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EVALUATING VISUAL PERFORMANCE AND CLINICAL EFFICIENCY: Fixed Power Monofocal Toric IOLs Versus Light Adjustable Lenses in Minimonovision

A comparative analysis supports IOL selection
for patients and practices.



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A new study informs decision-making when pairing IOLs with patients.

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Robert F. Melendez, MD, MBA: Modern cataract patients maintain elevated expectations regarding freedom from spectacles and superior visual quality, leading to remarkable advances in premium cataract procedures that enable us to fulfill these demands. Beyond benefiting from enhanced surgical technologies, improved preoperative measurements, and refined IOL calculation methods, we now possess an extensive array of premium IOLs and postoperative management strategies.

Today's discussion centers on the Clareon® Monofocal and Toric IOLs (Alcon), representing fixed optical power monofocal and toric lenses that deliver excellent distance acuity with astigmatic correction when the toric variant is employed, alongside the Light Adjustable Lens™ (LAL; RxSight), representing a postoperative power adjustable monofocal IOL. We will share our individual experiences with these lens platforms and discuss our current utilization patterns. Additionally, we will examine the visual performance and efficiency findings from a direct-comparison study performed by Clayton G. Blehm, MD, and his colleagues evaluating these two platforms,¹ while considering how these results may influence our clinical practices.

Let's first examine the Clareon Monofocal and Toric IOL technology alongside the LAL technology utilized in this comparative analysis.

TECHNOLOGICAL CHARACTERISTICS AND PLATFORM DISTINCTIONS

Clayton G. Blehm, MD: Similar to most IOLs implanted post cataract extraction, Clareon Monofocal and Toric IOLs deliver fixed optical correction for spherical and cylindrical refractive errors. These lenses provide sustained refractive stability and patient satisfaction by employing

a glistering-free hydrophobic acrylic material (characterized as modified Miyata scale 0 or <25 MV/mm²) with clinically validated axial and rotational stability characteristics.^{2,3,*†‡}

Current published studies show that the Clareon monofocal consistently delivers excellent binocular distance acuity and approximately 20/32 mean intermediate

acuity, results that are consistent with what I see in my own clinical research.⁴

Cristos Ifantides, MD, MBA: The LAL is the first FDA-cleared IOL capable of postoperative adjustment to address astigmatism (0.75 D to 2.00 D) and spherical error (-2.00 D to +2.00 D) through ultraviolet light treatment.⁵

The LAL's uniqueness lies in its UV-sensitive monomers integrated within a 3-piece foldable silicone IOL. UV light applications, delivered via the Light Delivery Device after pupillary dilation, are conducted a few weeks after implantation and serve to polymerize the monomers to alter the lens' configuration. This process produces spherical and/or cylindrical power modifications.

We have utilized the LAL since its market introduction, especially for post-refractive surgery cases. Although it certainly maintains a position in our therapeutic arsenal, we have reduced our use of this lens due to the resource-demanding nature of postoperative lens adjustments.

Dr. Melendez: In my experience of implanting approximately 300 LALs, I find patients generally require two to four postoperative UV light applications, followed by two lock-in treatments, to achieve the desired refractive outcomes. We have yet to establish the long-term behavior with the LAL.

Dr. Ifantides: That represents one of the current discussions within our community. Does the LAL deliver superior refractive results compared to other fixed-power lenses, and does it maintain refractive stability?

Dr. Blehm: Having now utilized the LAL in approximately 200 cases, I find it worthwhile to discuss the clinical outcomes vis a vis the substantially higher investment of time and resources for both the clinician and the patient.

Dr. Melendez, what represents your target refraction for LAL patients?

Dr. Melendez: The majority of my LAL patients desire excellent distance vision. Unless a patient has previously had monovision, I start by targeting plano for both eyes and then using the UV light applications in the nondominant eye to move toward -0.75 D to -1.25 D or \geq -1.50 D (monovision) if the patient desires for minimonovision or monovision,

respectively. If prior patient experience guarantees they want monovision, I will target -1.00 D in the nondominant eye at the time of surgery. From my experience, progressing from -1.00 D to additional minus power proves easier than moving in the reverse direction.

Dr. Ifantides: When I initially began using the LAL, I targeted -1.00 D for the nondominant eye for minimonovision and subsequently moved more myopic for full monovision. However, after discussing depth-of-focus of the LAL with colleagues, I changed my methodology to target plano and then adjust toward minus.

As our experience with the LAL increases, we are discovering that increasing the number or strength of UV treatments may have unwanted impact on the optic quality of the lens, such as changing its spherical aberration. I personally have observed a compromise between the magnitude of refractive correction to extend depth of vision and visual quality. Therefore, I have returned to my original methodology, targeting closer to the final refractive goal for my starting point.

INVESTIGATION METHODOLOGY AND OBJECTIVES

Dr. Blehm: That introduces our discussion regarding why we conducted this comparative investigation. When creating some degree of minimonovision, does a genuine difference exist in refractive accuracy and visual range between utilizing a fixed-power monofocal lens versus the LAL?

By most standards, outcomes with the LAL lens are excellent and only further improving with experience. However, my colleagues and I wondered if these outcomes with the LAL were genuinely better in terms of refractive accuracy and range of vision than what can be achieved with a fixed-power monofocal IOL. Thus, we designed a study to compare the Clareon monofocal/toric IOLs with the LAL.

All patients possessed between 0.75 D to 2.50 D of corneal astigmatism, in keeping with the FDA-approved label for

the LAL lens. We prospectively enrolled and randomly allocated patients to the Clareon group (n = 70) and the LAL group (n = 68). No significant demographic differences existed between groups.

Our objective was to deliver strong distance and intermediate vision while preserving stereoscopic vision. Thus, we targeted plano for the dominant eye and -1.00 D for the nondominant eye. For the LAL group, the refractive target was set at +0.25 D for both eyes post-surgery, which could be subsequently adjusted using UV treatments to the final refractive target of -1.00 D minimonovision.

All patients underwent femtosecond laser-assisted cataract surgery. IOL power was calculated using the Barrett Universal II formula and confirmed using intraoperative biometry. Astigmatism was corrected using either femtosecond arcuate incisions or toric IOLs in the Clareon group. Arcuate incisions were not used in the LAL group.

COMPARATIVE VISUAL PERFORMANCE ANALYSIS

Dr. Melendez: Let us examine the binocular visual performance data, beginning with defocus curve assessments conducted 3 months following surgical intervention or upon completion of UV modification and lock-in protocols for the LAL cohort (when the adjustment process extended beyond the three-month timeframe).

Dr. Blehm: The binocular defocus curves demonstrated remarkable similarity between both IOL platforms across the range of +1.00 D to -2.50 D of induced defocus (Figure 1). These represent target-corrected binocular measurements, reflecting patients' anticipated visual performance when achieving the desired refractive outcome of plano or -1.00 D for dominant and nondominant eyes, respectively. Statistical analysis revealed no statistically significant differences between the groups ($P > 0.05$).

Regarding binocular visual acuity measurements, both cohorts demonstrated excellent performance

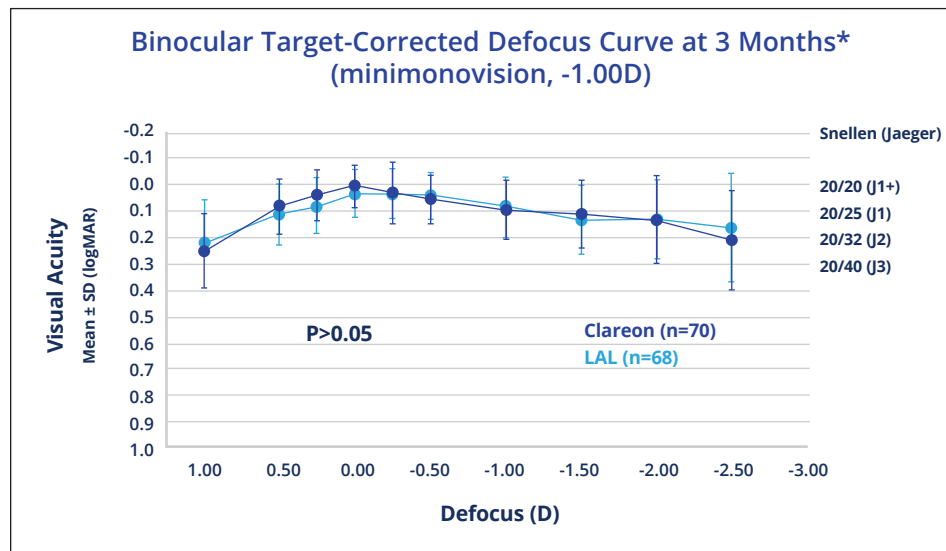


Figure 1. No statistically significant differences were detected between the two groups at 3 months* when both groups were corrected for minimonovision with -1.00 D offset ($P > 0.05$).

visual performance (noninferiority threshold: 0.1 logMAR). With the -1.00 D minimonovision configuration, patients in both groups achieved satisfactory uncorrected distance and intermediate vision. The LAL group showed only a modest difference of a 3.5-letter gain in UCVA, an amount that likely lacks clinical significance.⁶ Particularly noteworthy is the binocular distance-corrected intermediate visual acuity at 66 cm achieved with the Clareon monofocal/toric IOL of 20/30 (0.17 logMAR), which aligns with previously published findings.⁴

Dr. Melendez: What findings emerged regarding monocular visual acuity performance?

Dr. Blehm: As with binocular outcomes, monocular visual acuity data revealed clinically comparable outcomes between both groups at 3 months post-intervention. The nondominant eyes, targeted for -1.00 D refraction, demonstrated an average uncorrected VA of 20/25 for intermediate and J2-J3 for near, and improved over the plano-targeted dominant eyes. Monocular UCDVA predictably declined to approximately 20/40 (Figure 3).

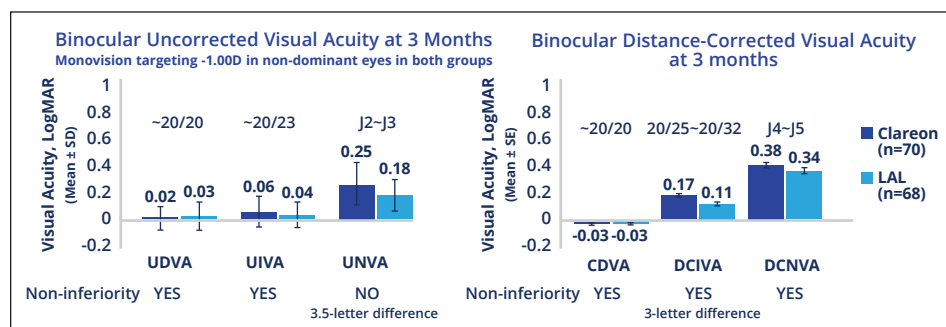


Figure 2. Noninferiority was found between the two groups for all binocular distance-corrected VAs and uncorrected distance and intermediate VAs at 3 months.*

Dr. Ifantides: The similarity in monocular visual acuity performance between the two groups is particularly striking. This suggests we must carefully evaluate the burden we place on patients and clinical staff relative to potential gains with the LAL. The necessity of completing UV treatment protocols before achieving astigmatism correction and target refraction adjustment demands multiple extended clinic visits for both patients and our practice. It was unexpected to discover that such significant effort only yields comparable clinical outcomes.

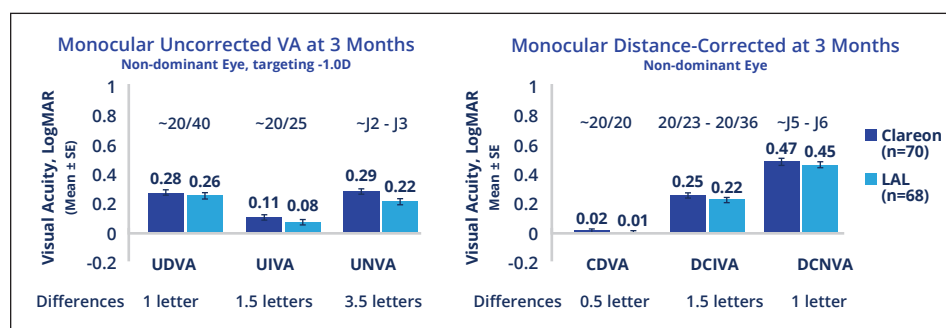


Figure 3. Non-dominant eyes in both groups showed improvement in UNVA (J2-J3), but UDVA decreased to ~20/40 at 3 months.* Monocular distance-corrected VAs showed ≤1.5-letter differences at distance, intermediate, and near at 3 months.*

* 3 month visit = 3 months after surgeries or after the final lockin if it is longer than 3 months after the surgeries

at the 3-month assessment (Figure 2). Noninferiority analysis confirmed between groups for

distance-corrected visual acuities across all three tested distances, as well as for uncorrected distance and intermediate

Dr. Melendez: Dr. Blehm, do the UV treatment protocols provide any measurable depth-of-focus enhancement?

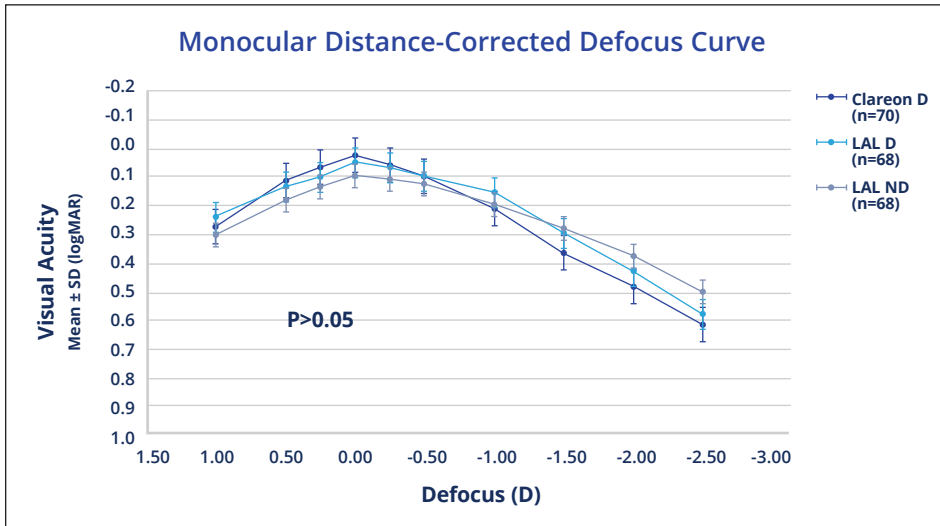


Figure 4. No statistically significant differences were observed on monocular distance-corrected defocus curves among three groups at 3 months* ($P > 0.05$).

Dr. Blehm: Analysis of monocular defocus curves included a separate evaluation of Clareon eyes as well as dominant and nondominant LAL eyes, with the latter receiving more extensive UV treatment to achieve the target -1.00 D refraction (Figure 4). The data suggest potential trade-offs where distance vision may be compromised to achieve slight improvements in intermediate to near visual performance.

Dr. Ifantides: While no statistically significant differences emerged among

the three monocular defocus curves (Figure 4, $P > 0.05$), the trending patterns are noteworthy. The trend toward superior visual acuity around plano with Clareon, even compared to dominant eyes of LAL patients that were preoperatively targeted at +0.25 D and adjusted to plano through UV treatment, was unexpected to me.

Dr. Blehm: We tracked the changes of higher-order aberrations (HOAs), including spherical aberration (SA), on all patients with iTRACE (Tracey

Technologies). While greater research is needed, our observations indicated there may be a correlation between greater UV treatment and changes in internal HOA, SA, and depth of focus.

REFRACTIVE PRECISION AND TARGETING ACCURACY

Dr. Melendez: How did the two cohorts compare in terms of refractive outcomes and targeting precision?

Dr. Blehm: Approximately 93% of the eyes in both groups achieved a spherical equivalent within 0.50 D of the intended target, and 97% of the eyes in both groups fell within 0.50 D of residual astigmatism at the final measurement. The final study measurement was taken 3 months post-surgery for the Clareon group or after the final lock-in UV treatment for the LAL group, if the UV treatment process took longer than 3 months.

Refractive outcomes at the 1-month and 3-month assessments, particularly regarding astigmatism management, warrant attention (Figure 5). While both groups demonstrated excellent refractive outcomes at 3 months, the Clareon group demonstrated consistent outcomes at 1 and 3 months, whereas the LAL group had greater residual astigmatism and refractive error at 1 month. This difference reflects the absence of astigmatism correction until UV treatment initiation at a minimum of 3 weeks following LAL implantation.

Dr. Ifantides: The exceptional performance of the Clareon IOLs is remarkable and reflects the substantial improvements in our IOL power calculation formulas over the past decade. Ancillary technologies have significantly reduced risks of toric lens misalignment and inaccurate corneal astigmatism treatment. For LAL-implanted eyes, both astigmatism correction and spherical adjustment necessitate multiple lengthy postoperative appointments. Considering all factors, I continue to question the value proposition of the LAL relative to

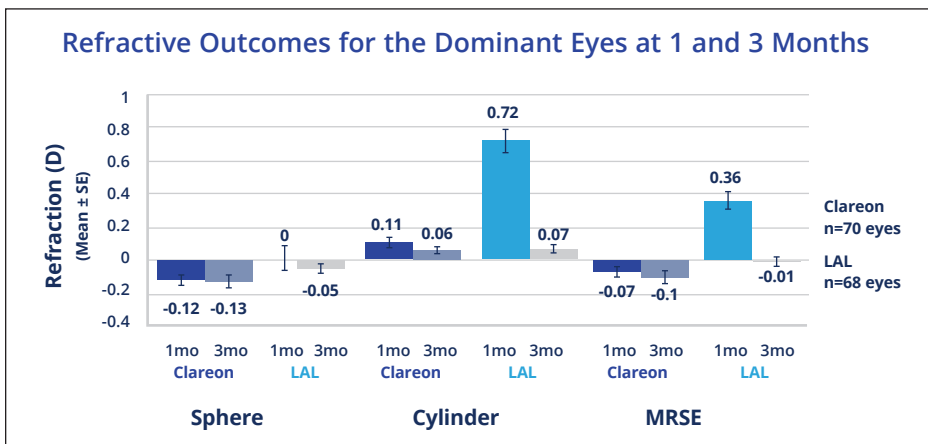


Figure 5. Both Clareon and LAL achieved excellent refractive outcomes at 3 months.* Note that there was no astigmatism correction until UV treatments started at least 3 weeks after LAL implantation.

the substantial effort invested by both patients and our practices.

CLINICAL EFFICIENCY AND RESOURCE UTILIZATION ASSESSMENT

Dr. Melendez: Dr. Blehm, did your investigation include specific efficiency metrics?

Dr. Blehm: We quantified visit frequency and time intervals from the second eye's surgery to routine care completion. The LAL group required significantly more resources compared to the Clareon group: approximately 1.1 visits over 31.7 days (Clareon) versus 4.2 visits over 53.9 days (LAL) ($P < 0.01$ and $P < 0.001$).

All enrolled patients committed to predetermined refractive targets, as designed by the study protocol, and were not able to make individual adjustments. Frankly, this meant we avoided dealing with patient indecision or pursuing the elusive "patient satisfaction" refractive endpoint typical with LAL treatments.

QUANTITATIVE CHAIR TIME ANALYSIS

Dr. Melendez: In Dr. Blehm's investigation, LAL patients averaged three additional visits for UV light treatments. However, in my clinical practice, patients with complex cases often require six to eight visits to achieve their target refraction.

My colleagues and I are conducting a prospective time & motion analysis, comparing real-world postoperative chair time for the LAL/LAL+ versus presbyopia-mitigating PanOptix® or Vivity® lenses.⁷ We track physicians' and technicians' time spent with patients post-surgery, excluding patient travel time and clinic waiting periods, including pupil dilation. At 3 months, patients required approximately 159 minutes versus 59 minutes of chair time ($P < 0.001$) and 7.8 visits versus 4.5 visits ($P < 0.001$) with LAL/LAL+ versus PanOptix/Vivity, respectively.

As practice owners, we must consider the time spent on UV light treatments versus time that could be spent on new patient consultations, the economics of

chair time when using these two different IOL platforms.

Dr. Ifantides: The significant increase in chair time with the LAL isn't just a problem for surgeons and practices, it also represents a significant treatment burden for patients. When you add increased costs and time to both the patient and the practice, further analyzing the value of LAL lenses is essential. The combination of the study on the effectiveness and efficiency of Clareon monofocal/toric IOLs versus LAL minimonovision⁸ with your chair-time study⁷ really calls into question the need to ask so much from ourselves and our patients.

Dr. Melendez: Although each UV treatment for LAL only takes about 2 minutes, our time & motion study revealed these visits can easily extend to 2 hours once you include examination, refraction, dilation (to 7 mm diameter), addressing questions, and waiting time in busy clinics.⁷

Dr. Ifantides: While some colleagues have suggested reducing preoperative consultations since the patient's refractive error will be corrected with UV treatment in the clinic postoperatively, I disagree with this approach. The LAL is a premium lens with a premium price, and patients naturally have high expectations. Therefore, they must understand that they will not experience their final vision until completion of all UV light treatments. Assuming minimal preoperative coaching is unrealistic.

Dr. Blehm: I concur completely. There exists a defined process, and establishing expectations beforehand is crucial. Patients must understand the complete journey and their responsibilities, including wearing UV protection glasses outdoors immediately post-surgery.

Dr. Melendez: When utilizing LALs for complex cases such as post-radial keratotomy, patients may require six or

seven UV light treatments. Additional factors, including ocular dryness or visual fluctuation, can influence treatment timing decisions.

Dr. Blehm: LAL patients sometimes exhibit "chasing their tail" behavior. They may request ongoing adjustments, only to decide that a previous outcome was preferable and ask to go back. This adds significant chair time.

Dr. Melendez: Our LAL experience confirms that 'adjustable' does not equal 'reversible'. Target chasing cannot continue indefinitely.

PATIENT SATISFACTION METRICS AND SPECTACLE INDEPENDENCE

Dr. Melendez: Dr. Blehm, did patient-reported spectacle independence and satisfaction align with visual performance outcomes in your study?

Dr. Blehm: At 1 month, the Clareon group demonstrated high spectacle independence rates. The LAL group showed lower rates because its UV treatments had not commenced. At 3 months, both groups achieved similarly high spectacle independence at distance and intermediate, with a small advantage at near for the LAL group without statistically significant difference ($P > 0.05$). Both groups reported high satisfaction with visual outcomes, with 83% for Clareon and 89% for LAL patients ($P > 0.05$).

Dr. Melendez: Clareon and LAL patients with minimonovision both performed well at distance and intermediate. Our direct comparison revealed a similar visual range, spectacle independence, and patient satisfaction at 3 months. The intermediate visual acuity with fixed-power monofocal lenses exceeded my expectations, since we don't routinely measure or inquire about intermediate vision. The Clareon monofocal lens achieved binocular 20/30 DCIVA and 20/23 UIVA with minimonovision, which impressed me significantly.

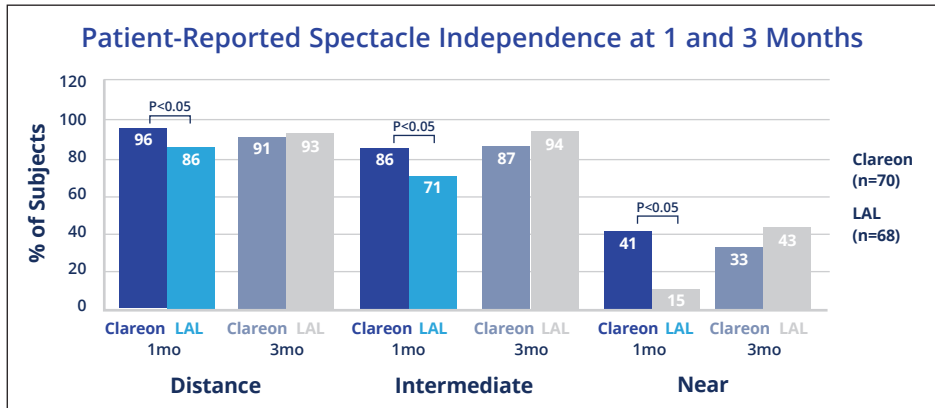


Figure 6. Both groups had a high degree of spectacle independence at distance and intermediate at 3 months, with a slight edge for the LAL at near ($P > 0.05$).

CONTRAINDICATIONS AND CLINICAL COMPLICATIONS

Dr. Blehm: Due to potential viral reactivation from UV light exposure, any history of ocular herpes simplex virus (HSV) infection represents a contraindication for LAL. While all patients denied such history during enrollment, two of 68 LAL patients developed HSV keratitis following initial UV treatment. The infection resolved after antiviral therapy, but UV treatment was still delayed and prolonged.

Dr. Ifantides: Additional HSV keratitis screening would be challenging, but systematic data collection might reveal a higher prevalence.

Dr. Melendez: Were the seven LAL patients and two Clareon patients who were reported to have dry eye disease (DED) removed from the study?

Dr. Blehm: While UV treatments were paused in patients who showed refractive instability with mild to severe DED, no patients were excluded from analysis. After the DED treatment was administered and refractive stability was restored, UV treatments continued.

Dr. Melendez: From the outset, it is essential to inform patients with high levels of preoperative astigmatism

that, after the initial IOL implantation, their astigmatism will not be corrected and their vision may be compromised for several weeks or months until the UV treatment is completed.

Dr. Blehm: Examining refractive and visual-outcome changes in the LAL group from 1 to 3 months reveals that a large percentage of patients did not achieve their desired outcomes by 1 month (Figure 6). Unlike patients who receive a toric IOL, LAL patients with substantial astigmatism who must wait at least 17 days (manufacturer recommendation) before their first UV light treatment will not have functional vision immediately postoperatively.

Dr. Melendez: Would you consider prescribing temporary eyeglasses or contact lenses post-surgery?

Dr. Blehm: There are no optimal solutions for this interim period, as LAL patients already wear UV-protection glasses and contact lenses shortly after cataract surgery presents challenges.

Dr. Melendez: Research demonstrates that monovision, including minimonovision, reduces stereopsis and contrast sensitivity.⁹ If absolutely excellent binocular vision at distance, intermediate, and near is desired, a different lens technology is required.

In these cases, my preferred lens for spectacle independence at all distances and true binocular stereo vision is the PanOptix® trifocal IOL (Alcon). This lens provides excellent vision at near (16 inches) and intermediate (24 inches), while maintaining very good distance vision. Having multiple options in our toolkit is important.

CLINICAL PRACTICE EVOLUTION AND FUTURE DIRECTIONS

Dr. Melendez: Dr. Ifantides, what aspects of this study impressed or surprised you most?

Dr. Ifantides: This investigation has been genuinely enlightening. I had primarily reserved LAL for post-refractive surgery patients and for patients who have very high expectations of spectacle independence. However, the data from this comparative study do not show superior vision or an extended range of vision with LAL in normal cataract patients. Therefore, it makes me wonder if LAL will provide better outcomes on these two aspects. In addition, I can do it with less financial and treatment burden for the patient and my practice. As is the goal with good science, I will undoubtedly modify my clinical practices.

Dr. Blehm: I was gratified to learn that I am able to offer my patients similarly high visual outcomes with Clareon, with less burden for the patient and the surgeon.

Dr. Melendez: While I see these studies influencing my practice, I still see LAL being a good option for some specific patient groups, such as those who have undergone prior radial keratotomy, LASIK, or PRK, as I believe these patients may benefit more from LAL technology.

I will reconsider my approach for patients with pre-existing monovision. I had assumed these patients were ideal LAL candidates, but the study showed that Clareon monofocal/toric minimonovision provided excellent distance and good intermediate vision

and allowed patients to return to work sooner.

Dr. Blehm: The beauty of contemporary ophthalmology lies in continuously expanding our therapeutic toolkit with excellent options. I believe LAL technology is beneficial and will reserve it specifically for select post-refractive surgery patients and those at high risk for refractive targeting challenges. However, it's remarkable that even standard monofocal lenses, which we consider basic technology, can deliver such exceptional refractive outcomes.

Dr. Ifantides: No single lens fits every patient, so it is comforting to know that we have multiple options that can achieve excellent results.

Dr. Melendez: Dr. Blehm, I deeply appreciate your team's efforts with this investigation. The study design was robust and its results are solid, showing no significant differences between the Clareon monofocal/toric platform versus LAL regarding refractive outcomes, distance and intermediate visual acuity, and patient-reported spectacle independence and satisfaction with minimonovision.

Based on these findings and our clinical experiences, we have a better understanding of these lenses' value for specific patients and situations. Highlighting this is crucial for helping our colleagues nationally and internationally make decisions based on optimal patient outcomes and lifestyle considerations. ■

†Compared in vitro with TECNIS® OptiBlue® ZCB00V, TECNIS® ZCB00, Vivinex® XY-1, Eternity® Natural Uni W-60 and enVista® MX60. (Surface haze and SSNGs: n=10 lenses per group, P<0.001; Glistenings: n=30 IOLs per group, P<0.001).

‡Based on in vitro examinations of glistenings, surface haze and SSNGs.
*Trademarks are the property of their respective owners.

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IMPORTANT PRODUCT INFORMATION - CLAREON® FAMILY OF IOLS

CAUTION: Restricted by law to sale by or on the order of a physician.

DESCRIPTION: The Clareon® Family of Lenses are artificial lenses implanted in the eye of adult patients following cataract surgery. The Clareon® Aspheric Hydrophobic Acrylic IOLs are designed to allow for clear distance vision. However, you will likely still need glasses for reading and for distance vision particularly if you already have astigmatism. The Clareon® PanOptix® Trifocal Hydrophobic IOL is a type of multifocal lens designed to allow for clear distance, intermediate, and near vision with the potential to be more independent of the need to use glasses for daily tasks. The Clareon® Vivity® Extended Vision Hydrophobic Posterior Chamber IOL provides clear distance vision, and better intermediate and some near vision compared to a monofocal IOL. The Clareon® Aspheric Toric, Clareon® PanOptix® Toric, and Clareon® Vivity® Toric IOLs are also designed to correct pre-existing corneal astigmatism, which is the inability of the eye to focus clearly at any distance because of difference curvatures on the cornea, and provide distance vision.

WARNINGS / PRECAUTIONS: You may experience and need to contact your eye doctor immediately if you have any of the following symptoms after cataract surgery: itching, redness, watering of your eye, sensitivity to light. The safety and effectiveness of these IOLs have not been established in patients with eye conditions, such as an increase in eye pressure (glaucoma) or complications of diabetes in the eye (diabetic retinopathy). As with any surgical procedure, there are risks involved. These risks may include but are not limited to infection, damage to the lining of the cornea, the retinal layer which lines the inside back wall of your eye may become separated from the tissue next to it (retinal detachment), inflammation or swelling inside or outside the eye, damage to the iris (the colored diaphragm around the pupil), or an increase in eye pressure that cannot be controlled by medicine and secondary surgical procedure. There is a possibility that the IOL may be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision, or it may cause visual symptoms. The Clareon® Aspheric Toric, Clareon® PanOptix® Toric, and Clareon® Vivity® Toric IOLs correct astigmatism only when placed in the correct position in the eye. There is a possibility that these Toric IOLs could be placed incorrectly or could move within the eye. This may result in less improvement or a reduction in vision because your astigmatism has not been fully corrected, or it may cause visual symptoms. With the Clareon® PanOptix® and Clareon® Vivity® IOLs, there may be a loss of sharpness of your vision that may become worse in dim light or in foggy conditions. There is also a possibility that you may have some visual effects such as rings or circles (halos) around lights at night. You may also have trouble seeing street signs due to bright lights or glare from oncoming headlights.

ATTENTION: As with any surgical procedure, there are risks involved. Prior to surgery, ask your eye doctor to provide you with the Patient Information Brochure for the lens to be implanted. This Brochure which will inform you of the risks and benefits associated with the IOL. Discuss any questions about possible risks and benefits associated with your eye doctor.