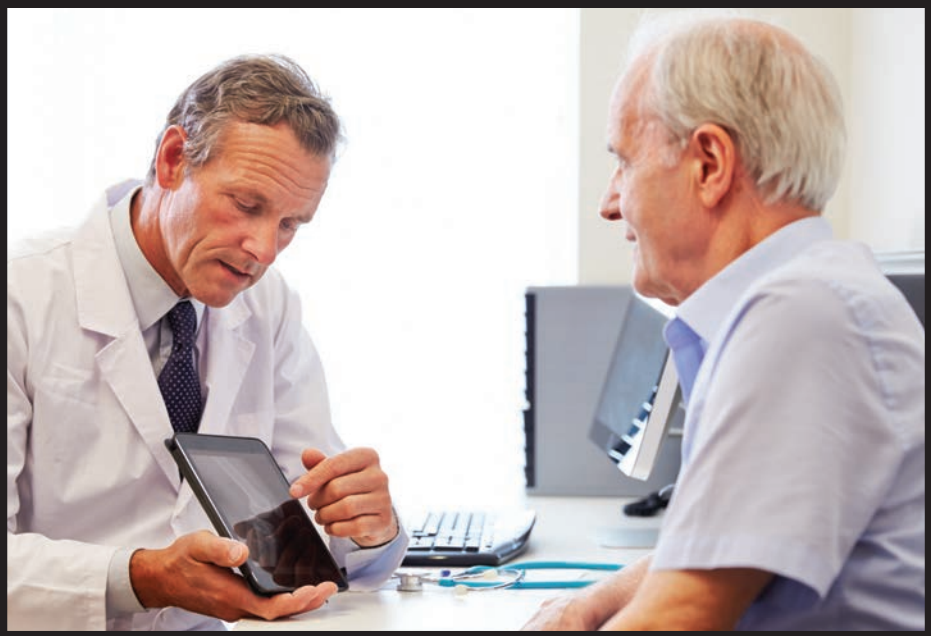

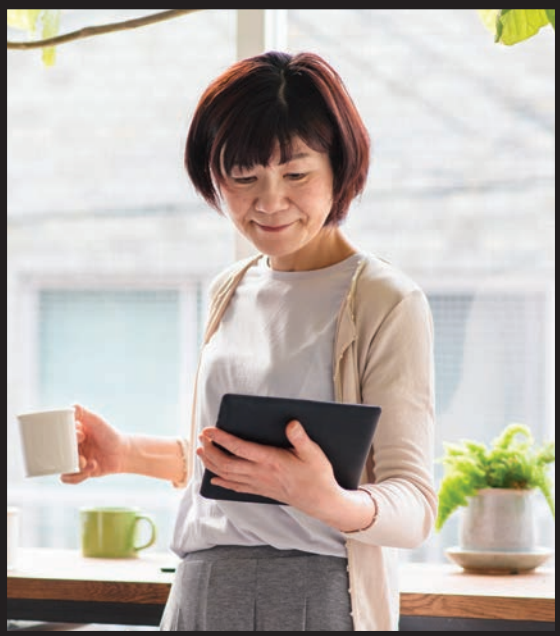

Clinical and Practical Considerations for

Extended Depth of Focus IOLs

A Unique Optical Design for a Different Kind of Lens

Best Practices for Patient Selection

Setting Patient Expectations

Extended Depth of Focus Toric IOLs

Tips for Selecting a Target

Johnson & Johnson VISION

CLINICAL AND PRACTICAL CONSIDERATIONS FOR

Extended Depth of Focus IOLs

DEAR COLLEAGUE,

In July 2016, a new category of IOLs was approved for use in the United States. The TECNIS Symfony® IOL and TECNIS Symfony® Toric IOL are the first extended depth of focus lenses to be approved by the U.S. Food and Drug Administration.

Extended depth of focus lenses are unique in that they are neither multifocals nor are they accommodative IOLs. However, the TECNIS Symfony® is a presbyopia-correcting lens and the TECNIS Symfony® Toric IOL addresses both presbyopia and astigmatism.

In this supplement, surgeons with vast experience implanting TECNIS Symfony® IOLs will offer in-depth explanations about what makes extended depth of focus lenses different and what steps you can follow chairside and in the OR to maximize patient satisfaction and visual outcomes.

The availability of TECNIS Symfony® IOLs truly represents a great opportunity for patients since it provides a full range of continuous high-quality vision at all distances. The TECNIS Symfony® Toric IOL is the first presbyopia-correcting lens available in the United States for the 33%[1] of the population who have significant levels of astigmatism.

In light of these benefits, surgeons across the US, like those featured here, are discovering that patients will often choose this new category of lens over the standard monofocal lens. And, in certain cases, surgeons choose them over a multifocal. In the pages that follow, experts will delineate when and why they reach for TECNIS Symfony® IOL.

Richard L. Lindstrom, MD

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Richard Lindstrom is the Founder and attending surgeon of Minnesota Eye Consultants and Adjunct Professor Emeritus at the University of Minnesota Department of Ophthalmology

1. Market Scope, Data as of 2013. Comprehensive Report on Global IOL Market.

A UNIQUE OPTICAL DESIGN
for a Different Kind of Lens

By Karolinne Maia Rocha, MD, PhD

The TECNIS Sym*fony*® IOL and the TECNIS Sym*fony*® Toric IOL feature a new technology that surgeons can offer to cataract patients as an alternative to monofocal or multifocal IOLs. These newer IOLs incorporate an innovative diffractive design and achromatic technology that make the lens different compared to diffractive bifocal and trifocal multifocal IOLs.

A multifocal IOL works by taking different images at different distances and separating them. Conversely, the TECNIS Sym*fony*® IOL elongates the focus—hence the term "extended depth of focus." The proprietary diffractive echelette design introduces a novel pattern of light diffraction that elongates the focus, resulting in an extended range of vision of about 1.50D—sufficient to provide full range of vision. In addition, achromatic technology reduces chromatic aberration to boost image quality.

ECHELETTES AND ACHROMAT TECHNOLOGY IN DETAIL

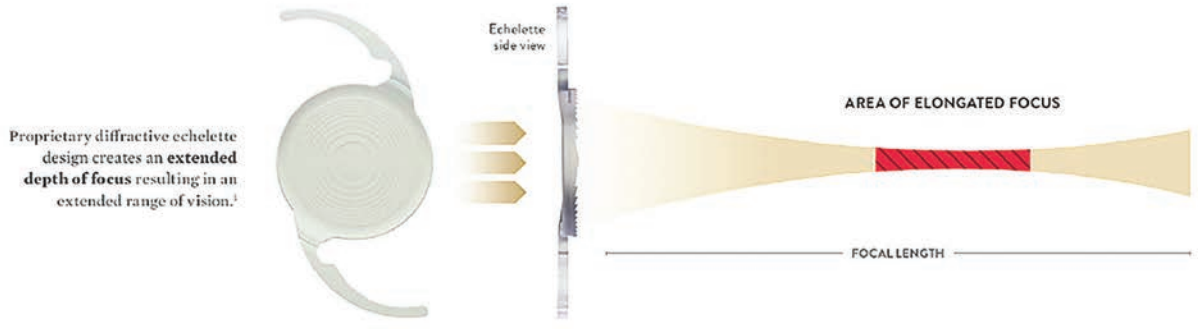
The TECNIS Sym*fony*® IOL features the same single-piece acrylic design as other lenses on the TECNIS platform. As such, it offers the same remarkable spherical aberration correction that's typical with this entire family of lenses. It also has a diffractive grating that makes many surgeons think of a multifocal lens; however, there are differences. The nine echelettes on a TECNIS Sym*fony*® IOL are taller than those on the TECNIS® Multifocal IOL, and they're slightly angled. This elongates the focus area rather than splitting the light and creating a second focal point. This helps enhance near and intermediate vision without compromising distance vision.[1]

The TECNIS Sym*fony*® IOL design also allows for less chromatic dispersion, which delivers contrast sensitivity with no clinically significant difference compared to a monofocal IOL.[1] By correcting the chromatic aberration, you can increase potential acuity or, if needed, have decentration tolerance.

QUALITY VISION AT ALL DISTANCES

In clinical trials, subjects implanted with the TECNIS Sym*fony*® IOL achieved mean binocular uncorrected vision of 20/20 for intermediate distance and between 20/25 and 20/32 for near.[1] Remarkably, these gains in

HOW A DIFFRACTIVE ECHELETTE DESIGN CREATES EXTENDED DEPTH OF FOCUS



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..

near vision did not come at the expense of distance vision. On the contrary, patients had a high quality of vision at distance. Specifically, in clinical trials, monocular and binocular distance visual acuities were clinically comparable to that of the monofocal control group.[1]

This optical achievement is a direct result of the unique TECNIS Symfony® IOL design. It corrects for both spherical aberration and chromatic aberration, and it mitigates the effects of presbyopia.

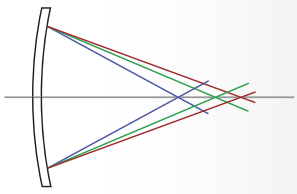
NIGHT VISION SYMPTOMS

Nighttime visual disturbances have long challenged surgeons who implant presbyopia-correcting IOLs. Although the TECNIS Symfony® IOL does not eliminate all concerns of glare and halo, the spontaneous reports of severe night vision symptoms were low in clinical studies.[1] In fact, the vast majority of subjects implanted with the TECNIS Symfony® lens had no spontaneous reports of halo, glare, or starbursts; and of those who did report symptoms, most experienced only mild or moderate symptoms, with less than 3% classifying their symptoms as "severe."[1]

ACTIVE CORRECTION OF CHROMATIC ABERRATION

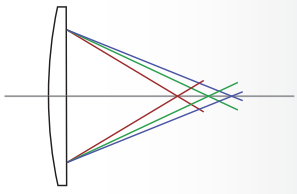
Cornea

All corneas have a similar amount of chromatic aberration



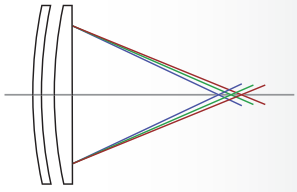
Lens with Achromatic Technology

Proprietary Achromatic Technology is optimized to counteract the chromatic aberration of the cornea



Cornea + Lens with Achromatic Technology

The net result is reduced chromatic aberration



MULTIFOCALS WORK DIFFERENTLY THAN EXTENDED DEPTH OF FOCUS

A multifocal IOL works by taking different images at different distances and separating them. Conversely, the TECNIS Symfony® IOL elongates the focus—hence the term "extended depth of focus."

The nine echelettes on the TECNIS Symfony® IOL are taller than those on the TECNIS® Multifocal, and they're slightly angled. This elongates the focus area rather than splitting the light and creating a second focal point. This helps enhance near and intermediate vision without compromising distance vision.

This qualitative leap is largely attributable to the contrast sensitivity that is seen in TECNIS Symfony® IOL patients. While IOLs are commonly judged by their ability to deliver quantitative vision, as measured by Snellen, contrast sensitivity is essential too—especially in low light and when performing visually demanding tasks such as driving.

This qualitative measure of vision is where the TECNIS Symfony® IOL excels. In fact, the difference in contrast sensitivity with the TECNIS Symfony® IOL was not clinically significant compared to contrast sensitivity with an aspheric monofocal IOL.[1,2]

Karolinne Maia Rocha is the Director of Cornea Service Medical University of South Carolina (MUSC), Storm Eye Institute in Charleston.

1. TECNIS® Symfony DFU
2. DOF2015CT0020_Symfony®_MTF_versus_competition

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. 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.

SETTING PATIENT EXPECTATIONS

By Sumit (Sam) Garg, MD

Setting patient expectations is key to succeeding with any premium lens and, despite its stable optics, the TECNIS Symfony® IOL is no exception. You still need to talk about expectations. It is our job to make sure that the patient understands that no lens is perfect. In my clinic, I tell patients that we currently have a lot of very good lenses to choose from. Then, I explain that the one we ultimately select will be the one that is best for them and their individual needs.

There are several dos and don'ts that move the needle of understanding for patients. The patient expectation conversation is a little different with extended depth of focus lenses versus the conversation you might have with a patient who is receiving a multifocal lens.

OUTLINE THE OPTIONS

Take the time to discuss different lens options with your patients. You don't necessarily need to go over every available lens in depth, but explain the differences of the options that might reasonably suit a patient's individual needs.

When appropriate, offer the patient a comparison of the differences in visual performance with a multifocal lens versus the visual performance with an extended depth of focus lens. When doing this, it's helpful to emphasize that vision simulators/applications are very helpful. If a patient is willing to use glasses for near vision on occasion in exchange for high-quality vision across all distances, he or she may be a good candidate for the TECNIS Symfony® IOL.

GETTING REAL WITH SYMFONY®

With the introduction of the TECNIS Symfony® IOL for presbyopia mitigation, we can predictably achieve very good outcomes. However, we should never offer perfection or use any terminology that might make patients expect it.

When you talk to a patient about the TECNIS Symfony® IOL, it's helpful to emphasize that your goal is to achieve quality of vision. This means they may continue to need reading glasses on occasion, but in return they will likely have a greater range of vision. Make sure the patient is clear that this is the trade-off. They must be willing to accept it. Although many patients will wear glasses less often,[1] don't lead patients down the road where that's what they're promised to get.

Even though the TECNIS Symfony® IOL is not a multifocal, you may get some starbursts in the beginning, so make sure patients anticipate this. When they do, most patients will be very accepting of it.

Use real life examples to explain what extended depth of focus means. The ability to provide continuous vision for distance through intermediate into near with TECNIS Symfony® IOL[2] means the patient should be able to drive a car, work at their computer and surf the web on a handheld device. These concrete examples address functional concerns that are important to many of our active cataract patients.

MAKE THE MESSAGE STICK

However technical your discussion becomes, always

WHAT NOT TO DO

Avoid these pitfalls when discussing extended depth of focus lenses:

- Don't rush through your discussion without explaining how the TECNIS Symfony® IOL works. When patients understand how the technology works, they are likely to be more accepting of minor imperfections in vision.
- No matter how excited you are about this new technology, don't let it spill over too much into your discussion with the patient. You should never overhype the TECNIS Symfony® IOL— or any other lens for that matter.
- Never say, "trust me you'll be fine." Patients appreciate understanding how the technology works and why.
- No matter what IOL you are talking about, never say, "this is a perfect lens."

- Sumit (Sam) Garg, MD

return to the basic point, which is that the goal of the TECNIS Symfony® IOL is to increase range of vision while maintaining good visual quality.

Patients will forget what you told them preoperatively, so I often direct them to the Vision Simulator. I also explain that cataract surgery is not an acute event. It is a process.

Sumit Garg is the Vice Chair of Clinical Ophthalmology, Medical Director, and an Associate Professor in Cataract, Refractive, External Disease and Corneal Surgery at the Gavin Herbert Eye Institute at the University of California, Irvine.

1. TECNIS Symfony® IOL DFU
2. Cochener B, et al. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. J Cataract Refract Surg. 2016;42:1268-75.

BEST PRACTICES
for Patient Selection

By Karolinne Maia Rocha, MD, PhD

There are many factors to consider when deciding whether a patient is a good candidate for a presbyopia-correcting lens. In my practice, I look at four key areas when selecting patients for the TECNIS Symfony® lens:

- Patients' expectations
- Special anatomic considerations
- Ocular surface health
- Biometry

By focusing closely on each of these areas, I can make a recommendation with confidence.

PATIENTS' EXPECTATIONS

No matter what lens you use, it is essential to communicate effectively with patients to find out what their visual goals are. Find out how your patients really spend their time. Assess patients' personalities, their occupation and expectations. In my practice, I do not use lifestyle questionnaires to get these answers. Although several excellent questionnaires are available, they are only a starting point and patients' responses need to be confirmed with more specific verbal probing.

REMEMBER THIS

No matter what type of cataract procedure you are performing, it is always important to assess the ocular surface first. Whether it is a result of aqueous deficiency or meibomian gland dysfunction, always treat dry eye before taking your final measurement or before implanting a lens.

For example, a patient may indicate on a questionnaire that she watches a lot of television, indicating that distance vision may be her greatest need. However, I've found that, in many cases, this information can be misleading. Imagine that you were to ask this same patient to talk to you about how she watches television. The conversation could be a game-changer if you learn that your patient spends most of her time just listening to the television while she looks at her phone, iPad or laptop. In this case, you'd discover that correcting for intermediate and near vision may be an even greater patient benefit.

ANATOMIC CONSIDERATIONS

I offer the TECNIS Symfony® IOL to a vast majority of my patients because the lens offers high-quality continuous vision with low incidence of halos and glare.[1] Interestingly, I've found that I implant more TECNIS Symfony® Toric IOLs than non-toric TECNIS Symfony® lenses. However, I would not use a TECNIS Symfony® IOL in a patient with wet AMD, dry AMD categories three or four, epiretinal membrane with macular thickening, glaucoma, uveitis, diabetic macular edema, corneal scar, or higher order aberrations >0.5µm for a 6-mm pupil size.

On the other hand, the TECNIS Symfony® IOL may be a good option for patients that are not good candidates for traditional multifocal IOLs.

OCULAR SURFACE HEALTH

No matter what type of cataract procedure you are performing, it is always important to assess the ocular surface first. Whether it is a result of aqueous deficiency or meibomian gland dysfunction, always

WARNINGS

Patients with any of the conditions described in the Directions for Use 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.

treat dry eye before taking your final measurement or before implanting a lens.

As most doctors have experienced, even same-day keratometric readings and optical biometry measurements can differ. For this reason, I always take two corneal maps. And if a patient has ocular surface disease, such as dry eye and epithelial basement membrane dystrophy, I treat it first and then I retest prior to surgery. In these cases, a dynamic measurement of the point spread function over 20 seconds using double-pass wavefront technology tells me whether the patient is ready to undergo surgery.

BIOMETRY

Biometry is critical to assure outstanding outcomes. I perform Placido topography and Scheimpflug tomography in every patient. I use optical biometry routinely and double-check the measurements with immersion A-scan biometry in special cases (dense cataracts, posterior staphyloma, vitreous opacities, etc).

I use the SRK-T formula, Barrett and Warren Hill calculators. For calculating TECNIS Symfony® Toric IOLs, I use the Baylor nomogram and the Barrett toric calculator.

It is very important to correct astigmatism. Although the TECNIS Symfony® IOL is tolerant to astigmatism[2,3] and decentration,[4] we want to make sure that we are doing everything we can to optimize visual outcomes. Correcting astigmatism ensures high-quality full range of vision for our patients.

Karolinne Maia Rocha is the Director of Cornea Service Medical University of South Carolina (MUSC), Storm Eye Institute in Charleston.

1. TECNIS Symfony DFU
2. DOF2016CT0025 TECNIS Symfony Toric Result
3. SC20160OTH0004 Preclinical Evaluation of Tolerance to Astigmatism with an ERV IOL
4. DOF2016CT0023 TECNIS Symfony® IOL Tolerance to decentration

WHAT PATIENTS AND SURGEONS Appreciate Most

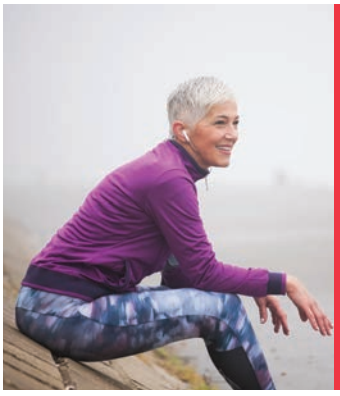
By Mark H. Blecher, MD

The approval of the TECNIS Symfony® Toric IOL has opened up an entirely new segment for ophthalmology. The ability to address both presbyopia and astigmatism in one surgery is a significant advance that both patients and surgeons enjoy for a number of reasons.

LESS CONFUSING FOR PATIENTS

Monovision toric lenses have been moderately popular and patients definitely appreciate it when we can correct their astigmatism. But for many patients, this just isn't enough. The limited visual function they provide can be confusing to patients. And for surgeons, it's difficult to explain that we plan to get rid of the astigmatism with a toric lens, yet the patient will still need to wear glasses.

With the TECNIS Symfony® Toric IOL, the premium lens conversation is much easier. We are correcting vision in a very noticeable way. The lens uses TECNIS Symfony® IOL extended depth of focus technology, providing a wide range of vision. In addition, it has the TECNIS® Toric IOL astigmatism correction we've used for years. Now we can offer excellent presbyopia mitigation to patients with astigmatism who we couldn't offer it to before. For me, being able to say



WE CAN DO THAT FOR YOU

The ability to address both presbyopia and astigmatism in one surgery is a significant advance. The TECNIS Symfony® Toric is the first presbyopia-correcting lens available in the United States for the 33% of the population who have significant levels of astigmatism. Indeed, the approval of the TECNIS Symfony® Toric IOL has opened up an entirely new segment for ophthalmology.

"we can do that for you," makes all the difference. Recommending the TECNIS Symfony® Toric IOL has become a no brainer in cases where it is indicated.

PRESBYOPIA-CORRECTING IOL THAT'S NOT A MULTIFOCAL

For surgeons who have shied away from presbyopia-correcting technology but believe in correcting astigmatism with toric IOL technology, the TECNIS Symfony® Toric IOL may be an excellent new entry point. As with all premium lenses, and especially with presbyopia correcting procedures, patient selection and education is important. But the TECNIS Symfony® IOL is a forgiving lens and brings extended depth of focus with tolerance to astigmatism and decentration. Patients achieve *quality* of vision benefits across the entire range with low glare and halo.

The TECNIS Symfony® IOL echelettes elongate the focal range rather than splitting the light and creating a second focal point. This helps provide intermediate and near vision with low incidence of glare and halo and without compromising distance vision.[1] The TECNIS Symfony® IOL also corrects for chromatic dispersion, which improves image contrast, allowing you to further increase visual quality.

TRUSTED TORIC PLATFORM

The TECNIS Symfony® Toric IOL is implanted in the same way as the TECNIS® Toric IOL, making adoption and integration simple. In my practice, I implant a lot of toric IOLs, but now I have converted almost all of my toric patients to the TECNIS® Toric IOL.

You can use the TECNIS® Toric calculator to select the lens and implantation axis. The A constant for the Symfony® Toric IOL is the same as that of the TECNIS® Toric IOL. Also, the operative procedure is identical to that of the TECNIS® Toric IOL.

Toric IOLs provide more stable and predictable refraction than manual incision surgery and can reduce dependence on spectacles and contact lenses over a patient's lifetime.[3,4] Coupling these benefits with presbyopia mitigation is truly a game changer.

Mark Blecher is the Co-Director of the Cataract Department at the Wills Eye Hospital, Philadelphia, PA.

1. TECNIS® Symfony DFU
2. TECNIS® Symfony DFU
3. Mingo-Botin D, et al. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700–8.
4. Hirnschall N, et al. Correction of moderate corneal astigmatism during cataract surgery: Toric intraocular lens versus peripheral corneal relaxing incisions. J Cataract Refract Surg. 2014;40:354–61.

TIPS FOR SELECTING A TARGET

By Keith Walter, MD

Not every patient who walks into your office is a great candidate for a TECNIS Symfony® IOL. Besides the obvious excluding factors like macular degeneration, corneal disease, or severe glaucoma, you must consider how the patient presents and what their specific needs and wants are. Then, of course, you need to determine whether or not you can deliver them, which involves selecting the right target.

GET TO KNOW THE PATIENT

You can't select the right target if you don't know where to aim. As such, an essential first step is getting to know your patient.

If your patient expresses interest in being less dependent on glasses, sit down and discuss where exactly the patient likes to read. "Reading" means a lot of different things to different people. Do they like to read three paperback novels a week? Is most of their reading on their laptop or other electronic device? Maybe they almost never read, but when they do it's a GPS or a cellphone text. Where do they like to hold their reading material? Do they have any hobbies that require very near focus? For example, do they enjoy woodcarving, quilting, or tying flies? Depending on these answers, you can tailor your recommendation and, later, select your target accordingly.

Satisfied TECNIS Symfony® IOL patients will be those individuals who primarily want great distance and intermediate with some reading vision. These are typically patients who don't read a lot of books, but are more engaged in electronic media. For example, this is your avid golfer who only needs to read her rangefinder or scorecard; your active outdoorsman who loves to camp, hunt, and fish but hates when rain spatters his glasses.

I also like to have a brief discussion about side

effects and gauge the patient's reaction as I explain it. All diffractive lenses have some amount of halos, but less than 3% of TECNIS Symfony® IOL patients have spontaneously reported incidence of severe night vision symptoms.[1] It's also important to recognize that most patients adapt to these issues over time.

I explain halos by comparing them to small floaters. In other words, most of the time we don't notice them because our brain suppresses them as "background" and unimportant. But, now that I've mentioned them, many of you immediately have noticed your own floaters dancing across this page. Where were they a paragraph ago? They were there, you just didn't notice them due to neuro-adaptation.

Luckily, most patients are comforted by this analogy and it gives me a great gauge to determine how they will adapt post-op. But, if my patient remarks that this would be a major issue because their floaters are currently making them "insane," or if they have a history of not dealing with minor issues, I recommend an advanced technology monofocal platform instead of TECNIS Symfony® IOL.

BEYOND THE BASICS

Once the basics are covered, I prefer to begin targeting with the dominant eye first when possible. I want to maximize distance acuity and cut down on glare or halos, especially in the patient's dominant eye. For the second eye, I do the exact same thing about 70-80% of the time, since most patients can function at all ranges without glasses once they regain binocularity with both TECNIS Symfony® IOLs targeted for distance. Occasionally, patients will need a low-powered reading glass for tasks like removing a splinter, reading a medicine package insert, or reading small print in low light.

For the other 20-30% of second eyes, when a patient expresses a desire for more reading ability, I will target their non-dominant eye between -0.5D or -0.75D. This works especially well for those patients who have a history of monovision contact lens wear.

Since satisfaction is driven largely by individual patient preference, choosing a target with the TECNIS Symfony® IOL should be determined largely by what you discover about the patient's lifestyle and behaviors. From there, thanks to the range of vision that's possible with Symfony®, patients experience high levels of satisfaction.[2,3]

Nighttime visual disturbances have long challenged surgeons who implant presbyopia-correcting IOLs. Although the TECNIS Symfony® IOL does not eliminate all concerns of glare and halo, the incidence of night vision symptoms was low in clinical studies. All diffractive lenses have some amount of halos, but less than 3% of TECNIS Symfony® IOL patients spontaneously reported incidence of severe night vision symptoms.*

*TECNIS® Symfony® IOL DFU

POST-OPERATIVE NEUROADAPTATION

Caution patients not to expect their vision to be perfect on POD#1. Patients need to give it time for their brain to get used to the optics of the lens. Set these expectations with referring doctors as well. Explain that it is important to give a little time to settle in. Tell patients this prior to surgery and then remind them again postoperatively. If a patient believes he will be able to see perfectly at all distances, then we have not done our job at setting appropriate expectations, no matter how stellar our outcomes may be. Neuroadaptation time varies from patient to patient.

- Sumit (Sam) Garg, MD

Keith Walter is the Professor at Wake Forest University Eye Center – Winston-Salem, NC.

1. TECNIS® Symfony® IOL DFU
2. DOF2016CT0024 Concerto Study Report,
3. DOF2015OTH0009 Symfony Harmony Observational Study

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 preopera tive 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 condi tions 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, and 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.

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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

PP2017CT0241

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR *TECNIS*® TORIC 1-PIECE IOL

Rx ONLY

INDICATIONS: The TECNIS® Toric 1-Piece posterior chamber lens is 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.

WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances described in the TECNIS® Toric 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. These circumstances include recurrent severe anterior or posterior segment inflammation or uveitis; 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); a compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; or patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL. Children under the age of 2 years are not suitable candidates for intraocular lenses. The clinical study for the TECNIS® Toric 1-Piece IOL did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter. The TECNIS® Toric 1-Piece IOL should not be placed in the ciliary sulcus. Rotation of the TECNIS® Toric 1-Piece IOL away from its intended axis can reduce its 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.

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. Do not soak or rinse with any solution other than sterile balanced salt solution or sterile normal saline. Do not store in direct sunlight or at greater than 113oF. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Toric 1-Piece IOL with the intended axis of placement. When the insertion system is used improperly, the haptics of the TECNIS® Toric 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. The use of methods other than the TECNIS® Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the clinical 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. The safety and effectiveness of the toric intraocular lens have not been substantiated in patients with certain preexisting ocular conditions, and intraoperative complications. 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. Preexisting conditions include: 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, or irregular corneal astigmatism. Intraoperative conditions include: excessive vitreous loss, capsulotomy by any technique other than a circular tear, the presence of radial tears known or suspected at the time of surgery, situations in which the integrity of the circular tear cannot be confirmed by direct visualization, cataract extraction by techniques other than phacoemulsification or liquefaction, situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.), capsular rupture, significant anterior chamber hyphema, uncontrollable positive intraocular pressure, zonular damage. All preoperative surgical parameters are important when choosing a toric lens 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 clinical study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study. Note that the TECNIS® Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options. Do not reuse, resterilize, or autoclave.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of an IOL may include but are not limited to: endophthalmitis/intraocular infection, hypopyon, pupillary block, retinal detachment, IOL dislocation, persistent corneal stromal edema, persistent cystoid macular edema, or secondary surgical intervention (including implant repositioning, removal, or other surgical procedure). The most frequently reported cumulative adverse event that occurred during the TECNIS® Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures). Other reported events included cystoid macular edema which occurred at a rate of 2.9% and retinal detachment which occurred at a rate of 0.6%.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE *TECNIS*® MULTIFOCAL FAMILY OF 1-PIECE IOLS

Rx ONLY

INDICATIONS: The TECNIS® Multifocal 1-Piece intraocular lenses 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.

WARNINGS: Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the Directions for Use that could increase complications or impact patient outcomes. 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. The lens should not be placed in the ciliary sulcus. Inform patients about the possibility that a decrease in contrast sensitivity and an increase in visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions.

PRECAUTIONS: Prior to surgery, 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. The long-term effects of intraocular lens implantation have not been determined. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. Do not reuse, resterilize or autoclave.

ADVERSE EVENTS: The rates of surgical re-interventions, most of which were non-lens related, were statistically higher than the FDA grid rate for both the ZMB00 (+4.00 D) and ZLB00 (+3.25 D) lens models. For the ZMB00, the surgical re-intervention rates were 3.2% for first eyes and 3.3% for second eyes. The re-intervention rate was 3.3% for both the first and second eyes in the ZLB00 group.

ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

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