its position in the capsular bag.<sup>13</sup> The optic also filters UV-light and optical power ranges from +5 to +34 D.<sup>15</sup> The diffractive optic directs equal amounts of light (41%) to both near and distant primary foci, irrespective of pupil diameter, with the remaining 18% lost to high-order scattering.<sup>16</sup> Additionally, the optic is aspheric to compensate for corneal aberrations.<sup>13</sup>

**Clinical Performance and Adverse Effects of Intraocular Lenses**

Early reports indicated that implantation of the Crystalens® significantly improved near vision<sup>17-19</sup> with further improvements occurring over time.<sup>1</sup> However, a recent meta-analysis observed large discrepancies in the ability of the Crystalens® to correct for presbyopia,<sup>20</sup> and a recent study discerned no improvement in near vision at all.<sup>21</sup> Some patients seem to lose the accommodative effect of the Crystalens® over time, which is not seen with multifocal IOLs.<sup>22-24</sup> Due to the flexible nature of the haptics, optical tilting may occur in normally implanted individuals resulting in a condition known as Z syndrome and leading to the loss of visual acuity (VA) at all distances.<sup>25,26</sup> The problem may be corrected by neodymium-doped yttrium aluminum garnet (Nd:YAG) laser posterior capsulotomy,<sup>25,26</sup> that may also be used to correct for post-operative opacification of the posterior capsule.<sup>18</sup> Three-piece foldable lenses with prolene haptics tend to undergo a myopic shift over time, and mild myopic shift can also be seen with the Crystalens® at one year after surgery.<sup>18,27</sup>

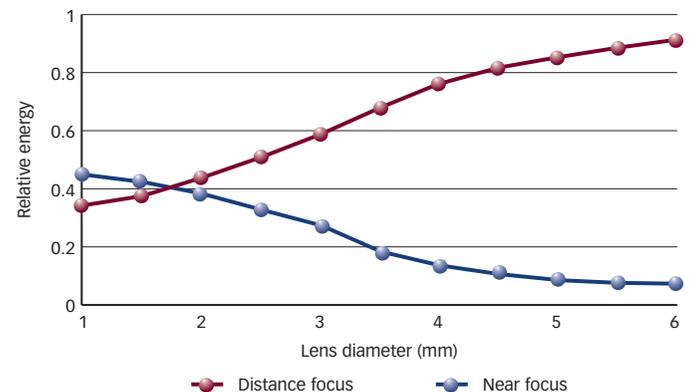
Implantation of ReZoom® improves near vision to an equal or greater extent than accommodative IOLs<sup>16,28</sup> with increased spectacle independence.<sup>16</sup> There is no significant drop in quality of vision over time.<sup>29</sup> However, since multifocal IOLs increase the depth of field by providing multiple distinct foci, they are associated with a number of optical defects including reduced contrast sensitivity, glare, halos, and night vision disturbances, a problem not associated with monofocal IOLs.<sup>30</sup> Although the ReZoom® IOL has been designed to reduce glare and halos, they are still apparent.<sup>16,29</sup> In addition, higher intraocular aberrations can occur with ReZoom®.<sup>31</sup>

**Figure 1: Anatomy of the AcrySof® IQ ReSTOR® Intraocular Lens**



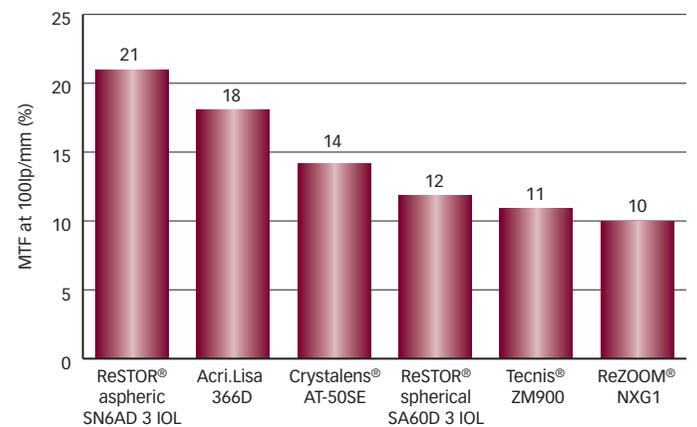
A: Side view of the AcrySof® IQ ReSTOR® IOL with +3 diopters (D) add power. B: Front view of the complete intraocular lens (IOL) including optic and haptic arms. Note that the IOL is yellow due to the presence of the blue-light-filtering chromophore. C: Comparison of the +4 D (top) and +3 D (bottom) IOL apodized diffractive zones. Reproduced with permission from Alfonso et al, 2009.<sup>32</sup>

**Figure 2: Relative Light Distribution of the AcrySof® IQ ReSTOR® Intraocular Lens as a Function of Lens Diameter**



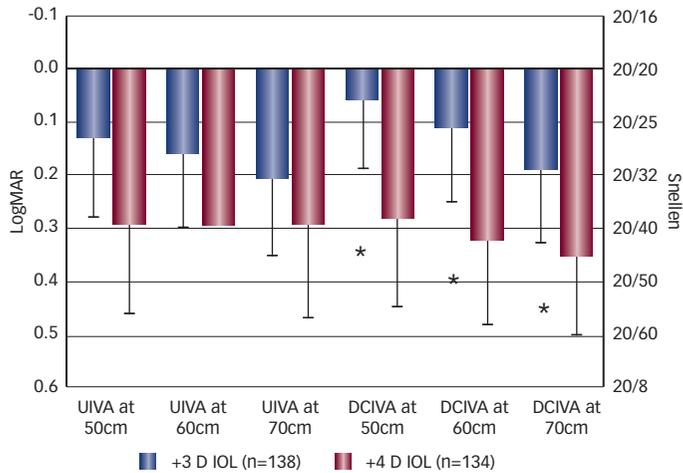
Reproduced with permission from Alfonso et al, 2009.<sup>32</sup>

**Figure 3: Optical Performance of Six Intraocular Lenses as Measured by Modulation Transfer Function in a Model Eye**



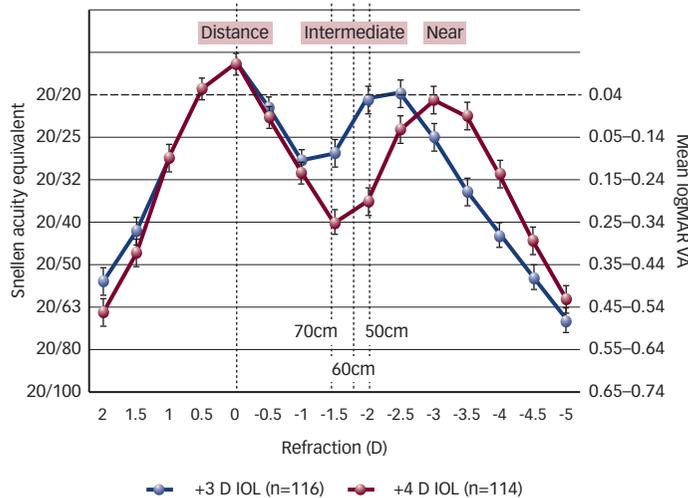
Modulation transfer function was calculated with a 5mm aperture, distance focus, at a discrete frequency of 100lp/mm. D = diopters; IOL = intraocular lens; MTF = modulation transfer function. Reproduced with permission from Maxwell et al, 2009.<sup>33</sup>

**Figure 4: Improved Binocular Intermediate Visual Acuity in +3 D Compared to +4 D Add Power AcrySof® IQ ReSTOR® Intraocular Lenses**



\* $p < 0.0001$ , Hommel procedure. Visual acuity is measured on the logMAR and Snellen scales. D = diopters; DCIVA = distance-corrected intermediate visual acuity; IOL = intraocular lens; UIVA = uncorrected intermediate visual acuity. Patients were evaluated six months post-operatively. Reproduced with permission from Maxwell 2009b.<sup>33</sup>

**Figure 5: Defocus Curves Demonstrate Better Intermediate and Equivalent Distant and Near Vision Acuity for +3 D Over +4 D Add Power AcrySof® IQ ReSTOR® Intraocular Lenses**



Mean binocular defocus curves of the best-case cohort with 95% confidence limits. Visual acuity is measured on the Snellen acuity equivalent and mean logMAR scales. Patients were evaluated six months post-operatively. D = diopters; IOL = intraocular lens; VA = visual acuity. Reproduced with permission from Maxwell 2009b.<sup>33</sup>

he greater amount of light provided at the near focus by the Tecnis® IOL means it is capable of restoring good quality near-vision, high rates of patient satisfaction, and spectacle independence<sup>35-37</sup> that are superior to that provided by refractive IOLs such as ReZoom®,<sup>38-40</sup> although this is not a universal finding.<sup>16</sup> Quality of near vision improves post-operatively.<sup>36,37</sup> The Tecnis® IOL is associated with optical defects including halos and glare, but these too are fewer compared with refractive IOLs<sup>38,39</sup> and they also abate over time.<sup>36</sup> However, aspheric IOLs are more closely associated with complications arising from tilt and decentration.<sup>41</sup>

## Apodized Diffractive Intraocular Lenses—ReSTOR®

### Physical Characteristics of the AcrySof® ReSTOR® Intraocular Lens

The new generation of AcrySof® IOLs (Alcon Laboratories, Inc.), the AcrySof® ReSTOR®, was approved in 2005 and is a single-piece, acrylic multifocal IOL comprising an optic with a central apodized diffractive zone for near vision surrounded by a refractive zone for distance vision.<sup>1</sup> Two haptic arms maintain its position in the capsular bag. The apodized diffractive zone consists of concentric diffractive steps that decrease in amplitude from the centre to the periphery (see *Figure 1*).<sup>10,32</sup> The most recent AcrySof® IQ ReSTOR® IOL, the AcrySof® IQ ReSTOR®, was approved in 2008 and has an aspheric optic to correct for corneal aberrations.<sup>1,42</sup> Optical power ranges from +6 to +34 D.<sup>41</sup> In addition to filtering UV-light, the AcrySof® IQ ReSTOR® optic has a proprietary covalently bonded blue-light filtering chromophore that makes it more analogous to the adult crystalline lens.<sup>42</sup> Inclusion of the chromophore has no adverse effect on a variety of visual parameters including VA.<sup>43</sup>

The principle difference between the AcrySof® IQ ReSTOR® IOL and the full optic diffractive IOLs such as the Tecnis® is the use of an apodized diffractive zone. In contrast to the full optic diffractive IOLs where the amount of light apportioned to near and distant foci is fixed, the AcrySof® IQ ReSTOR® IOL allocates light to near and distant foci depending on lighting conditions and pupil diameter. Thus, image quality is improved, minimizing visual disturbances (see *Figure 2*).<sup>10,32</sup> In normal lighting where pupil diameter is small, more light is apportioned to the near focus. In low lighting where pupil diameter is large, more light is apportioned to the distant focus.<sup>10</sup> Vision therefore varies in a manner that is consistent with natural pupil responses.

### Clinical Performance of the AcrySof® IQ ReSTOR® Intraocular Lens

In a recent optical bench test, the optical quality of six IOLs, including the AcrySof® IQ ReSTOR®, were compared using modulation transfer function and the US Air Force 1951 Resolution Target in a model eye.<sup>33</sup> Of the six IOLs, the AcrySof® IQ ReSTOR® consistently demonstrated excellent optical performance compared with the Crystalens®, ReZoom® and Tecnis® IOLs, and also older spherical iterations of the AcrySof® ReSTOR® IOL (see *Figure 3*).<sup>33</sup>

In clinical studies, the older iterations of the AcrySof® ReSTOR® IOL provide excellent distant and near vision acuity, with slightly poorer intermediate distance acuity, and many individuals achieved spectacle independence.<sup>44,45</sup> Furthermore, near vision acuity was equal to or better than that provided by other IOLs.<sup>28,39,46,47</sup> Recent comparisons of an older generation apodized diffractive AcrySof® ReSTOR® IOL to the AcrySof® IQ ReSTOR® with +4 D add power IOL demonstrated that the new IOL provided better distant and near vision acuity than its spherical counterpart, presumably due to the presence of the aspheric optic.<sup>48,50</sup> Intermediate distance acuity was not ideal, however.<sup>48</sup> The latest generation of apodized diffractive IOLs is the AcrySof® IQ ReSTOR®, approved in 2009, with +3 D add power that has a slightly longer reading distance (~41cm) than the AcrySof® IQ ReSTOR® IOL with +4 D add power (~33cm).<sup>32</sup> The AcrySof® IQ ReSTOR® IOL with +3 D add power also produced excellent near vision acuity and high levels of spectacle

independence,<sup>32,51</sup> and comparison with a monofocal AcrySof® IQ ReSTOR® IOL showed increased near vision acuity.<sup>52</sup> More recently, two studies comparing the +4 D and +3 D add power iterations observed equivalent distant and near vision acuity in the two IOLs, but the +3 D add power iteration improved intermediate distance vision (see Figures 4 and 5).<sup>34,53</sup>

### Patient Suitability for the AcrySof® IQ ReSTOR® Intraocular Lens

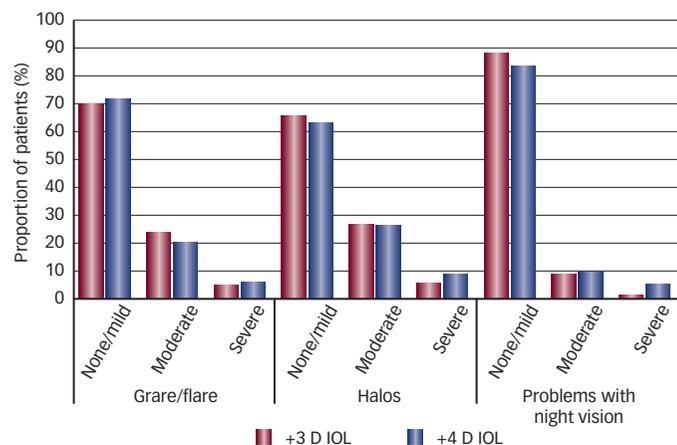
While the AcrySof® IQ ReSTOR® IOL is appropriate for use in any patient with visually significant cataracts and otherwise healthy eyes, careful preoperative judgment must be made to ensure safe treatment. Alternatives to IOL implantation should therefore be considered if patients suffer from one or more of the following retinal conditions including retinal detachment, significant irregular corneal aberration, corneal dystrophy or previous corneal transplant, amblyopia, shallow anterior chamber, inflammation of the anterior or posterior segments, aniridia, iris neovascularization, glaucoma, microphthalmos or macrophthalmos, and optic nerve atrophy.<sup>34,42</sup> Patients should understand that while VA across all distances may be restored to a high degree, and their spectacle independence may be significant, their reading or near vision acuity may be poor in low light situations and adverse optical effects may occur (see below). Furthermore, patients with other significant ocular morbidities such as corneal endothelial disease, macular degeneration or significant macular vascular occlusions, proliferative diabetic retinopathy, or irregular stigmatism may not achieve the same level of VA as patients without these problems. Surgical complications may include infection, corneal endothelial damage or edema, retinal detachment, vitritis, cystoid macular edema, transient or persistent glaucoma, hypopyon, and possible secondary surgical intervention.<sup>34,42</sup>

### Visual Disturbances and Patient Experience of AcrySof® IQ ReSTOR® Intraocular Lens

As with most multifocal IOLs, patients implanted with apodized diffractive IOLs are liable to suffer from photic problems including glare, halos, and night vision disturbances. Patients implanted with older, spherical iterations of the AcrySof® ReSTOR® IOL reported no severe visual phenomena and the majority exhibited only mild halos or glare.<sup>44,45</sup> Furthermore, >80% of patients reported never using spectacles for near vision.<sup>44,45</sup> In comparison to those implanted with the ReZoom® IOL, patients implanted with the spherical AcrySof® ReSTOR® IOL reported fewer and milder glare and halos and were more spectacle independent for near vision.<sup>39,46,47</sup> Comparison between AcrySof® ReSTOR® IOLs and the Tecnis® full optic diffractive IOL showed no differences in visual disturbances or spectacle independence.<sup>39</sup>

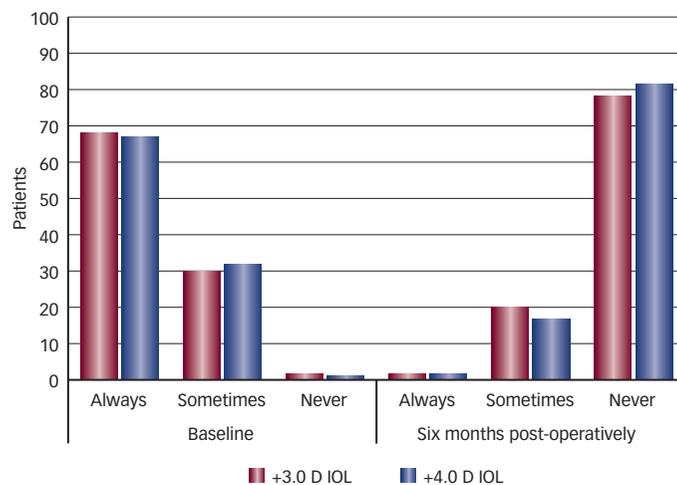
In patients implanted with the AcrySof® IQ ReSTOR® IOLs with either +3 D or +4 D add power, between 63 and 65% reported glare and halos as being either absent or mild, and between 83 and 88% reported mild or no night vision disturbances, with no significant differences between the two IOLs (see Figure 6).<sup>33</sup> Fewer severe photic disturbances were reported with the +3 D add power iteration, however (see Figure 6).<sup>34</sup> Furthermore, 78–81% of patients achieved spectacle independence for near vision in both groups (see Figure 7).<sup>34,51</sup> Mean overall patient satisfaction scores following implantation of the +3 D or +4 D add power IOLs were ≥8.3 (scale: zero=worst possible vision, 10=best

**Figure 6: Comparison of Visual Disturbances Reported by Patients Implanted with AcrySof® IQ ReSTOR® Intraocular Lenses with Either +3 D or +4 D Add Power**



Patients were evaluated six months post-operatively. D = diopters; IOL = intraocular lens. Reproduced with permission from Maxwell et al, 2009.<sup>34</sup>

**Figure 7: Comparison of Spectacle Independence Pre- and Post-operatively in Patients Implanted with AcrySof® IQ ReSTOR® Intraocular Lenses with Either +3 D or +4 D Add Power**



Patients were evaluated six months post-operatively. D = diopters; IOL = intraocular lens. Reproduced with permission from Maxwell et al, 2009.<sup>34</sup>

possible vision), indicating the vast majority of patients were satisfied with their vision.<sup>32,34,49,51</sup>

### Conclusion

While the original monofocal IOLs provided excellent distance vision in cataract patients, it is only in the past decade that the full range of VA normally provided by the crystalline lens is capable of being restored by the latest generation of IOLs. Different technologies are currently utilized to correct for presbyopia, including pseudophakic accommodation, refraction, and diffraction. The latest generation of apodized diffractive IOLs, the AcrySof® IQ ReSTOR®, provides excellent presbyopic correction and enables the vast majority of patients to achieve spectacle independence for near vision. Moreover, severe visual disturbances

are reduced with this type of IOL, so patient satisfaction is high. As the global aged population increases in size there will be greater demand for presbyopia correcting IOLs. Innovative solutions using new IOL

designs and materials to more accurately mimic normal vision will therefore remain an important and active area of research and development as the market for these products continues to grow. ■

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