

# Refractive lens exchange with a multifocal intraocular lens

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Refractive lens exchange with a multifocal intraocular lens is becoming a more popular method of refractive surgery in the presbyopic patient. The limitations of keratorefractive surgery have led to a resurgence of lens exchange surgery for patients with prescriptions outside the limits of corneal refractive procedures, in addition to patients with routine refractive errors requesting a surgical procedure to achieve emmetropia and also address presbyopia. Side effects of multifocal technology including unwanted photic phenomena and deterioration in contrast sensitivity are being further defined and evaluated to better assess the effects of these intraocular lenses on functional vision and patient satisfaction. Attention to detail in regards to proper patient selection, preoperative measurements, intraoperative technique, and postoperative management will ultimately result in excellent outcomes and improved patient acceptance of this effective technique. *Curr Opin Ophthalmol* 2003, 14:24-30 © 2003 Lippincott Williams & Wilkins.

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## Abbreviations

IOL intraocular lens

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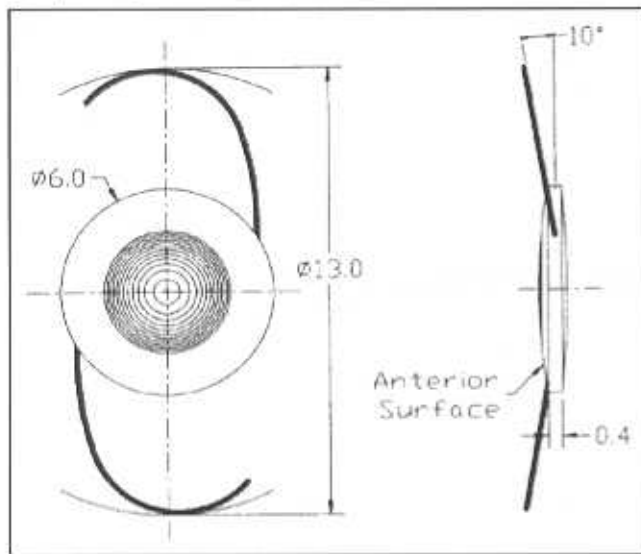
As the outcomes of cataract surgery continue to improve, the use of lens surgery as a refractive modality in patients without cataracts has increased in popularity. The removal of the crystalline lens and replacement with a pseudophakic lens for the purposes of reducing or eliminating refractive errors has been labeled with many titles. These titles include clear lensectomy [1,2], clear lens phacoemulsification [3], clear lens replacement, clear lens extraction [4-12], clear lens exchange, presbyopic lens exchange, and refractive lens exchange. The term *refractive lens exchange* appears to best describe the technique of removing the crystalline lens and replacing it with a pseudophakic lens in any aged patient for the purpose of reducing or eliminating refractive errors and/or addressing presbyopia.

## Multifocal lenses

Perhaps the greatest catalyst for the resurgence of refractive lens exchange has been the development of multifocal lens technology. Historically, multifocal intraocular lenses (IOLs) have been developed and investigated for decades. One of the first multifocal IOL designs to be investigated in the United States was the center-surround IOL, now under the name NuVue (Bausch & Lomb Surgical). This lens had a central near add surrounded by a distance-powered periphery. Other IOL designs include the 3M diffractive multifocal IOL (3M Corporation; St. Paul, MN), which has been acquired, redesigned, and formatted for the foldable AcrySof acrylic IOL (Alcon Laboratories; Dallas, TX) (Fig. 1). Pharmacia has also designed a diffractive multifocal IOL, the Ceeon 811E (Monrovia, CA), that has been implanted extensively outside of the United States. Alcon, Pharmacia, and Storz have also investigated three-zone refractive multifocal IOLs that have a central distant component surrounded at various distances by a near annulus [13].

The only multifocal IOL approved for general use in the United States is the Array (AMO; Advanced Medical Optics, Santa Ana, CA). The Array is a zonal progressive intraocular lens with five concentric zones on the anterior surface (Fig. 2). Zones 1, 3, and 5 are distance dominant zones, whereas zones 2 and 4 are near dominant. The lens has an aspherical component and thus each zone repeats the entire refractive sequence corresponding to distance, intermediate, and near foci. This results in vision over a range of distances. The lens uses 100% of the

**Figure 1. The Alcon MA60D3 diffractive multifocal intraocular lens (investigational device)**



(Courtesy of Alcon Research, Ltd.)

incoming available light and is weighted for optimum light distribution. With typical pupil sizes, approximately half of the light is distributed for distance, one third for near vision, and the remainder for intermediate vision. The lens uses continuous surface construction and consequently there is no loss of light through defraction and no degradation of image quality as a result of surface discontinuities [14]. The lens has a foldable silicone optic that is 6.0 mm in diameter, with haptics made of polymethylmethacrylate and a haptic diameter of 13 mm. The lens can be inserted through a clear corneal or scleral tunnel incision that is 2.8-mm wide, utilizing the Unfolder injector system manufactured by AMO.

### Clinical results

The efficacy of zonal progressive multifocal technology has been documented in many clinical studies. Early studies of the one-piece Array documented a larger percentage of patients who were able to read J2 print after undergoing multifocal lens implantation compared with patients with monofocal implants [15,16,17]. Similar results have been documented for the foldable Array [18]. Clinical trials comparing multifocal lens implantation compared with monofocal lens implantation in the same patient also revealed improved intermediate and near vision in the multifocal eye compared with the monofocal eye [19,20].

### Contrast sensitivity

Many studies have evaluated both the objective and subjective qualities of contrast sensitivity, stereoacuity, glare disability, and photic phenomena following implantation of multifocal IOLs. Refractive multifocal IOLs, such as the Array, have been found to be superior to diffractive

multifocal IOLs by demonstrating better contrast sensitivity and less glare disability [21]. However, more recent reports comparing refractive and diffractive IOLs have revealed similar qualities for distance vision evaluated by modulation transfer functions but superior near vision for the diffractive lens [22].

In regard to contrast sensitivity testing, the Array has been shown to produce a small amount of contrast sensitivity loss equivalent to the loss of one line of visual acuity at the 11% contrast level using Regan contrast sensitivity charts [16]. This loss of contrast sensitivity at low levels of contrast was only present when the Array was placed monocularly and was not demonstrated with bilateral placement and binocular testing [23]. Regan testing is perhaps not as reliable as sine wave grating tests that evaluate a broader range of spatial frequencies. Utilizing sine wave grating testing, reduced contrast sensitivity was found in eyes implanted with the Array in the lower spatial frequencies compared with monofocal lenses when a halogen glare source was absent. When a moderate glare source was introduced, no significant dif-

**Figure 2. The AMO Array foldable silicone multifocal intraocular lens**



(Courtesy of Advanced Medical Optics)



ference in contrast sensitivity between the multifocal or monofocal lenses was observed [24]. However, recent reports have demonstrated a reduction in tritan color contrast sensitivity function in refractive multifocal IOLs compared with monofocal lenses under conditions of glare. These differences were significant for distance vision in the lower spatial frequencies, and for near in the low and middle spatial frequencies [25]. A new aspheric multifocal IOL, the Progress 3 (Domilens Laboratories; Lyon, France), also demonstrated significantly lower mean contrast sensitivity with the Pelli-Robson chart compared with monofocal IOLs [26].

Ultimately, these contrast sensitivity tests reveal that to deliver multiple foci on the retina, there is always some loss of efficiency with multifocal IOLs when compared with monofocal IOLs. However, contrast sensitivity loss, random-dot stereopsis and aniseikonia can be improved when multifocal IOLs are placed bilaterally compared with unilateral implants [27]. A recent publication evaluating a three-zone refractive multifocal IOL demonstrated improved stereopsis, less aniseikonia, and greater likelihood for spectacle independence with bilateral implantation compared with unilateral implantation [28].

### Photic phenomenon

One of the potential drawbacks of the Array multifocal lens has been the potential for an appreciation of halos around point sources of light at night in the early weeks and months after surgery [29–30]. Most patients will learn to disregard these halos with time and bilateral implantation appears to improve these subjective symptoms. Concerns about the visual function of patients at night have been allayed by a driving simulation study in which bilateral Array multifocal patients performed only

slightly worse than patients with bilateral monofocal IOLs. The results indicated no consistent difference in driving performance and safety between the two groups [31]. In a study by Javitt et al. [32], 41% percent of bilateral Array subjects were found to never require spectacles compared with 11.7% of monofocal controls. Overall, subjects with bilateral Array IOLs reported better overall vision, less limitation in visual function, and less use of spectacles than monofocal controls [33•].

### Refractive lens exchange

A recent study reviewed the clinical results of bilaterally implanted Array multifocal lens implants in refractive lens exchange patients [34]. A total of 68 eyes were evaluated, comprising 32 bilateral and 4 unilateral Array implantations. One hundred percent of patients undergoing bilateral refractive lens exchange achieved binocular visual acuity of 20/40 and J5 or better, measured 1 to 3 months postoperatively. Over 90% achieved uncorrected binocular visual acuity of 20/30 and J4 or better, and nearly 60% achieved uncorrected binocular visual acuity of 20/25 and J3 or better (Fig. 3). This study included patients with preoperative spherical equivalents between 7 diopters of myopia and 7 diopters of hyperopia with most patients having preoperative spherical equivalents between plano and +2.50. Excellent lens power determinations and refractive results were achieved (Fig. 4).

### Patient selection

Specific guidelines with respect to the selection of candidates and surgical strategies that enhance outcomes with this IOL have been developed. AMO recommends using the Array multifocal IOL for bilateral cataract patients whose surgery is uncomplicated and whose per-

Figure 3. Clinical results of bilateral Array implantation following refractive lens exchange

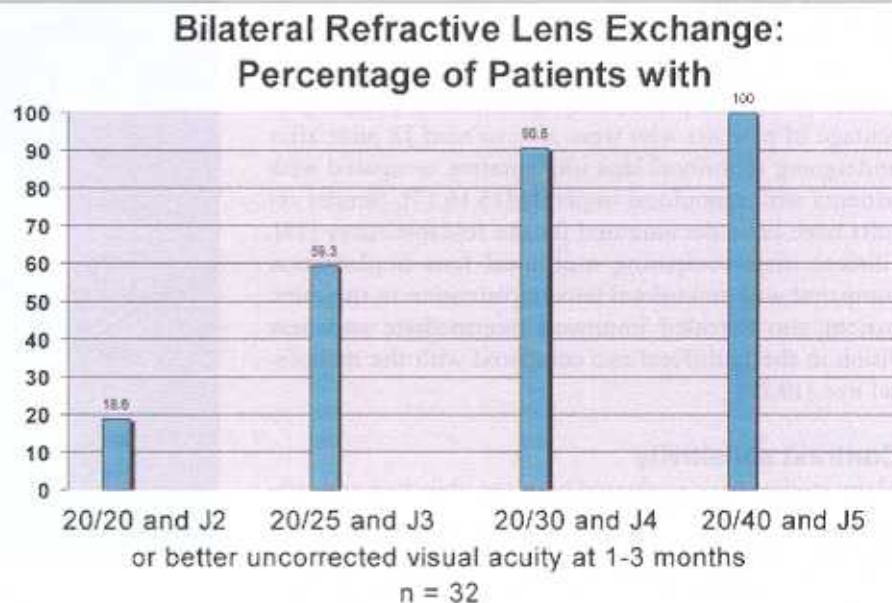
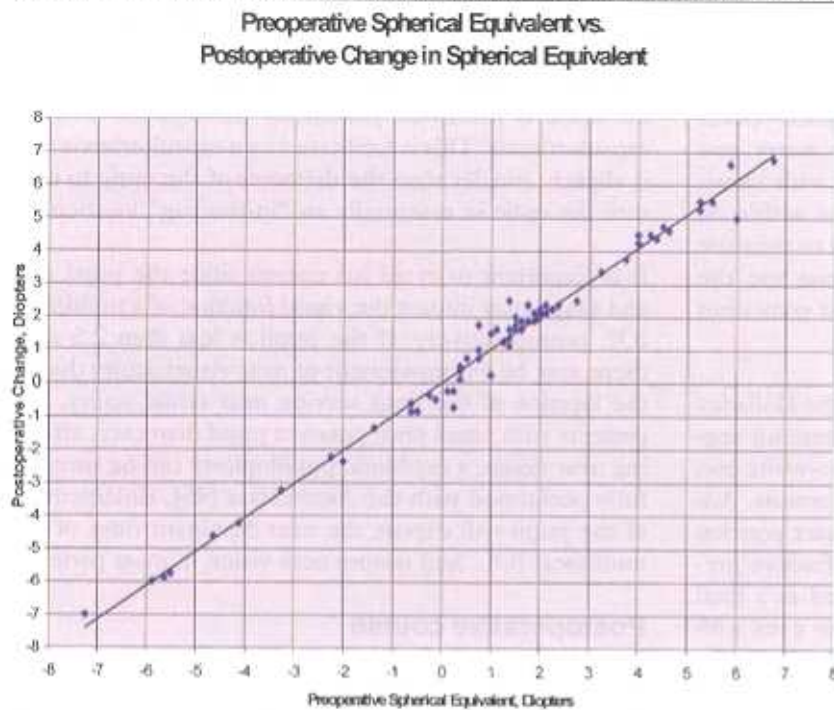


Figure 4. Scattergram demonstrating reduction of spherical equivalent in refractive lens exchange eyes



sonality is such that they are not likely to fixate on the presence of minor visual aberrations such as halos around lights. There is obviously a broad range of patients who would be acceptable candidates. Relative or absolute contraindications include the presence of ocular pathologies, other than cataracts, that may degrade image formation or may be associated with less than adequate visual function postoperatively despite visual improvement after surgery. Preexisting ocular pathologies that are frequently looked upon as contraindications include age-related macular degeneration, uncontrolled diabetes or diabetic retinopathy, uncontrolled glaucoma, recurrent inflammatory eye disease, retinal detachment risk, and corneal disease, or previous keratorefractive surgery. However, a recent study has revealed comparable distance acuity outcomes in Array and monofocal patients with concurrent eye disease such as macular degeneration, glaucoma, and diabetic retinopathy [35].

Utilization of these lenses in patients who complain excessively, are highly introspective, or obsess over body image and symptoms should be avoided. In addition, conservative use of this lens is recommended when evaluating patients with occupations that include frequent night driving and occupations that put high demands on vision and near work such as engineers and architects. Such patients need to demonstrate a strong desire for relative spectacle independence to be considered for a refractive lens exchange with Array implantation. Recent publications have found multifocal lens implantation to be a cost-effective option for low-income

patients and patients in developing countries where the added expense of near vision spectacles would be prohibitive [36,37]. Additionally, multifocal IOL implantation was found to be a viable option for pediatric cataract patients, thus eliminating spectacle dependence in this susceptible group of patients [38].

Finally, the patient's axial length and risk for retinal detachment or other retinal complications should be considered. Although many publications have documented a low rate of complications in highly myopic clear lens extractions [1,3,8,9,10], others have warned of significant long-term risks of retinal complications despite prophylactic treatment [39,40]. With this in mind, other phakic refractive modalities should be considered in extremely high myopes. If refractive lens exchange is performed in these patients, extensive informed consent regarding the long-term risks for retinal complications should naturally occur preoperatively.

### Preoperative measurements

The most important assessment for successful multifocal lens use, other than patient selection, involves precise preoperative measurements of axial length in addition to accurate lens power calculations. Some practitioners think that immersion biometry is necessary for accurate axial length determination. However, applanation techniques in combination with the Holladay 2 formula yield accurate and consistent results with greater patient convenience and less technician time. A newer device now available, the Zeiss IOLMaster, is a combined biometry



instrument for non-contact optical measurements of axial length, corneal curvature, and anterior chamber depth that yields extremely accurate and efficient measurements with minimal patient inconvenience. The axial length measurement is based on an interference-optical method termed partial coherence interferometry and measurements are claimed to be compatible with acoustic immersion measurements and accurate to within 30  $\mu\text{m}$ . Regardless of the technique being used to measure axial length, it is important that the surgeon use the biometry that he or she feels yields the most consistent and accurate results.

When determining lens power calculations, the Holladay 2 formula takes into account disparities in anterior segment and axial lengths by adding the white-to-white corneal diameter and lens thickness into the formula. Addition of these variables helps predict the exact position of the IOL in the eye and has improved refractive predictability. The SRK T formula can be used as a final check in the lens power assessment; and, for eyes with <22 mm of axial length, the Hoffer Q formula should be used for comparative purposes.

### Surgical technique

The multifocal Array works best when the final postoperative refraction has less than one diopter of astigmatism. It is, thus, very important that incision construction be appropriate with respect to size and location. A clear corneal incision at the temporal periphery that is 3 mm or less in width and 2 mm long is highly recommended [41]. The surgeon must also be able to use one of the many modalities for addressing preoperative astigmatism. Although both T and arcuate keratotomies at the 7-mm optical zone can be used, there is an increasing trend favoring 600- $\mu\text{m}$  deep limbal relaxing incisions for the reduction or elimination of preexisting astigmatism [42,43].

In preparation for phacoemulsification, hydrodelineation and cortical cleaving hydrodissection are important because they facilitate lens disassembly and complete cortical cleanup [44]. Complete and fastidious cortical cleanup will hopefully reduce the incidence of posterior capsule opacification whose presence, even in very small amounts, will inordinately degrade the visual acuity in Array patients. It is because of this phenomena that patients implanted with Array lenses will require YAG laser posterior capsulotomies earlier than patients implanted with monofocal IOLs.

### Complications management

When intraoperative complications develop they must be handled precisely and appropriately. In situations in which the first eye has already had an Array implanted, complications management must be directed toward finding any possible means of implanting an Array in the

second eye. Under most circumstances, capsule rupture will still allow for implantation of an Array as long as there is an intact capsulorrhexis. Under these circumstances, the lens haptics are implanted in the sulcus and the optic is prolapsed posteriorly through the anterior capsulorrhexis. This is facilitated by a capsulorrhexis that is slightly smaller than the diameter of the optic to capture the optic in essentially an "in-the-bag" location.

It is important to avoid iris trauma since the pupil size and shape may impact the visual function of a multifocal IOL postoperatively. If the pupil is less than 2.5 mm, there may be an impairment of near visual acuity due to the location of the rings serving near visual acuity. For patients with small postoperative pupil diameters affecting near vision, a mydriatic pupilloplasty can be successfully performed with the Argon laser [45]. Enlargement of the pupil will expose the near dominant rings of the multifocal IOL, and restore near vision in most patients.

### Postoperative course

If patients are unduly bothered by photic phenomena such as halos and glare, these symptoms can be alleviated by various techniques. Weak pilocarpine at a concentration of 1/8% or weaker will constrict the pupil to a diameter that will usually lessen the severity of halos without significantly effecting near visual acuity. Similarly, brimonidine tartrate ophthalmic solution 0.2% (Alpha-gan) has been shown to reduce pupil size under scotopic conditions [46•] and can also be administered in an attempt to reduce halo and glare symptoms. Another approach involves the use of over-minused spectacles to push the secondary focal point behind the retina and thus lessen the effect of image blur from multiple images in front of the retina [47]. Polarized lenses have also been found to be helpful in reducing photic phenomena. Perhaps the most important technique is the implantation of bilateral Array lenses as close in time as possible to allow patients the ability to use the lenses together, which appears to allow for improved binocular distance and near vision compared with monocular acuity. Finally, most patients report that halos improve or disappear with the passage of several weeks to months.

### Conclusions

Thanks to the successes of the excimer laser, refractive surgery is increasing in popularity throughout the world. Corneal refractive surgery, however, has its limitations. Patients with severe degrees of myopia and hyperopia are poor candidates for excimer laser surgery, and presbyopes must contend with reading glasses or monovision to address their near visual needs. The rapid recovery and astigmatically neutral incisions currently being used for modern cataract surgery have allowed this procedure to be used with greater predictability for refractive lens exchanges in patients who are otherwise not suffering from visually significant cataracts.

Successful integration of refractive lens exchanges into the general ophthalmologist's practice is fairly straightforward because most surgeons are currently performing small incision cataract surgery for their cataract patients. Although any style of foldable intraocular lens can be used for lens exchanges, multifocal intraocular lenses currently offer the best option for addressing both the elimination of refractive errors and presbyopia. Refractive lens exchange with multifocal lens technology is not for every patient considering refractive surgery but does offer substantial benefits especially in high hyperopes, presbyopes, and patients with borderline or soon to be clinically significant cataracts who are requesting refractive surgery.

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Photoc phenomena from the Array multifocal IOL were treated successfully in many patients with the placement of over-minused lenses in the spectacle correction. A characterization and review of some of the treatment options to address these aberrations is presented.