
The AMO Array Foldable Silicone Multifocal Intraocular Lens

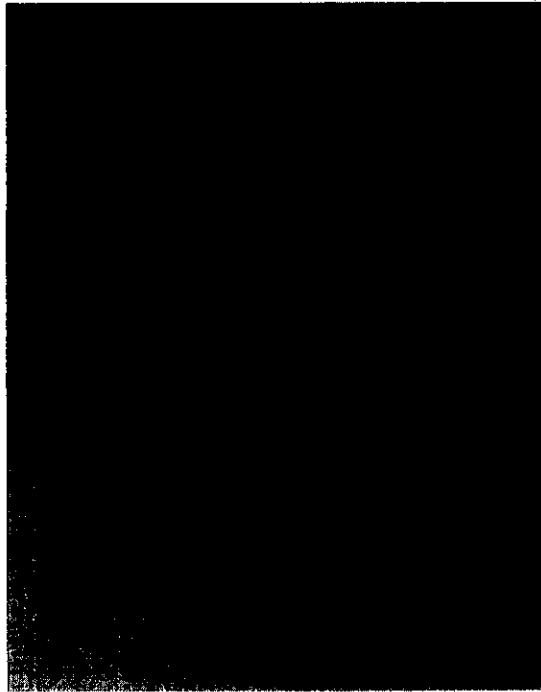
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Multifocal intraocular lens (IOL) technology offers patients substantial benefits. The elimination of a presbyopic condition and restoration of normal vision by simulating accommodation greatly enhances the quality of life for most patients. The only multifocal IOL available for general use in the United States is the AMO Array (Allergan Surgical Products, Irvine, CA). The advantages of astigmatically neutral clear corneal cataract surgery have allowed for increased utilization of multifocal technology in both cataract and clear lens replacement surgery. Careful attention to patient selection, preoperative biometry, and lens power calculations, in addition to meticulous surgical technique, will allow surgeons to offer multifocal technology to their patients with great success.

■ Lens Design

The principle of any multifocal design is to create multiple image points behind the lens. The goal of these lenses is to enable less reduction in visual acuity for a given amount of defocus by improving the depth of field. The AMO Array is a zonal progressive IOL with five concentric zones on the anterior surface (figure). 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 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 diffraction and no degradation of image quality as a



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result of surface discontinuities. 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, using the Unfolder injector system manufactured by AMO (Allergan).

■ Clinical Results

The efficacy of multifocal technology has been documented in many clinical studies. Early studies of the one-piece AMO Array IOL documented a larger percentage of patients who were able to read J2 print after undergoing multifocal lens implantation, as compared to patients with monofocal implants.¹⁻³ Clinical trials comparing multifocal lens implantation to monofocal lens implantation in the same patient also revealed improved intermediate and near vision in the multifocal eye as compared to the monofocal eye.^{4,5}

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

by demonstrating better contrast sensitivity and less glare disability.⁶ The Array does produce a small amount of contrast sensitivity loss equivalent to the loss of 1 line of visual acuity at the 11% contrast level using Regan contrast sensitivity charts.² This loss of contrast sensitivity at low levels is present only when the Array is placed monocularly and has not been demonstrated with bilateral placement and binocular testing.⁷ In addition to relatively normal contrast sensitivity, good random-dot stereopsis and less distance and near aniseikonia were present in patients with bilaterally placed implants as compared to those with unilateral implants.⁸

One of the potential drawbacks of the Array lens is the potential for an appreciation of halos around point sources of light at night in the early weeks and months after surgery.⁹ Most patients will learn to disregard these halos with time. 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 patients with bilateral Array multifocal lenses 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.¹⁰ In a study by Javitt and colleagues,¹¹ 41% of bilateral Array subjects were found never to require spectacles, as compared to 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 did monofocal controls.¹¹

■ Patient Selection

Our use of the Array multifocal IOL over the last 2.5 years has been extensive. We have used this device in approximately 30% of our cataract patients and in the majority of our clear lens replacement refractive surgery patients. As a result of our experience, we have developed specific guidelines with respect to the selection of candidates and surgical strategies that enhance outcomes with this IOL.

AMO recommends using the Array multifocal IOL for bilateral cataract patients whose surgery is uncomplicated and whose personality is such that they are not likely to fixate on the presence of minor visual aberrations such as halos around lights. Obviously, a broad range of patients would be acceptable candidates. Relative or absolute contraindications include the presence of ocular pathological processes (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 pathological processes that frequently are considered contraindications are age-related macular degeneration, uncontrolled diabetes or diabetic retinopathy, uncontrolled

glaucoma, recurrent inflammatory eye disease, retinal detachment risk, and corneal disease or previous refractive surgery in the form of radial keratotomy, photorefractive keratectomy, or laser-assisted in situ keratomileusis.

We avoid the use of these lenses in patients who complain excessively, are highly introspective and fussy, or obsess over body image and symptoms. We are conservative when evaluating patients with occupations that involve frequent night driving or that put high demands on vision and near work (e.g., engineers and architects). Such patients need to demonstrate a strong desire for relative spectacle independence in order to be considered for Array implantation.

In our practice, we have reduced patient selection to a very rapid process. Once we determine that someone is a candidate for either cataract extraction or clear lens replacement, we ask the patient two questions: First, "If we could put an implant in your eye that would allow you to see both distance and near without eyeglasses, under most circumstances, would that be an advantage?" Approximately 50% of our patients say no directly or indirectly. Negative responses may include, "I don't mind wearing glasses," "My grandchildren wouldn't recognize me without glasses," "I look terrible without glasses," or "I've worn glasses all my life." These patients receive monofocal IOLs. Of the 50% who say it would be an advantage, we ask a second question: "If the lens is associated with halos around lights at night, would its placement still be an advantage?" Approximately 60% of this group of patients say that they do not think they would be bothered by these symptoms, and they receive a multifocal IOL.

There are special circumstances in which implantation of a multifocal IOL should be strongly considered. Alzheimer's patients frequently lose or misplace their spectacles, and thus they might benefit from the full range of view that a multifocal IOL provides without spectacles. Patients with arthritis of the neck or other conditions with limited range of motion of the neck may benefit from a multifocal IOL rather than multifocal spectacles, which require changes in head position. Patients with a monocular cataract who have successfully worn monovision contact lenses should be considered possible candidates for monocular implantation. The same is true for certain professionals such as photographers who want to alternate focusing through the camera and adjusting imaging parameters on the camera without spectacles: In these patients, the focusing eye could have a monofocal IOL and the nondominant eye a multifocal IOL. We almost always use the Array for traumatic cataracts in young adults in order to facilitate binocularity at near, especially if the fellow eye has no refractive error or is corrected by contact lenses.

Prior to implanting an Array lens, we inform all candidates of the lens's statistics to ensure that they understand that spectacle independence is not guaranteed. Approximately 41% of the patients implanted with bilateral Array IOLs will never need to wear eyeglasses, 50% wear

glasses on a limited basis (such as driving at night or during prolonged reading), 12% will always need to wear glasses for near work, and approximately 8% will need to wear spectacles on a full-time basis for distance and near correction.¹¹ In addition, 15% of patients were found to have difficulty with halos at night, and 11% had difficulty with glare, as compared to 6% and 1%, respectively, in monofocal patients.

■ 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 believe that immersion biometry is necessary for accurate axial length determination. However, in our practice, we have found applanation techniques in combination with the Holladay II formula and the Holladay II back-calculation to yield accurate and consistent results while affording greater patient convenience and requiring less technician time. We currently are experimenting with the Zeiss IOLMaster for non-contact optical measurements. The IOLMaster is a combined biometry instrument for the measurement of axial length, corneal curvature, and anterior chamber depth. The axial length measurement is based on an interference-optical method termed *partial coherence interferometry*. Measurements are claimed to be compatible with acoustic immersion measurements and accurate to within 30 μm . This new technology offers the possibility of extremely accurate and efficient measurements with minimal patient inconvenience.

When determining lens power calculations, the Holladay 2 formula takes into account disparities in anterior segment and axial lengths by including the white-to-white corneal diameter and lens thickness in the formula. Addition of these variables helps predict the exact position of the IOL in the eye and has improved refractive predictability. As a final check in the lens power assessment, we also use the SRK T and the SRK II formulas and, for eyes of less than 22-mm axial length, the Hoffer Q formula for comparative purposes.

■ Surgical Technique

The multifocal Array works best when the final postoperative refraction has less than 1 D of astigmatism. Hence, it is very important that incision construction be appropriate with respect to size and location. We favor a clear corneal incision at the temporal periphery that is 3 mm or less in width and 2 mm long.¹² Each surgeon should be aware of his or her usual amount of surgically induced astigmatism by vector analysis. The

surgeon must also be able to use one of the many modalities for addressing preoperative astigmatism. Although we have utilized both T and arcuate keratotomies at the 7-mm optical zone, we currently favor limbal relaxing incisions^{13,14} created by a Force blade (Mastel Precision Surgical Instruments, Rapid City, SD) and a Nichamin nomogram.

In preparation for phacoemulsification, the capsulorrhexis must be round and sized so that there is a small margin of anterior capsule overlapping the optic circumferentially. This is important in order to guarantee in-the-bag placement of the IOL and prevent anteroposterior alterations in location that would affect the final refractive status. Hydrodelineation and cortical-cleaving hydrodissection are crucial in all patients because they facilitate lens disassembly and complete cortical cleanup.¹⁵ It is hoped that complete and fastidious cortical cleanup will reduce the incidence of posterior capsule opacification, the presence of which, even in very small amounts, will inordinately degrade visual acuity in Array patients. Because of these phenomena, patients implanted with Array lenses will require yttrium aluminum garnet laser posterior capsulotomies earlier than will patients with monofocal IOLs.

Minimally invasive surgery is key. Techniques that produce effective phacoemulsification times of less than 20 seconds and average phacoemulsification powers of 10% or less are highly advantageous and can best be achieved with power modulations (burst mode or two pulses per second) rather than continuous phacoemulsification modes.¹⁶

■ Management of Complications

When intraoperative complications develop, they must be handled precisely and appropriately. In situations in which the first eye has already received an Array lens implant, complications management must be directed toward finding any possible way of implanting an Array IOL in the second eye. Under most circumstances, capsule rupture will still allow for implantation of an Array lens 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 in order to capture the optic in essentially an in-the-bag location. If full sulcus implantation is used, then an appropriate change in the IOL power will have to be made to compensate for the more anterior location of the IOL within the eye. When vitreous loss occurs, a meticulous vitrectomy with clearing of all vitreous strands must be performed.

Iris trauma must be avoided because the pupil size and shape may affect the visual function of a multifocal IOL postoperatively. If the pupil measures less than 2.5 mm, impairment of near visual acuity may ensue

owing to the location of the rings serving near visual acuity. For patients with small postoperative pupil diameters affecting near vision, we have had success using the Argon laser to perform a mydriatic pupilloplasty.¹⁷

■ Postoperative Course

At every postoperative visit, we measure binocular as well as monocular uncorrected visual acuity at both distance and near. It is not uncommon to find the binocular acuity (which more closely simulates the way patients function on a daily basis) to be significantly better than the monocular acuity of either eye.

If eyeglasses are required postoperatively, the spherical correction should be determined by over-plusing the patient to a slight blur and gradually reducing the power until the best acuity is reached. Patients are able to focus through the near portions of their IOL, and thus it is possible to over-minus a patient if care is not taken to exaggerate the plus power. When using this defocusing technique, one must stop as soon as distance acuity is maximized to avoid over-minusing. The cylinder power should be the smallest amount that provides the best acuity. If add power is necessary, the full add power for the required working distance should be prescribed.

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 0.125% or weaker will constrict the pupil to a diameter that usually will lessen the severity of halos without significantly affecting near visual acuity. Another approach involves the use of over-minused spectacles in order to push the secondary focal point behind the retina and thus diminish the effect of image blur from multiple images in front of the retina. Polarized lenses have 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 promote improved binocular distance and near vision as compared to monocular acuity. Finally, most patients report that halos improve or disappear with the passage of several weeks to months.

■ Conclusion

We have had a great deal of success with the Array multifocal IOL in patients undergoing cataract and refractive surgery. We recognize that multifocal technology is not for every patient, but it does offer substantial benefits over monofocal lenses. Appropriate patient screening, accurate biometry and lens power calculations, and meticulous surgical technique

will allow surgeons to maximize their success with this lens. As with any new technology, there is a learning curve to Array IOL use, and we believe that the information provided in this chapter will help other surgeons to master the application of this technology.

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