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THE MODERN CATARACT PATIENT

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Modern life revolves around myriad digital tasks, making quality intermediate vision and functional near vision essential to most daily activities. In addition, we know that a range of vision cannot be provided at the expense of high-quality vision. Visual disturbances are thought to be the primary reason for slow market adoption of presbyopia-correcting lenses. Cathleen M. McCabe, MD, is joined by Iqbal Ike K. Ahmed, MD, FRCSC; John P. Berdahl, MD; Justin Schweitzer, OD; and Dagny Zhu, MD, to discuss how physicians can use the Alcon AcrySof IQ Vivity intraocular lens (IOL) to provide high-quality, extended depth-of-focus vision without the compromises of diffractive IOL technology to meet the demands of modern cataract patients' lives.

CURRENT PRESBYOPIC LENS OPTIONS

Cathleen M. McCabe, MD: There are currently multiple lenses in the market that attempt to address presbyopia in different ways beyond monofocal monovision or monofocals with some added asphericity. We have extended depth-of-focus (EDOF), and multifocal or trifocal IOLs. But the adoption of presbyopia-correcting lenses has been very slow. In 2019, an ASCRS survey calculated that only 8% of IOL implantations used a presbyopia-correcting lens.[1] Even with the availability of an advanced trifocal lens, the PanOptix Trifocal IOL (Alcon), ESCRS survey data only showed implantation in the presbyopia category elevated to 9%.[2] This may be due to visual disturbances that can occur with many of those diffractive presbyopia-correcting lenses. Let's start by understanding the difference between EDOF lenses and monofocal lenses that may have a slightly extended range of vision.

Iqbal Ike K. Ahmed, MD, FRCSC: This is a topic that can create some confusion. The TECNIS Eyhance IOL (Johnson & Johnson Vision) is marketed as an "enhanced" monofocal lens. These "enhanced" monofocal IOLs may change the central power of the optic to provide some additional range of vision, but not to the extent that meets the ANSI/AAO EDOF criteria. In fact, there are no standards from ANSI or FDA that define an "enhanced" monofocal. The Eyhance IOL has a central curvature that may provide some intermediate vision, but not to the level as a defined presbyopia-correcting EDOF lens.[3-6] The Eyhance monofocal lens appears to have an adverse event profile and contrast sensitivity very similar to the TECNIS Monofocal IOL (Johnson & Johnson Vision).[5,6] When I choose to implant an "enhanced" monofocal IOL in a patient, I very clearly set correct expectations for my patients. If they get intermediate vision benefit, that is icing on the cake. If a patient requires very good and consistent intermediate vision and some near vision, then I need to think about a non-diffractive EDOF IOL. It's important to understand the presbyopia correcting and monofocal IOL categories and not confuse the technologies.

Dr. McCabe: Let's take a deep dive into how EDOF lenses for managing presbyopia are classified according to ANSI and AAO based on their clinical performance.[3,7] An EDOF lens must:

- Have its monocular depth of focus at least 0.5 D greater than the monofocal control at 0.2 logMAR (20/32);
- Provide mean monocular photopic DCIVA (66 cm) superior to a monofocal;
- Provide monocular DCIVA of 0.2 logMAR or better in 50% of eyes; and
- Provide mean monocular BCDVA that is non-inferior to a monofocal lens.

The AcrySof IQ Vivity IOL does meet and, in fact, exceed the criteria for an EDOF lens. In the Vivity FDA registration study[8], we see that close to 73% of the 107 study patients who received the Vivity lens achieved 0.2 logMAR or better monocular DCIVA, and the mean DCIVA is superior to the monofocal control used in the study. Eyhance, however, hasn't been shown to meet the EDOF standard for providing an extended depth of vision. Going beyond the standard is even more interesting. What is missing in the ANSI standard description is any quantification of visual disturbances. What makes the Vivity IOL distinct is that it goes beyond the ANSI standard by maintaining a low incidence of visual disturbances as a result of its unique non-diffractive design.

Dagny Zhu, MD: It's also important to note that monofocal IOLs are not completely immune to glare, halos, and starbursts. There are some patients who experience visual disturbances with monofocal lenses as well. Fortunately, they are at a very low percentage and do not require extensive preoperative counseling. For the most part, I am able to present the Vivity IOL to my patients in the same way I talk to them about a monofocal IOL when it comes to overall quality of vision. They might have a low incidence of visual disturbances right after surgery, but they are usually milder, and patients are much less likely to experience them long-term or require an IOL exchange. Presenting the Vivity IOL is definitely a lot easier and takes less chair time compared to the traditional diffractive presbyopia-correcting IOLs in my practice.

X-WAVE MECHANISM OF ACTION

Dr. McCabe: Let's talk about the specifics of the Vivity IOL design and the exact mechanism of action. How does this lens actually meet the standards for an EDOF lens and have a great visual disturbance profile?

Dr. Zhu: I'm excited to talk about this because I know a lot of our colleagues are still skeptical that this lens can provide a continuous extended range of vision without utilizing diffractive technology. Vivity is a non-diffractive EDOF IOL, and when you look at it with the naked eye, it looks like a monofocal IOL. But when you look at it under the microscope, you can see that there is something different in the central 2.2 millimeters of the optic, and that is the X-Wave Technology (Alcon).

This X-Wave (non-diffractive) Technology uses two surface transition elements to stretch and shift light to provide an extended range of vision without ever splitting the light. The first element is a slight elevation in the center that stretches the light resulting in a continuous extended focal range, and the second element is a slight change in the curvature that shifts the light so that all of the usable energy is employed. As the wavefront travels through the lens, you can see there is an overall stretching of light (Figure 1). This is accomplished by delaying the wavefront that passes through the central portion so that it ends up focusing closer in front of the retina. That is what provides an intermediate to functional near range of vision. The wavefront that passes through the periphery of the lens is advanced and moves quicker, so it focuses further back, closer to the retina, and provides the distance range of vision.

When we see a visual simulation of how the light energy is utilized in various IOLs, we can see that diffractive and non-diffractive EDOF IOLs behave differently (Figure 2).[9,10] The PanOptix Trifocal IOL is providing a full range of vision, including near. The Vivity IOL does not have the same range of vision as a trifocal, but it provides a continuous range of vision that is extended significantly beyond what is available with a monofocal IOL without splitting the light like other diffractive EDOF lenses.

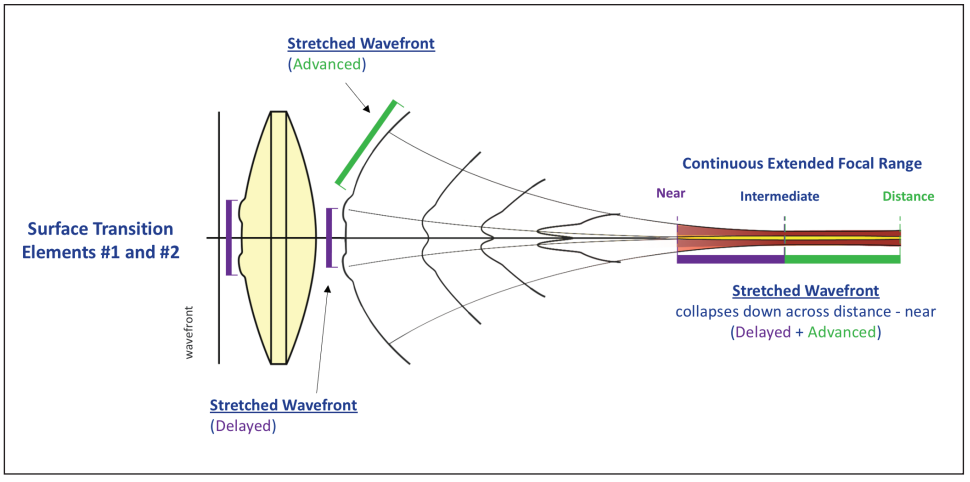

Figure 1. The Vivity IOL uses two surface transition elements (X-Wave Technology) to stretch and shift the wavefront to provide a continuous extended focal range.

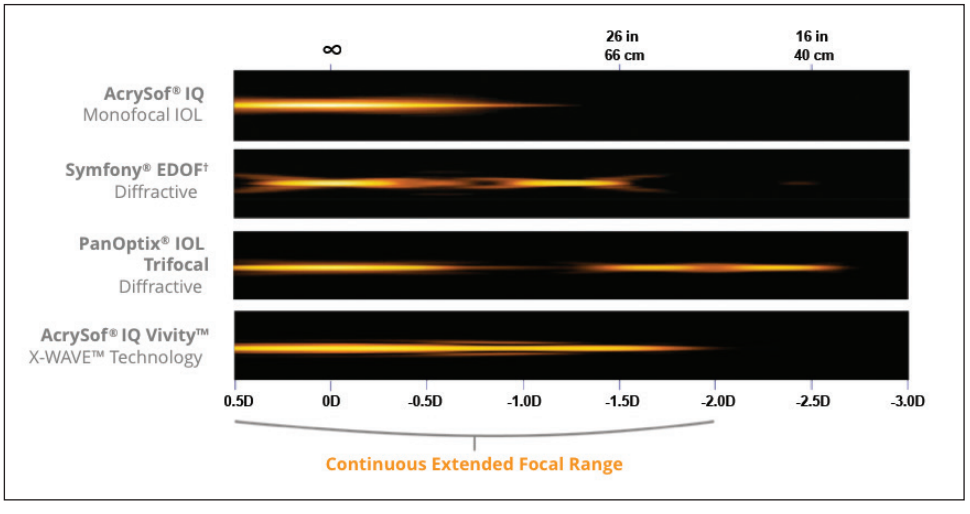

Figure 2. Simulated comparison of light energy distribution (photopic through-focus point spread function) in various lenses.[10]

Dr. McCabe: This is really an altogether different optical design, and it's exciting to dive into how it works. Now let's discuss the clinical trial data to see how this X-Wave Technology is performing.

VIVITY CLINICAL TRIAL RESULTS

John P. Berdahl, MD: The Vivity IOL was evaluated in two prospective, multicenter, randomized, controlled clinical trials, one in the United States[8] and one outside the United States.[11] Combined, more than 250 adults with cataracts had bilateral implantation of the Vivity IOL and close to the same number of control patients were implanted with the AcrySof IQ monofocal IOL (Alcon). The goal was to evaluate the safety and efficacy of the lens in cataract patients who had low levels of astigmatism (<1.00 D).

Let's start with looking at the US registration study results. Overall, the 6-month postoperative monocular photopic distance corrected visual acuities (BCDVA and DIVA) and depth of focus data showed Vivity IOL met ANSI EDOF standard discussed above.[8]

Understanding the defocus curve for the IOLs that we use is really essential to

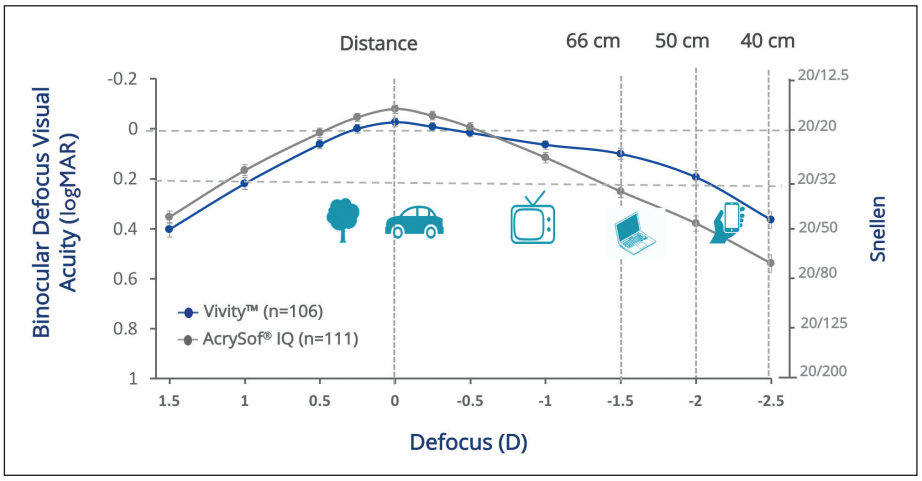

Figure 3. Binocular defocus curve of the Vivity IOL shows an extended range of focus superior to an aspheric monofocal IOL.[8]

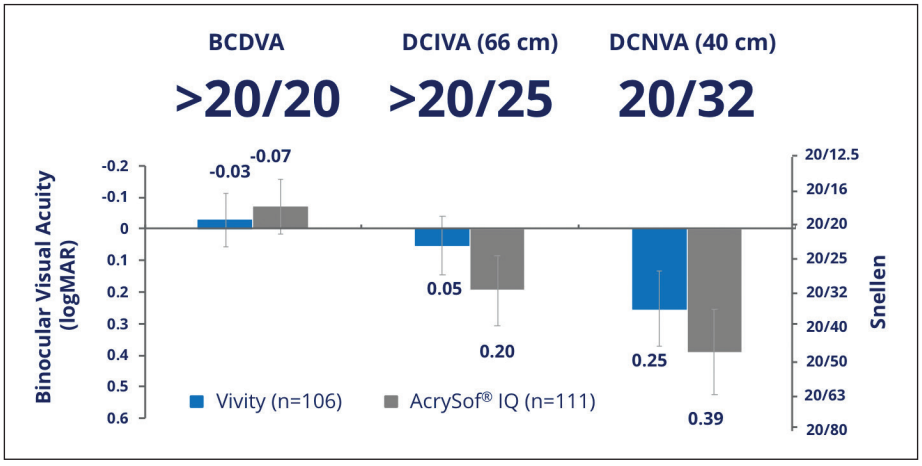

Figure 4. Binocular distance corrected VAs at 6 months in the US Vivity registration study.[8]

being able to match the technology to the goals of the individual patient (Figure 3). With the Vivity IOL, we see a defocus curve that is fairly flat around plano and smoothly extends to -2.00 D, indicating that Vivity provides continuous extended range of vision from distance to intermediate and functional near with good tolerance to small refractive error.

Dr. McCabe: Six-month binocular data from the trials also showed that both the Vivity EDOF and the AcrySof monofocal IOLs created best corrected distance vision better than 20/20.[8] You start to see a separation of performance as you approach intermediate and near vision. The Vivity IOL is better at both 66 cm and 40 cm compared to the monofocal IOL (Figure 4). Although it doesn't achieve the visual acuity level of PanOptix at near, Vivity does provide excellent functional near vision.

Dr. Berdahl: The data from the US study also shows that at 6 months postoperation, 98% of Vivity-implanted patients achieved 20/32 (0.2 logMAR) or better at distance, 97% achieved that at intermediate, and 58% achieved that at near.[8]

AN EXTENDED RANGE OF VISION IN THE REAL WORLD

Dr. McCabe: Now, let's discuss how we talk to patients about their visual expectations.

Justin Schweitzer, OD: When I introduce Vivity to patients, I tend to focus on functional near vision to set appropriate vision expectation. I don't talk a lot about distance vision because I'm not worried about that with Vivity. I give them real-world examples, and functional near vision is being able to put on makeup in the mirror or writing the score on your golf card. Those are examples of functional near activities that the patient will likely want to perform. Reading a book or newspaper for 2 hours are examples of detailed near visual activities that are going to be challenging with an EDOF implant, so patients need to temper their expectations in that regard or consider a trifocal IOL. With Vivity, I let them know they will be able to check a text on their phone, but they may have to increase the font size sometimes.

Dr. McCabe: I usually tell patients that they will be able to see who is calling them without having to put on their glasses. Dr. Zhu, do you have any other pearls for talking to patients?

Dr. Zhu: I show my patients the near reading card around 40 cm and point to the J3 line, explaining that the majority of my patients that receive bilateral Vivity IOLs can read at the J3 line. That is the functional near vision needed for many daily activities, like putting on makeup or seeing who is calling, and patients are very happy with that. It is a much greater range than they would get with a monofocal IOL or an "enhanced" monofocal, so if you set the correct expectations ahead of time, they are happy.

Dr. Ahmed: I find it important to clarify functional near and intermediate vision. When we talk about intermediate vision, that is typically defined as around 66 cm, or what you need to use a computer. Many people confuse the intermediate vision with the vision required for cell phone usage, which, for most people, means the functional near vision with phone held at around 40 cm. Patients want to be able to see their phones without putting on their glasses or enlarging the font to the point that there is only one word per line in a text. Having a functional near vision at J3 level should enable most people to comfortably use their phones, and that is where Vivity can really deliver.

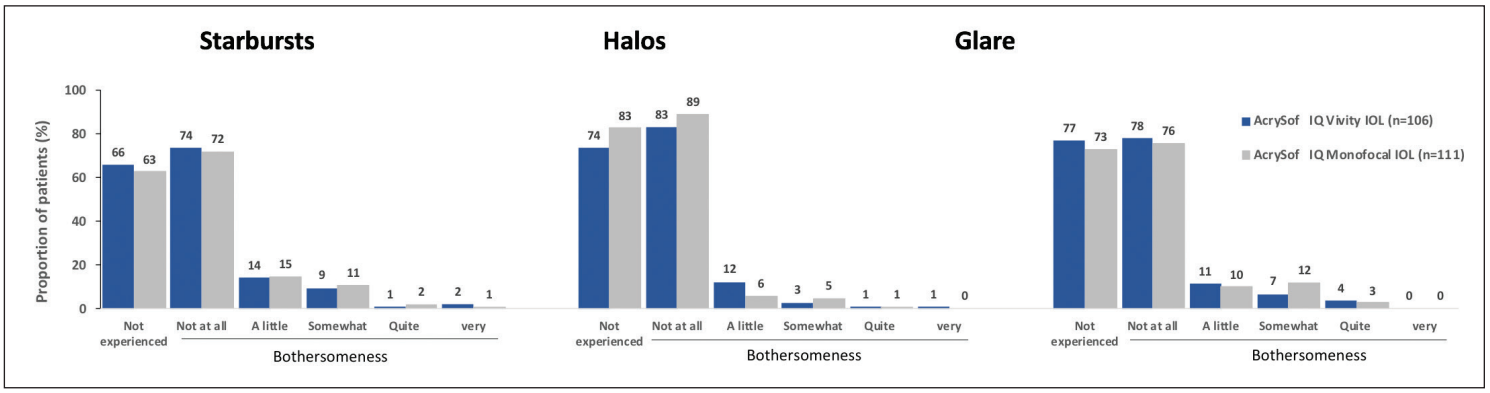

Figure 5. In the US registration trial, both the Vivity IOL and the AcrySof IQ monofocal IOL have low incidence of visual disturbances. A high percentage of patients reported "not experiencing" or "not bothered" at all by starbursts, halos, and glare. Note: Percentage of patients who reported "not bothered at all" includes those not experienced and those experienced but not bothered at all.

VISUAL DISTURBANCES

Dr. Berdahl: While IOLs are often designed around what we want them to do, this lens was perhaps designed around what we do not want it to do, and that is to create more visual disturbances. We know that visual disturbances are the major cause of unhappiness for patients, and the Vivity lens was designed to stretch and shift the wavefront to get as much intermediate vision as possible with low visual disturbances.

Dr. McCabe: Visual disturbances are a huge issue for patients, but when I tell a patient they are a risk factor for a presbyopia-correcting lens, they don't always understand what that means. A real strength of the Vivity IOL studies was how visual disturbance feedback was elicited from patients, by giving them very specific examples. Dr. Schweitzer, can you talk about that?

Dr. Schweitzer: Yes, these data were very eye opening to me. The study used a validated questionnaire to assess the frequency, severity, and bothersomeness of visual disturbances in an objective manner. The study had patients view control photographs of varying amounts of dysphotopsia, night vision disturbances, or other visual issues, and then report what they were seeing. In addition, patients could give a subjective assessment of how bothersome their visual disturbances were. When you look at starbursts and glare, greater than 74% of patients either did not experience them at all or, if they did experience them, were not bothered by them at all (Figure 5).[8] With halos, 83% of patients either did not experience them or were not bothered by them.[8] Perhaps more telling, 2% or less of patients did find each of those seven surveyed visual disturbances to be very bothersome in either the Vivity or the monofocal IOL implanted group.[8] That is why I can spend the majority of my time talking to the patient about intermediate vision and functional near vision, and much less time talking to them about visual disturbances. These study findings have really aligned with what I see with my patients in real-world settings.

Dr. McCabe: I agree, I don't feel that I have to address visual disturbances with the Vivity IOL to the same extent as diffractive IOLs, just as I don't address them with patients who get a monofocal IOL. Dr. Ahmed, are the data from the OUS study showing similar outcomes?

Dr. Ahmed: Both the US and OUS studies used validated questionnaires. It's one thing to ask a patient to report the severity of halos on a scale of zero to four, and it's another thing to show a patient standardized photographs and, based on those direct comparisons, report objectively what they are seeing. The data from the OUS study and the US study are very similar and show that the monofocal lens and the Vivity IOL provide low incidence of visual disturbances (Figure 6). I remained a little skeptical after seeing the trial data, but over almost a year of implanting Vivity in hundreds of patients, my clinical experience is similar to the study data with minimal complaints of glare,

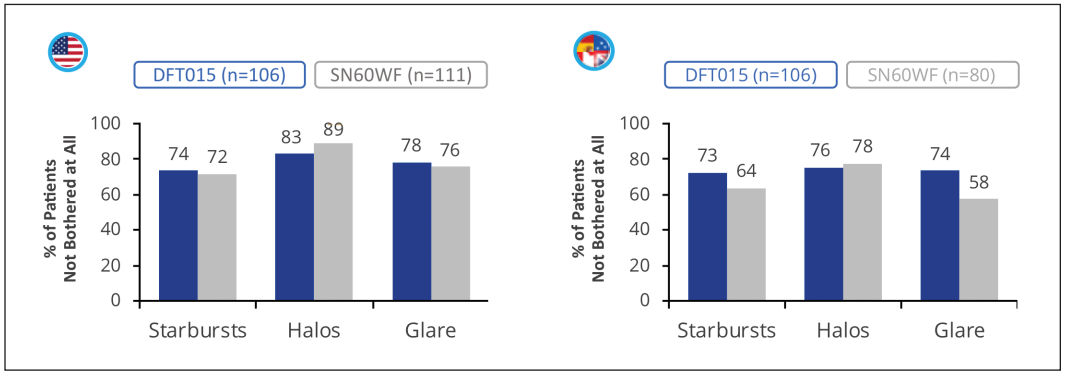

Figure 6. The percentage of patients "not bothered at all" by various visual disturbances was high in both the Vivity IOL and the monofocal control groups.[8,11]

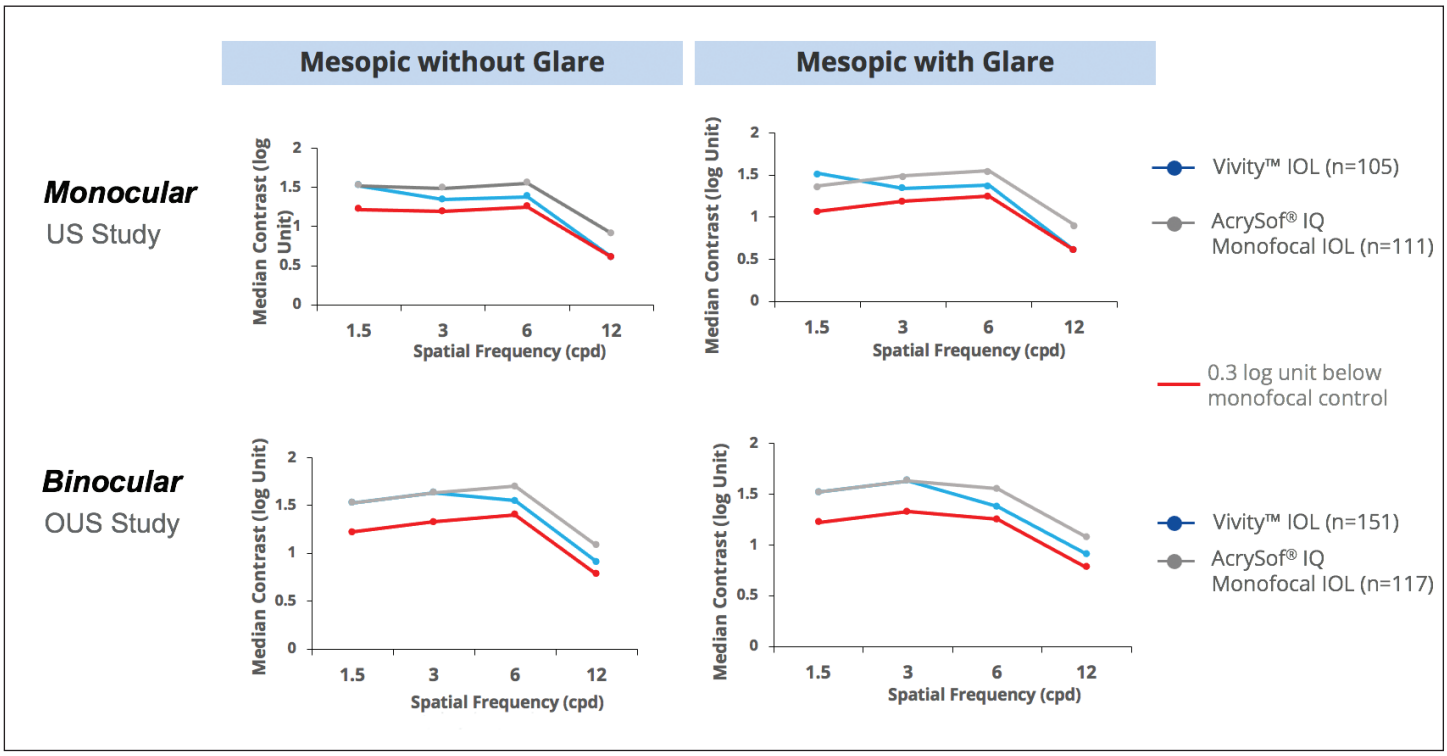

Figure 7. Mesopic contrast sensitivity results from two Vivity registration studies. Neither monocular (US) nor binocular (OUS) mesopic contrast sensitivity measurements in the two Vivity clinical registration studies showed clinically meaningful loss with Vivity versus monofocal IOL according to ISO 11979-7 standard. (Cpd, cycles per degree).

halos, or night vision issues.

Dr. Berdahl: What these data really show is how important a control group is. We all have a really good sense of how a monofocal IOL performs, and the take-home point is that Vivity, compared to a monofocal IOL, provides an extended range of vision from distance to near while maintaining a low incidence of visual disturbances, and we don't hear significant complaints from those patients.

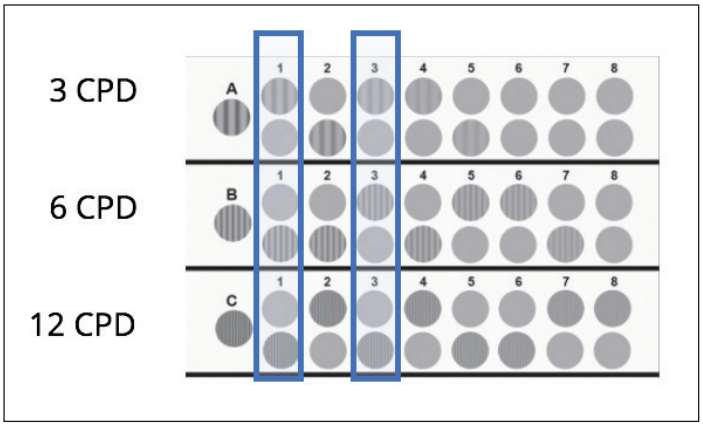

Figure 8. Sine-wave gratings used for contrast sensitivity (CS) testing in clinical studies. Each spatial frequency (e.g. 3 cpd) shows a reference patch (single circle) and then a pair of patches, one with a pattern at a specified contrast level and one without a pattern (blank). Each adjacent column represents ~0.15 log unit of CS difference. ISO standard 11979-7 defines the clinical meaningful CS change as 0.3 log unit loss (e.g. Column 1 vs. 3 or Column 2 vs. 4) at 2 or more spatial frequencies (e.g. 6 and 12 cpd).

CONTRAST SENSITIVITY

Dr. McCabe: Let's talk about another aspect of quality of vision: contrast sensitivity. It's hard for us to know what a reasonable surrogate is for quality of vision, and the closest we are able to quantitatively assess it is by measuring contrast sensitivity. We know that the US FDA labeling says that most patients implanted with the Vivity IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL, and that patients should be informed of the risk before implantation of the Vivity IOL.*[8] Dr. Berdahl, can you walk us through the contrast sensitivity test and the results with the Vivity IOL?

Dr. Berdahl: When a patient comes in and is frustrated with his or her quality of vision, the first thing I do is acknowledge that, and acknowledge that we are not really good at testing for that. Life is not black letters on a white screen in a dark room. We live in low lighting conditions, we have headlights coming at us in the dark when we are driving, and we live in various shades of gray with a huge range of other colors that may not be as vibrant. Visual quality is not the visual acuity we measure on a Snellen

*__Warning__: Most patients implanted with the Vivity IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic.

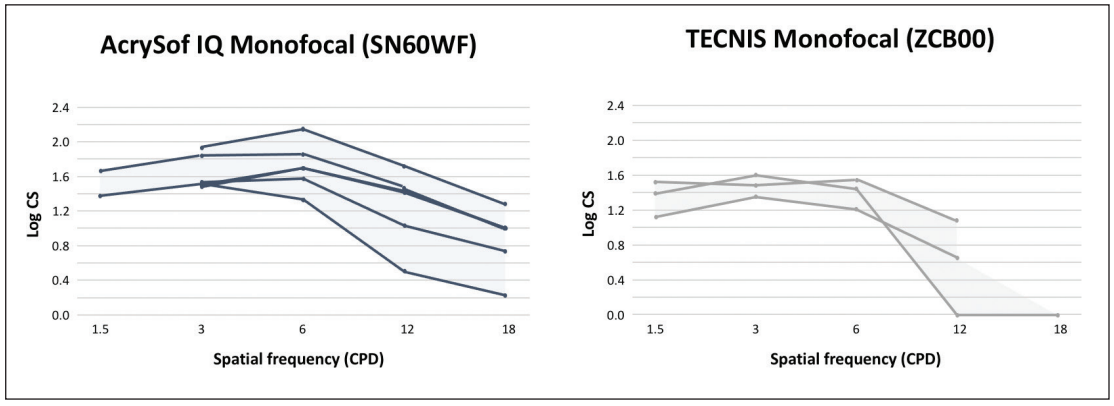

Figure 9. Contrast sensitivity measurement is subjective and has high variability. The plots contain monocular mesopic contrast sensitivity with glare data from various peer-reviewed papers[5,14-20] on two monofocal IOLs using sinewave grating based tests. The shaded areas show the high variation of contrast sensitivity results from different studies on the same aspheric monofocal IOL.

chart. Instead we may hear patients complain about waxy vision or difficulty reading signs at night, even though they can see them during the day.

Contrast sensitivity is probably our current best means of measuring this quality of vision. Contrast sensitivity testing is the measurement of how light a gray bar can appear and still be viewed, and how close together those gray bars can appear and be visually distinguished is the spatial frequency component. In contrast sensitivity testing, which is generally only done in clinical trials, we measure both the relative darkness and spatial frequency. Because we don't do this in daily clinical practice, it's hard to say what is clinically meaningful. According to the ISO standard, a clinically meaningful reduction in contrast sensitivity is a 0.3 log unit reduction at 2 or more spatial frequencies both monocularly or binocularly.[12]

In the US study, monocular contrast sensitivity was tested at mesopic light levels with and without glare.[8] Mesopic lighting with glare was considered the most visually compromising condition that could be experienced in a real-world setting. In this situation, a 0.3 log unit difference was seen between Vivity IOL eyes and monofocal IOL control eyes only at one high spatial frequency (12 cpd). However, patients in the OUS study were tested binocularly, which is how patients actually experience the world, and showed no difference greater or equal to 0.3 log unit at any tested spatial frequencies.[11] Neither monocular nor binocular mesopic contrast sensitivity measurements in the two Vivity clinical registration studies showed clinically meaningful loss with Vivity versus monofocal IOL according to ISO standard (Figure 7).[8,11]

Dr. McCabe: Dr. Ahmed, can you go into a little more detail on what this means for patients?

Dr. Ahmed: When we think about significant visual loss, we talk about 2 lines of vision (3 lines or 15 letters considered by FDA). To us, that would be pretty significant and clinically relevant. Transferring that idea of two lines of vision to two sine wave gratings, which is how we measure contrast sensitivity, isn't the same thing. When I think of 0.3 log unit loss, or two of those circles (e.g. Column 1 vs. 3) in the highest spatial frequency (12 cpd) in mesopic condition with one eye (Figure 8), it is barely discernible for most people. I think the take-home message here is that we have to be careful statistically and mathematically with what we can measure in terms of contrast sensitivity.

Dr. Berdahl: A lot of times we think of monovision with monofocal IOLs as a very safe way to correct presbyopia, but it has been shown that the binocular contrast sensitivity can decrease significantly to or below the level of monocular contrast with the traditional monovision due to the binocular inhibition.[13]

Dr. Ahmed: I think that quality of vision is very important, and, in our practice, we do measure it regularly. However, this is a difficult

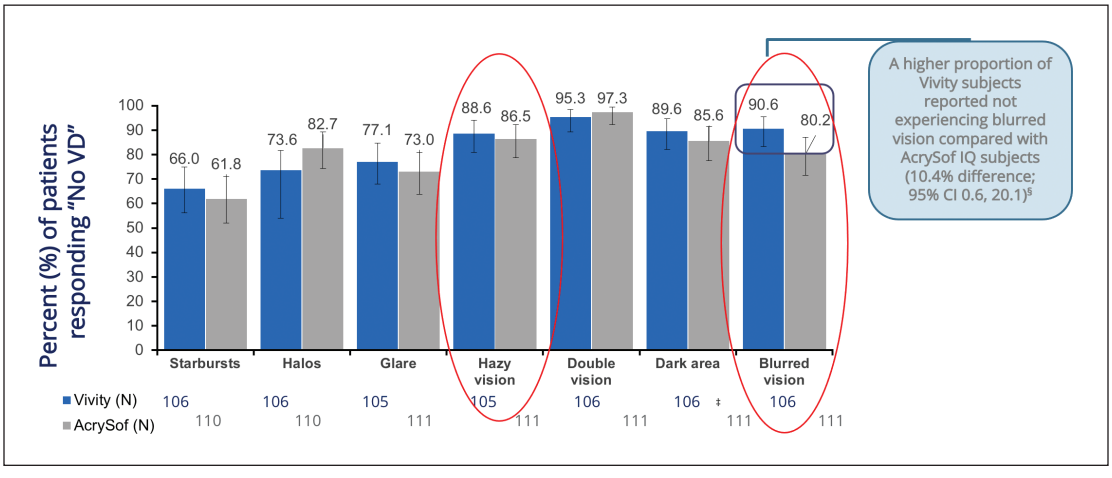

Figure 10. A high percentage of Vivity-implanted patients reported no experience of "Hazy or Blurred Vision," which are the terms patients often use to describe contrast sensitivity issues. The validated Questionnaire for Visual Disturbance (QUVID) was used in the US Vivity Registration study.[8]

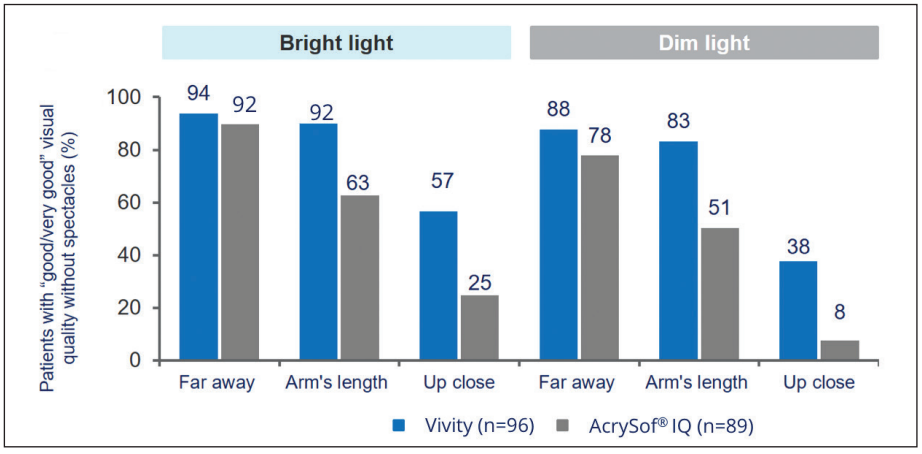

Figure 11. Similar or more Vivity-implanted patients reported "good or very good" vision without spectacles under both bright and dim light. The validated IOLSAT Questionnaire was used in the US Vivity Registration study.

and subjective test. As just stated, even individuals with great vision may struggle to recognize the gratings, especially when it comes to high spatial frequencies with variable intensities. The test itself is very much subjective, and we do need a better understanding of our metrics. Even monofocal lenses show a variability from high end to low end that can make interpretation difficult (Figure 9). Thus, it is really important to listen to our patients and not just look at an eye chart or a sine wave grating. In the OUS study of the Vivity IOL, we looked at binocular vision, and the binocular contrast sensitivity was very good, even by ANSI standards.

Dr. Berdahl: I want to put Dr. Ahmed on the spot a little bit. Dr. Ahmed, would you go so far to say we are denying some people the advanced IOL technology because we over-represent some tests, and that technology really should be available to more patients?

Dr. Ahmed: I think it's an evolving field. Some of the older presbyopia-correcting IOLs were not as strictly evaluated in terms of contrast sensitivity in studies, whereas some of the modern presbyopia-correcting IOLs, which have been very strictly evaluated, have much-improved technology. We may need to think twice about just looking at certain criteria, contrast log units, which don't have a clear or direct clinical link to performance or patient satisfaction yet.

If you were to poll surgeons and ask them what contrast sensitivity means to them in terms of patient function, most would talk about how patients perform in dim lighting. That may be dusk, or a room with low lighting. Looking at some of the surveys that have been done, that is what most of us think of when we consider contrast sensitivity. If we look back at some of the different aspects when we studied visual disturbances, hazy vision and blurry vision would be similar to low contrast sensitivity, or hazy, waxy vision. Something critical in our studies is that we have a control group with a monofocal lens, and you can see there is actually no significant difference in terms of hazy or blurred vision between patients who received the monofocal IOL in the control group or those who received the Vivity IOL (Figure 10). In fact, Vivity patients had less blurred vision than patients in the control group.[8] This is not surprising considering the increased range of vision of the EDOF IOL. Certainly, this data on patient-reported blurred or hazy vision does not support concern for single high spatial frequency monocular contrast reduction having any subjective patient impact.

Now, to take this one step further, we can look at another subjective questionnaire in these studies. The IOLSAT Questionnaire was used in this case to assess satisfaction with visual quality. Rather than asking about visual disturbances, this questionnaire asks patients how they perform and what their quality of vision is at far, arm's length, or up close in bright condition and dim lighting. Dim lighting is where we are really concerned about loss of contrast. Again, Vivity performed better at near and arm's length and similar at distance compared to the monofocal IOL (Figure 11).[8]

To summarize, although we can debate specific testing technologies and the clinical significance of sine wave gratings, all of the subjective and objective data we collected show that, in terms of visual acuity at different distances and quality of vision, Vivity performs similar to or better than the monofocal AcrySof IOL.

SURGEON EXPERIENCE WITH VIVITY

Dr. McCabe: Clinical trial data is always interesting and important, but we know that the real world is different. Study patients have been treated like VIPs. They received exceptional technology at no additional expense, and they just tend to be happy patients. If someone is not relatively easygoing, they don't volunteer for a clinical trial. Are the study data really representative of your experience implanting Vivity in patients?

Dr. Zhu: I'm happy to report that my experiences do align with the FDA study. I'm pleasantly surprised as patients get a little bit more functional near vision than I was expecting. Seventy-five percent of my patients are getting around J3 or better at 40 cm, but there is a large portion that is consistently hitting J2, or sometimes even J1.

Dr. Berdahl: I'd like to point out that this lens is designed for surgeons who maybe haven't had a good experience with multifocal IOLs, specifically with diffractive optics, or who perhaps don't have the ability to offer a postoperative enhancement procedure. We know that with some diffractive lenses, there is very little tolerance for residual refractive error. With a flat defocus curve, if you are slightly off on either side of plano, the Vivity IOL is much more forgiving. You may lose some functional near vision, but the distance vision is still going to be very good. This is helpful for

surgeons just becoming acquainted with presbyopic IOL technology.

Dr. Schweitzer: We are also seeing very nice outcomes that reflect the clinical trial, and the flat defocus curve around distance really is very forgiving. There is something to be said for this, as it allows patients to have nice, clear distance vision. I have no hesitation offering this lens to patients who are demanding of high-quality distance vision because of the forgiveness inherent to that flat defocus curve.

Dr. Ahmed: One consideration when looking at results is whether they are monocular or binocular testing. Many of the FDA clinical reports show monocular testing, which may be appropriate in some situations. However, real-world binocular vision is by far a more important metric for our patients. When we implant the Vivity IOL in both eyes, we see an improvement in some of those functional outcomes like Dr. Zhu mentioned.

Dr. McCabe: How are you targeting the refractive results with this lens?

Dr. Ahmed: I'm typically targeting for plano, as is recommended on the label. I will say that I have pushed the limits in some patients. In some patients we have aimed the non-dominant eye for a slight myopic result, perhaps -0.5 D, which would be considered micro-monovision. But because the focused zones are very much overlapping, we are not creating two separate focal points at distance. This retains very good distance vision while pushing the patient a little bit more towards J1 for that functional near vision. This is still a case-by-case discussion, but we have had some experience with this and may spread the limit a little bit for patients.

Dr. Berdahl: Hitting the refractive target in post-refractive eyes remains more difficult than with an untouched cornea, because you wonder if the prior surgery is altering how light is transmitted through the cornea and how that might combine with different optics. I find that the Vivity IOL is forgiving because it is not splitting light and the wide landing zone with the flat defocus curve makes it easy for us to provide good distance vision performance.

Dr. Schweitzer: To add to that, post-refractive patients are accustomed to having very good distance vision and they don't want to give that up. Although the Vivity IOL has not been studied in patients with previous corneal refractive surgery, it is a good option for us to consider because it is forgiving at distance, and it provides the added benefit of intermediate vision, which a post-refractive patient likely also does not want to give up.

PATIENT SELECTION

Dr. McCabe: Are there certain patient populations where you think Vivity fits particularly well?

Dr. Zhu: A lot of my patients had LASIK many years ago, and they come back to me wanting to be free from spectacles again. I tell them that with time, their eyes have changed and they are never going to get that back. But I do have options that may reduce their dependence on spectacles. For me, Vivity fills a gap where otherwise I might have used a monofocal IOL with a monovision approach, which many patients don't tolerate. I do implant diffractive or trifocal IOLs on occasion, but there are some patients who are not a good fit for that option based on their higher order aberrations (HOA). Personally, I am comfortable implanting the Vivity EDOF IOL in this patient population. I have been able to increase the pool of patients receiving much-wanted presbyopia-correcting technology. I think that the Vivity lens is a little bit more forgiving and achieves great quality of vision while still maintaining a high level of spectacle independence.

There is not a perfect lens for every patient, but by matching the lens to the patient's visual needs, anatomy, and physiology, we get as close as we can to identifying their individual ideal lens. I think it's important to note that different IOLs fill different roles and complement rather than cannibalize each other. In my practice, I use both trifocal IOLs and the Vivity EDOF IOL, every day making the determination of whether a patient would be better off with one or the other. Vivity definitely lets me expand the pool of patients who are potential candidates for a presbyopia-correcting IOL.

Dr. Ahmed: It is important to look at a patient's occupational issues and their interests, in addition to considering any comorbidities in the eye. Glaucoma is a reason to be careful. We know that it can affect contrast sensitivity, but I don't think it's an absolute reason not to use multifocal presbyopia-correcting technology. I do warn patients, especially those with moderate to severe disease, but we have discussed Vivity's performance, and I personally do feel more comfortable using this lens in glaucoma patients, especially those at an early glaucoma stage. If a patient is not a good candidate for a diffractive presbyopia-correcting lens for another reason, they may still be a good candidate for

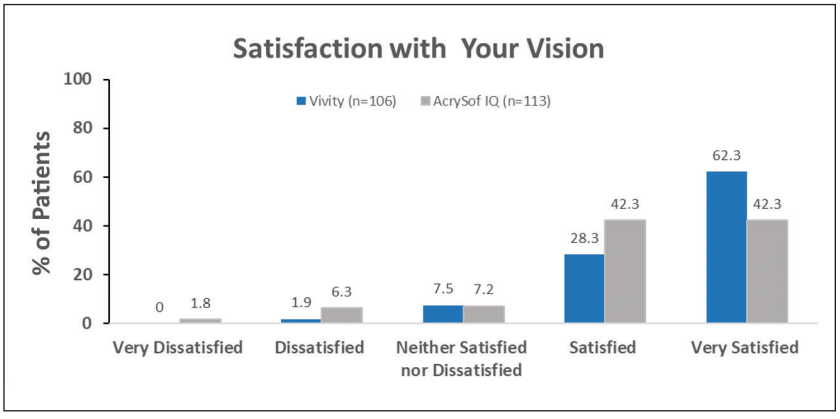

Figure 12. More than 90% of patients receiving the Vivity IOL were satisfied with their vision, a greater percentage than those that received the AcrySof IQ monofocal IOL.

Vivity, in my opinion. In our own experience with small series of patients that have had Vivity implanted, it is a lens that remains in consideration when other multifocal IOLs may not.

Dr. Schweitzer: I agree with Dr. Ahmed on glaucoma patients. We are careful, but we see so many glaucoma patients who don't want a traditional monofocal implant. They want to have independence from spectacles at distance and intermediate, so we have utilized the Vivity lens in our glaucoma patients. We have also utilized this IOL in patients with a few guttata or small epiretinal membrane just outside the macula when we were hesitant to use a diffractive IOL.

Dr. Berdahl: Although the safety and efficacy have not been established in cataract patients with glaucoma, we should use sound medical judgement when treating these patients. If I feel that we can keep the glaucoma under control and it's not going to progress, for example, in a patient with pre-perimetric glaucoma who has well-controlled IOP, I feel very comfortable using the Vivity IOL.

PATIENT SATISFACTION

Dr. McCabe: The US clinical trial for Vivity showed that more than 90% of patients were "satisfied" or "very satisfied" with their vision, and 90% reported that they would have the same lens implanted again (Figure 12).[21] Does the patient satisfaction data reflect what you are seeing in your own practices?

Dr. Berdahl: I would say that we have a high percentage of satisfied patients, and that is due to both the education we are able to provide preoperatively and the work we are able to do postoperatively. We have not enhanced any patients postoperatively.

Dr. Zhu: When I initially saw the 90% satisfaction rate, I thought that was really great. But, I wondered what was bothering those 10% in the FDA trial? It's probably not the quality of vision because we have seen the visual disturbance profiles and patient-reported quality of vision in Vivity versus the monofocal IOL group. I would surmise that the 10% were disappointed because they did not achieve as much near vision as they had hoped. However, if you are able to educate patients on why they may not be an ideal candidate for a multifocal IOL, while explaining that there's another lens that can give great intermediate and even functional near with low incidence of visual disturbances, then they'd be a lot happier with their outcomes. This is especially true if you help patients realize how much more they would be gaining with the Vivity IOL compared to a traditional monofocal, which would require them to use readers in almost all conditions. Once patients understand that the Vivity offers the better chance for achieving spectacle independence in their particular case, I think that the satisfaction rate would be high.

Dr. Ahmed: Satisfaction equates to meeting expectations. My approach has been to use a top-down approach. I start by discussing the options for a full range of vision, such as a trifocal IOL, and explain both the positives and the negatives, particularly in regard to night vision issues. That sorts out the good candidates. For those who are not good candidates for a trifocal, I introduce the non-diffractive EDOF IOL and tell them that they will still get some benefits of an extended range of vision with low incidence of visual disturbances. This really shows them that they are gaining something and losing something. I minimize what the Vivity IOL might achieve at near because then I am meeting and exceeding their expectations, and patient satisfaction is even higher.

I believe that every patient should be given a chance to have a trifocal IOL if they are a good candidate. That should be our first null hypothesis. From there, we go into other options. This helps patients understand their perspective of options and increases their satisfaction.

Dr. McCabe: I like to use the comparison that everything after 40 is a compromise! But I agree that we have many excellent solutions, and I find the best strategy is to understand the needs of the patient and have them take ownership of the option they have chosen.

HOW DOES VIVITY CHANGE YOUR CLINICAL PRACTICE?

Dr. McCabe: We focus a lot on patient selection and patient satisfaction with IOLs, but we often forget to discuss surgeon profiles. The reality is that many surgeons, for whatever reason, are not comfortable with multifocal technology. The Vivity IOL is a nice way for these surgeons to enter the arena of presbyopia-correcting technology. It is a forgiving lens that can be used in a wider range of patients with less potential downside. Vivity will allow surgeons to gain experience with presbyopia-correcting options. What are your thoughts?

Dr. Berdahl: I agree that Vivity is a good lens for surgeons who are a little uncomfortable with diffractive multifocal or trifocal technology. The long landing strip that you get with the flat defocus curve is helpful. The fact that patients should have a low incidence of glare and halo is also helpful. As long as it is made clear that this lens should provide good distance, intermediate, and some functional near vision, Vivity is a really great place for surgeons to start.

Dr. Schweitzer: On the optometrist side, I have colleagues who may not recommend a diffractive IOL because they don't feel that the visual quality is where they hope to be. This is an opportunity for them to get comfortable comanaging with a presbyopic IOL that has a low incidence of visual disturbances. If they make that referral to a surgeon who is offering Vivity, they are going to have fun on the postoperative end with a happy patient who has great distance vision and some independence from their spectacles—maybe not complete independence, but some independence.

Dr. Ahmed: I have spoken to many colleagues who have dabbled in presbyopia-correcting lenses. They have tried a few multifocal IOLs and maybe had one patient who had bitter complaints

of halo and glare that turned them away from the whole category. Visual disturbances are one of the biggest reasons for dissatisfaction from patients who are not properly selected and educated. A low incidence of visual disturbances gives surgeons more confidence to try the Vivity IOL.

Dr. Zhu: I have a lot of young colleagues who are sticking with monofocals and reluctant to take that first jump into the diffractive multifocal arena. They don't want to have unhappy patients as they're just starting their career. I think the Vivity is the gateway lens that will get them to the next step, because as we've said, it's very forgiving. It gives similar quality of distance vision to a monofocal with so much better intermediate and functional near. Current adoption of premium correcting IOLs is still around 8-9%. I think that's going to jump a lot higher with the Vivity lens.

CONCLUSION

Dr. McCabe: I think we all agree that the clinical trial data for Vivity are very positive. The extended range of vision from distance to intermediate and functional near, with forgiving refractive targeting around distance and a low incidence of visual disturbances, really make the Vivity IOL an excellent presbyopia-mitigating option for many patients. This can be a simple and straightforward area of expansion for a practice and provides a great benefit to our patients. ■

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