

Multifocal Intraocular Lenses

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The youthful unaberrated human eye has become the standard by which the results of cataract and refractive surgery are evaluated. Contrast sensitivity testing has confirmed the decline in visual performance with age, and wavefront science has helped explain that this decline occurs because of increasing spherical aberration of the human lens. Because the optical wavefront of the cornea remains stable throughout life, the lens has started to come into its own as the primary locus for refractive surgery. Laboratory studies of accommodation have confirmed the essentials of Helmholtz's theory and clarified the pathophysiology of presbyopia. What remains is for optical scientists and materials engineers to design an intraocular lens (IOL) that provides unaberrated optical imagery at all focal distances. This lens must compensate for any aberrations inherent in the cornea and either change shape and location or employ multifocal optics.

Accommodative IOLs have made their debut around the world (CrystaLens, Eyeonics and ICU [Aliso Viejo, California], HumanOptics [Erlangen, Germany]). Clinical results indicate that restoration of accommodation may be achieved, at least to some extent, with axial movement of the lens optic [1]. Newer dual optic designs (Synchrony, Visiogen [Irvine, California], and Sarfarazi, Bausch & Lomb [San Dimas, California]) may allow greater amplitude

of accommodation. Flexible polymers designed for injection into a nearly intact capsular bag continue to show promise in animal studies [2]. These lens prototypes require extraction of the crystalline lens through a tiny capsulorrhexis and raise concerns about leakage of polymer in capsulotomy using the yttrium-aluminum-garnet laser following the development of posterior or anterior capsular opacification. A unique approach in laboratory development involves the use of a thermoplastic acrylic gel that may be shaped into a thin rod and inserted into the capsular bag (SmartLens, Medennium, Irvine, California). In the aqueous environment at body temperature it unfolds into a full size flexible lens that adheres to the capsule and may restore accommodation. Another unique design involves the light adjustable lens, a macromer matrix that polymerizes under ultraviolet radiation (LAL, Calhoun Vision, Pasadena, California). An injectable form of this material might enable surgeons to refill the capsular bag with a flexible substance and subsequently adjust the optical configuration to eliminate aberrations.

Although these designs show promise for restoration of accommodation and elimination of aberrations, multifocal technology also offers an array of potential solutions. Multifocal IOLs allow multiple focal distances independent of ciliary body function and capsular mechanics. Once securely placed in the capsular bag, the function of these lenses will not change or deteriorate. Additionally, multifocal lenses can be designed to take advantage of many innovations in IOL technology that have already improved outcomes, including better centration, prevention of posterior capsular opacification, and correction of higher order aberrations.

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The fundamental challenge of multifocality remains the preservation of optical quality, as measured by modulation transfer function on the bench or contrast sensitivity function in the eye, with simultaneous presentation of objects at two or more focal lengths. Another significant challenge for multifocal technology continues to be the reduction or elimination of unwanted photic phenomena, such as halos. One question that the designers of multifocal optics must consider is whether two foci, distance and near, adequately address visual needs, or whether an intermediate focal length is required. Adding an intermediate distance also adds greater complexity to the manufacturing process and may degrade the optical quality of the lens.

Recent advances in aspheric monofocal lens design may lend themselves to improvements in multifocal IOLs. The spherical aberration of a manufactured spherical IOL tends to worsen total optical aberrations. Aberrations cause incoming light that would otherwise be focused to a point to be blurred, which, in turn, causes a reduction in visual quality. This reduction in quality is more severe under low luminance conditions because spherical aberration increases when the pupil size increases. The Tecnis Z9000 IOL (AMO, Santa Ana, California) has been designed with a modified prolate anterior surface to reduce or eliminate the spherical aberration of the eye. The Tecnis Z9000 shares basic design features with the CeeOn Edge 911 (AMO), including a 6-mm biconvex square-edge silicone optic and angulated cap C polyvinylidene fluoride (PVDF) haptics. The essential new feature of the Tecnis IOL, the modified prolate anterior surface, compensates for average corneal spherical aberration and reduces total aberrations in the eye. The SofPort AO is a purely aspheric IOL design (Bausch & Lomb, Rochester, New York), whereas the AcrySof HOA is a single-piece acrylic IOL with a negative spherical aberration contour on the posterior surface.

Clinical studies show significant improvement in contrast sensitivity and functional vision with the Tecnis prolate IOL [3]. AMO has united this foldable anterior prolate design with a diffractive multifocal posterior surface previously available on a polymethylmethacrylate (PMMA) platform (Fig. 1). Improved visual performance and increased independence for patients constitute the fundamental concept behind this marriage of technologies. This new prolate, diffractive, foldable, multifocal IOL has received the CE Mark in Europe. US Food and Drug Administration (FDA)-monitored clinical trials began in 2004.

Multifocal technology has already improved the quality of life for many pseudophakic patients by re-



Fig. 1. The Tecnis Z9000 and ZM001 and CeeOn 811E lenses.

ducing or eliminating their need for spectacles. All persons over 40 years of age know that presbyopia can be a particularly maddening process. Giving surgeons the ability to offer correction of presbyopia by means of multifocal pseudoaccommodation will enhance their practices and serve their patients well.

This article reviews clinical and optical data for three unique lens designs: the ReSTOR diffractive IOL, the Vision Membrane, and the ReZoom refractive multifocal IOL.

Stephen Lane

ReSTOR diffractive intraocular lens

Approximately 90 million people in the United States are currently presbyopic [4]. IOLs, which traditionally have been targeted to correct for distance vision, have recently been modified to improve the condition of presbyopia. These technologies are also being developed and used in cataract surgery to replace the functioning of the natural crystalline lens, improving the quality of life of cataract patients by reducing their need for spectacles. In an FDA clinical trial, the AcrySof ReSTOR (Alcon Lab Inc., Fort Worth, Texas) apodized diffractive IOL provided uncorrected visual acuity of 20/40 or better throughout the distant to near visual range, with no restrictions on pupil size. Most critically, following cataract surgery, 80% of patients receiving the ReSTOR IOL bilaterally achieved total spectacle freedom.

The AcrySof ReSTOR apodized diffractive IOL was approved by the FDA for use in cataract surgery



Fig. 2. Design of the AcrySof ReSTOR IOL.

in March 2005. Under a revised Medicare policy, patients can choose to purchase this lens, Medicare will continue existing reimbursement amounts for the cataract surgery, and patients may elect to pay additional charges for the advanced technology of the ReSTOR lens.

Lens description

Optical design. The AcrySof ReSTOR IOL is an apodized, diffractive, single piece, foldable, hydrophobic acrylic, posterior chamber IOL (Fig. 2). The 6.0-mm biconvex optic is composed of a proprietary acrylic material selected for its high refractive index, flexibility, and biocompatibility with the eye. The AcrySof ReSTOR IOL uses a unique apodized diffractive technology to focus light. The ReSTOR has

a central 3.6 mm apodized diffractive optic region where 12 concentric diffractive zones on the anterior surface of the lens divide the light into two diffractive orders to create two lens powers. The lens provides one optical power for distance vision and a separate lens power for near vision. The add power of the ReSTOR IOL is +4 D at the lens, which provides about 3.2 D of add power at the spectacle plane. The diffractive steps introduce phase delays of light at the zone boundaries. Unlike the step heights of full optic diffractive lenses, which are all the same, the ReSTOR lens uses step heights that decrease with increasing distance from the lens center by a process termed *apodization*. Apodization greatly increases the proportion of energy directed to the distance focus for larger pupil diameters. For example, at a 5-mm pupil, the theoretic proportion of energy at the design wavelength that is directed into the distance lens power is more than double the amount provided by a full optic diffractive lens (Fig. 3) [5,6].

Minimization of photic phenomena. The ReSTOR IOL is designed with the apodized diffractive grating limited to the central 3.6 mm of the optic. The largest diffractive step is at the lens center and sends the greatest proportion of the energy to the near focus. As the steps move away from the center, they gradually decrease in size, blending into the periphery and sending a decreasing proportion of energy to the near focus. When the pupil is small, such as when

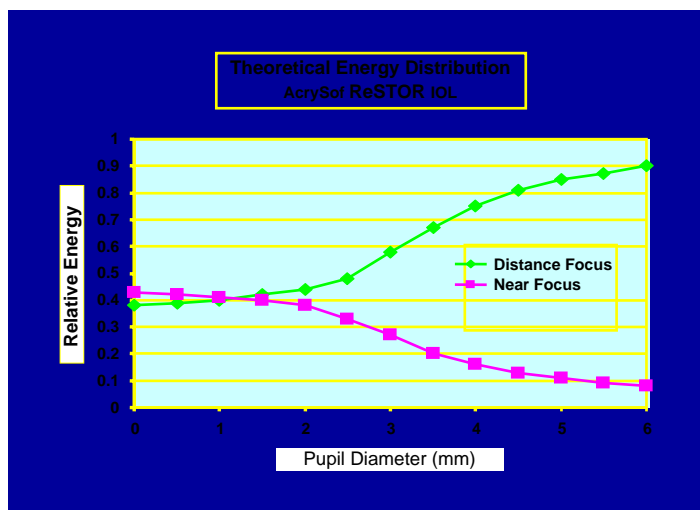


Fig. 3. Proportion of energy for the ReSTOR lens is theoretically more than double the amount that is provided by a full optic diffractive lens.

reading, the lens provides excellent near and distance vision. In dim light conditions when the pupil is enlarged, the lens becomes a distant dominant lens, providing excellent distance vision while reducing visual disturbances.

Clinical testing

Study description. A global multicenter open label study was completed in the United States and Europe comparing bilateral implantation of the AcrySof ReSTOR apodized diffractive IOL with that of the AcrySof MA60BM monofocal IOL. The trial implanted 566 subjects with the AcrySof ReSTOR IOL and 194 subjects with the AcrySof MA60BM. The study examined patients 120 to 180 days postoperatively from the second eye implant. Patient inclusion criteria included age over 21 years, bilateral cataract removal using phacoemulsification, with an IOL implanted in the capsular bag, and completion of bilateral implantations within 90 days of each other. The inclusion criteria required a potential postoperative visual acuity of 20/40 (0.34 logMAR) or better, astigmatism less than 1.0 D, and clear intraocular media.

Data were collected for distance and near visual acuity, pupil size, contrast sensitivity, night driving, visual disturbances, quality of life, spectacle use, and safety, and substudies collected data on defocus and intermediate vision. In addition to efficacy data, safety data were collected.

Study results

Near visual acuity. Near uncorrected visual acuity demonstrated a mean Snellen visual acuity score of 20/25 for ReSTOR subjects and 20/50 for

monofocal subjects [7,8]. Binocular uncorrected near visual acuity results demonstrated that 96.7% of the ReSTOR patients achieved 20/40 or better, with 40% having 20/20 or better vision. In comparison, 40.8% of the control subjects had 20/40 or better vision, and only 3.2% achieved 20/20 or better (Fig. 4).

Distance visual acuity. Evaluation of distance vision, uncorrected and best corrected for the implanted subjects, indicated comparable distance vision for the ReSTOR IOL compared with the monofocal IOL. Of subjects implanted with the ReSTOR IOL, 99.3% achieved 20/40 or better visual acuity compared with 97.5% of the monofocal group. Best corrected distance results showed that 100% of the ReSTOR and monofocal subjects achieved 20/40 or better visual acuity (Fig. 5).

Combined visual acuity. Binocular results for combined near and distance vision were significantly better for the ReSTOR IOL when compared with the monofocal lens. For uncorrected vision, 97.2% of ReSTOR patients achieved 20/40 or better visual acuity for distance and near, whereas only 40.9% of the monofocal group achieved these results. Of the ReSTOR patients, 84.3% achieved 20/25 or better distance visual acuity and 20/32 or better near vision. Only 22.7% of the control group reached these visual outcomes (Fig. 6).

Intermediate vision. Intermediate vision results with the AcrySof ReSTOR apodized diffractive IOL shown in Table 1 demonstrate that this lens provides functional intermediate visual acuity while outperforming the monofocal control. In a substudy that examined

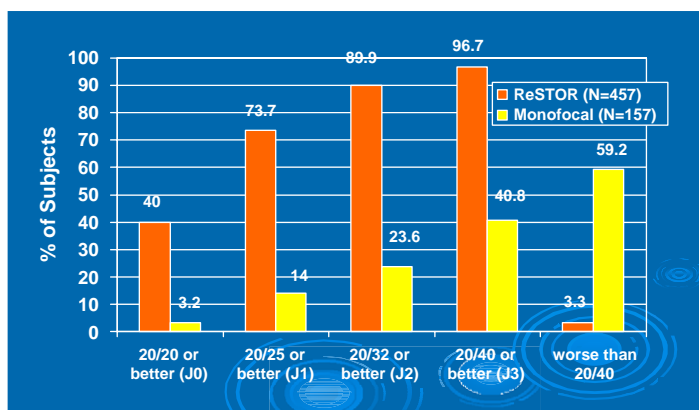


Fig. 4. Binocular uncorrected near visual acuity demonstrating that 96.7% of the ReSTOR patients had 20/40 vision or better.

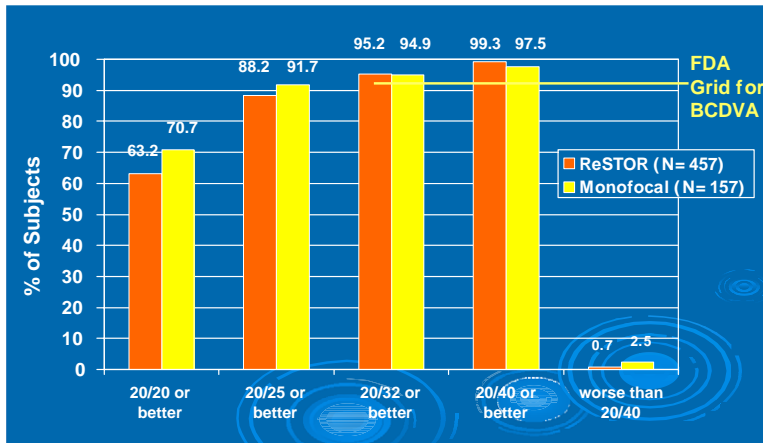


Fig. 5. Binocular uncorrected distance visual acuity demonstrating that 99.3% of the ReSTOR patients had vision of 20/40 or better.

the pupil size and depth of focus achieved with the ReSTOR and monofocal lenses, the results demonstrated a broader functional range of near, intermediate, and distance vision for the AcrySof ReSTOR IOL subjects. The binocular refraction defocus curve (US Intermediate Vision Study, $n=34$) demonstrated visual acuity of better than 20/20 for the near and distance focus and functional intermediate visual acuity better than 20/40 (Fig. 7).

Quality of life. Patients were asked to complete a questionnaire at the preoperative visit, at 30 to 60 days after the first implant, and at 120 to 180 days after the second implant. The primary objective of the questionnaire was to rate the subject's level of satisfaction with their vision.

Spectacle freedom. Freedom from spectacle wear was categorized by subjects selecting "never" in queries regarding the use of glasses postoperatively. Eighty percent of patients who were implanted with bilateral ReSTOR lenses reported never wearing glasses, and 17% reported occasional use of spectacles. Only 8% of the monofocal group reported spectacle freedom. Data collected from the Summary of Safety and Efficacy reports demonstrated that 41% of Array and ReZoom patients and 25.8% of Crystalens subjects achieved total spectacle freedom (Fig. 8).

Patient satisfaction. Patients in the study rated their vision satisfaction on a scale from 0 to 4. A rating of 4 indicated that the patient was completely satis-

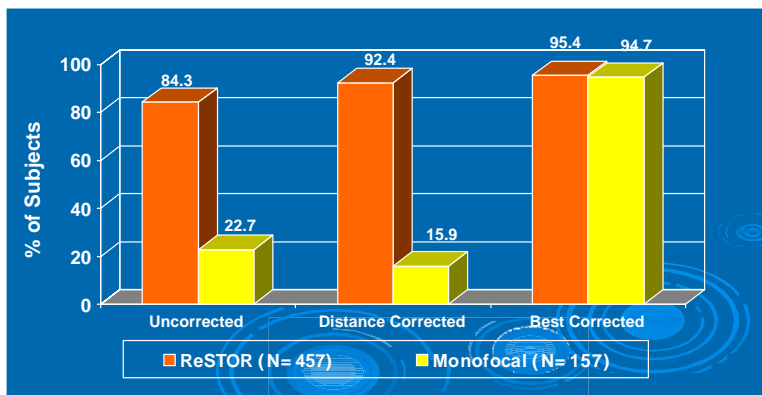


Fig. 6. Binocular uncorrected vision for distance and near visual acuity combined. For uncorrected vision, 84.3% of the ReSTOR patients had 20/25 or better vision compared with 22.7% of control patients.

Table 1
Intermediate vision results with the AcrySof ReSTOR apodized diffractive IOL

Parameter	Total sample size	Percent 20/40 or better		
		50 cm	60 cm	70 cm
Uncorrected				
ReSTOR	34	82.4*	85.3	67.6
Control	27	59.3	66.7	63.0
Distance corrected				
ReSTOR	34	64.7	70.6	52.9
Control	27	59.3	66.7	77.8

* Statistically different from control at 0.05 level.

fied with their vision. ReSTOR patients averaged a score of 3.5 compared with a rating of 3.0 for monofocal patients. ReSTOR and monofocal patients had an average vision satisfaction score of 0.6 before IOL implants.

When asked to rate their vision on a scale from 1 to 10, with 10 being the best possible vision, patients with bilateral ReSTOR implants averaged a score of 8.7 compared with their baseline mean of 4.2. When asked whether they would have the same lenses implanted again, over 96.9% of the ReSTOR patients said yes.

Visual disturbances. To assess the incidence and impact of visual disturbances such as glare and halos, subjects were asked to rate the impact of any observed phenomena on a scale from 1 to 7 (easily tolerated to incapacitating effect). The subjects were asked specific questions about glare, halos, and problems with night vision. Although there were signifi-

cantly more glare/flare, night vision problems, and halos for subjects implanted with ReSTOR lenses than for subjects implanted with the monofocal control lens, these differences were observed as increases in the frequency of reports of “mild” or “moderate” symptoms. No significant differences were noted in severe symptoms between the ReSTOR and control group. The ReSTOR patients reported having less night vision problems than the Crystalens or Array patients based on published Summary of Safety and Efficacy reports (Figs. 9 to 11).

Contrast sensitivity. Results of contrast sensitivity testing demonstrated no clinically significant differences between the monofocal and ReSTOR IOL subjects in mesopic (2.5 cd/m²) and photopic (85 cd/m²) conditions (Figs. 12 and 13).

Night driving. Night driving performance was tested using the Night Driving Simulator developed and validated by Vision Sciences Research (San Ramon, California). Bilaterally implanted patients (23 ReSTOR IOL patients and 25 monofocal controls) were tested to determine visibility distances for the detection and identification of road warning signs, message signs, and road hazards under various conditions. The simulated driving scenes were a city street at night with streetlights and a rural highway with low beam headlights. Testing in both driving scenes was conducted under clear, inclement weather (fog), and glare conditions.

There are no absolute detection and identification distances for all targets to determine safety and efficacy. Actual visibility distances, excluding individual

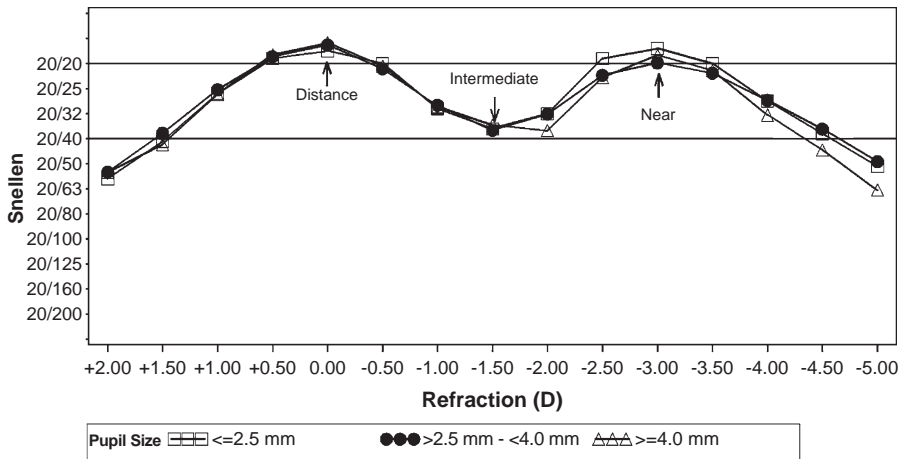


Fig. 7. The ReSTOR lens demonstrated no pupil size restriction. The defocus curves were within one line among groups when stratified by pupil size.

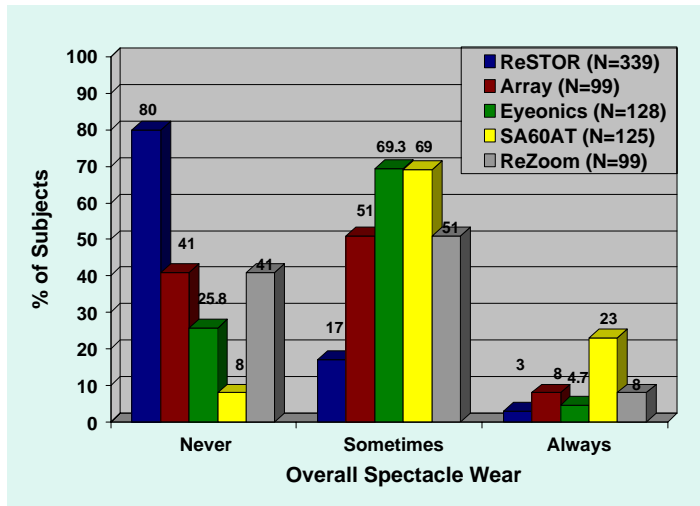


Fig. 8. Eighty percent of ReSTOR patients reported never needing to wear glasses.

differences, depend on the target size, contrast (sign age, clean or dirty sign), background clutter (oncoming vehicle headlights, street and store lights) and vehicle headlight conditions (low or high beams, clean or dirty lens). The ability of ReSTOR IOL patients to detect and identify road signs and hazards at

night was similar to that of monofocal controls under normal visibility driving conditions.

The sign identification test in rural conditions under fog and glare showed a greater difference in the performance between the monofocal and ReSTOR subjects than under normal night conditions. In

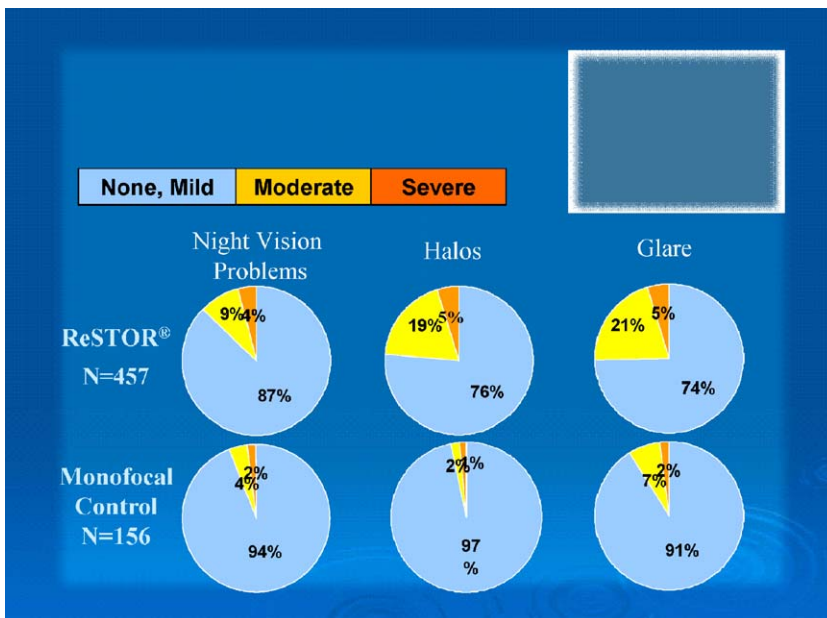


Fig. 9. Visual disturbances for the ReSTOR versus monofocal control groups.

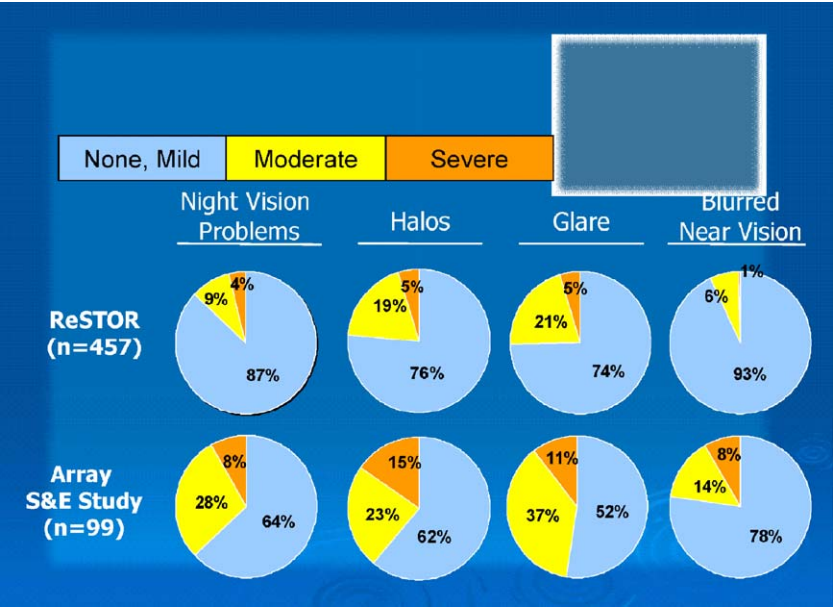


Fig. 10. Visual disturbances for the ReSTOR versus Array groups. The results in the ReSTOR group were favorable in regard to night vision, halos, glare, and blurred near vision.

all instances, the mean differences were less than 15%. In city driving conditions, the sign identification test under glare conditions demonstrated that the ability of the ReSTOR subjects to identify the text sign was reduced on average by 28% when

compared with monofocal controls. For warning signs under glare conditions and for text and warning signs under fog conditions, the differences between the ReSTOR and control subjects were all less than 15%.

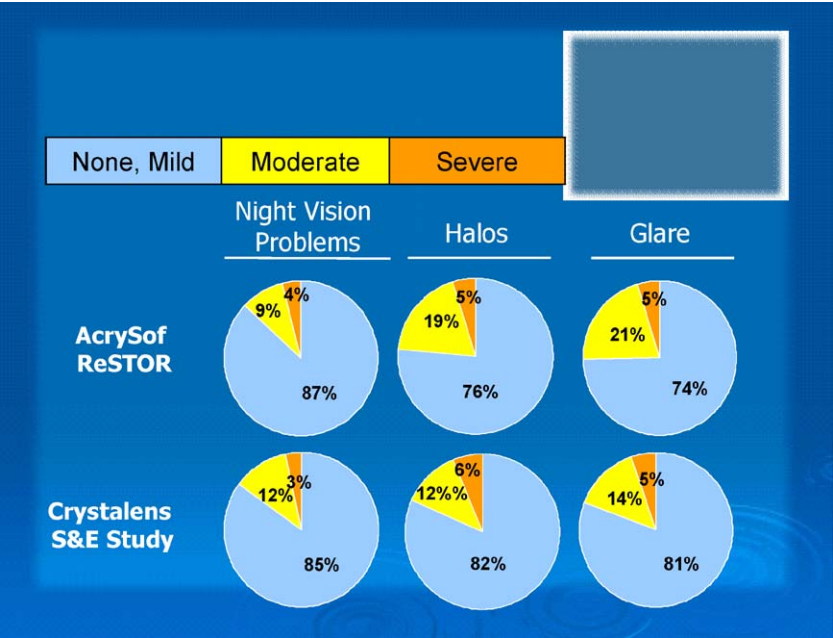


Fig. 11. Visual disturbances in the ReSTOR versus Crystalens groups. The results for these two lenses were similar.

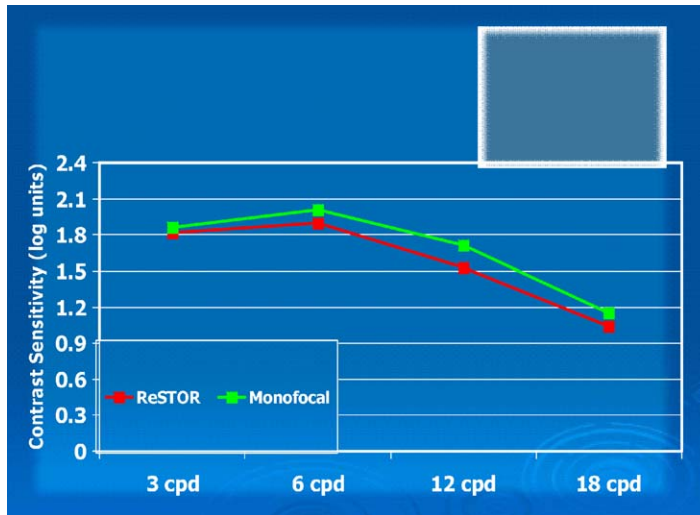


Fig. 12. Binocular contrast sensitivity, photopic and no glare.

Testing to measure the ability to detect hazards in rural and city driving conditions demonstrated that, under all conditions, the difference between the control and ReSTOR patients was less than 15%, except for rural conditions with glare, for which the average difference was 19.7% [9].

Adverse events. Out of the 566 ReSTOR IOL subjects, only 1 required lens explantation owing to visual disturbances. Other IOL replacements occurred

for the following reasons: biometry error (2), incorrect power or operating error (2), decentered IOL owing to trauma (1), and patient dissatisfaction (1).

The incidence of cumulative adverse events for the ReSTOR IOL compared favorably with the FDA historical grid rates. A single occurrence of pupillary block exceeded the FDA grid rate. No persistent adverse events were observed in any patients implanted with the ReSTOR IOL.

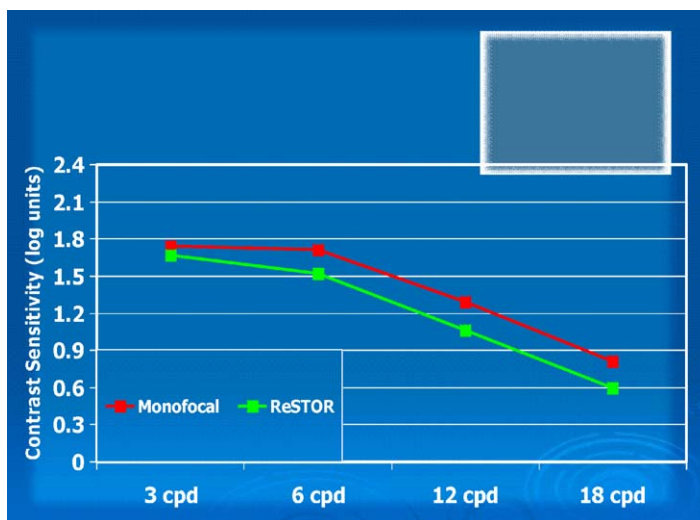


Fig. 13. Binocular contrast sensitivity, mesopic conditions with glare.

Summary

The AcrySof ReSTOR apodized diffractive IOL is designed to maintain distance visual acuity and to improve the quality of near vision while minimizing visual disturbances. FDA clinical study results demonstrate that the lens provides excellent near vision, with functional intermediate vision and uncompromised distance vision. Visual quality ratings are high, with most patients achieving uncorrected distance and near visual acuity values that provide total spectacle freedom in 80% of subjects. More patients report spectacle freedom with this lens than with the AcrySof monofocal, AMO ReZoom, Array zonal refractive, or Crystalens.

The AcrySof ReSTOR apodized diffractive IOL achieves a high level of spectacle freedom owing to unique apodized diffractive technology that delivers superior clinical outcomes. Achieving spectacle freedom allows recipients of this technology to improve their quality of life.

Lee Jordan and Mike Morris

Multi-order diffractive optics: the Vision Membrane

The practice of refractive surgery has created a dynamic and steady flow of new concepts and products in an attempt to improve results. A major shift in the philosophy of refractive surgery is slowly emerging as the limitations of keratorefractive surgery become more evident.

Corneal optical aberrations are inherent in the process of changing the shape of the cornea. No amount of "custom cornea" ablation can reduce the significant aberrations caused by the correction of moderate to severe ametropia. In addition, all efforts to correct presbyopia at the surface of the cornea are doomed to failure, because the creation of a bifocal cornea creates too much distortion of distance vision. The only possible method of performing aberration-free refractive surgery for all degrees of ametropia is an IOL type device.

The advantages of diffractive optics when compared with refractive optics for the correction of presbyopia have been well established in pseudophakic bifocal IOL trials in Europe and the United States. These two items, the limitations of keratorefractive surgery and the advances in diffractive optics, have rekindled major interest in anterior chamber IOLs as potentially the best method of correcting moderate to severe ametropia as well as presbyopia. The Vision Membrane device employs a

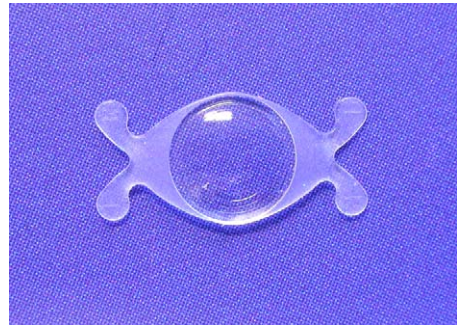


Fig. 14. The Vision Membrane employs a radically new approach to the correction of ametropia and presbyopia.

radically new approach to the correction of ametropia and presbyopia (Fig. 14).

Historical development

Refractive surgery has recently enjoyed much popularity owing to introduction of the excimer (ultra-violet) laser, which is used in performing LASIK and photorefractive keratectomy (PRK). LASIK and PRK are performed on the cornea and generally provide excellent results; however, several factors, such as prolonged healing times, corneal irregular astigmatism, halos at night, and the expense and maintenance of the laser, have encouraged the continued development of IOLs for refractive surgery purposes.

A phakic IOL provides better quality of vision than LASIK or PRK, especially as the refractive error increases. Implantation of the Vision Membrane requires a 3- to 4-minute surgical procedure using topical anesthetic. Recovery of vision occurs within minutes and is not subject to healing variation. Many cataract surgeons would rather use their intraocular surgical skills to perform refractive surgery than LASIK.

Until recently, the use of phakic IOLs has been limited for various reasons. With anterior chamber IOLs, the thickness of the IOL necessitates a smaller diameter optic to eliminate endothelial touch. These small diameter IOLs cause significant glare because the IOL is centered on the geometric center of the cornea, not on the pupil, which is usually displaced from the corneal center. This disparity of centration creates a small effective optic zone and a large degree of glare as the pupil increases in diameter. Iris-fixed IOLs can provide excellent optical results but can be tricky to implant and can be significantly decentered. The true incidence of cataract formation caused by phakic posterior chamber IOLs will be determined in the future. The risks, imprecise refractive results, and inadequate correction of presbyopia associated with removal of the clear crystalline lens that may

still possess 1.00 D of accommodation seem excessive, unwise, and clinically lacking to many ophthalmic surgeons.

The Vision Membrane is based on the proposition that an ultrathin, vaulted, angle-fixated device with a 6.00-mm optic will be the simplest and safest IOL to implant and will provide the best function. Of course, the quality of results in the marketplace of patients and surgeon opinion will determine the realities of success for all of these products and procedures.

Description

The Vision Membrane is a thin vaulted membrane implanted in the anterior chamber of the eye that is capable of correcting refractive errors (nearsightedness, farsightedness, astigmatism) as well as presbyopia. Depending on the material, the Vision Membrane ranges from about 450 to 600 μm in thickness for all refractive powers in comparison with approximately 800 to 1200 μm for a standard intraocular lens based on refractive optics. The Vision Membrane employs sophisticated contemporary diffractive optics rather than refractive optics to focus incoming light. These dimensions and the vaulted shape provide an excellent blend of stability, flexibility, and small incision compatibility.

The design of the Vision Membrane provides the following major advantages concerning implantation, intraocular safety, and improved function:

- The Vision Membrane is very foldable and can be implanted through an incision less than 2.60 mm wide.
- There is greater space between the Vision Membrane and the delicate corneal endothelium as a result of the curved optic.
- The optic can be at least 6.00 mm in diameter to eliminate halos and glare in almost all cases, unlike the 4.50 mm optic of the pioneering Baikoff IOL.
- The quality of the image formed by the diffractive optics is equal to that of an optic employing refractive optics.
- No peripheral iridotomy is necessary, because the Vision Membrane is vaulted and does not create pupillary block.
- The Vision Membrane is angle fixated, allowing for a simpler implantation technique.
- The broad haptic design and the extremely hydrophobic nature of silicone prevent anterior synechiae.
- The extreme flexibility and vault of the Vision Membrane in the anterior chamber allow for one size that fits almost all eyes.

Currently, the Vision Membrane is constructed entirely of medical grade silicone, which has been used as an IOL material for more than 20 years and is approved by the FDA. Unlike standard IOLs, which use refractive optics, the diffractive optics of the Vision Membrane do not rely significantly on the index of refraction of a given material to gain the desired refractive effect.

Multi-order diffractive optics

The most significant technologic advance embodied in the Vision Membrane is the optic based on the principle of multi-order diffraction (MOD). The MOD principle allows the Vision Membrane to be constant in thinness for all refractive powers and eliminates chromatic aberration, which has made conventional diffractive optics unusable in IOLs in the past.

A conventional diffractive optic lens uses a single diffraction order in which the optical power of the lens is directly proportional to the wavelength of light (Fig. 15A). With white light illumination, every wavelength focuses at a different distance from the lens. This strong wavelength dependence in the optical power produces significant chromatic aberration in the image. For example, if one were to focus a green image onto the retina, the corresponding red and blue images would be significantly out of focus and would produce red and blue halos around the focused green image. The result with white light is a

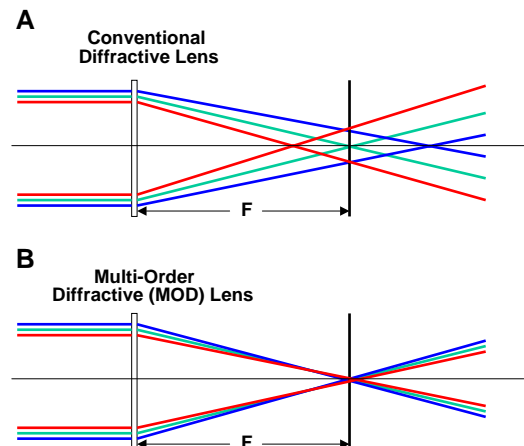


Fig. 15. (A) A conventional diffractive lens is highly dispersive and focuses different wavelengths of light to different focal positions. (B) An MOD lens brings multiple wavelengths across the visible spectrum to a common focal point and is thereby capable of forming high quality images in white light.

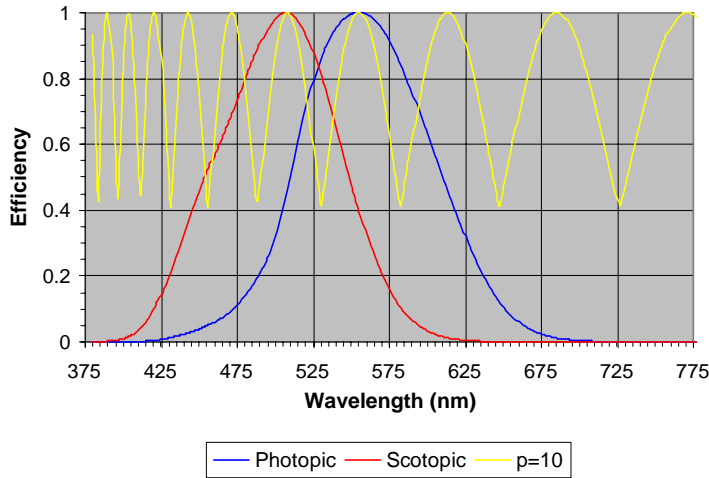


Fig. 16. Diffraction efficiency versus wavelength for a $p=10$ MOD lens.

highly chromatically aberrated image with severe color banding observed around the edges of objects that is completely unacceptable.

In contrast, the Vision Membrane uses a sophisticated MOD lens that is designed to bring multiple wavelengths to a common focus with high efficiency, forming sharp clear images in white light. As illustrated in Fig. 15B, with an MOD lens, the various diffractive orders bring different wavelengths to the common focal point.

The MOD lens consists of concentric annular Fresnel zones (see Fig. 14). The step height at each zone boundary is designed to produce a phase change of $2p$ in the emerging wavefront, where p is an integer greater than one. Because the MOD lens is

purely diffractive, the optical power of the lens is determined solely by choice of the zone radii and is independent of lens thickness. Because the MOD lens has no refractive power, it is completely insensitive to changes in curvature of the substrate; hence, one design is capable of accommodating a wide range of anterior chamber sizes without introducing an optical power error.

To illustrate its operation, consider the example of an MOD lens operating in the visible wavelength range with p equal to 10. Fig. 16 illustrates the wavelength dependence of the diffraction efficiency (with material dispersion neglected). Note that several wavelengths within the visible spectrum exhibit 100% diffraction efficiency. The principal feature of

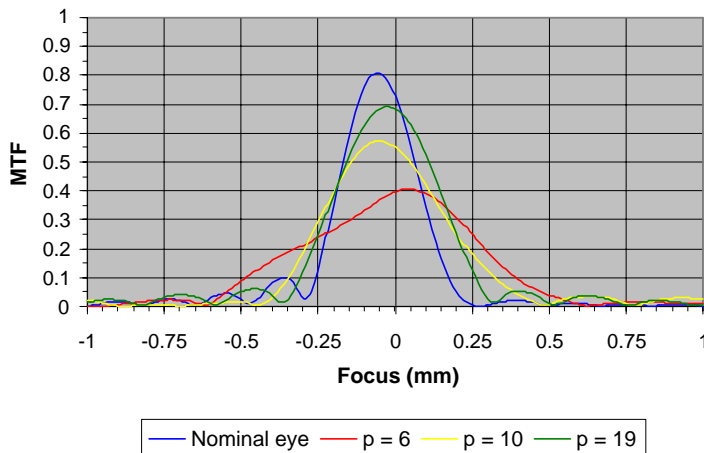


Fig. 17. Through focus polychromatic MTF at 10 cycles per degree for three different MOD lens designs ($p=6, 10$, and 19), together with an MTF for a nominal eye.

the MOD lens is that it brings the light associated with each of these high efficiency wavelengths to a common focal point; hence, it is capable of forming high quality white light images. For reference, the photopic and scotopic visual sensitivity curves are also plotted in Fig. 16. Note that with the p equal to 10 design, high diffraction efficiencies occur near the peak of both visual sensitivity curves.

Fig. 17 illustrates the on-axis, through-focus, polychromatic MTF at 10 cycles per degree with a 4-mm entrance pupil diameter for three different MOD lens designs ($p=6$, 10, and 19), together with the MTF for a “nominal eye.” Both the $p=10$ and $p=19$ MOD lens designs yield acceptable values for the in-focus Strehl ratio and exhibit an extended range of focus when compared with a nominal eye. This extended range of focus feature is expected to be of particular benefit for the emerging presbyope (typically aged 40 to 50 years).

Intended use

Currently, there are two forms of the Vision Membrane. One form is intended for the correction of nearsightedness and farsightedness (“single power VM”). The second form is intended for the correction of nearsightedness or farsightedness plus presbyopia (“the bifocal VM”). The range of refractive error covered by the single power VM will be from -1.00 D through -15.00 D in $.50$ D increments for myopia and $+1.00$ D through $+6.00$ D for hyperopia in $.50$ D increments.

Patients must be 18 years old or older with a generally stable refraction to undergo Vision Membrane implantation. The bifocal Vision Membrane can be used in presbyopes as well as in patients who already have undergone posterior chamber IOL implantation after cataract extraction who have limited reading vision with this conventional form of IOL.

Summary

The Vision Membrane is a form of IOL that can correct refractive error and presbyopia. The $600\text{-}\mu\text{m}$ thinness and high quality optic are achieved by using contemporary diffractive optics and medical grade silicone, which has been used and approved for the construction of IOLs for many years. The Vision Membrane possesses a unique combination of advantages not found in any existing IOL. These advantages consist of simultaneous flexibility, a large optic (6.00 mm), the correction of presbyopia and refractive error, and increased safety by increasing the clearance between the implant and the delicate

structures of the anterior chamber, that is, the iris and corneal endothelium.

It is likely that refractive surgery in the near future will encompass a tremendous increase in the use of anterior chamber IOLs. The Vision Membrane offers major advantages for the correction of ametropia and presbyopia. LASIK and PRK will remain important procedures for the correction of low ametropia and for refining pseudophakic IOL results, such as astigmatism. Anterior chamber IOL devices such as the Vision Membrane may be expected to attract ocular surgeons with cataract/IOL surgery skills into the refractive surgery arena because the results will become more predictable, the incidence of bothersome complications will be greatly reduced, and the correction of presbyopia will be possible.

Once again, refractive surgery is continuing to evolve. Several factors are responsible for this evolution as well as a major revolution in refractive surgery (see Fig. 14).

Nicholas Tarantino and R. Bruce Wallace

Refractive multifocal optics: the ReZoom intraocular lens

Until September 1997, the only available IOLs in the United States were monofocals, which provided good vision at distance only. Spectacles were typically needed for near-vision activities such as reading. The FDA approval of the Array SA40N multifocal IOL heralded a new era in the field of presbyopic correction.

The Array IOL is designed with five annular refractive zones arranged such that the first, third, and fifth zones are distance dominant, whereas the second and fourth zones provide near power. Numerous studies have demonstrated that the Array IOL is as safe and effective as monofocal IOLs in correcting far through near vision [10–12]. An increased perception of halos when compared with the effects of monofocal IOLs seems to be an acceptable compromise to enhanced near and distance vision with this lens [13].

Physical description

Innovations in the design platform of the Array IOL led to the release of a second-generation multifocal IOL, the ReZoom multifocal IOL. Approved by the FDA in March 2005, this IOL is a refractive multifocal IOL like the Array IOL. The refractive design was enhanced to improve optical performance

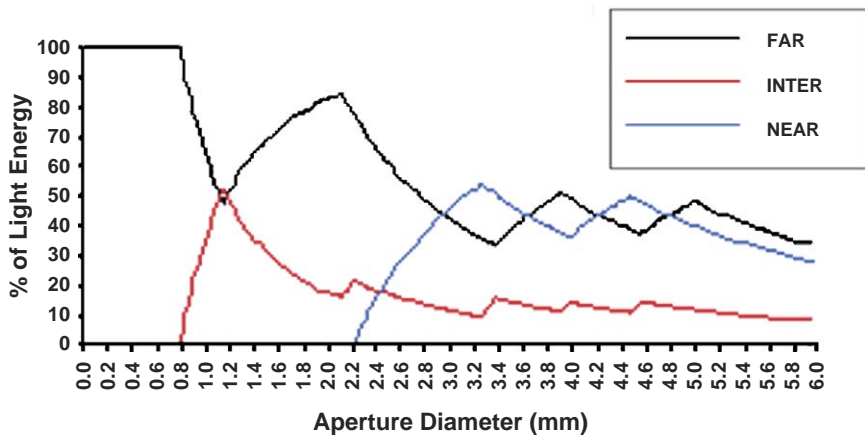


Fig. 18. Percent of light energy per image positions for the Array IOL.

while providing distance, intermediate, and near vision to cataract patients, especially hyperopic ones. The refractive surface is now on a hydrophobic acrylic platform incorporating the OptiEdge design.

The ReZoom IOL is a flexible three-piece lens designed to permit implantation in the capsular bag and to minimize decentration. It comes in a wide range of diopter powers ranging from +6.0 to +30.0 D in 0.5 D increments. The ReZoom lens optic is 6 mm in diameter. The PMMA haptics are in a modified C configuration. The overall diameter of the lens is 13 mm.

Zones

The ReZoom IOL employs the basic distance dominant design of the Array IOL. Distance domi-

nance in a multifocal lens means that the central zone is dedicated to far power. Distance dominance provides excellent twilight vision without compromising reading vision.

The zonal-progressive design of these lenses incorporates a continuous range of foci (Figs. 18,19). The multifocal area of the lens is contained within the full 6-mm optic and is composed of five zones specifically proportioned to provide good visual function across a range of distances in varying light conditions. These five concentric refractive zones allow for alternating distance and near vision such that zones 1 (the central zone), 3, and 5 are distance dominant while zones 2 and 4 are near dominant. Aspheric transitions between the zones provide balanced intermediate vision (Fig. 20).

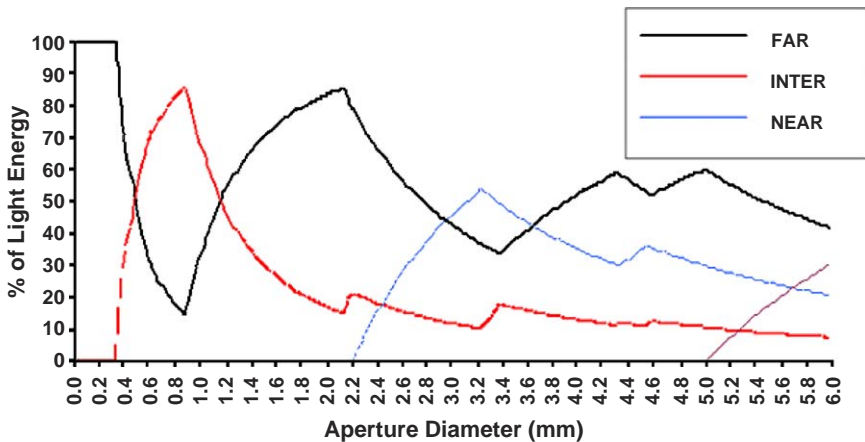
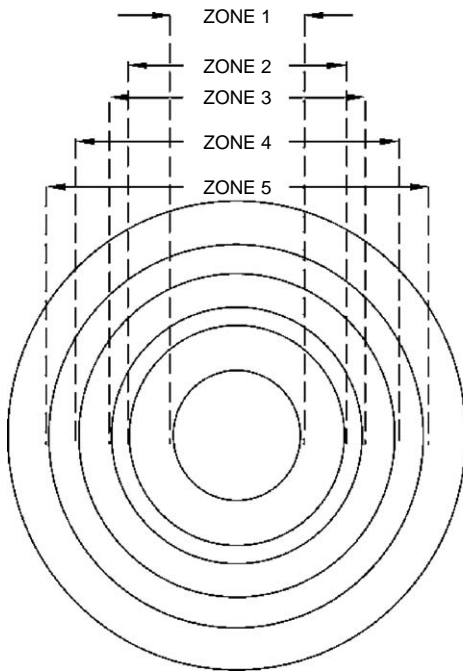


Fig. 19. Percent of light energy per image positions for the ReZoom IOL.



NOTE: Zones 1,3 and 5 are distance-dominant.
Zones 2 and 4 are near-dominant

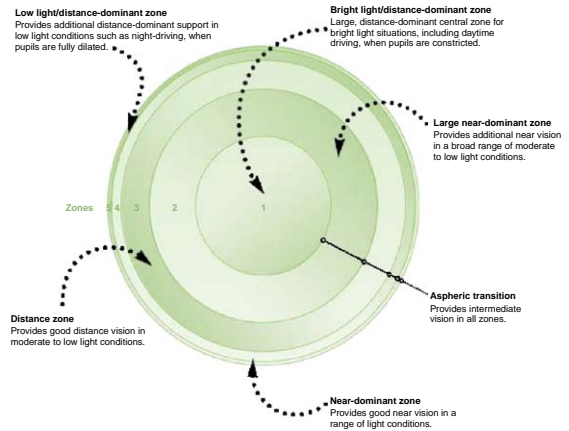


Fig. 20. Diagram of refractive zones of the ReZoom IOL.

Balanced View Optics

Multifocal IOLs provide simultaneous vision, that is, a simultaneous projection of in- and out-of-focus images of the same object on the retina. The projection of out-of-focus images leads to the perception of halos around bright images at night [14]. The ReZoom IOLs Balanced View Optics technology manipulates light distribution to reduce symptoms of dysphotopsia in dim light conditions. When compared with the Array IOL, the distance and near zone areas of the ReZoom IOL have been adjusted purposefully to decrease unwanted halos under low light conditions without affecting good distance through

near vision. The presence of intermediate power also allows the formation of images on the retina, even if distance and near powers form slightly out-of-focus images on the retina (Fig. 21).

Lens selection

Clinical experience indicates that emmetropia should be targeted; however, any error in the refractive target that must occur should be on the side of slight hyperopia (± 0.25 D). The goal of the lens power calculation should be to achieve all of the benefits of near through distance vision for the aphakic patient. The patient should be plano to

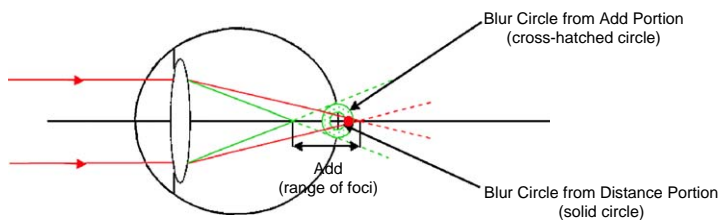


Fig. 21. Emmetropia: intermediate observation with the ReZoom IOL.

slightly hyperopic to provide good near vision as well as good distance vision for driving.

Add power

In presbyopic correction, add power must augment distance correction to bring the near point within reading range. If the add power is too high, the near point will be too close and the range of focus reduced. Theoretically, +4.0 D of add power yields approximately +3.0 D add power in the spectacle plane, resulting in a near point of 33 cm or 14 in. With the ReZoom lens, the near-dominant zones (zones 2 and 4) provide +3.5 D of add power at the IOL plane for near vision, yielding approximately +2.57 D add power in the spectacle plane. This correction translates to a near point of 39 cm or 16 in. The +3.5 D add power of the ReZoom IOL provides sufficient power for good functional near vision; it also provides a more usable working distance at near and an opportunity for better intermediate vision than a multifocal IOL with a higher add power.

Clinical studies

Clinical data have demonstrated the ability of refractive multifocal IOLs such as the ReZoom IOL to provide better intermediate vision in a comparison with monofocal IOLs. A prospective randomized study showed statistically significant better mean binocular and monocular distance corrected intermediate visual acuity in subjects with bilateral multifocal IOLs when compared with subjects with bilateral monofocal IOLs using the defocus method (ReZoom labeling, 2005, ver. 2.0, AMO, Inc.).

In a recent study, Longhena and coworkers [15] compared the ReZoom IOL with the Array IOL with respect to visual function, patient satisfaction, and quality of life. A total of 30 patients (60 eyes) received a ReZoom or an Array IOL after phacoemulsification. Six months postoperatively, all of the subjects expressed satisfaction with the results of the surgery. Distance vision was similar in the two groups; however, 80% of ReZoom patients (24 of 30) were spectacle independent compared with 60% of Array patients. No glare or halos were reported by 80% of ReZoom patients compared with 40% of Array patients.

Another study by Dick [16] compared visual acuity, photic phenomena, and defocus acuity curves of the ReZoom IOL and Array IOL. Similar defocus acuity curves were observed with both lenses, indicating good near and excellent intermediate vision. ReZoom patients reported spectacle independence at distance (100%), intermediate (95%), and near vision (71%). Patients with the ReZoom IOL reported a

reduction in photic phenomena, that is, halos and starbursts, when compared with patients with the Array IOL.

Early results with the acrylic ReZoom IOL indicate a clinical performance superior to that of its silicone predecessor. With appropriate patient selection, successful multifocal IOL implantation should be attainable with the ReZoom IOL.

References

- [1] Doane J. C&C CrystaLens AT-45 accommodating intraocular lens. Presented at the XX Congress of the ESCRS, Nice, September, 2002.
- [2] Nishi O, Nishi K. Accommodation amplitude after lens refilling with injectable silicone by sealing the capsule with a plug in primates. *Arch Ophthalmol* 1998; 116(10):1358–61.
- [3] Packer M, Fine IH, Hoffman RS, et al. Initial clinical experience with an anterior surface modified prolate intraocular lens. *J Refract Surg* 2002;18.
- [4] Lee J, Bailey G. Presbyopia: all about vision. Irvine (CA): Refractive; 2004.
- [5] Kohnen T. Near and distant VA with the AcrySof ReSTOR IOL. Presented at the ASCRS Symposium, San Francisco, 2003.
- [6] Davison JA, Simpson MJ. How does the ReSTOR lens work? *Rev Refract Surg* 2004;18–20.
- [7] Davison US and the EU investigators. Global results with the AcrySof ReSTOR apodized diffractive IOL. Presented at the ASCRS Symposium on Cataract, IOL, and Refractive Surgery, Washington, DC, April 2005.
- [8] Mirshahi A, Evdokia T, Kohnen T. Presbyopia II: multifocal IOL AcrySof ReSTOR. Department of Ophthalmology, Johann Wolfgang Goethe-University, Frankfurt am Main Germany, November, 2004.
- [9] AcrySof ReSTOR, Physician Labeling. Rev.1 Fort Worth (TX): Alcon Laboratories; 2004.
- [10] Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation: a multinational clinical trial evaluating clinical, functional, and quality-of-life outcomes. *Ophthalmology* 2000;107(11):2040–8.
- [11] Javitt JC, Wang F, Trentacost DJ, et al. Outcomes of cataract extraction with multifocal intraocular lens implantation: functional status and quality of life. *Ophthalmology* 1997;104(4):589–99.
- [12] Sen HN, Sarikkola A-U, Uusitalo RJ, et al. Quality of vision after AMO Array multifocal intraocular lens implantation. *J Cataract Refract Surg* 2004;30: 2483–93.
- [13] Steinert RF, Aker BL, Trentacost DJ, et al. A prospective comparative study of the AMO Array zonal-progressive multifocal silicone intraocular lens and a monofocal intraocular lens. *Ophthalmology* 1999; 106(7):1243–55.
- [14] Rommel JG. The Array multifocal intraocular lens:

- a new horizon. Bull Soc Belge Ophtalmol 2001;280:45–9.
- [15] Longhena P, Gaiba G, Brandi L, et al. Array MIOL vs a multifocal IOL with new profile and material: ReZoom. Presented at the American Society of Cataract and Refractive Surgery conference. April 16–20, 2005, Washington, DC.
- [16] Dick HB. Experience with the ReZoom IOL: comparing this lens with the Array. Cataract Refract Surg Today 2005;5(6):1–2.