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Drs. Donnenfeld, Solomon, Blecher, Clinch, Hamilton, Lahners, Shapiro and Yeu are paid consultants of Johnson & Johnson Surgical Vision, Inc.

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### Dear Colleague,

As a profession, we've witnessed a significant change in cataract surgery during the past two decades. The technology we use, the techniques we perform and the expectations of the patients who we treat are all much different than what many of us were accustomed to when we entered our careers. This is a good thing.

Indeed, patients may be harder to please, but that's because we've raised the bar so high. In 1990, the goal was happy patients. But "happy" was nothing more than what was expected. As refractive cataract surgeons, we don't want to merely deliver the expected. We want to offer more. And now we can, with options to personalize vision based on patients' visual goals.

In 2019, the cataract surgeon's goal should not be "happy patients" — it should be "ecstatic patients" — in other words, patients whose expectations have been exceeded. In the following pages, you will garner advice from a group of surgeons who have been leading the charge in educating our colleagues about how to be more than "good enough."

As you'll read, exceeding expectations begins by setting them properly in the first place and making sure your patients are truly prepared, physically and emotionally, for premium surgery. Both before and after surgery, patients need our support. In the unfortunate event that a patient is unhappy, what we say to patients can have just as much impact on their ultimate satisfaction as what we do to fix it.

This report will also cover the art of astigmatism management and the evolving science of personalizing vision using one or more IOL designs to match patients' lifestyles as closely as possible.

Finally, two surgeons will share their personal stories of success with TECNIS Symfony® IOL, illustrating what it's like to experience extended depth of focus (EDOF) vision from a surgeon's point-of-view and demonstrating how the TECNIS® platform can help improve outcomes in your practice.



Eric D. Donnenfeld, MD



Kerry Solomon, MD

# The Art of Good Medicine

By Eric D. Donnenfeld, MD



Several years ago, I was asked to speak at the FDA on behalf of LASIK, at a time when there was some talk about possibly pulling the approval due to patient complaints. Frankly, I braced myself for what I thought would be a lot of angry tales by unreasonable people, but what I came away with was different. In fact, it was helpful.

The one clear message I came away with was that these patients were not primarily unhappy with their vision; they were unhappy because they felt abandoned by their doctors. I swore to myself then that I would never let a patient feel abandoned.

No matter how trivial you think your patient's complaint is, it's important to the patient, and you need to listen and agree with them, and try to find a solution. You have to stop and take a deep breath and be genuinely supportive of your patients.

Yes, you will sometimes have patients who will test you, but the key is to always let the patient know that you have their best interest at heart and leave no stone unturned until you get their problem resolved. The art of medicine is to keep your patient close to you, even when the dynamic has changed. Your staff can also help with this too. For example, if you or your staff receive a call about an unhappy patient, get that patient in right away and don't make them wait. Have your staff perform refraction, OCT and topography the moment they arrive. Make sure they collect everything you will need so you're prepared with answers.

Then, when the patient arrives in your chair, you don't have to send them away for more tests. You are there with answers, solutions and apologies. For example, I say something along the lines of the following:

'Mrs. Jones, you must be very unhappy with the results. As we discussed before surgery, this can happen and I apologize that it happened to you. We're going to work together to make this better as quickly as possible. I will do everything it takes to fix this.'

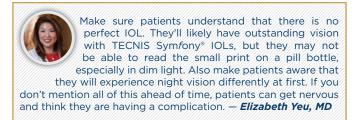
After hearing this honest speech, you'll likely diffuse the anger and bond together.

# Patient Education Strategies for Seamless Communication With Patients



By Kerry Solomon, MD

How we communicate with patients is essential to our ultimate success as surgeons. If you want happy patients, provide accurate information that helps your patient to make an informed decision that suits his or her lifestyle. Here are several pearls that have helped us strengthen relations with our patients.



- Make your website a useful information hub. Your website can
  be a very effective way to provide education about the options
  for cataract surgery. When the patient calls for an appointment,
  or a screening reveals cataract development, you can direct
  them to immediate answers on a whole range of topics. Always
  include the link to your website when you send out a letter to
  prospective surgical candidates.
- Give patients something to read while they wait. Make sure
  educational materials are at the ready in your waiting areas and
  exam rooms.
- Consistently update your social media. Don't let your online presence get stale. You are cutting-edge. Your sites should reflect that.
- Provide written pre- and postop instructions. We create practice-branded versions for our patients.
- Invite family members. There's a lot of information to absorb and remember, so I always recommend that patients bring a family member or a friend with them.
- Spend time with patients. I like to spend the time needed to educate patients, and patients appreciate the opportunity to talk directly with their surgeon.
- Avoid duplication. There's a lot of information to share and
  it doesn't all have to come from the same person. Patients
  interact with several staff members as they make their way
  through the practice. Give each person a small part in patient
  education. We've scripted out our entire office process so the
  patients don't get redundancy. Consistent communication is
  very important.
- Provide a recommendation. Patients are looking for your guidance. You're the doctor and they want to know what you think is best. This doesn't make you pushy and it doesn't make you a salesman. It makes you an expert and educator.
- Develop packages. This keeps things simple for the staff and patients. It incorporates non-covered services and provides a strategy for enhancements.
- Talk about enhancements. No matter how good a surgeon you are or how great the technology is, there will still be a percent-



The J&J Vision Lifestyle Questionnaire enables you to collect important patient information that will help define patients' vision goals. It also provides your staff with a quick reference to aid in consistent communication.

age of people that need an enhancement. If you talk about this before surgery, patients don't perceive it as a complication.

Involve staff in new technology launches. Make sure your staff
has a clear understanding of what's important to you. When you
add a new technology, roll it out together. If your staff has any
hesitations, talk openly about it.

Patient communication should be as seamless and thorough as possible. Although every conversation is as unique as the patient is, the format and take-home messaging should always be the same.

We have the ability to deliver great outcomes to our patients, but we must never forget that personalities play a part in how these are perceived.



Everyone wants to be an overachiever, so don't make the mistake of telling patients what only some patients can achieve. For example, if I say, 'within one week, 50% of my patients can work at a computer,' then 50% of my patients may fail. I tell all my patients it's going to take some time to be able to work comfortably

at the computer. This way, the vast majority of my patients feel they've beaten the odds and have exceeded expectations. —  $\it Thomas\ E.\ Clinch,\ MD$ 

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 preexisting 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.

## **Personalizing Vision With PCIOLs**

By Elizabeth Yeu, MD



When I started implanting TECNIS Symfony® IOLs, my presbyopia-correcting lens rates jumped from less than 10% to 20%-25%. I attribute this to the confidence I have in EDOF technology and the quality of vision that these lenses provide for my patients.

Initially, when you're starting with a lens that you don't have much experience with, bilateral implantation helps you get used to the technology and understand what type of vision it offers. The range of vision that the TECNIS Symfony® IOL provides is a great personal fit for a significant portion of my patient population, so bilateral implantation is very common in our practice. However, with time, some surgeons find that in certain cases, personalizing vision may involve a TECNIS Symfony® IOL in one eye and a TECNIS® Multifocal in the other eye.



If your patient has excellent distance but is underwhelmed by the near vision postoperatively, hand them a reading card and then turn on the light. You'll be amazed by how much of a difference this makes. Extra light helps. Remember,

these are great implants but they don't have little headlights in them. The patient's use of light readers isn't driven by a lack of focus, it's from the magnification they can get. — Mark H. Blecher, MD

#### **Case in Point**

Patients with notable near vision needs may require a little more near than the TECNIS Symfony® IOL is designed to provide. But before you jump into a multifocal, you need to determine how adverse the patient is to potential dysphotopsias. If I don't foresee any concerns, I consider using a mid-add multifocal in the non-dominant eye with a TECNIS Symfony® IOL in the dominant eye.

For example, I recently treated a 61-year-old female executive assistant. She's on the computer for more than six hours per day and wears her glasses the whole time she's at work. She is 5'1", and desired sharp distance and a range of vision for computer use. She also loves to read, spending about two hours per day with a paperback. Since she plans on retiring within the next few years, her reading vision is particularly important. Notably, she was very concerned about night vision symptoms.

Manifest refraction was  $-2.25 + 0.50 \times 170 (20/30)$  OD and  $-2.00 + 0.50 \times 180 (20/30)$  OS.

As you can see on her topography, she has with-the-rule astigmatism of less than 1D, with low higher-order aberrations.

#### **Treatment Plan**

I had two big concerns with regard to this patient: her



When I think there may be a benefit to using a low add multifocal along with a TECNIS Symfony\* IOL, I prefer to operate on the dominant eye first. Then, if the patient is not completely comfortable, I will implant a TECNIS\* 3.25D multifocal in the

second, non-dominant eye. Approximately 80% of my presbyopia-correcting IOL patients receive bilateral TECNIS Symfony\* IOLs. In the remaining 20%, I aim for dominant eye distance with the TECNIS Symfony\* IOL and then use the TECNIS\* 3.25D add IOL in the non-dominant eye. — *Eric D. Donnenfeld, MD* 

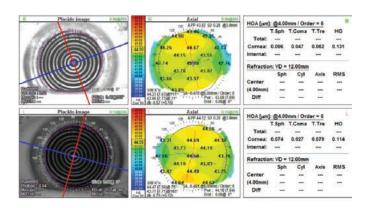
adversity to any night dysphotopsias and her near vision needs. She's also short, yet desires reading as well as computer distances. Plus, she has low cylinder.

For all of these reasons, the upfront patient education and expectation-setting was critical in this case. Still, I knew I could make the patient happy. My plan was to start with a mid-add multifocal in the non-dominant eye with a plano goal. Then, I would wait a bit to determine how to proceed in the dominant eye.

In previous cases, when I've been very concerned about dysphotopsia, I have used a monofocal in the second/dominant eye. But, this patient needed the intermediate for her computer, was thoroughly counseled and was responding well with the multifocal.

We proceeded with TECNIS Symfony® IOL in the second eye, and today she's functioning exactly as she hoped.





WARNINGS for TECNIS Multifocal and TECNIS Symfony IOLs: Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions, these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions.

# Managing Presbyopia and Astigmatism in Today's Demanding Cataract Patients

By Mark H. Blecher, MD

You can have the best-performing lens ever manufactured, but it won't do you any good if you leave too much cylinder behind. To get the most from an intraocular lens, we need to do our best to address anything over 0.5D of cylinder. Although this can sometimes be challenging, it's worth striving for. The TECNIS Symfony® Toric IOL has been instrumental in achieving high satisfaction in my astigmatic patients.

#### **Practical Pearls**

To properly and adequately address astigmatism at the time of cataract surgery, we need to start with superb measurements. You can't count on your measurements if the ocular surface is diseased. Always address dry eye and optimize the corneal surface prior to surgery. If the topography doesn't look good, your keratometry and your biometry will not be reliable, and you should not use those numbers. No one wants to perform an enhancement—it's expensive and patients aren't thrilled about undergoing a second surgery.

Once the ocular surface is healthy and you're confident in your measurements, good technique with the TECNIS Symfony® Toric IOL may help minimize malrotation. For example, be careful about fluid by ensuring that you get all of the viscoelastic out from behind the lens. Also, position the lens before you tap it down into the capsular bag so you don't create tension in the bag at the end of surgery, since this can release and cause the lens to rotate. You want the lens to be perfectly aligned before you settle it. Once you are sure your alignment is correct, snug it against the capsule and leave it.

Finally, at the end of the case, be careful with the flow so as not to create movement in the chamber. These are small details, but collectively they can make a difference.

If you're struggling a little bit to remove viscoelastic without moving the toric, consider using bimanual IA instead of coaxial. I prefer a bimanual technique because it makes it easier to get viscoelastic out from behind the lens. Also, some of the bimanual irrigators have a small rubber tip, which you can use to nudge the lens right where you want it.



It's important to educate referring doctors on a regular basis. In our practice, we hold seminars about every three or four months where we explain the optics, the benefits, and our experience. We also invite referring doctors to come to our practice and watch their own patients have surgery. — Kerry Solomon, MD

#### Case

Soon after we got the TECNIS platform, my 66-year-old practice administrator announced that she wanted cataract surgery. She was currently wearing gas permeable contact lenses and hated them. Her pre-op exam revealed the following:

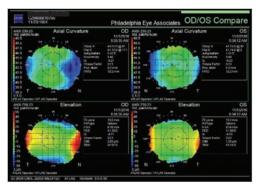
MR +4.50 + 1.50 x 83 +5.25 + 1.00 x 90 Ks 41.41/43.77 x 83 41.82/44.12 x 94

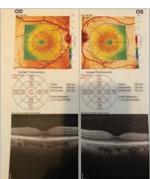
Holliday II and ORA were used for IOL selection. As you can see, her corneal topography revealed normal astigmatism, and her macular OCT looked good so we decided to proceed with the TECNIS Symfony\* Toric IOL.

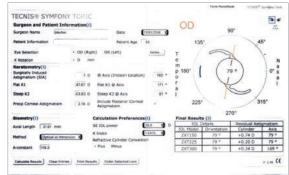
I used the toric calculator from Johnson & Johnson Vision, which gives you the option to put in posterior corneal astigmatism correction. I use this all the time and it gives me great results. You can access the calculator at https://www.surgical.jnjvision.com/support/online-tools/toric-calculator. Post-op, the patient described her vision as excellent and she couldn't be happier. She sees 20/20+ OD, and OS and near vision are J1 OU at 14 inches.

#### **Strive for Greatness**

The TECNIS Symfony® Toric IOL has improved my practice in so many ways—not the least of which is due to how happy my practice administrator is today! In addition to that, correcting astigmatism when you're treating cataracts and mitigating the effects of presbyopia is a no-brainer. You have to do it to achieve a premium result. Astigmatism correction, combined with the TECNIS platform and EDOF optics, has been a game changer for me and for my patients.







## **How to Manage the Unhappy Patient**

By Rex Hamilton, MD, MS, FACS



A 64-year-old female presented to me with a request to wear glasses less often. Her exam was normal, with the exception of cataracts. She was right-eye dominant. Importantly, the patient plays competitive tennis, so depth perception was particularly important to her.

We used several IOL calculators and ultimately settled on a 23.5 lens (See Figure 1).

#### Figure 1

#### TECNIS Symfony® IOL OS (first eye)

ASCRS calculator target plano

- Haigis-L: 23.5 D
- Barrett True K: 22.0 D
- Shammas: 23.0 D

Central 2 mm K H1 22.5 D ORA: 23.5 D

LENS CHOICE: 23.5 D

At post-op week 1, UCDVA was 20/60 and UCNVA was J1. Understandably, no matter how great her cell phone now looked, the patient complained that she couldn't see the street signs.

#### Second Eye Calculation Strategy

In this case, I employed a technique I call a "back calculation" using the Holladay IOL Consultant.

First, enter IOL implanted in first eye and the first eye post-op MRx. You also enter formula used for first eye. As you move through the formula, it will tell you what you should have used for the K reading in that first eye. I call this the "True K."

In this case, I should have used the 49.39 on that first eve.

The next step is to look at the Delta K between the two eyes as follows:

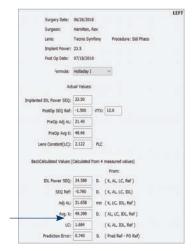
Step 2: Delta K

- Sim K from 2nd eye
  - Sim K from 1st eye
  - $= \Delta K$
- ΔK = 48.44 48.71 =-0.27 D

Step 3:  $2^{nd}$  eye Alt K = True K  $1^{st}$  eye +  $\Delta$ K

• 49.39 - 0.27 = 49.12 D

Step 4: IOL calculation using 2<sup>nd</sup> eye Alt K



#### Winning With the Second Eye

In the second eye, we used Holladay I using the new K that we calculated. The ORA suggested a 21, predicting +.31. I put in a 21, and the patient ended up spot-on plano and is much happier.

When you miss the first eye, the second becomes all that much more important. This approach is very helpful in such cases.

# **Managing Dysphotopsia in PCIOL Patients**

By Thomas E. Clinch, MD



A 51-year-old Hispanic gentleman presented with a one-year history of a progressive decrease in vision in his right (non-dominant) eye, associated with increased night vision disturbances and sensitivity to light. I knew the patient quite well because he brings his mother in to see me every three to four months for a glaucoma check-up. In 2005, I also performed uncomplicated monovision LASIK on this patient in his left (dominant) eye, and he was extremely happy with the results.

Now, several years later, the patient was reporting blurred vision. VA was 20/200 in his right (near vision) eye, with glare down to 20/100 due to unilaterally, visually significant cataract.

#### **Surgery and Early Post-Op**

Importantly, the patient is 5"1' and has short arms. Due to this, as well as how happy he currently was with his monovision, I decided to implant a ZLBOO. At the Day 1 and Day 8 follow-ups, this otherwise very optimistic patient was very unhappy. He said he felt like he was looking underwater and

everything was foggy. UCVA was 20/70, and MR was  $\pm$ 0.75 20/25.

#### What Should We Do Next?

I explained to patient that I wanted to wait at least one month to allow the eye to convalesce both physically as well as from a neuro-adaptive standpoint. Spectacles were dispensed to allow the patient to separate symptoms due to the IOL versus refractive error, and I conveyed that we would work as a team to get him functioning in the interim so we could determine the appropriate next step.

When the patient returned at post-op day 28, he reported that his vision was much better with the glasses, but that he was still having a lot of night vision disturbances, although to a lesser degree.

#### **Second Surgery**

In this case, I had the luxury of knowing that I was treating a patient who has a very positive attitude, which gave me some confidence in my clinical decision-making. So, I

explained to him that I thought we should exchange out the ZLB00 because I believed this would reduce the dysphotopsias and give him better functionality, although likely at the expense of some of near vision. He understood that we needed to compromise, but was happy with the plan. Importantly, I also prepared him for the fact that his vision would likely be blurry for the first day or two. This is important to emphasize with all lens exchange patients. Make sure they know that it may get a little worse before it gets better.

#### **Lessons Learned**

The patient is now doing very well and he feels his distance vision is excellent.

For me, there were a lot of takeaways from this case. First, mild to moderate myopes are challenging cases. Their functionality at near is often more important than they think it will be. And, if the patient has a history of monovision with LASIK or monovision with contacts, it's critical to realize that monovision after cataract surgery is very different. As patients age, the range of focus diminishes.

# Why I Rarely Explant

By William J. Lahners, MD, FACS



During the past 12 months, I've performed approximately 2,000 cases. About 1,500 of these cases involved the use of a femtosecond laser, and presbyopia-correcting lenses were implanted in 850 of them (TECNIS Symfony® IOL: 800; TECNIS® Multifocal: 50). My overall explantation rate for these cases was 0.11% (2/1700). This is a notable improvement compared with my earlier explantation rates using other lenses.

#### The Honeymoon Phase

When the TECNIS Symfony® IOL came out in 2016, we adopted it immediately. I evaluated the science and was confident in the technology. Something was different, and it wasn't anything we were doing differently. On the contrary—we were doing everything the same.

#### **Don't Loosen Standards**

From the outset, we were extremely strict about whom we offered TECNIS Symfony® IOL technology to. No matter what you hear about how forgiving an EDOF lens may be or how high the quality of vision is, we don't believe in lowering the inclusion criteria.

We perform macular OCTs and topographies on every single patient, and we look for absolutely beautiful, perfect, healthy eyes in all cases—without this, we don't offer a PCIOL. I firmly believe that this is a significant contributor to our success.

#### **Help Patients Achieve Success**

You'll never make everyone happy all of the time, but it is a mistake to rush in and make big changes prematurely. When a patient expresses disappointment, don't rush straight to explantation. Instead, try to be thoughtful about what to do next and take it slow.

Start by considering the usual suspects. Look for ametropias, early posterior capsular opacification (PCO), cystoid macular edema (CME) and and macula pathology. Next, consider the

It's okay to sympathize with a patient's negative impression of their surgical result. You want to make sure you are on the same team. I never disagree with patients about their beliefs. I let them know I'm in this with them. When you agree with your patient and you sympathize with their disappointment, you're in a much better place to improve it. Say something along the lines of: 'I'm as disappointed as you are that you're not performing a little bit better. Let me explain to you what's going on here and how we're going to fix it.' — Rex Hamilton, MD, MS, FACS

patient's personality and state of mind. Some people are not as well-equipped to deal with stresses and require a little bit more sympathy and TLC. Undergoing cataract surgery and adapting to a whole new optical system is a stressful event—even when it turns out perfectly.

Whatever the patient's unique situation may be, it's important that we, as doctors, approach them with confidence, a plan and a timeline. We need to provide a foundation of support. Unless the patient is acting very badly and appears extremely unstable, I believe in helping them walk slowly to whatever the next step may be.

#### **Next Steps**

If you discover a real problem, address it head on. Whether that requires dry eye therapy, psychological support or YAG, get in there and do it. In our practice, we YAG early and often. But before we do, we always have a conversation with the patient that's aimed at helping them recommit to making the lens work.

Finally, in the extremely unlikely event that explantation becomes necessary, in our practice, we refund the patient down to the next level, determine a distance or near target using a monofocal lens, and bill it out as IOL exchange due to mechanical failure of IOL.

PRECAUTIONS for TECNIS Symfony IOLs: 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.

# TECNIS Symfony IOL Through My Eyes

By Michael B. Shapiro, MD, MS



I've been performing presbyopia-correcting cataract surgery for more than 30 years, beginning with monovision surgery and later moving on to multifocal IOLs. With the early-generation lenses, patients frequently reported that they had "nothing in the middle," meaning there was an intermediate vision sacrifice. But, in the right patients with the right expectations, this was still considered a success as long as the patient was pleased.

Over the years, we endeavored to improve our outcomes and began to have a lot of success when we began using the low add TECNIS® Multifocal lenses. Patients were happy, but when they asked me what lens I would pick for myself, I still couldn't say I'd select a multifocal. I do a lot of night driving, and I stare at eye charts all day. Multifocals are a good fit for many of my patients, but I needed something different. As great as I believe this technology is, patients are skeptical of anything you wouldn't select for yourself.

#### **Defining Moments**

In 2016, the TECNIS Symfony® IOL was introduced. My first patient was a very active 68-year-old, -9.00D golfer who happened to also be a referring optometrist's father. He underwent successful surgery and was ecstatic with the results

Since then, the TECNIS Symfony® IOL quickly became my lens of choice. I've implanted more than 266 eyes.

Only two of my TECNIS Symfony® IOL patients have ever asked me for any type of correction for the distance. These were for driving at night and for unusually long distance vision.

What I have found most remarkable with TECNIS Symfony® IOL has been the intermediate vision benefits. My patients' ability to view cell phones, computers and iPads has been outstanding. All of a sudden, my answer to "what would you do if you were me?" has changed. I would consider a PCIOL after all.

#### **Eureka**

I took a long look in the mirror and realized that I was a 60-year-old ophthalmologist who was not happy with his vision. Even though I could refract myself to 20/20 and almost 20/15, I had cataracts in both eyes and was developing a very annoying progressive myopia.

Not long ago, I didn't need to wear any correction, but recently I started wearing a contact lens in one eye for monovision. Then the next thing I knew, the other eye



It's great that we have the option of personalized vision, and I think it works for a lot of people. But I prefer a bilateral TECNIS Symfony\* IOL. — Rex Hamilton, MD, MS, FACS

became more myopic. Now I was playing with the oculars when performing surgery and wearing glasses at night to counteract the monovision. It all became too much. I thought to myself, why am I allowing myself to struggle with this?

#### "Go Time"

I wasn't sure which eye was dominant, but my right eye was bothering me more, so I started with that. I had cataract surgery with the TECNIS Symfony® IOL on May 8, 2018 and everything went great.

A week later, I had surgery on my left eye. The procedure was at 4pm, and at approximately 9pm, I started experiencing a mild rainbow effect around lights, as well as a little bit of achiness. But, about an hour later, everything seemed fine.

#### My Outcome

When someone asks if I'm happy with my TECNIS Symfony® IOLs, I say, 'no' because the truth is I am ecstatic. What this procedure has done for me is nothing short of remarkable. I had a 1+ nuclear sclerotic change, and still the improvement in the brightness and contrast sensitivity is excellent. Imagine what that would be like for a patient who has a 3+ nuclear sclerotic cataract.

My uncorrected visual acuity is now 20/30 OD, 20/20 OS and 20/15 OU. Near vision OU is J1+. The intermediate vision is outstanding.

#### **How to Describe Concerns**

Almost every surgeon I talk to asks what I think about the night phenomenon. It does feel different at first, but it has not stopped me.

Colleagues are also curious about the concept of binocular vision. In my eyes, the additive effect of using the two eyes together really makes a big difference.

Finally, with regard to neuroadaptation: It's real and it works like we expect it to. I'm very type A about my night vision and was cataloging everything that I saw, but now I don't think about it.

In short, bilateral TECNIS Symfony® IOLs are one of the best things I've ever done for myself.

WARNINGS: 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.

# 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.
- I. 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:

- 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 defeated.

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 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 under any of the conditions described in the Directions for Use should weigh the potential risk/benefit ratio prior to implanting a lens. Some visual effects associated with multifocal IOLs may be expected

because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions, these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions. Patients with a predicted postoperative astigmatism >1.0D may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence. Care should be taken to achieve centration, as lens decentration may result in patients experiencing visual disturbances, particularly in patients with large pupils under mesopic conditions. 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.

Patients with certain medical conditions may not be suitable candidates for IOLs. Consult the Directions for Use for more information.

#### 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 patient. There were no patients 21 years old or younger included in the clinical studies; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group. The central one millimeter area of the lens creates a far image focus, therefore patients with abnormally small pupils (~1mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however, because this multifocal design has not been tested in patients with abnormally small pupils, it is unclear whether such patients will derive any near vision benefit. Autorefractors may not provide optimal postoperative refraction of multifocal patients; manual refraction is strongly recommended. In contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Care should be taken when performing wavefront measurements as two different wavefronts are produced (one will be in focus (either far or near) and the other wavefront will be out of focus); therefore incorrect interpretation of the wavefront measurements is possible. The long-term effects of intraocular lens implantation have not been determined; therefore implant patients should be monitored postoperatively on a regular basis. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively. Do not resterilize or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or over 45 C (113 F). Emmetropia should be targeted as this lens is designed for optimum visual performance when emmetropia is achieved. Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded. When the nsertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

#### ADVERSE EVENTS:

The most frequently reported adverse event that occurred during the clinical trials of the TECNIS Multifocal lenses was surgical re-intervention,

most of which were non-lens-related. Lens-related reinterventions occurred at a rate of 0.6% to 1.0%. Other surgical re-interventions included lens exchanges (for incorrect IOL power), retinal repair, ruptured globe repair, macular hole repair, removal of retained lens material, treatment injections for cystoid macular edema and iritis, and blepharoplasty.

#### ATTENTION:

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

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