The Latest Trends in Presbyopia-Correcting IOLs

Why I prefer an apodized, diffractive, multifocal lens for presbyopes.

BY STEPHEN S. LANE, MD

Few technologies have altered my practice as much as presbyopia-correcting IOLs. When one reflects on the limited success of designs such as the Array lens (Abbott Medical Optics Inc., Santa Ana, CA) in the mid-1990s (when near vision was achieved, but with unacceptably high visual disturbances for many patients), it would have been difficult to predict that multifocality as a means of achieving presbyopic correction would deliver not only outstanding clinical results, but more importantly, excellent patient satisfaction and acceptance.

This article summarizes my thoughts on some of the major themes in the area of presbyopia-correcting IOLs. These include the current state of the art in lens design, the best methods to evaluate visual performance, and, perhaps most importantly for ophthalmologists and their patients, some of the clinical outcomes that have been achieved with various lens alternatives.

PRESBYOPIA-CORRECTING OPTIONS: DIFFRACTIVE TECHNOLOGY DOMINATES

Early presbyopia-correcting IOL alternatives (eg, the Array lens and, later, the ReZoom multifocal IOL [Abbott Medical Optics Inc.]) were based on a zonal refractive design with alternating zones of near and far vision. These lenses were sensitive to both pupil size and lens position within the pupil, which reduced their effectiveness. Every change of zone from near to far also created a transition zone where light was not focused for near or distance, which contributed to the potential for visual disturbances. These IOLs with refractive optics also had design limitations in terms of how much add power they could provide.

Diffractive IOL technology relies on the wave properties of light to allow incoming light to be directed to a near or far focus. This technology is less sensitive to the lens' position in the eye and can provide higher add powers relative to zonal refractive designs. Traditional full-optic diffractive lenses (eg, the Tecnis Multifocal IOL [Abbott Medical Optics Inc.]) split incoming light in a fixed proportion. More advanced designs that include apodization (eg, the AcrySof IQ ReSTOR IOL +3.0 and +4.0 D [Alcon Laboratories, Inc., Fort Worth, TX]) allow for the selective distribution of light based on pupil size. This means they can reduce the proportion of near light in dim lighting/large-pupil conditions (such as when driving at night), thereby minimizing the potential for glare and halos better than a full-optic, non-apodized design. For instance, with the Tecnis Multifocal ZMB00 full-optic diffractive design, halos were reported to be severe for 18.3% of patients (Table 28, TMF Single Piece ZMB00 Package Insert).* With the AcrySof IQ ReSTOR +3.0 D apodized partial-optic diffractive design, halos were reported to be severe for only 6.5% of patients (Table 30A, ReSTOR Directions for Use - DFU).* *(*Per independently conducted studies and directions for use; "severe" grading may be defined differently in each.)*

The alternative to any multifocal IOL design is an accommodating lens. To date, the only FDA-approved lens in this category is the Crystalens Accommodating IOL (Bausch + Lomb, Rochester, NY). The challenge with any accommodating lens is the reliance on patient-specific characteristics for adequate performance. The size of the capsule, the strength of the zonules, and even the degree of capsular fibrosis will

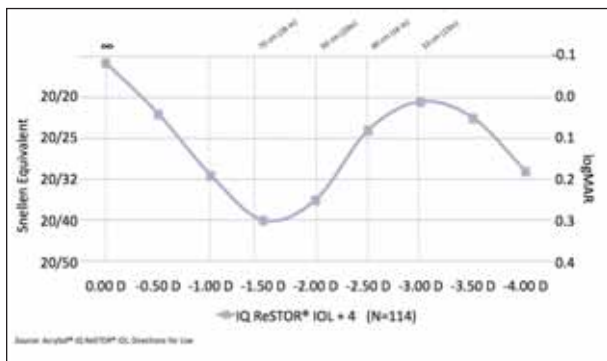

The AcrySof IQ ReSTOR IOL +3.0 D.

Figure 1. Mean defocus curve for the AcrySof IQ ReSTOR IOL +4.0 D; binocular, best case, 6 months postoperatively.

likely affect the amount of force applied in the resting (nonaccommodative) and accommodative states. The inherent variability introduced by these factors will in turn affect the predictability of the lens' distance refraction as well as the amount of accommodation it can achieve, as my colleagues and I demonstrated in our clinical trial investigation described herein.

The 2009 ESCRS and ASCRS member surveys showed that the apodized, diffractive, multifocal option (AcrySof IQ ReSTOR IOL +3.0 and +4.0 D) is the preferred presbyopia-correcting IOL alternative for patients undergoing cataract surgery, with more than half of the surgeons indicating it is the lens they use most often.[1,2] The predictability of this IOL's distance refraction, the percentage of patients achieving good near vision, and the low incidence of visual disturbances are the most likely factors to account for its performance. I believe the design improvements to the optics of the +3.0 D version of the lens, which allow for improved intermediate acuity, account for the clear preference for this model—in the United States, for example, more than 98% of the AcrySof IQ ReSTOR lenses implanted are the +3.0 D add. The effect of these design improvements is clearly evident in the relative defocus curves of the two models.

THE DEFOCUS CURVE: A STANDARD PERFORMANCE METRIC FOR PRESBYOPIA-CORRECTING IOLs

The availability of different presbyopia-correcting IOLs has created a need for ways to compare their visual performance. Subjective patient questionnaires are useful in this regard. However, an objective, clinically relevant measure of visual performance is also required. The defocus curve for any given lens is such a measure. Several defocus curves are shown in the figures on this and the following page.

The defocus curve is simply a summary of the level of visual acuity a lens provides at a variety of vergences. To generate a defocus curve, the physician first corrects a

given eye for best distance vision. Then, he or she introduces successively greater amounts of defocus through negatively and positively powered lenses, typically in 0.50 D increments, and retests the patient's visual acuity. The most important range of the defocus curve is from 0.00 to -4.00 D; these vergences are the optical equivalent of objects from infinity (0.00 D) to approximately 10 inches (-4.00 D).

Figure 1 shows the mean defocus curve for the AcrySof IQ ReSTOR IOL +4.0 D. The different vergences run across the bottom of the graph, and the vertical scale shows the visual acuity measures. The shape will be similar for any multifocal IOL, with peaks of good vision expected at the designated near and far points of the lens and the gradual degradation of the vision between these points. What does the curve tell us?

In the case of the AcrySof IQ ReSTOR IOL +4.0 D in Figure 1, at zero vergence (an object at infinity), the mean UCVA is better than 20/20. The lens was designed to provide +4.00 D at the IOL plane, which is about +3.00 D at the corneal plane. It is no surprise, then, that there is a second peak of vision at -3.00 D on the defocus curve. Mean visual acuity was near 20/20. The -3.00 D vergence suggests that the best near vision will be obtained at a near point approximately 13 inches from the patient's eye. Finally, the "trough" of the defocus curve occurs at a vergence of approximately -1.50 D, or 26 inches from the patient's eye. The mean visual acuity is lowest at this point, at around 20/40.

Figure 2 shows the defocus curve for the Tecnis Multifocal IOL. Like the AcrySof IQ ReSTOR IOL +4.0 D, the Tecnis Multifocal IOL has a +4.00 D add at the IOL plane and about a +3.00 D add at the corneal plane. This is reflected in the defocus curve, where the peak of near vision is approximately -3.00 D, with an expected 13-inch near point. Intermediate vision is worst at -1.50 D (object distance around 26 inches).

The +3.0 D version of the AcrySof IQ ReSTOR IOL was introduced after the +4.0 D design based on two of the aforementioned observations. The 14-inch near point of the +4.0 D optic was considered too close by many patients,
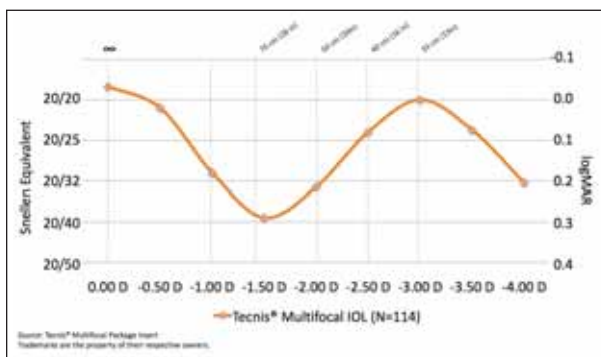

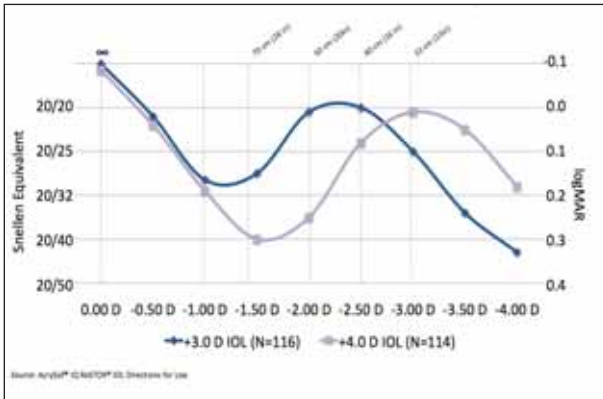Figure 2. Mean defocus curve for the Tecnis Multifocal IOL.

Figure 3. Mean defocus curve for AcrySof IQ ReSTOR IOLs; binocular, best case, 6 months postoperatively.

Figure 4. Binocular near visual acuity at 40 cm, with best distance correction at 4 months postoperatively.

and the intermediate vision was considered inadequate, particularly for those using computers. The AcrySof IQ ReSTOR IOL +3.0 D is exactly the same design as the +4.0 D version, but with a lower add power (+3.00 D at the IOL plane, or approximately 2.50 D at the corneal plane). The defocus curve for this lens elegantly demonstrates the effects of the new design and is to be compared/contrasted with that of the +4.0 D version of the lens (Figure 3).

The distance visual acuity (at zero vergence) is similar between both AcrySof ReSTOR lenses, and it is better than 20/20. The peak of the near point of the AcrySof IQ ReSTOR IOL +3.0 D averages 20/20 and occurs at between -2.00 and -2.50 D (corresponding to objects between 16 and 20 inches from the patient's eye). This gives the patient a better range of near vision. The "trough" of the defocus curve occurs between -1.00 and -1.50 D (intermediate vision, about 30 inches from the patient's eye), and the minimum visual acuity averages better than 20/25, a 1.5-line improvement over the previous +4.0 D design of the lens.

It is easy to compare the two lenses, then, in the context of the defocus curve. One can readily appreciate the differences in optical performance, with a further near point and better intermediate vision clearly evident in the defocus curve for the AcrySof IQ ReSTOR IOL +3.0 D relative to the +4.0 D version.

It is important to remember that these curves are based on a best distance correction, so the lens' performance over a range of distances is being evaluated, rather than the accuracy of the IOL calculation. However, presuming that a near-plano result can be obtained in patients, one can set expectations for patients' postoperative vision on the basis of the defocus curve.

NEAR AND INTERMEDIATE VISUAL ACUITY TESTING: A PROXY FOR THE DEFOCUS CURVE

Although we may not want to generate a defocus curve for all our patients due to the time-consuming nature of the exercise, we can still get a sense of how well different
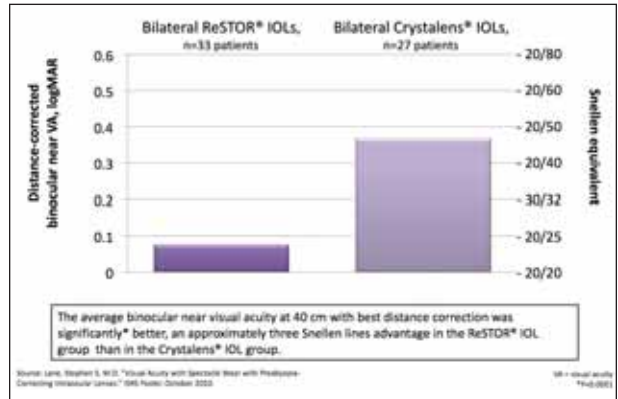
"The defocus curve is the best objective, clinical measure of visual performance for a presbyopia-correcting IOL."

presbyopia-correcting lenses are working in our practices by collecting visual acuity data at several distances. Testing at a given distance is like looking at a vertical cross-section of the defocus curve. Choosing appropriate testing distances can not only confirm that our results are consistent with a given defocus curve, but also identify differences between alternatives to presbyopia-correcting IOLs, as Figure 3 illustrates.

CLINICAL OUTCOMES: VISUAL ACUITY AND SPECTACLE INDEPENDENCE WITH PRESBYOPIA-CORRECTING IOLs

Technology provides viable presbyopia-correcting IOLs, and the defocus curve can help us interpret how the lenses are performing. The most important factor in the success of these IOLs, however, is how well they meet the patient's needs. Individuals who desire a presbyopia-
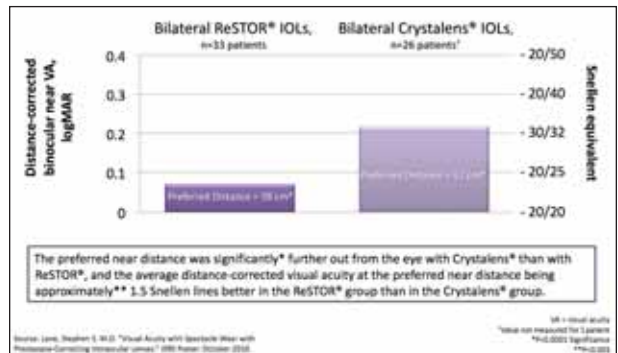

Figure 5. Binocular visual acuity at preferred near distance, with best distance correction at 3 months postoperatively.

correcting IOL tell us they want good vision at all distances so they will not need glasses.

Results from a multicenter, randomized, prospective study my colleagues and I conducted comparing bilaterally implanted AcrySof IQ ReSTOR +3.0 D lenses to bilaterally implanted Crystalenses were reported at the 2010 International Society of Refractive Surgery meeting.[3] We were interested in the acuity provided by these two lens alternatives for near vision as well as the preferred near point. We were also interested in the predictability of the postoperative correction and the degree of spectacle independence reported by patients. Our findings are summarized here.

Figure 4 shows the binocular visual acuity at 40 cm (16 inches) when the patients were best corrected for distance vision. The average patient implanted bilaterally with the AcrySof IQ ReSTOR IOL +3.0 D had a visual acuity of between 20/20 and 20/25, whereas the average bilateral Crystalens HD patient had a visual acuity of 20/40 to 20/50—a clinically and statistically significant difference.

Figure 5 shows the binocular UCVA at the preferred near point, with that near point identified. The preferred near point for the AcrySof IQ ReSTOR IOL +3.0 D patients was 38 cm (15 inches), with an average visual acuity of 20/20 to 20/25. The average visual acuity for the Crystalens patients was 20/32, significantly lower than that for the AcrySof ReSTOR group. The preferred near distance for the Crystalens was significantly farther from the eye as well: 51 cm (20 inches, or about 5 inches farther away than for the AcrySof IQ ReSTOR IOL +3.0 D).

Figure 6 shows the patient-reported spectacle wear. Note that 83% of bilaterally implanted AcrySof IQ ReSTOR IOL +3.0 D patients reported never wearing glasses versus 38% of the bilaterally implanted Crystalens patients. Eight percent of the Crystalens patients reported wearing glasses all the time, but no AcrySof IQ ReSTOR patients reported this. Additionally, only 20% of the Crystalens patients had a manifest distance refraction of greater than 1.00 D from the intended target. All patients in the AcrySof IQ ReSTOR IOL
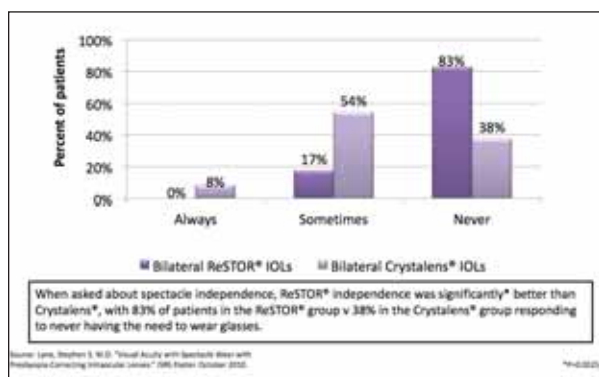
> "In our randomized, multicenter study, 83% of bilaterally implanted AcrySof IQ ReSTOR IOL +3.0 D patients reported never wearing glasses versus 38% of the bilaterally implanted Crystalens patients."

+3.0 D group achieved a manifest spherical equivalent within 1.00 D from the intended.

In summary, the patients implanted bilaterally with the AcrySof IQ ReSTOR IOL +3.0 D in this study had a measurably better result with regard to the correction of their presbyopia compared with the bilaterally implanted Crystalens HD patients. The former group had more predictable distance correction, had better near visual acuity, and were far more likely to be free of spectacles.

These results are consistent with my earlier statement that apodized diffractive technology is today's preferred method of IOL correction for presbyopia. I believe that before accommodating IOL technology can provide similar-quality near vision and similar rates of spectacle independence, several improvements will be required: better predictability of distance refraction, a higher add range, and less variability in results.

The apodized diffractive technology of the AcrySof IQ ReSTOR IOL +3.0 D offers visual performance at all distances by successfully providing patients with good distance, intermediate, and near vision. The defocus curve from the lens is predictive of patients' success, and our recent clinical results highlight the ability of this lens to provide significantly better near vision, a significantly higher likelihood of hitting the refractive target for distance, and higher spectacle independence rates when compared with current accommodative IOL technology. ◆

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Figure 6. Spectacle independence 3 months postoperatively.