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*EXTENDED DEPTH OF FOCUS AND
YOUR PRACTICE*



A new class of IOL that
offers patients a
continuous full range
of high-quality vision.

EXTENDED DEPTH OF FOCUS AND YOUR PRACTICE

A new class of IOL that offers patients a continuous full range of high-quality vision.

DANIEL H. CHANG, MD; ERIC D. DONNENFELD, MD; JAMES C. LODEN, MD; AND FARRELL “TOBY” TYSON II, MD



There is an extraordinary demand by patients for improved quality of vision and quality of life after cataract surgery with a reduction in how often they wear glasses. Patients are more active than ever before and are researching opportunities to improve their vision. These same patients are also more sophisticated and educated in their health care decisions. They perform

research online, speak with friends, and use social media to make choices about their vision, with and without the recommendation of their eye care provider.

Now, with the introduction of the **TECNIS Symfony** IOL (AMO), there is a new category of IOL. With the **TECNIS Symfony** IOL, patients can enjoy near vision with no compromise to their distance correction. No lens is perfect, but **TECNIS Symfony** IOL allows for a high quality of vision over a range of distances without compromising distance vision.¹

The **TECNIS Symfony** IOL extended-depth-of-focus (EDOF) IOL is a new class of lens that provides an important opportunity for our patients who are interested in wearing glasses less often for both distance and near vision. The **TECNIS Symfony** IOL differs from multifocal IOLs, which are really bifocal lenses, in that it provides a continuous range of vision by spreading out light along a range, instead of splitting it between two distinct points. **TECNIS Symfony** IOL is also available as a toric IOL.

In the clinical trials, the lens provided exceptional quality of vision at distance with low levels of glare and halo.¹ This quality of vision is accomplished by a dramatic reduction in chromatic aberration and optimization of negative spherical aberration. **TECNIS Symfony** IOL is a surgeon-friendly lens, because it gives us all the opportunity to provide our patients with excellent quality of vision with a low rate of dissatisfaction.²

Today, we will hear from a group of superb cataract surgeons who will share their experiences with the **TECNIS Symfony** IOL.
—Eric D. Donnenfeld, MD

“As our surgical solutions improve, our attitude toward treating the condition of presbyopia needs to evolve as well.

—Daniel H. Chang, MD

THE CURRENT IOL OPTIONS

Barriers to PCIOLs

James C. Loden, MD: What are the barriers that surgeons face when adopting presbyopia-correcting IOLs (PCIOLs)?

Farrell “Toby” Tyson II, MD: One of the barriers is actually hitting the target. If we are off by a foot, it does not really matter in 20 feet, but if we are correcting presbyopia with multifocals, we have to be very accurate with not only the distance target but the near target as well. Then, we get into the possibility of dysphotopsia or visual disturbances such as glare or halos. With the currently available options for accommodating lenses, there is a concern that, even if we hit our target for distance, our outcomes will change over time.

Dr. Loden: Adding to what you said, Dr. Tyson, with a true diffractive optic multifocal lens of the current technology, we really have to be within 0.25 D for high patient satisfaction. A 0.50 D of cylinder often makes a huge difference; a 0.50 D of sphere makes a huge difference. Dr. Chang, tell us about some of the barriers you have seen.

Daniel H. Chang, MD: The barriers start with patients’ expectations. Do patients realize they have a choice of seeing better without glasses? Do they recognize there is more work—and cost—involved? From a surgeon’s standpoint, there needs to be a fundamental attitude shift in our field. Presbyopia is a disease process that must be treated, whether with surgery or with glasses. If we do not offer surgical correction of presbyopia, we leave our patients with no choice but to rely on

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.

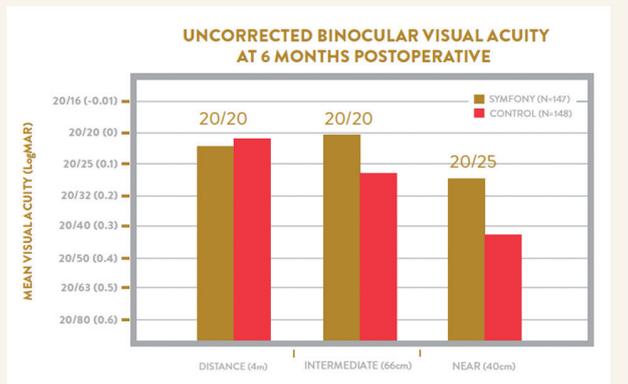


Figure 1. TECNIS Symfony IOL delivers excellent uncorrected visual acuity at all distances.¹

glasses. There are risks associated with bifocal glasses such as increased trip hazards.³⁻⁵ As our surgical solutions improve, our attitude toward treating the condition of presbyopia needs to evolve as well. Ultimately, surgeons need to be confident in the level of patient satisfaction that they can reliably deliver.

Eric D. Donnenfeld, MD: The greatest barrier in my experience to surgeons' adoption of PCIOLs is the quality of vision at distance. Many surgeons tried early-generation, high-add multifocal IOLs and found an unacceptable incidence of glare, halos, and waxy vision at distance. The current low-add multifocal IOLs with high negative spherical aberration are better tolerated than the original multifocal IOLs we first used.⁶ As surgeons we sometimes rely too much on defocus curves rather than quality of vision. Patients expect good near vision with a premium PCIOL, but they demand good distance vision.

THE SYMFONY IOL

A Smooth Transition

Dr. Loden: In my practice, I am seeing a lot of younger cataract patients: some are in their 40s, and a lot of 50-year-olds. These active patients live in the intermediate range. How do you feel about these younger cataract patients?

Dr. Chang: For some time, our perception of what patients need has been driven by our use of the terminology "distance and near," but the world is not distance and near; it is a continuous range of visual needs. When we bring something in from the distance, it does not suddenly show up at near; instead, we bring it continuously from distance through intermediate to near until we can see it. Whether it is a tablet, a menu, or a price tag, we continuously move in and out, so to have that continuous range of vision would be functionally better than a single focal point of sharp vision like we get from multifocals. The low-add lenses improved intermediate vision, but with the TECNIS Symfony IOL, it will truly be a smooth transition (Figure 1).

Dr. Tyson: With this type of technology, there is not a defocus curve where it starts at a peak at distance and then

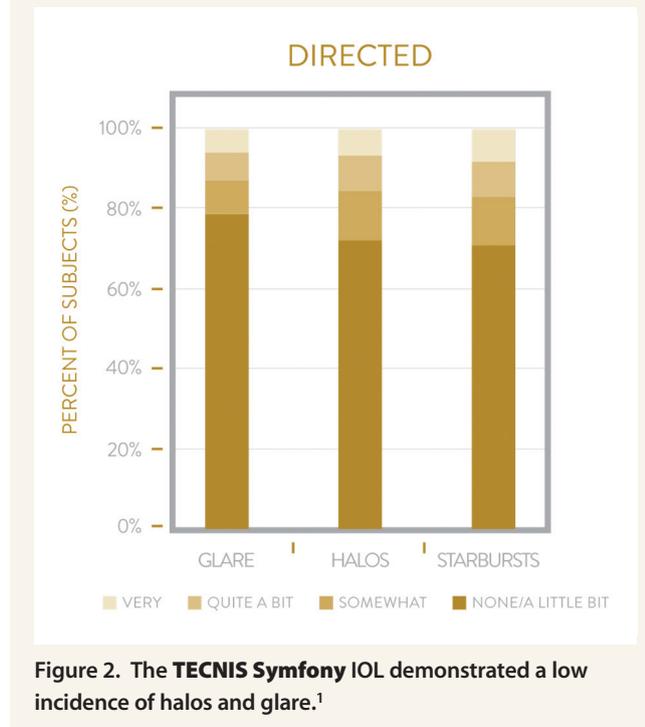


Figure 2. The TECNIS Symfony IOL demonstrated a low incidence of halos and glare.¹

gradually declines on a regular slope. It is a fairly flat defocus curve from about plano to about 1.50 D, and then it starts to fall off more. Dr. Chang is correct: this is a very usable range. It is not just quality of the vision at one point in space; it is quality of vision maintained over a large range of vision.

What I like about this lens is that it allows us to use it in a lot of unique situations where we do not have good options. This lens gives us a bigger landing zone, because we do not have to be perfect surgeons. We can have some residual error and still have a happy patient with a lot of range of depth of focus.

Functionality and Sustainability

Dr. Loden: What are you telling patients to expect from a night-driving standpoint from the TECNIS Symfony IOL?

Dr. Chang: With the TECNIS Symfony IOL, incidence of halos are low, and some patients are noting the starbursts at night more prominently. Frequently described as fuzz around lights, sprays of light, or lines around light, these potential starburst symptoms typically are not bothersome but should be discussed with the patient before surgery.

Dr. Donnenfeld: The TECNIS Symfony IOL had excellent patient satisfaction and low glare and halos (Figure 2).¹ I was very comfortable placing this lens in patients who do considerable night driving, and many of my patients achieve a UCVA of better than 20/20 at distance along with good near vision. However, I do counsel patients that, while the TECNIS Symfony IOL has good quality of vision at distance, it is not as good as a monofocal IOL. I continue to prefer a monofocal IOL in eyes with macular degeneration, keratoconus, or significant glaucoma.

WARNING: 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. 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.

Dr. Loden: Let us talk about sustainability. What will we see 5 or 10 years from now with these IOLs?

Dr. Tyson: I have seen glistenings develop in certain acrylic IOLs. On a monofocal platform, glistenings have not really affected a patient's visual acuity very much. These patients start at 100% light transmission, and when the glistenings develop, they lose as much as 15%.⁷ They are now at 85% light transmission, which they really do not notice. Patients that initially had good outcomes with that technology are all of a sudden starting to experience a decrease in their quality of vision, and it is a progressive problem. Patients expect that a premium product is going to last a lifetime. **TECNIS Symphony** IOLs are not associated with glistenings.⁸

Dr. Chang: There have been many claims that glistenings are not clinically significant. I think it is obvious to all of us when we see them that something is happening in the eye, even though traditional clinical testing such as Snellen visual acuity may not show it, if you put a lens with glistenings on an optical bench, you can demonstrate forward light scattering. Forward light scattering, which likely leads to glare, can reach levels comparable to a 70-year-old human lens. Recent studies now demonstrate the reduction in contrast sensitivity due to glistenings.^{7,9,10} While some patients may only have mild glistenings, others are severe. I do not like anything that is unpredictable. I want consistency, particularly in a premium product.

Patients' Satisfaction

Dr. Loden: How satisfied were your patients with the **TECNIS Symphony** IOL?

Dr. Tyson: What is wonderful is that these patients are not coming back to my clinic to complain. These patients are so happy that I have to call them in to come back, because their vision is so good they think they never need to come see me again. As surgeons, we want a lens that not only makes patients happy but also makes us look good in the process.

Dr. Chang: In my experience, the **TECNIS Symphony** IOL just works. Since FDA approval, I have begun to use the **TECNIS Symphony** IOL in many of my patients, including patients in whom I previously would not have recommended surgical presbyopia correction. They are experiencing good quality far vision with a continuous range of quality vision through intermediate and into near.

Dr. Loden: In Europe, greater than 94% of **TECNIS Symphony** IOL patients said that they would recommend it to family and friends in one study, and 98% said they would recommend the lens in a second study (Figure 3).² I just examined a patient who was 20/20 brisk uncorrected

but 20/15 with a refraction of -0.25 D x -0.75 D @ 89°. In my experience, if this patient had a traditional multifocal implanted, there would be a nearly 100% chance that the patient would be dissatisfied.

Patients' Expectations and Low Spectacle Wear

Dr. Loden: How do you set expectations with the **TECNIS Symphony** IOL? What do we really need to convey to patients?

Dr. Tyson: I tell patients that they will have excellent vision at distance and intermediate, and that they may occasionally need reading glasses to see up close. When they come in for their 1-month checkup, I likely have exceeded their expectations on their near vision capabilities. In the old days, we had very long discussions about all the limitations of the lenses.

Dr. Chang: Currently, when I talk to patients about PCIOLs, I talk about quality and range of vision and night vision symptoms. With the **TECNIS Symphony** IOL, the depth of focus is excellent and there is a low incidence of halo and glare.^{1,6}

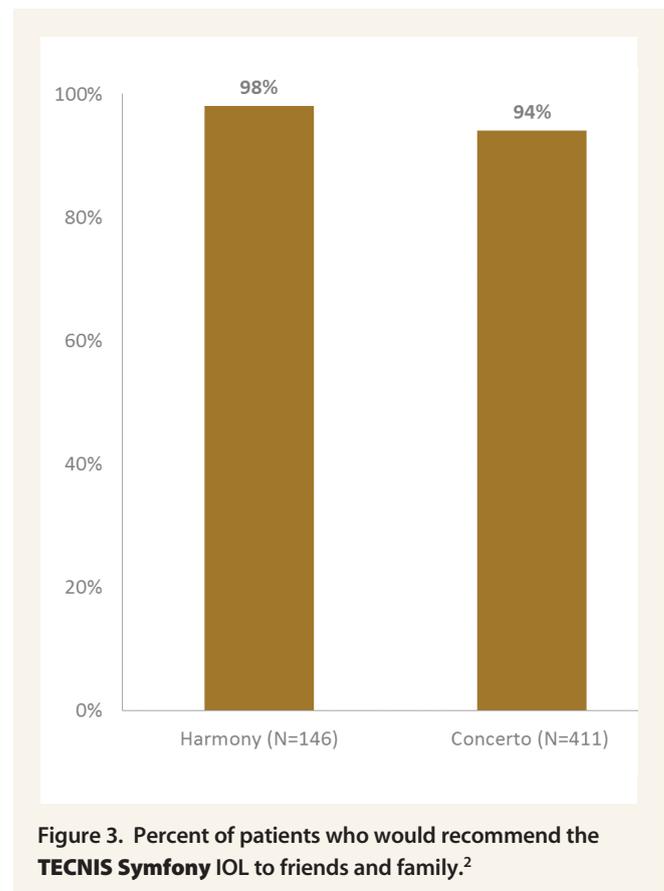


Figure 3. Percent of patients who would recommend the **TECNIS Symphony IOL to friends and family.²**

Dr. Donnenfeld: The number one rule for all of us is to do what is best for our patients. When I discuss cataract surgery with patients, I always include management of presbyopia. With the **TECNIS Symphony IOL**, I discuss expectations of good quality of vision at distance and intermediate and the possibility the patient will need some correction for near.

Dr. Loden: Dr. Chang, what are your patients looking for in terms of spectacle wear?

Dr. Chang: Most patients recognize that there may be some compromises. I have always told patients that they may occasionally wear glasses for some activities but, for some activities, they should be able to function without glasses. If you tell them that they will never wear glasses again, you are probably going to have unhappy patients. If you say there are certain circumstances when glasses may be needed, then patients will expect it and tend not to mind that as much.

Dr. Donnenfeld: Most patients reported wearing spectacles none or a little bit of time with the **TECNIS Symphony IOL**. Some of my patients wear glasses for reading at near distances, but most do not. I do counsel my patients that they may need to wear reading glasses, but the quality of vision at distance is a great benefit of the **TECNIS Symphony IOL**.

ASTIGMATISM CORRECTION WITH TECNIS SYMPHONY TORIC IOL

Dr. Tyson: The design of the **TECNIS Symphony Toric IOL** is tolerant to astigmatism (Figure 4). With this technology, the chromatic aberration and the contrast are so high that it allows us to spread that defocus curve.

We are all used to seeing aspheric toric designs right now, but this is the next level. This is like the super-contrast toric lens. We are already fixing the asphericity, but now we are going to fix the chromatic aberrations in the

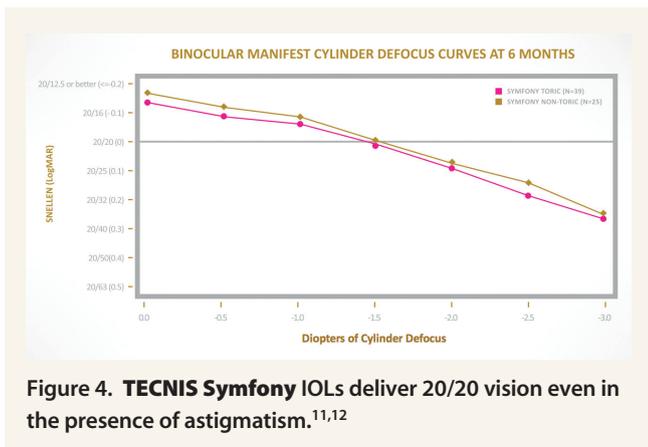


Figure 4. TECNIS Symphony IOLs deliver 20/20 vision even in the presence of astigmatism.^{11,12}

system. These toric lenses are not only going to have more range of vision, but the quality of vision is going to be excellent as well.

Dr. Loden: The **TECNIS Symphony** platform is very forgiving. Even if we slightly change the centration of the lens on the pupil, it will maintain image quality throughout 0.75 mm of decentration.¹ This is the first time we have had a presbyopia-correcting toric lens of a different design other than accommodating in the United States.* It is a real breakthrough for us.

Dr. Donnenfeld: The **TECNIS Symphony Toric IOL** is an added bonus. This is the first diffractive toric IOL available for mitigating presbyopia and correcting astigmatism in the United States.* Approximately 40% of patients have more than 0.75 D of cylinder, so this will greatly help improve UCVA.¹³ Uncorrected astigmatism reduces patients' quality of vision, particularly with multifocal IOLs.¹⁴

ADVICE FOR SURGEONS NEW TO EDOF

Dr. Loden: There are two tips I would give to someone just starting out with the **TECNIS Symphony IOL**. The first is do not tell patients that they will be spectacle independent. I think this is a very important point to drive home to patients. Tell them that they will likely need low-powered (+1.00 or +1.50 D) readers for fine print. The second is that, although the glare and halo reports are reduced compared to other presbyopic diffractive optic lenses, patients may still experience a low incidence of glare or halos, so do not promise them no glare or halos.

What would you tell someone starting out for the first time about patient selection?

Dr. Chang: With any kind of refractive procedure, it is important to think about two main categories. The first is the subjective component: patients' personality, their occupation, their expectations, whether they are easy to work with, and even how they treat your staff. The second is the objective component: their current visual experience, their refractive error, the density of their cataract, and other potential ocular pathology. To assess the first category, I use a questionnaire (Figure 5) that asks those questions. It not only screens the patient but also allows the patient to start thinking about the possibility of reducing his or her need for glasses. For the second category, I use the standard battery of tests we do for cataract evaluations to make sure that the patient will do well. Traditionally, hyperopes are patients who are easy to satisfy. The low myopes tend to be the hardest patients to satisfy. You want to set yourself up for success early on so you can gain confidence and then move forward.

*Based on CMS designation

INDICATIONS FOR USE: The TECNIS Symphony 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.

CHROMATIC ABERRATION

BY DANIEL H. CHANG, MD

Aberrations cause blur, so the more aberrations you can correct, the better the quality of vision. We have heard a lot about spherical aberration, which is when the central and peripheral rays of light entering the eye are focused differently. Chromatic aberration is when the different components of white light—the different wavelengths or colors—are focused differently. One of the key components to minimizing chromatic aberration, which can cause blur and waxy-type images, is to use a material with low dispersion properties (a high Abbe number) that focuses colors together. The **TECNIS** acrylic has great dispersion properties, and the **TECNIS Symphony** IOL uses diffractive technology to focus all the colors even better.

Yes, the echelette design of the rings actively reduces chromatic aberration even more than the **TECNIS** acrylic material itself. This IOL actually corrects the naturally occurring chromatic aberration of the cornea.¹⁵ By minimizing chromatic aberration, the lens is maximizing image quality and contrast (Figure).

There are different ways of characterizing chromatic aberration, but a simple way of looking at it is measuring the refractive difference between red (700 nm) light and blue (450 nm) light. If you look at the ReStor lens and specifically the AcrySof material (Alcon), it is a high-index material that really creates a high amount of color dispersion. This makes a huge difference for the quality of the image that you start off with. AMO does bench top testing using white light. Many other labs perform bench top testing with green light, but the world is not green.

Dr. Donnenfeld: The **TECNIS Symphony** IOL is a great lens for the cataract surgeon who has been sitting on the EDOF sidelines. Patients are happy with their distance vision. Beginning surgeons need to hit their mark on sphere. Surgeons need to use modern IOL formulas—Barrett Universal II, Holladay 2, Haigis, etc—and perform optical biometry.

Dr. Tyson: Preoperative biometry is always crucial to any cataract surgery. This is best accomplished with optical biometry and optimized IOL constants. The ocular surface should be optimized before biometry readings are taken to maximize the accuracy of our diagnostics. This coupled with the use of the Koch nomogram for the inclusion of posterior corneal astigmatism allows for outstanding outcomes even without intraoperative aberrometry. (Editor's Note: AMO offers a toric calculator at www.tecnistoriccalc.com).

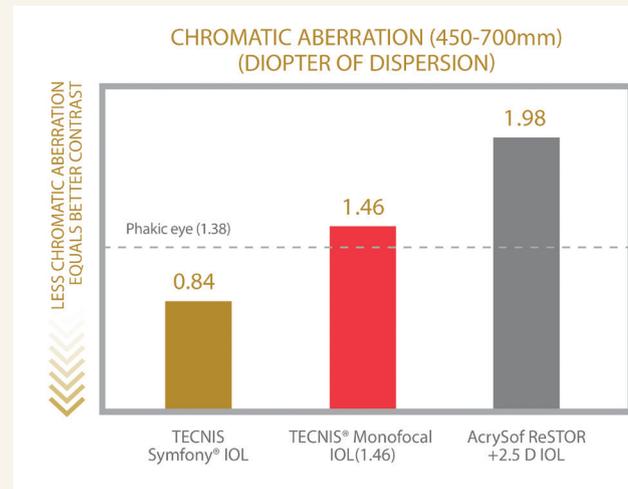


Figure. Less chromatic aberration provides better contrast.

The world is colorful light, so if you use green light, you lose that whole component of the testing.

The other thing that we are starting to learn is that the actual spatial frequency of the target that you are testing affects your results. For PCIOLs, you have to look at different spatial frequencies and be able to combine their relative contributions. Just like the fact that the world is not made of one color, the objects in the world are not made of one spatial frequency. AMO has been a pioneer in developing bench top eye modeling, allowing them to understand and to create lenses using advanced optical concepts to provide better clinical solutions for surgeons and patients.

CONCLUSION

Dr. Loden: I predict the **TECNIS Symphony** IOL will jump-start the PCIOL market for several reasons. First, the EDOF optics mitigate halo issues that discouraged adoption of traditional PCIOLs. Second, we now have a toric platform. In the past, surgeons had to resort to bioptics (IOL implantation followed by LASIK/PRK) for patients with over 1.25 D of astigmatism. Now, you have the option to correct higher amounts of astigmatism and address presbyopia and a platform that is predictable.

Dr. Chang: Even though the **TECNIS Symphony** IOL may look cosmetically similar to a multifocal IOL, its application of diffractive optics technology is quite different. In fact, it is so different that the FDA made the **TECNIS Symphony** IOL the first in an entirely new category of lens: an EDOF IOL. What this means is that surgeons who may have previously shunned multifocal IOLs due to concerns about image quality or night vision symptoms should consider trying the **TECNIS Symphony** IOL.

LIFESTYLE VISION QUESTIONNAIRE (CATARACT)

Name _____ Date _____

By combining his extensive expertise, surgical skill, and the best technology available, Dr. Chang can give you the optimal combination of vision quality and lifestyle convenience. The following questions will help Dr. Chang to determine how best to achieve your visual goals.

1 Although I may currently need glasses, my preference after surgery is to:

- See both far and near *without* glasses
- See far without glasses but wear glasses to see near
- Rely on glasses to see both far and near

2 Think of your vision in terms of three zones:

- *Far* (driving, TV, golf, tennis)
- *Intermediate* (computer, cooking, gardening)
- *Near* (reading, cell phone, sewing, make-up)

For which zone would you be more willing to wear glasses?

- Far
- Intermediate/Near

3 At night, I am okay with some glare and halos around lights as long as I can drive comfortably.

- Agree
- Disagree

4 If not covered by insurance, I would consider paying out of pocket to reduce my need for glasses.

- Agree
- Disagree

5 How many hours per day do you spend:

_____ Driving
 _____ On the computer
 _____ Reading (books, tablet, smartphone)

6 What is/was your primary occupation?

 I am retired (list previous occupation)

7 Please list up to three favorite hobbies:

8 Please place an “X” on the following scale to describe your personality as best you can:

Easygoing Perfectionist

Please Sign Here: _____

Thank you for completing this questionnaire.

Figure 5. Dr. Chang’s Lifestyle Vision Questionnaire.

AND YOUR PRACTICE

Dr. Donnenfeld: For surgeons who have been waiting for a better PCIOL to enter the world of refractive cataract surgery, this is it, and the time is now. We can also feel better about recommending **TECNIS Symfony IOL** for a wider range of patients—patients who are more demanding, those who drive a lot at night. I am also excited about the **TECNIS Symfony Toric IOL**, which is the first toric presbyopia-correcting diffractive IOL in the United States.* **TECNIS Symfony IOL** gives us all the opportunity to provide our patients with excellent quality of vision with a low rate of visual disturbance. I would like to thank my colleagues for all of their valuable pearls of wisdom regarding the **TECNIS Symfony IOL**. ■

*Based on CMS designation

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

Rx Only:

INDICATIONS FOR USE:

- The TECNIS Symphony Extended Range of Vision IOL, Model ZXROO, 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 ZXROO IOL is intended for capsular bag placement only.
- The TECNIS Symphony 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® Symphony IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.
3. The TECNIS® Symphony 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. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS® Symphony and TECNIS® Symphony Toric IOLs, Models ZXROO, 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.
5. The effectiveness of TECNIS® Symphony Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated.
6. Rotation of TECNIS® Symphony 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.
7. AMO IOLs are single-use devices only. Do not reuse this IOL.

PRECAUTIONS:

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. When performing refraction in patients implanted with the TECNIS® Symphony 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. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS® Symphony IOL optical design. 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. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions. When the insertion system is used improperly, TECNIS® Symphony 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. The safety and effectiveness of TECNIS® Symphony 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 in which 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.

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® Symphony Toric IOL with the intended axis of placement. 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. 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® Symphony Toric IOL. All preoperative surgical parameters are important when choosing a TECNIS® Symphony 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. 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. 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 Symphony 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.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS 1-PIECE IOL

Rx Only

INDICATIONS:

The TECNIS 1-Piece lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

WARNINGS:

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The TECNIS 1-Piece IOL should not be placed in the ciliary sulcus.

PRECAUTIONS:

Do not reuse, resterilize, or autoclave.

ADVERSE EVENTS:

In 3.3% of patients, reported adverse events of cataract surgery with the 1-Piece IOL included macular edema.

ATTENTION:

Reference the Directions for Use for a complete listing of indications and important safety information.