Personalizing Vision:

A patient-centric approach to delivering outstanding outcomes.

- How to assess patients' visual goals
- Lens design and materials
- Tips for your first Personalized Vision cases
- Post implantation outcomes with extended depth of focus and multifocals
- Visual outcomes and patient satisfaction with Personalized Vision strategies

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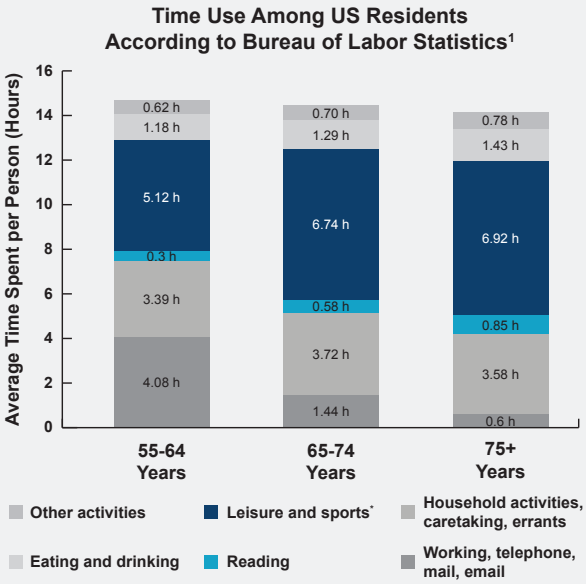
Johnson & Johnson VISION

Personalizing Vision: A patient-centric approach to delivering outstanding outcomes.

Cataract surgery presents a wonderful opportunity for patients to be less dependent on glasses so they have the freedom to enjoy a youthful lifestyle and their favorite activities—sometimes, for decades to come. Consider that last year nearly one million Americans had cataract surgery at age 65 or younger.[2,3] Unlike previous generations, today's cataract patients are not only having surgery while they're still very active, they are also increasingly engaged in visually-demanding activities. For example, more than 70% of Americans over age 50 own smart-phones[4] and spend about 4 hours per week on social media.[5] The boomer generation is also working longer, constituting about one-forth of the workforce.[6] In fact, one in ten predict they will never retire.[7]

Our goal as cataract surgeons should center on finding out what's important to each patient and then selecting a surgical plan that is unique to that patient.



*Leisure and sports activities included exercise, recreation, socializing and communicating, watching TV, relaxing or thinking, playing games, using a computer for personal interest, playing or listening to music, and attending arts, cultural, and entertainment events. Many of these activities require intermediate vision. Figure excludes sleeping and personal care activities.

Personalized Vision is an excellent way to achieve this and it's much easier than you might suppose. In the pages that follow, surgeons who have studied and embraced Personalized Vision share their strategies and advice, as well as findings from clinical studies evaluating the implantation of a TECNIS Symfony® IOL in one eye and a TECNIS® Multifocal +3.25 D IOL in the fellow eye.

*— **Eric Donnenfeld, MD***

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Assessing Cataract Patients' Visual Goals and Expectations

By Karolinne Maia Rocha, MD, PhD

No matter what IOL you choose, assessing a patient's unique visual goals is crucial to providing a satisfactory outcome. Once patients are in your chair, engage them in conversation to find out what they do and how they spend their time. Are they having trouble hitting a golf ball, driving or reading? Which of these do they most want you to address?

You can get the information to begin a conversation from the Johnson & Johnson Surgical Vision Questionnaire. But don't stop there. Keep in mind that you want to also provide as much continuous vision as possible. Personalized Vision is a great way to do just that.

Keep It Simple

Standardize the surgical consult. Train your staff and referring optometrists on how to educate patients on premium technologies. Everyone should be speaking the same language and using the same materials at all times. This ensures consistency and quality of the patient conversations.


Johnson & Johnson VISION

VISION FOR YOUR LIFESTYLE.

SURVEY FOR CATARACT PATIENTS

You have an important decision to make about your vision future.
This survey is designed to help us understand your vision goals so we can provide you with the best possible lens for your lifestyle.

1 **Throughout the day, you perform activities that require your eyes to focus at different distances.**
Circle or write in the activities that are most important for your lifestyle:

DISTANCE
Driving · Golf · Sporting events · Scenery
OTHER

INTERMEDIATE
Car dashboard · Computer · Grocery shopping · Mobile phone or tablet
OTHER

NEAR
Fine print · Games & puzzles · Sewing · Makeup
OTHER

American adults spend >11 hours per day using media/electronics, many of which require intermediate vision.[8]

Today's patients spend substantial time on activities that require intermediate and distance vision.

When you're ready to discuss options, keep the conversation simple. Don't get mired down in a complex discussion about technology and optics—this is generally too technical to be meaningful to the patient. Instead, focus your conversation on visual goals.

For example, a conversation about mitigating the visual handicap of presbyopia will make much more sense to most patients than comparing and contrasting multifocality versus extended depth of focus. These are concepts that are important for surgeons to understand, but most patients can't relate. That being said, we can still explain how these two options are experienced differently. For instance, if you want to proceed with bilateral TECNIS Sym*f*ony® IOLs, you might explain that your goal is to make it easier for the patient to drive, use a computer, and scroll through messages on a cell phone, but they still may have difficulty reading the fine print on a medicine bottle.

If you are considering Personalized Vision with a TECNIS Sym*f*ony® IOL in one eye and a TECNIS® Multifocal +3.25 D IOL in the fellow eye, you could expand upon the previous description by adding that this combination may also make the patient less dependent on glasses when they're enjoying the Sunday paper or sewing or working on a crossword puzzle. Whatever the near task may be, if it's something that the patient is very passionate about, we should factor that into our treatment plan.

The Importance of Lens Design and Materials in IOL Selection

By Daniel H. Chang, MD

Many attributes deserve consideration when selecting an IOL platform. Many of these are practical concerns such as how well the IOL handles in the OR and how easily it unfolds. But optics is at the top of my "must-have list" and this can't be measured using only a Snellen chart. If you ask patients what quality of vision looks like, they'll likely describe it using terms like vibrancy, sharpness, color, and contrast. This is how patients experience their everyday lives.

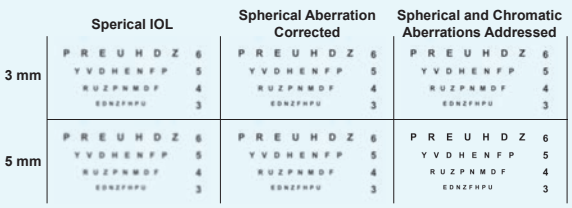
Spherical Aberration

Scientifically speaking, quality of vision is about minimizing aberrations, such as spherical aberration and chromatic aberration. Spherical aberration is a fourth order aberration that generally reduces retinal image contrast and affects visual quality—particularly under mesopic conditions.

IOL material and design affects aberrations, and minimizing aberrations maximizes optical quality.[13] In other words, correcting corneal spherical aberration can improve image quality, and as spherical aberration is reduced, image contrast is increased.[13]

Spherical aberration is additive and young healthy eyes have little net spherical aberration. In patients undergoing cataract surgery, we should endeavor to correct it. While it is different for everyone, average corneal spherical aberration is 0.27 microns, and only TECNIS® IOLs correct the full spherical aberration of the average cornea.[13]

TECNIS® deliver highest-quality* vision by addressing both chromatic and spherical aberrations[14]



Simulated images for illustrative purposes only. *Against IOLs that correct only spherical aberrations based on technical features.

Safety/Falls

By Daniel H. Chang, MD

Presbyopia correction isn't just a luxury or a convenience—it's a question of safety. **Falls are the leading cause of serious injury in the elderly and bifocal, multifocal, and progressive glasses increase patients' risk of falling**. In fact, this eyewear makes patients 2.3 times more likely to fall, and more than one in every three falls are attributable to bifocal glasses.[9]

What happens when our elderly patients fall? In a typical year, 800,000 elderly people are hospitalized for falls, with more than 27,000 of these resulting in death—meaning more elderly people die from falling than they do from breast or prostate cancer.[10]

These statistics are not usually at the top of our minds as ophthalmologists because we don't see these patients as a result of their falls. They don't come to our clinic and complain, they go to the emergency room, or to the funeral home. But we can (and do) help these patients all the time, perhaps without even realizing it. That's because cataract surgery reduces the fall rate by one third.[11] And for patients who say they regularly take part in outdoor activities, eliminating bifocal glasses can reduce falls by up to 40%.[12]

Chromatic Aberration

Chromatic aberration is caused by the chromatic dispersion of light through optical materials. The phakic eye has a baseline longitudinal chromatic aberration due to the cornea and the crystalline lens. In pseudophakic eyes, the IOL implanted can potentially increase or decrease the eye's longitudinal chromatic aberration relative to the phakic state, depending on the properties of the IOL.[15]

Both the cornea and the lens induce chromatic aberration in the eye, causing light to blur. As white light passes through an optical system, each of its component wavelengths bends independently. By Snell's law, faster-moving, longer wavelengths bend less than slower-moving, shorter wavelengths, dispersing the various

colors to different focal points along the optical axis. This dispersion is referred to as longitudinal chromatic aberration.

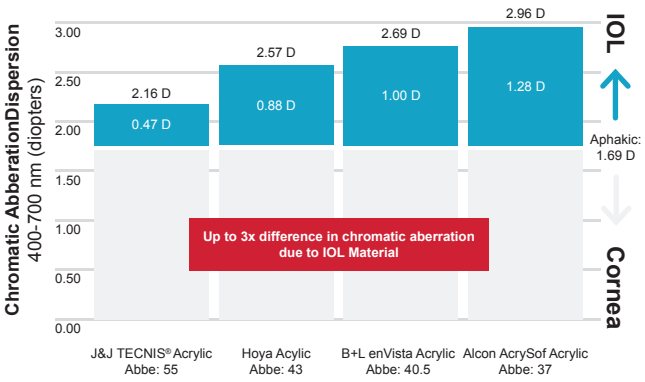
Unlike spherical aberration, chromatic aberration is similar in all eyes. The average amount of chromatic aberration in an aphakic eye (from the cornea alone) is 1.69D. Importantly, chromatic aberration is additive, which means that the IOL you choose will add to whatever chromatic aberration is already present in the cornea. TECNIS® IOLs were designed to minimize chromatic aberration and avoid making it worse than the aphakic eye.

What's even more remarkable is that the TECNIS Sym*f*ony® doesn't simply minimize the addition of chromatic aberration; it was engineered to reduce it. In fact, the TECNIS Sym*f*ony® IOL delivers contrast sensitivity with no clinically significant difference compared to a high quality aphakic monofocal IOL,* yet patients enjoy the added benefit of continuous range of vision.[16,17]

Quantity and Quality

TECNIS® IOLs were designed to deliver high quality vision. This optical platform quality, combined with the unique extended depth of focus properties of the TECNIS Sym*f*ony® IOLs provide high-quality, continuous vision at

There is up to 3 times difference in chromatic aberration due to IOL material.[19]



all distances, day and night.[16,17] Consider:

- 91.2% achieved 20/25 or greater uncorrected distance visual acuity.[18]
- 96.6% achieved 20/25 or greater uncorrected intermediate visual acuity.[18]
- 84.4% achieved 20/32 or greater uncorrected near visual acuity.[18]

As our experience with EDOF has grown, so too has our ability to Personalize Vision even further, providing more options for patients who have greater near vision desires.

You're The Expert: Make a Recommendation

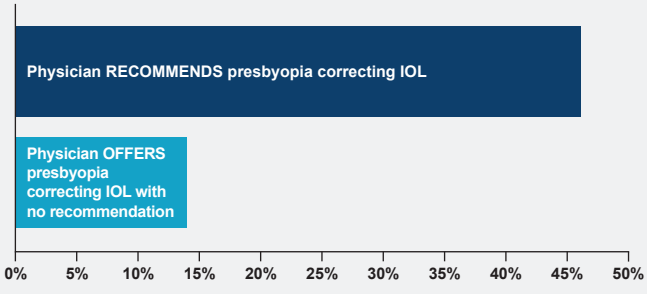
Once you have a clear understanding of the patient's desires and have reviewed the history and relevant pre-operative exam findings, review the treatment options with the patient. Importantly, do not make assumptions about patients' financial situations.

Explain the benefits and the possibility of visual complications with each option. Patients usually have questions, so be ready to answer them. Furthermore, if a family member is present at the exam, ask him or her if they have any questions.

Once you agree upon a plan to achieve the patient's visual goals, confidently articulate the steps. If your plan depends upon the outcome of pending tests, say so, but make it clear that you know what you will do with the results.

Patients are twice as likely to choose a presbyopia-correcting IOL when you make a recommendation.[20]

Likelihood of patient selecting a presbyopia correcting IOL when surgeon RECOMMENDS versus OFFERS



N = 143

D.S. Howard & Associates Market Research, August 2016

***WARNING**: The TECNIS Symfony® IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity. Patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.



Getting Started with Personalized Vision

By Eric Donnenfeld, MD; Mark Kontos, MD; and Kerry Solomon, MD

As surgeons, we know that refractive cataract surgery involves compromise that's difficult for patients to understand without experiencing it. With out-of-pocket presbyopia-correcting procedures, patient expectations are understandably high. The reality is that patients expect exceptional outcomes and quality of vision at all distances. Fortunately, as our experience with TECNIS Sym*f*ony® IOLs has grown, we have found ways to personalize vision so that each patient's treatment plan is customized to their unique preference and visual demands. For a growing number of our colleagues Personalized Vision using the TECNIS Sym*f*ony® in one eye and the TECNIS® Multifocal +3.25D in the fellow eye has proven to deliver outstanding results and high patient satisfaction.

First Cases

If you are new to TECNIS Sym*f*ony® IOLs, we recommend that you begin with several bilateral implantations before personalizing vision by combining treatment with a multifocal. TECNIS Sym*f*ony® is very unique in that it is the ONLY FDA-approved extended depth of focus IOL[21] and it provides high-quality, continuous vision at all distances, day and night.[16,17] Multifocal IOLs heralded a change in our ability to offer good visual acuity at distance and near, but many patients reported a gap in intermediate vision or a less than optimal vision experience at night or in dim environments. The introduction of the extended depth of focus IOL was therefore a breakthrough in the ability to better meet the evolving needs of our active presbyopic patients. However, since this is a very different kind of IOL, it may be helpful to have a full understanding of how patients experience and react to extended depth of focus before combining it with other types of IOLs.

In our own practices, we are moving in the direction of Personalized Vision more often but we still perform bilateral TECNIS Sym*f*ony® procedures often.

Personalized Vision Pearls

- **Get comfortable** with several bilateral TECNIS Sym*f*ony® IOL cases before mixing lenses.
- **Discuss** lifestyle and find out what's important to each patient.
- **Perform a thorough** ocular surface evaluation and pre-treat dry eye and MGD before obtaining final IOL measurements.
- **Customize** your preferred lens combination based on the patient's **unique** preference and visual demands.
- **Set appropriate** patient expectations.
- **Aim to provide** as much continuous vision as possible.
- **Determine** which eye to start with. In most of our cases, this is the dominant eye.
- **Assess the patient** after the first eye is implanted to determine whether to proceed with your original surgical plan.

Clinical Options

Two important considerations when selecting Personalized Vision using the TECNIS Sym*f*ony® in one eye and the TECNIS® Multifocal +3.25D in the fellow eye are:

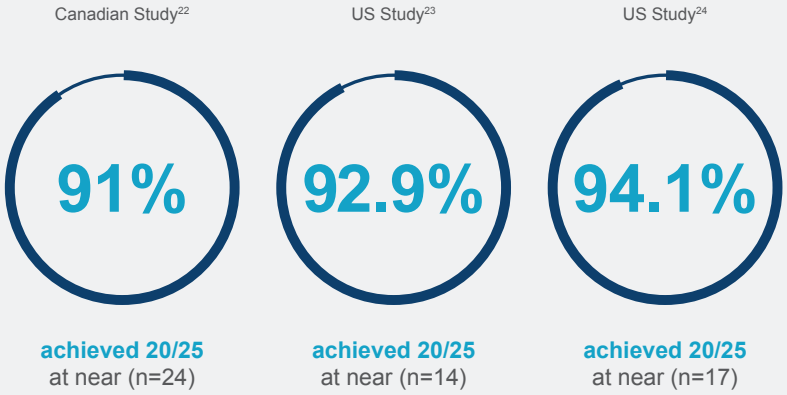
1. Which eye should you start with?

2. How should you combine lenses based on eye dominance?

In most cases, we begin with the TECNIS Sym*f*ony® IOL in the dominant eye. If you perform surgery on the non-dominant eye first, from a neuroadaptation standpoint, it can throw patients off a bit because you've improved the vision in the weaker eye. This can make the period between the two surgeries more challenging for the patient. The other risk when starting with the non-dominant eye is that the patient won't even realize the improvement because they are still relying so heavily on the vision in their dominant eye.

Personalized Vision with the TECNIS Symfony® IOL and the TECNIS® Multifocal +3.25 D provides excellent full range of vision with outstanding near visual acuity as evidenced in several recent studies.

Canadian study conducted by Dr. Jeffrey Machat.[22]
US study conducted by Dr. Mark Kontos.[23]
US study conducted by Dr. Kerry Solomon.[24]



Although we typically start with the dominant eye, in certain cases starting with the TECNIS® Multifocal +3.25D in the non-dominant may be wise—particularly if you have significant concerns that the patient will have a hard time adjusting to any potential night vision symptoms based on personality or concerns that the patient may have voiced during the consult. If the patient is happy after the first surgery, we'll usually proceed as planned by implanting the TECNIS Symfony® IOL in the dominant eye. However, if the patient is not responding in a positive way to the TECNIS® Multifocal +3.25D in the non-dominant eye, we can put a monofocal in the dominant eye.

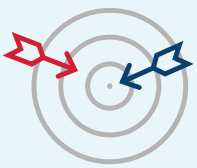
A New Era

As the studies here reveal, Personalized Vision can offer outstanding outcomes, and the skills required to achieve them are not foreign to experienced cataract surgeons. For example, just as with any presbyopia-correcting procedure, Personalized Vision requires close inspection of lifestyle, history, exam findings and measurements.

TECNIS Symfony® IOLs gave us so much of what we were looking for in an IOL, and with the option of Personalized Vision, we can further refine this for those patients who want to achieve superb vision from near to far, and anywhere in between.

Pre-operative Dry Eye and MGD Management Essentials

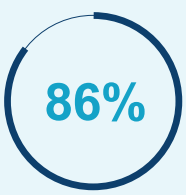
In a cataract and refractive surgical practice, it is imperative to diagnose dry eye disease preoperatively, since this can affect your preoperative biometry measurements. Research shows that patients who had osmolarity scores within normal limits were within a half diopter of intent, whereas 17% of those with hyperosmolarity would have missed their IOL calculation by more than a diopter.[25]



17% **of patients with hyperosmolarity** missed the IOL calculation by **MORE THAN A DIOPTER**[25]

Patients who had **osmolarity scores within normal limits** were within a **1/2 DIOPTER**[25]

Look at the tear film, the topography, the cornea, the conjunctiva and the lids. Importantly, express the meibomian glands to assess meibomian gland function and, if it is available in your practice, perform meibography with LipiScan™ or LipiView® to assess meibomian gland structure. Meibomian gland dysfunction (MGD) has been shown to affect 86% of patients with dry eye. MGD has also been shown to worsen in the post-operative period, after cataract surgery.[27,28]



Percentage of patients with dry eye affected by MGD[26]

Outcomes Post-Implantation of an Extended-Depth-of-Focus Intraocular Lens When Combined with a Multifocal +3.25 D Add Intraocular Lens

By Kerry D. Solomon, MD

Since their introduction, we've been implanting TECNIS Sym*f*ony® IOLs bilaterally with great success but have continued to look for ways to deliver a little more near vision. Over the years, we've collected historical data on patients implanted with bilateral TECNIS Sym*f*ony® IOLs targeted for emmetropia OU or nanovision* (dominant eye: emmetropia and non-dominant eye: -0.50 D). For this current study,[24] we used these two groups as a historical control, comparing them to patients receiving a Personalized Vision procedure using a TECNIS Sym*f*ony® IOL in the dominant eye and a TECNIS® Multifocal +3.25 D in the non-dominant eye.

After reviewing the data for 71 patients (emmetropia n=29, nanovision n=25, Personalized Vision n=17), we found that:

- Binocular UCNVA uncorrected near vision acuity was significantly better in the Personalized Vision group ($p<0.001$) compared to the emmetropia OU and nanovision groups. In fact, 94.1% of patients who received TECNIS Sym*f*ony® IOL in the dominant eye and a TECNIS® Multifocal +3.25 D in the non-dominant eye had uncorrected near of 20/25 or better.

Visual Function Outcomes

71 Patients

(emmetropia n=29, nanovision n=25, Personalized Vision n=17)

94.1% of patients who received TECNIS Sym*f*ony® IOL in the dominant eye and a TECNIS® Multifocal +3.25 D in the non-dominant eye had **uncorrected near of 20/25 or better**.

- Personalized Vision and nanovision appear to improve near visual acuity without decreasing distance or intermediate visual acuities.

Given the outstanding results we have seen thus far with a Personalized Vision approach, we have chosen to continue enrolling patients in this ongoing study.

Avoid Common Pitfalls

Many problems stem from poor communication. Consider the following pitfalls:

❑ Whatever lens combination you select, be **honest and upfront** with patients about what they can expect postoperatively.

❑ Be very careful when patients say they want to "get rid of glasses." **Don't over promise**. Focus on the words "less often" when referring to post-op reliance on glasses.

❑ **Set reasonable timelines** for neuro-adaptation of reading at intermediate and near distances.

❑ **Explain visual disturbances,** letting patients know that these should become less noticeable over time but some patients might notice them permanently.

❑ Keep in mind that low myopes in particular are used to sharp near without glasses and binocularity. It's especially hard for this group to relate to the reality of any visual struggle, so **choose your words wisely** when describing presbyopia-correcting IOLs.

❑ If a low myope requests a monofocal, **be certain to clarify** how their refractive status will change after surgery.

❑ Always aim to **under promise and over deliver**. Emphasize that the surgery is intended to help reduce dependence on glasses, not restore their 20-year-old eyes.

*Since the Symfony IDE protocol states that emmetropia is within +/- 0.5D, then targeting Nanovision which is also within +/- 0.5D, then Nanovision in this case is equivalent to emmetropia.

Analysis of Patient Satisfaction, Visual, and Functional Outcomes After Bilateral vs. Paired Extended Range of Vision / +3.25 D Multifocal IOL Implantation

By Mark Kontos, MD

I've been implanting bilateral TECNIS Symfony® IOL for two years. These patients report good quality of vision and high levels of satisfaction, but as I began exploring personalizing vision with TECNIS Sym*f*ony® IOLs and TECNIS® Multifocal +3.25 D, I discovered that mixing the two often gave patients outstanding near vision. As such, I initiated a study in my practice. My goal was to capture the best of both IOLs—the continuous vision from the TECNIS Sym*f*ony® and the near from the TECNIS® Multifocal +3.25 D.

We broke the study participants up into two groups.[23]

- Group 1 consisted of 11 patients who had TECNIS Sym*f*ony® IOLs implanted bilaterally.
- Group 2 consisted of 14 patients with a TECNIS Sym*f*ony® IOL in one eye and TECNIS® Multifocal +3.25 D IOL in the other eye.

At four months post-op we measured bilateral uncorrected visual acuity, spectacle independence, and overall satisfaction and found that 92.9% of patients with a TECNIS Sym*f*ony® IOL in one eye and TECNIS® Multifocal +3.25 D IOL in the other eye achieved 20/25 or better uncorrected bilateral distance vision, as well as 20/25 or better uncorrected bilateral near vision and likewise stated that they were satisfied or very satisfied overall.

I don't promise my patients that they won't wear glasses after surgery, which means that in the majority of these cases I'm over delivering and giving my patients more than what I told them I was going to give them, which is outstanding for my practice as well as for the patient.

Since presenting this data at ASCRS in 2019, I have continued to collect data and have been moving more of my patients into Personalized Vision with a TECNIS Sym*f*ony® IOL in one eye and TECNIS® Multifocal +3.25 D IOL in the other eye with continued success.

Visual Function and Patient Satisfaction[23]

14 Patients

TECNIS Sym*f*ony® IOL in one eye & TECNIS® Multifocal +3.25 D IOL in the other eye

At four months post-op we measured bilateral uncorrected visual acuity, spectacle independence, and overall satisfaction and found that the patients with a TECNIS Symfony® IOL in one eye and TECNIS® Multifocal +3.25 D IOL in the other eye achieved the following:

92.9%

had uncorrected bilateral distance vision of 20/25 or better.

had uncorrected bilateral near vision of 20/25 or better

stated they were satisfied or very satisfied overall

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS SYMFONY® EXTENDED RANGE OF VISION IOLS

Rx Only

INDICATIONS FOR USE

The TECNIS Symfony Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only.

The TECNIS Symfony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.

WARNINGS:

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight:

a. Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.
b. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
c. Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).
d. A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
e. Circumstances that would result in damage to the endothelium during implantation.
f. Suspected microbial infection.
g. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
h. Children under the age of 2 years are not suitable candidates for intraocular lenses.
i. Congenital bilateral cataracts.
j. Previous history of, or a predisposition to, retinal detachment.
k. Patients with only one good eye with potentially good vision.
l. Medically uncontrollable glaucoma.
m. Corneal endothelial dystrophy.
n. Proliferative diabetic retinopathy.

2. The TECNIS® Symfony IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.
3. The TECNIS® Symfony IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity.
4. Because the TECNIS® Symfony IOL may cause a reduction in contrast sensitivity compared to a monofocal IOL, patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.
5. Some visual effects associated with the TECNIS® Symfony IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome or very bothersome in some people, particularly in low-illumination conditions. On rare occasions, these visual effects may be significant enough that the patient may request removal of the IOL.
6. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS® Symfony and TECNIS® Symfony Toric IOLs, Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.
7. The effectiveness of TECNIS® Symfony Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated.
8. Rotation of TECNIS® Symfony Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.
9. AMO IOLs are single-use devices only. Do not reuse this IOL.

PRECAUTIONS:

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient.
2. When performing refraction in patients implanted with the TECNIS® Symfony IOL, interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is recommended.
3. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS® Symfony IOL optical design.
4. Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power.
5. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.
6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
7. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens.
8. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.
9. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.
10. When the insertion system is used improperly, TECNIS® Symfony IOLs may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided with the insertion instrument or system.
11. The safety and effectiveness of TECNIS® Symfony IOLs have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below for examples). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions:

Before Surgery

- Pupil abnormalities
- Prior corneal refractive or intraocular surgery
- Choroidal hemorrhage
- Chronic severe uveitis
- Concomitant severe eye disease
- Extremely shallow anterior chamber
- Medically uncontrolled glaucoma
- Microphthalmos
- Non-age-related cataract
- Proliferative diabetic retinopathy (severe)
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Irregular corneal astigmatism
- Amblyopia
- Macular disease
- Pregnancy

During Surgery

- Excessive vitreous loss
- Non-circular capsulotomy/capsulorhexis
- The presence of radial tears known or suspected at the time of surgery
- Situations involving the integrity of the circular capsulotomy/capsulorhexis
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage.

12. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or overinflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Symfony Toric IOL with the intended axis of placement.
13. The PCA is based on an algorithm that combines published literature (Koch et.al, 2012) and a retrospective analysis of data from a TECNIS Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in a prospective clinical study and may yield results different from those in the TECNIS Toric intraocular lens labeling. Please refer to the AMO Toric Calculator user manual for more information.
14. The use of methods other than the TECNIS Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the parent TECNIS® Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS Toric Calculator (www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS® Symfony Toric IOL.
15. All preoperative surgical parameters are important when choosing a TECNIS® Symfony Toric IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes, and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism.
16. All corneal incisions were placed temporally in the parent TECNIS® Toric IOL U.S. IDE study. If the surgeon

chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study for the parent TECNIS® Toric IOL. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
17. Potential adverse effects (e.g., complications) associated with the use of the device include the following:
• Infection (endophthalmitis)
• Hypopyon
• IOL dislocation
• Cystoid macular edema
• Corneal edema
• Pupillary block
• Iritis
• Retinal detachment/tear
• Raised IOP requiring treatment
• Visual symptoms requiring lens removal
• Tilt and decentration requiring repositioning
• Residual refractive error resulting in secondary intervention.
Secondary surgical interventions include, but are not limited to:
• Lens repositioning (due to decentration, rotation, subluxation, etc.)
• Lens replacement
• Vitreous aspirations or iridectomy for pupillary block
• Wound leak repair
• Retinal detachment repair
• Corneal transplant
• Lens replacement due to refractive error
• Unacceptable optical/visual symptoms
• Severe inflammation

SERIOUS ADVERSE EVENTS.
The most frequently reported serious adverse events that occurred during the clinical trial of the Tecnis Symfony lens were cystoid macular edema (2 eyes, 0.7%) and surgical reintervention (treatment injections for cystoid macular edema and endophthalmitis, 2 eyes, 0.7%). One eye was reported with pupillary capture and the eye that had endophthalmitis also had a small hypopyon. No other serious adverse events and no lens-related adverse events occurred during the trial.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR LIPIFLOW® THERMAL PULSATION SYSTEM
Rx Only
INDICATIONS
The LipiFlow® Thermal Pulsation System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.
CONTRAINDICATIONS
Do not use the LipiFlow® System in patients with the following conditions. Use of the device in patients with these conditions may cause injury. Safety and effectiveness of the device have not been studied in patients with these conditions.
• Ocular surgery within prior 3 months, including intraocular, oculo-plastic, corneal or refractive surgery procedure
• Ocular injury within prior 3 months
• Ocular herpes of eye or eyelid within prior 3 months
• Active ocular infection
• Active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months
• Eyelid abnormalities that affect lid function
• Ocular surface abnormality that may compromise corneal integrity
PRECAUTIONS
The Activator or Activator II (Disposable) may not fit all eyes, such as eyes with small palpebral fornices.
Use of the LipiFlow® System in patients with the following conditions may result in reduced treatment effectiveness because these conditions may cause ocular symptoms unrelated to cystic meibomian glands and require other medical management. Safety and effectiveness of the device have not been studied in patients with these conditions.
• Moderate to severe (Grade 2-4) allergic, vernal or giant papillary conjunctivitis
• Severe (Grade 3 or 4) eyelid inflammation. Patients with severe eyelid inflammation should be treated medically prior to device use.
• Systemic disease conditions that cause dry eye
• Taking medications known to cause dryness
• Esthetic eyelid and eyelash procedures
In addition, the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient's dry eye symptoms.
ADVERSE EFFECTS
Potential adverse effects that may occur as a result of the procedure include, but are not limited to, the onset or increase in: Eyelid/eye pain requiring discontinuation of the treatment procedure; Eyelid irritation or inflammation; Ocular surface irritation or inflammation; and Ocular symptoms (e.g., burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light).
Potential serious adverse events (defined as permanent impairment or damage to a body structure or function or necessitates medical or surgical intervention to preclude permanent impairment or damage to a body structure or function) that are not anticipated because of the device mitigations to prevent occurrence include:
Thermal injury to the eyelid or eye, including conjunctiva, cornea or lens; Physical pressure-induced injury to the eyelid; and Ocular surface (corneal) infection.
ATTENTION
Reference the LipiFlow Thermal Pulsation System Instructions for Use for a complete listing of indications, warnings, and precautions.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR LIPISCAN™ DYNAMIC MEIBOMIAN IMAGER
Rx Only
INDICATIONS
LipiScan™ Dynamic Meibomian Imager (DMI) is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands.
CONTRAINDICATIONS
No contraindications have been identified for the LipiScan™.
PRECAUTIONS
Caution: Disinfect the surfaces of the chin rest, forehead rest and Handheld Near Infrared (IR) Lid Everter with isopropyl alcohol immediately prior to use and prior to storage to prevent cross-contamination and patient infection.
ADVERSE EFFECTS
There are no known or anticipated adverse effects associated with use of this device.
ATTENTION
Reference the LipiScan Dynamic Meibomian Imager Instructions for Use for a complete listing of indications, warnings, and precautions.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR LIPIVIEW® II OCULAR SURFACE INTERFEROMETER
Rx Only
INDICATIONS
The LipiView II Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of:
Specular (interferometric) observations of the tear film. Using these images, LipiView II measures the absolute thickness of the tear film lipid layer. Meibomian glands under near-infrared (NIR) illumination. The ocular surface and eyelids under white illumination.
CONTRAINDICATIONS
Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for LipiView II.
PRECAUTIONS
The following patient conditions may affect the interferometry assessment of a patient's tear film using LipiView II:
Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications. Advise patients not not instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®, Systane Balance®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least four (4) hours after the instillation of all other ophthalmic drops prior to device use.
Soft or rigid contact lens wear. Advise patients to remove contact lenses at least four hours prior to device use.
Use of oil-based facial cosmetics around the eye.
Eye rubbing.
Recent swimming in a chlorinated pool. Advise patients to not to swim for at least 12 hours prior to device use.
Any ocular surface condition that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.
ADVERSE EFFECTS
There are no known or anticipated adverse effects associated with use of this device.
ATTENTION
Reference the LipiView II Ocular Surface Interferometer Instructions for Use for a complete listing of indications, warnings, and precautions.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR MEIBOMIAN GLAND EVALUATOR (MGE)
Rx Only
INDICATIONS
The Meibomian Gland Evaluator is a hand held instrument used by a physician to evaluate Meibomian gland secretions in adult patients during a routine eye examination. The instrument provides a standardized method to apply consistent, gentle pressure to the outer skin of the lower eyelid while visualizing the secretions from the Meibomian gland orifices through a slit lamp biomicroscope.
CONTRAINDICATIONS
No contraindications are known.
PRECAUTIONS
Do not depress the shaft to the endpoint of the spring. Do not apply any additional force after the shaft has been depressed approximately 6 mm. Applying additional force negates the benefit of using the instrument to apply standard force.
Familiarity with use of a slit lamp biomicroscope is required to use Meibomian Gland Evaluator for assessment of the meibomian gland secretions.
ADVERSE EFFECTS
Potential adverse effects that are unlikely but may occur with use of the Meibomian Gland Evaluator include but are not limited to:
Skin abrasion (e.g., from a rough surface on the device)
Eye abrasion (e.g., from improper contact of the instrument with the eye)
Infection of the skin or eye (e.g., from improper or lack of disinfection after use and between patients)
Allergic or toxic reaction (e.g., from exposure to any residue on device during user handling)
ATTENTION
Reference the Meibomian Gland Evaluator Package Insert for a complete listing of indications, warnings, and precautions.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the TECNIS Multifocal Family of 1-Piece IOLs
Rx Only
INDICATIONS: The TECNIS Multifocal 1-Piece IOLs are indicated for primary implantation for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag. **IMPORTANT SAFETY INFORMATION:** Inform patients of possible contrast sensitivity reduction and increases in visual disturbances that may affect their ability to drive at night or in poor visibility conditions. The lenses should not be placed in the ciliary sulcus. Weigh the potential risk/benefit ratio for patients with conditions that could be exacerbated or may interfere with diagnosis or treatment. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma.
ATTENTION: Reference the Directions for Use labeling for a complete listing of Indications and Important Safety Information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION for the TECNIS Toric 1-Piece IOL
Rx Only
INDICATIONS: The TECNIS Toric 1-Piece posterior chamber lenses are indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag.
IMPORTANT SAFETY INFORMATION:
Rotation can reduce astigmatic correction. Misalignment greater than 30° may induce refractive error. Accurate keratometry, biometry and www.TecnisToricCalc.com are recommended to optimize visual outcomes. Weigh the potential risk/benefit ratio that could increase pre-existing complications or impact patient outcomes. Variability in any preoperative measurements can influence outcomes.
ATTENTION: Reference the Directions for Use labeling for a complete listing of Indications and Important Safety Information.

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