Strategies for Managing Advanced Technology IOLs in Today's Cataract Patient

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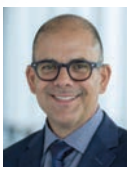

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Cataract surgery is always changing.

Innovation plays a large part in this, but so too does our understanding of how to be an effective partner in a patient's journey. Optometry plays a key role and serves an important function in caring for patients as they set out to learn about their options, ultimately making choices that will affect the remainder of their lives. We also frequently oversee their care in the days, weeks, and months following surgery. This too is a critical time.

As technology evolves and patients' expectations are heightened, we are faced with a great responsibility that requires deep clinical understanding. To address this need, a panel of optometrists met at the American Optometric Association meeting in Denver to evaluate several aspects of modern cataract care. In the following pages, you'll learn about all stages of care as they pertain to the OD.

Following a lively discussion on the optometrist's role and changing demographics, each of the panelists presented on specialty areas including pre-operative care and ocular surface management, extended depth of focus and multifocal technologies, astigmatism management, and post-operative care.

-- Paul Karpecki, OD, FAAO

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Cataract Surgery and the Optometrist

Proceedings from a roundtable event held at
the American Academy of Optometry Meeting.

Q **DR. KARPECKI: What is the optometrists' role in contemporary cataract patient care?**

DR. BLOOMENSTEIN: In my opinion, our most important job is to understand the options for cataract surgery patients and to select a surgeon who uses technology that we believe is best for our patients.

DR. BLACK: I would add some more jobs to that list. We need to properly select patients and educate them. I want the patient to understand and be part of the pre-operative care process. This, of course, begins with education.

DR. KARPECKI: When do you diagnose cataracts and start educating patients about the condition?

DR. DEVRIES: Sooner rather than later. At the first sign of early cataracts, I believe a patient should be advised. If a patient is not advised and they happen to see their primary care physician who informs them that they have a cataract, they are upset. I see this frequently in our referral center and the patient will state: "I recently had an eye exam and my optometrist didn't tell me I had a cataract." This results in an erosion of confidence in their optometrist.

DR. SCHMIDT: The education begins the moment you make the diagnosis. Then, over time, you'll need to escalate the conversation and get more into depth with respect to the effects of astigmatism and presbyopia, so the patient develops a better understanding when it's time to make decisions about surgery.

"I want the patient to understand and be part of the pre-operative care process. This, of course, begins with education."

Optometrists perform an estimated

88 MILLION

refractive eye exams annually*

* http://reviewob.com/wp-content/uploads/2016/11/8-21-13stateofoptometryreport.pdf

DR. BLOOMENSTEIN: Once you've diagnosed the cataract, there are four stages of pre-operative care. To begin, you have to get to know the patient's needs and wants. You also need to gather all relevant clinical information. Third, offer education on clinically appropriate options. Finally, you must pre-treat any ocular surface health issues if indicated.

DR. KARPECKI: Many optometrists discuss the different surgical options—for example, whether to undergo conventional surgery or laser-assisted cataract surgery. Do you believe in this approach?

Dr. Black: You don't have to drill down too deep on optics and science, but I believe in educating patients about the categories of IOLs that they may be candidates for, based on what I currently know about their eyes and lifestyle. This may seem like a lot, but many of these patients are making a decision that will affect the next 20 years or so of their lives. It's important to them and they deserve to be well informed.

DR. KARPECKI: In some cases, if you think you know a lot about the patient and his or her finances, would you refrain from discussing premium surgery options?

DR. SCHMIDT: It's a big mistake to make assumptions about how much money a patient can or will spend for surgery. We make clinical decisions, not financial ones. Our job is to inform and leave the value decision up to each individual patient.

DR. KARPECKI: I agree. No matter what you think you know about a patient's circumstances, you're dishonoring them if you withhold information and deny them the opportunity altogether.

DR. DEVRIES: It's also important to recognize that surgical practices can be very busy environments, where patients are shuffled from one test to another. This can be stressful for some patients—especially if they are hearing a multitude of new terms for the first time. If patients are discussing cost for the first time at the surgery center, it can catch them a little off guard. Prepare your patients for what to expect so they don't make knee-jerk decisions just because they feel rushed. It also helps if you pay a visit to the surgical center since this will help you to more effectively communicate what the experience is like.

"Mention details about how the patient responded to previous vision correction."

DR. KARPECKI: Mutual patient care between an OD and MD is built on relationships and respect. How do you interact with the surgeons to whom you refer patients?

DR. DEVRIES: The optometrist provides a level of value to the surgeon that directly affects patient care. In most cases, the surgeon interacts with the patient for a very short time compared to a long history that is often shared with the primary eye care provider.

870,000
CATARACT PROCEDURES
on people younger than 65 YEARS in the U.S. alone*.

*2015 Comprehensive Report on the Global IOL Market. Market Scope

DR. SCHMIDT: Details matter. A thorough letter detailing relevant information about the patient and what would work and why can prove extremely useful to the surgeon. For example, mention details about how the patient responded to previous vision correction, such as monovision or progressive lenses.

Demographics

Q **DR. KARPECKI: Are optometrists ready for the silver tsunami—meaning the onslaught of baby boomers who develop cataracts?**

DR. BLACK: I would start by saying that the tsunami is not necessarily silver. In the United States alone, an estimated 870,000 cataract procedures were expected

2/3 of Americans age fifty own smartphones*

20% use social media one or more hours per day*

* AARP Getting to Know Americans Age 50+, 2014

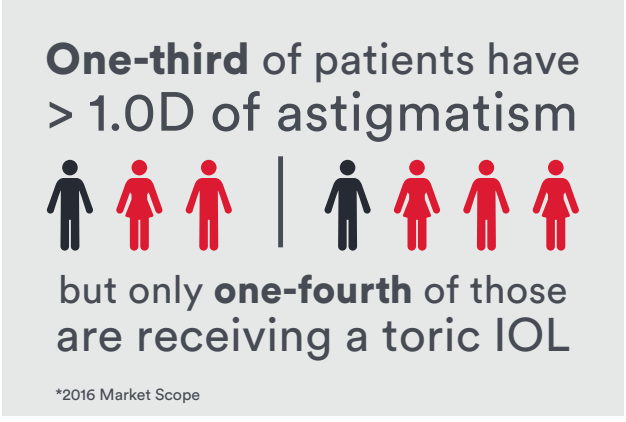
to be performed on people younger than 65 years—in just one year's time. This illustrates to me that we are beginning to address cataracts before the lens is so ripe that vision has deteriorated to 20/40 or has significantly affected the patient's ability to function.

DR. BLOOMENSTEIN: It would behoove us to think more carefully about what it means to have cataracts. From the moment you recognize the condition, you need to monitor it and begin planning for the months or years ahead.

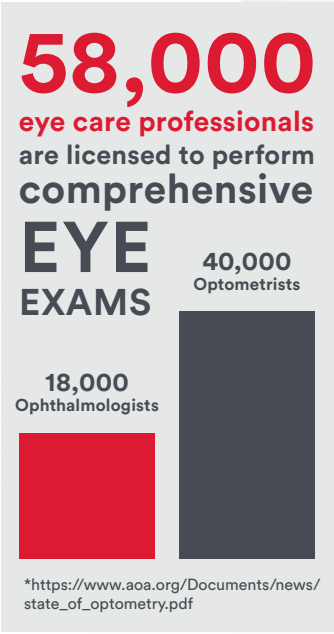
DR. SCHMIDT: Today's cataract patients also have vastly different lifestyles than their parents had. Nearly two-thirds of Americans age 50 own smartphones, and 20 percent use social media one or more hours per day.

DR. DEVRIES: Cataract patients are also remaining in the workforce longer—the boomer generation still constitutes about one-third of the workforce, and one in ten say they will never retire.

DR. BLOOMENSTEIN: When you consider the visual demands of older Americans in the workforce, these patients' needs have to be addressed at each and every one of their annual exams. This presents both a challenge and an opportunity for all eye care providers.



DR. BLACK: Let's take a closer look at who is tasked with performing these exams. Fifty-eight thousand eye care professionals are licensed to perform comprehensive eye exams; only 18,000 of these are ophthalmologists, whereas 40,000 are optometrists. This is certainly reflected in the number of exams performed by ODs. Optometrists perform an estimated 88 million refractive eye exams annually of the 104 million performed by all eye care professionals, or 85 percent of all comprehensive eye exams.



DR. KARPECKI: Every patient over the age of 50 is impacted by presbyopia[1], but how many of these patients do you think receive a presbyopia-correcting IOL during cataract surgery?

DR. DEVRIES: I would think it should be very high, but according to the data, only 6.5% receive a PCIOL. This is astonishing considering that patients who don't have presbyopia treated at the time of cataract surgery must treat those conditions with glasses for the rest of their lives.

DR. SCHMIDT: Not fully addressing visual needs doesn't stop with presbyopia. Patients who don't have astigmatism treated at the time of cataract surgery also must treat those conditions with glasses for the rest of their lives. But, guess what? One-third of patients have > 1.0D of astigmatism, but only 1/4 of those patients are receiving a toric IOL.

How to Resolve Ocular Surface Issues Preoperatively

By Doug Devries, OD

It should be common knowledge that you should not send a patient for cataract surgery before addressing problems with the ocular surface. Consider the consequences:

- Patients who had osmolarity scores within normal limits were within a half diopter of intent, whereas 17% of those with hyperosmolarity would have missed their IOL calculation by more than a diopter.[2]
- MGD decreases ocular comfort.[3,4]
- Cataract surgery can worsen dry eye disease for months after surgery.[5]

If you think these patients aren't presenting in your practice, think again. Research shows that 63% of pre-cataract surgical patients have a TBUT of less than 5 seconds, a hallmark sign of evaporative dry eye.[6] And, in this same study, only 22% of these patients had been previously diagnosed with dry eye, which illustrates how important it is to actively look for ocular surface problems at any pre-operative cataract examination.

Since the publication of the original TFOS DEWS report, either meibomian gland dysfunction (MGD) or evaporative dry eye has been accepted as the most common subtype of DED in both clinic and population based studies.[7, 8] In one study, up to 86% of dry eye patients had signs of MGD.[9]

Diagnosis

If you send a patient with ocular surface disease to a surgery center, you're setting everyone up for potential problems and disappointment. Most surgeons don't want to have to explain to patients that they need to wait when you sent them there with the idea that it was time for surgery.

MGD is a Leading Cause of Dry Eye[10]

In one study, up to 86% of dry eye patients had signs of MGD.[11]

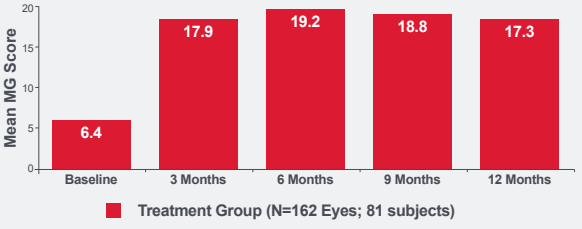
This is also a blemish on the optometrist since it can diminish the trust that the patient has in your diagnostic skills.

How can this be avoided? In our practice, to get to the root cause, we turn to dynamic meibography. Imaging the eyelids with LipiScan® Dynamic Meibomian Imager or LipiView® II Ocular Surface Interferometer makes visualization of gland structure straightforward. Both devices feature Dynamic Meibomian Imaging® that offers fast, high-definition gland scans. The LipiView® II also provides real-time measurement and visualization of lipid layer thickness and allows you to evaluate the dynamic response of the lipids to blinking.

Mean Meibomian Gland Secretion Score[12]

12-Month Cohort with one LipiFlow® Treatment

For the 86% of Treatment group subjects who received one LipiFlow treatment, a sustained mean improvement in MG function was observed from the Baseline (6.4 ± 9.1) to 12 Months (p<0.0001)



Treatment

I'm a strong advocate of treating the root cause of disease instead of simply trying different therapies aimed at addressing symptoms. The LipiFlow® Thermal Pulsation System has allowed us to achieve this in a growing number of cases. The LipiFlow® System comfortably delivers automated therapeutic energies to the meibomian glands while protecting the delicate structures of the patient's eye. The technology applies a combination of heat and pressure to the inner eyelid to remove gland obstructions and stagnant gland content. The therapeutic motion also provides proximal-to-distal peristalsis to clear gland contents.

Cataract patients are a part of the fabric of primary care. Fortunately, diagnosing and treating ocular surface disease is no longer the tremendous challenge it once was. Now it's up to us to put it into practice.

Differentiating Extended Depth of Focus from Multifocal

By Sondra Black, OD

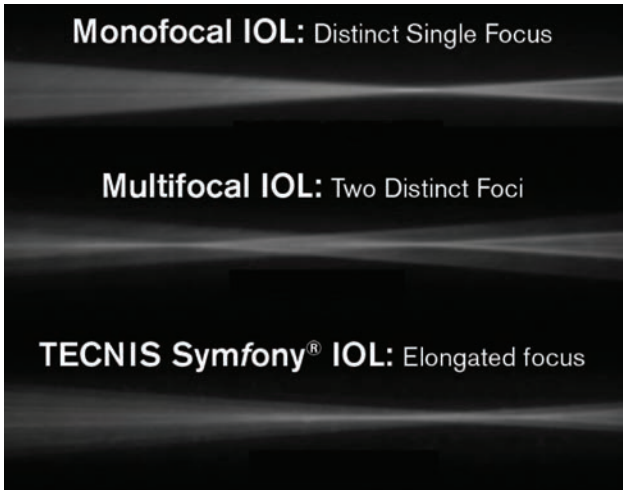
The TECNIS Symfony® IOL and the TECNIS Symfony® Toric IOL are part of the TECNIS platform, but they are not monofocal or a multifocal lenses. In fact, the TECNIS Symfony® was categorized differently by the FDA—to a lens class termed Extended Depth of Focus (EDOF).

EDOF works differently than a multifocal. 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."

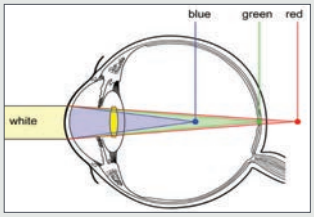
EDOF Design

The TECNIS Symfony® 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 it look a little bit like a multifocal lens; however, there are big differences.

The nine echelettes on the TECNIS Symfony® 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 provide intermediate and near vision with low incidence of glare and halo and without compromising distance vision.[18]



UNDERSTANDING CHROMATIC ABERRATION



The power of the eye is wavelength dependent. Colors that are out of focus cause blur and reduce contrast. The phakic eye has approximately 1.38D of chromatic aberration between 450nm and 700nm.[13] Pseudophakic eyes have between 1.45D and 2D of chromatic aberration, depending on the dispersion of the IOL material.[14]

The proprietary achromatic technology of TECNIS Symfony® IOL not only reduces chromatic aberration but actually corrects chromatic aberration of the cornea.[15]

What's more, it corrects chromatic aberration for far, intermediate, and near to deliver a sharp image over the entire range of vision.[16, 17]

Quality of Vision

Qualitative vision is just as important as quantitative vision, and the optical design of the TECNIS Symfony® IOL addresses both of these. To begin, the TECNIS Symfony® IOL design also allows for less chromatic dispersion, which delivers contrast sensitivity with no clinically significant difference compared to a monofocal IOL.[18,19] By correcting the chromatic aberration, potential acuity or quality of vision may increase.

Patients implanted with the TECNIS Symfony® IOL achieved mean binocular uncorrected vision of 20/20 for intermediate distance and between 20/25 and 20/32 for near in clinical trials.[18]

But what about distance vision? With the TECNIS Symfony® IOL, monocular and binocular distance visual acuities were clinically comparable to those of the monofocal control group in clinical trials.[18] In other words, patients had a high quality of vision at all distances, and gains in near vision did not come at the expense of distance vision.

The Importance of Treating Astigmatism

By Marc Bloomenstein, OD, FAAO

Astigmatism is a problem when it stands in the way of good post-operative results. Even the smallest amount of astigmatism can leave patients with less-than-desirable visual results. Residual astigmatism is one cause of glare, halos, shadowing and a decrease in the quality of vision—none of which makes for a great refractive result. But how much astigmatism is too much to ignore? In my opinion, any astigmatism over 1.00D should be addressed. Unfortunately, as you'll see, in many cases, it's not.

Even the smallest amount of astigmatism can leave patients with less-than-desirable visual results. Residual astigmatism is one cause of glare, halos, shadowing and a decrease in the quality of vision—none of which makes for a great refractive result.

What's Standing in the Way?

More than 37 percent of the population has significant levels of astigmatism.[1] If one of these patients sat in your exam chair and requested contact lenses, would you prescribe a spherical lens or a toric lens? The answer is obvious, yet toric IOLs appear to be far less popular. One-third of patients have >1.0D of astigmatism but only one-fourth of those patients receive a toric IOL.

Prior to the introduction of the TECNIS Symfony® Toric IOL, one possible explanation for this gap may have been that there was no FDA-approved IOL that could mitigate the effects of both astigmatism and presbyopia. That made it challenging to present a premium lens to a patient who would still have significant vision problems post-operatively. If you are offering a premium procedure at a premium price, yet explaining that either the presbyopia symptoms or the astigmatism symptoms will remain, you are engaging in a challenging conversation with your patient. However, this is no longer the case.

More than 37 percent of the population has significant levels of astigmatism. If one of these patients sat in your exam chair and requested contact lenses, would you prescribe a spherical lens or a toric lens?[1]

LENTICULAR VS. CORNEAL ASTIGMATISM

Corneal astigmatism will continue to impact the visual system after cataract surgery. On the other hand, lenticular astigmatism will not continue to impact the visual system after cataract surgery. However, lenticular astigmatism needs to be understood preoperatively to assess the true corneal astigmatism levels.

Why IOLs?

Uncorrected (residual) astigmatism will reduce the ability of IOLs to work at all distances. As such, addressing astigmatism is as important as managing the spherical component.

Toric IOLs provide more stable and predictable refraction than manual incision surgery and can reduce dependence on glasses.[20, 21] These benefits, combined with mitigating the effects of presbyopia, make the TECNIS Symfony® Toric IOL a welcome addition to our vision-correction armementarium. The approval of the TECNIS Symfony® Toric IOL gives patients the choice to address both presbyopia and astigmatism in one surgery.

The TECNIS Symfony® Toric IOL has the TECNIS® Toric IOL astigmatism correction that surgeons are accustomed to using, but has the added feature of extended depth of focus technology to provide a wide range of vision. This can make implanting a presbyopia-correcting toric lens a familiar
experience for many surgeons, even those who have long implanted torics, yet shied away from presbyopia-correcting technology.

The Symfony has four toric models in the United States to correct up to approximately 3.00D of astigmatism at the corneal plane. Models ZXT150, ZXT225, ZXT300, and ZXT375 correct 1.03D, 1.54D, 2.06D and 2.57D of astigmatism at the corneal plane, respectively.

My advice: Inform your patients about the effects of astigmatism on their vision and provide an opportunity to learn more about addressing presbyopia and astigmatism at the same time in one procedure.

See important safety information continued on page 10.

Post-Operative Care

By Eric Schmidt, OD

In addition to offering patient education and guidance, optometrists need to be able to confidently care for cataract patients postoperatively. This involves caring for the health of the eye, monitoring changes in vision, managing patients' expectations, and addressing any dissatisfaction that patients may experience.

Clinical and Refractive Exams

At the Day 1 visit, review medications with the patient and check IOP to see if it's too high or too low. The wound should be secure and the cornea should be clear. Look for any edema. The anterior chamber should be well-formed with about 2+ cell and the IOL should be well-centered in the pupil. At this visit, you should check distance vision only. It is not appropriate to check near vision at this early stage. Finally, review instructions with the patient and fax the results of your exam to the surgeon.

When the patient returns at the week-1 visit, review the history, and confirm medications again. Check IOP again. At the slit lamp, look closely for infection or increased signs of inflammation. You should see clear to < grade 2 cell. Check uncorrected vision again at distance.

When checking near vision at the 1-week visit, do so with good lighting. Importantly, when refracting TECNIS Sym*f*ony® IOL patients, push plus and interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Finally, fax your exam results to the surgeon.

At the 1-month visit, check IOP again. At the slit lamp, the cornea should be clear. The anterior chamber should be well-formed with no cell and the IOL should be well-centered in the pupil. Look for any surface disease. Evaluate the posterior capsule and perform a thorough fundus exam, checking the peripheral retina and confirming that there is no CME.

A key element of the 1-month visit is to determine how well the patient is functioning. Check uncorrected vision at distance and near with good lighting, and set upon the final refraction. Finally, fax your results to the surgeon.

NIGHT VISION

Night-vision symptoms are a valid concern when choosing a presbyopia-correcting IOL. The TECNIS Sym*f*ony® IOL does not eliminate all concerns of glare and halo, but the spontaneous reports of night vision symptoms were low in clinical studies.[18] In fact, the vast majority of TECNIS Sym*f*ony® patients had no spontaneous reports of halo, glare, or starbursts overall. Among those who did report night vision symptoms, most experienced only mild or moderate symptoms, with less than 3% classifying their symptoms as "severe."[18]

The priority at the 3-month exam is to identify the presence of posterior capsular opacification and to optimize outcomes by treating any visual fluctuation resulting from ocular surface disease. As always, all of this should be communicated back to the surgeon.

Closing the Circle

In many ways, post-operative care is an extension of the work that was done pre-operatively—both in terms of managing surface disease as well as in managing patients' expectations.

Before referring the patient to surgery, you should be very confident that you've resolved any ocular surface disease, including MGD. If the patient is battling dry eye and MGD, it's important that they are educated about what to expect in the post-operative period. Any problems that you don't discuss before surgery, patients perceive as the doctor's fault.

The same concept applies to visual expectations. We were not born with extended depth of focus. As such, patients need to be aware that there will be a period of neuroadaptation. Explain this ahead of time, and then again after surgery, so there are no surprises.

The possibility wearing glasses and contact lenses less often is one that many aging patients readily embrace, but it is a journey that requires a knowledgeable guide. As your patients' primary partner in vision and ocular health, it's up to us to be there every step of the way.

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

Rx Only

WARNINGS:

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

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

a. Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.

b. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.

c. Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).

d. A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.

e. Circumstances that would result in damage to the endothelium during implantation.

f. Suspected microbial infection.

g. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.

h. Children under the age of 2 years are not suitable candidates for intraocular lenses.

i. Congenital bilateral cataracts.

j. Previous history of, or a predisposition to, retinal detachment.

k. Patients with only one good eye with potentially good vision.

l. Medically uncontrollable glaucoma.

m. Corneal endothelial dystrophy.

n. Proliferative diabetic retinopathy.

2. The TECNIS® Symfony IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus.

3. The TECNIS® Symfony IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity.

4. Because the TECNIS® Symfony IOL may cause a reduction in contrast sensitivity compared to a monofocal IOL, patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.

5. Some visual effects associated with the TECNIS® Symfony IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome or very bothersome in some people, particularly in low-illumination conditions. On rare occasions, these visual effects may be significant enough that the patient may request removal of the IOL.

6. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS® Symfony and TECNIS® Symfony Toric IOLs, Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.

7. The effectiveness of TECNIS® Symfony Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated.

8. Rotation of TECNIS® Symfony Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.

9. AMO IOLs are single-use devices only. Do not reuse this IOL.

PRECAUTIONS:

1. Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient.

2. When performing refraction in patients implanted with the TECNIS® Symfony IOL, interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is recommended.

3. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS® Symfony IOL optical design.

4. Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power.

5. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.

6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.

7. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens.

8. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved.

9. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

10. When the insertion system is used improperly, TECNIS® Symfony IOLs may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided with the insertion instrument or system.

11. The safety and effectiveness of TECNIS® Symfony IOLs have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below for examples). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions:

Before Surgery

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

During Surgery

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

12. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or overinflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Symfony Toric IOL with the intended axis of placement.

13. The PCA is based on an algorithm that combines published literature (Koch et.al, 2012) and a retrospective analysis of data from a TECNIS Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in a prospective clinical study and may yield results different from those in the TECNIS Toric intraocular lens labeling. Please refer to the AMO Toric Calculator user manual for more information.

14. The use of methods other than the TECNIS Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the parent TECNIS® Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS Toric Calculator (www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS® Symfony Toric IOL.

15. All preoperative surgical parameters are important when choosing a TECNIS® Symfony Toric IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes, and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism.

16. All corneal incisions were placed temporally in the parent TECNIS® Toric IOL U.S. IDE study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study for the parent TECNIS® Toric IOL. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.

17. Potential adverse effects (e.g., complications) associated with the use of the device include the following:

- Infection (endophthalmitis)
- Hypopyon
- IOL dislocation
- Cystoid macular edema
- Corneal edema
- Pupillary block
- Iritis
- Retinal detachment/tear
- Raised IOP requiring treatment

• Visual symptoms requiring lens removal
• Tilt and decentration requiring repositioning
• Residual refractive error resulting in secondary intervention.
Secondary surgical interventions include, but are not limited to:
• Lens repositioning (due to decentration, rotation, subluxation, etc.)
• Lens replacement
• Vitreous aspirations or iridectomy for pupillary block
• Wound leak repair
• Retinal detachment repair
• Corneal transplant
• Lens replacement due to refractive error
• Unacceptable optical/visual symptoms
• Severe inflammation

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

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

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

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

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

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

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

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