Achieving Sharper Vision Through Optical Synergy

With the TECNIS 1-Piece IOL

TECNIS lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.
Optimize Visual Outcomes Through Optical Synergy

The Building Blocks for Sharper Vision

An important aspect in providing optimal visual outcomes is selecting an IOL uniquely designed with a multitude of advanced technologies that deliver high-quality vision. The TECNIS 1-Piece IOL offers a proprietary combination of optic, material, and design technologies that work together, resulting in Optical Synergy intended to provide superior visual results.

Advanced Design Technologies That Create Optical Synergy

- Correction of spherical aberration to essentially zero for sharper vision, even in low-light conditions
- A higher Abbe number, and therefore lower refractive index, than any other IOL tested provides lower chromatic aberration for sharper vision
- Full transmission of healthy blue light for better scotopic sensitivity compared to blue-blocking IOLs
- Not associated with glistenings that may reduce contrast sensitivity and visual acuity
- 360° barrier edge provides uninterrupted contact to limit LEC migration

“[I know that I am giving my patients their best possible vision with the TECNIS IOL. The lens sets a new standard with a combination of optics, material, and design technologies that truly create optical synergy.’”

— Mark Packer, MD, Eugene, Oregon
Optical Synergy Depends on Zero Spherical Aberration

Essentially Zero Spherical Aberration Found in Patients With Supernormal Vision

- Contrast sensitivity and quality of vision peak between the ages of 19–25.
- At this time, the average spherical aberration of the eye is zero.
- The goal of an IOL should be to correct a patient’s total ocular spherical aberration to zero.

"Peak visual performance in young adults is associated with zero spherical aberration.” — Pablo Artal, PhD, University of Murcia, Murcia, Spain

For Sharper Vision, Target Zero Spherical Aberration

- The average ocular spherical aberration of TECNIS IOL eyes is not significantly different from zero.
- A lens that corrects spherical aberration to zero provides 13% better contrast than a lens that corrects to +0.10 microns of spherical aberration.

For Sharper Vision, Target Zero Spherical Aberration

- The TECNIS 1-Piece IOL was developed using the ACE (average cornea eye) model to compensate for the spherical aberration of the cornea.
- The ACE model was developed by collecting wavefront measurements from actual cataract patients.
- Multiple studies with over 500 patients combined have confirmed the accuracy of the ACE model.
- These studies show that the average human cornea has +0.27 microns of spherical aberration throughout life.
- The TECNIS Lens is the only IOL to compensate for the spherical aberration of the cornea with -0.27 microns.

Wavefront Synergy

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Improved Low-Light Optical Performance

- Fully correcting spherical aberration is especially important in low-light conditions.
- TECNIS 1-Piece IOL demonstrates better MTF efficiency in low-light conditions, which can provide a meaningful safety benefit to your patients.

MTF (50 c/mm) of IOLs in ACE model (5 mm pupil)

<table>
<thead>
<tr>
<th>Measure</th>
<th>TECNIS 1-Piece</th>
<th>AcrySof IQ</th>
<th>SofPort AO</th>
<th>Spherical IOL</th>
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<tbody>
<tr>
<td>Average Corneal SA</td>
<td>+0.27</td>
<td>+0.27</td>
<td>+0.27</td>
<td>+0.27</td>
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<tr>
<td>Lens SA†</td>
<td>-0.27</td>
<td>0.00</td>
<td>0.15</td>
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<td>0.00</td>
<td>+0.10</td>
<td>+0.27</td>
<td>+0.42</td>
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</tbody>
</table>

*Images simulated using ZernikeTool, 6 mm aperture, created by George Dai, PhD
† SA correction of lens at corneal plane
Optical Synergy Depends on Reduced Chromatic Aberration

IOLs are the Largest Contributor to Pseudophakic Chromatic Aberration

- Pseudophakic chromatic aberration is caused by the IOL optic material as well as the cornea and other ocular media.
- Because MOST pseudophakic chromatic aberration is caused by the optic material, it is important that the IOL not induce ocular chromatic aberration.
- Studies have shown that chromatic aberration from IOLs may negatively impact visual acuity, contrast sensitivity, and functional vision.

The Importance of Lens Material in Chromatic Aberration Reduction

- The Abbe number is a rating that indicates the amount of chromatic aberration caused by a lens material.
- The larger the Abbe number, the lower the amount of chromatic aberration present.
- The TEKNIS 1-Piece IOL provides lower ocular chromatic aberration than other lenses.
  - With an Abbe number of 55, TEKNIS 1-Piece IOL provides 12% better MTF performance compared to the AcrySof material.

Superior Visual Results From Combined Chromatic and Spherical Aberration Correction

- Several studies have shown that combining the correction of chromatic and spherical aberration provides better visual results than the sum of the two individual corrections.
- A recent study comparing the spherical and chromatic aberration reduction of TEKNIS 1-Piece and AcrySof IOLs found that TEKNIS 1-Piece IOLs provide a clinically significant 29% improvement in MTF performance.

Chromatic Aberration: Correction Spherical Aberration: Correction Combined correction: Improvement in MTF

Sharper Vision Through Optical Synergy.

Highest Abbe Number of IOLs Tested

- A large Abbe number indicates less chromatic aberration and better photopic performance.
- The Abbe number is inversely correlated to the refractive index of a material.
- The TEKNIS 1-Piece material was developed to have a high Abbe number and low RI number to reduce total ocular chromatic aberration.

Comparison of Abbe Number

- AMO® Acrylic Crystalline Lens: 47, 43, 42
- AMO® Silicone Crystalline Lens: 50, 40
- Alcon® Acrylic Crystalline Lens: 37
- Hoya Lens: 55
Optical Synergy Depends on Transmission of Healthy Blue Light

No Proven Benefit to Blocking Blue Light...Just Risk

- The latest AREDs study results show no effect of cataract surgery on the risk of advanced AMD progression.
- The significance and difference in these findings compared to earlier studies that reported an association can be attributed to:
  - Large number of participants with over 4,500 people
  - Follow-up length of 10 years on average
  - Inclusion of more people at a greater risk for AMD than population-based studies
- Blue light has been shown important for optimal scotopic vision and circadian health.

The Effects of Reduced Scotopic Sensitivity

- Scotopic vision declines with age, even in healthy eyes with no cataract or retinal problems.
- Loss of scotopic vision in older adults has been correlated with:
  - An increase in the risk of falling, hospitalization, and death (40% of adults >65 years of age fall each year).
  - Night-driving difficulties.
  - Peripheral vision problems.

Blue Light is Essential for Scotopic Vision

- Blue light provides 35% of scotopic sensitivity.
- TECNIS 1-Piece IOLs can provide up to 21% more scotopic sensitivity compared to a blue-blocking IOL.

The Importance of Circadian Rhythms

- Circadian rhythms are normal 24-hour cyclic activities in the body that affect sleep patterns, mood, memory, alertness, and systemic health.
- Blue light has been shown to enhance alertness even in blind persons.
- Blue light helps regulate melatonin levels, which influence circadian rhythms:
  - At night, maximal secretion of melatonin promotes a good night’s sleep.
  - During the day, the suppression of melatonin helps reduce sleepiness.

The Advantage of TECNIS 1-Piece IOL

- A UV-only blocking IOL restores effective retinal light exposure due to age-related yellowing of the crystalline lens and may help maintain melatonin suppression.
- Cataract surgery with a UV-blocking IOL that transmits blue light has been proven to decrease insomnia and daytime sleepiness.
Optical Synergy Depends on Best-quality Material

What Causes Glistenings?
- The causes of these microvacuoles have not been clearly delineated; however, suggested etiologies include:
  - Temperature changes
  - Inflammation
  - Lipids and proteins in the anterior chamber

Glistenings may Affect Visual Outcomes
- Glistenings have been reported to cause a loss in contrast sensitivity, decreased visual acuity, and light scatter:
  - IOLs with no glistenings were related to a 40% increase in contrast sensitivity at high spatial frequencies
  - Eyes with higher grades of glistenings had a small but significantly greater decrease in visual acuity than those with lesser grades
  - Acrylic lenses with grade 3+ vacuoles have a light scatter level higher than that of a healthy 70-year-old crystalline lens

TECNIS Material is not Associated With Glistenings
- Glistenings are most commonly reported in AcrySof IOLs
- A study revalidating temperature and glistening formation found:
  - Intracocular temperature fluctuations are the most likely cause for glistening formation
  - The AcrySof material shows more temperature-dependent water absorption, making it more susceptible to glistening formation

A Well-documented Problem
- Twenty years of studies document the presence of glistenings in the AcrySof IOL.
- Reported for over 15 years, glistenings are a relatively common occurrence in AcrySof IOL models (SA30AL, SA60AT, and MA60BM). Original studies suggested that the phenomenon was related to the AcrySof packaging system. In 1995, Alcon voluntarily withdrew the AcrySof lens from the market and replaced it in the original Wagon Wheel holder. However, glistenings continue to occur in the current AcrySof IOL, which is packaged in the Wagon Wheel system.

The Prevalence of Glistenings in AcrySof IOL
- A recent study of 260 eyes implanted with AcrySof IOLs found:
  - 60% of lenses had glistenings
  - 26.9% of lenses were considered to have moderate to severe glistenings
- Another study also found that in five patients with AcrySof lenses:
  - Grade 2 or higher glistenings at a mean follow-up of 2.4 years
  - There was a significant difference in visual acuity between eyes with less than grade 2 glistenings (20/22.1) and grade 2 or higher glistenings (20/25.5)
Optical Synergy Depends on Next Generation One-piece Design

The Achilles Heel of First-generation One-piece Lenses

- Posterior capsule opacification (PCO) is the most common complication following cataract surgery.
- First-generation one-piece lenses do not provide a continuous 360° sharp edge.

TECNIS 1-Piece IOL Provides Increased Protection

The TECNIS 1-Piece IOL was designed with multiple unique features that truly make it the next generation in one-piece lens technology:

- ProTEC 360° Edge Design to limit LEC migration
- Tri-Fix 3-Point Fixation for better stability and centration
- A proprietary surface treatment and polished haptics for ease of unfolding

Increased Stability With the Tri-Fix 3-Point Design

Offset haptics allow three points of capsular bag fixation, designed to provide refractive predictability, long-term stability, and centration.

- Complemented by the ProTEC 360° edge for an improved barrier effect that limits LEC migration onto the posterior capsule.
- Allows the LECs to close the capsular bag and help lock the lens in position for enhanced centration and stability.

Ease of Use and Optical Performance Without Compromise

- Refractive index designed to reduce chromatic aberration and dysphotopsias.
- Controlled center thickness for consistency of insertion.

“I’m especially impressed with the stability of the new TECNIS 1-Piece IOL. This aspect, combined with the 360° edge contact that helps minimize LEC migration, makes the TECNIS 1-Piece an excellent solution for many of my patients.”
— Donald R. Nixon, MD, FRSC, Ontario, Canada
Optical Synergy With TECNIS 1-Piece IOL

Superior visual results through a proprietary combination of optic, material, and design technologies working together.

Important Safety Information:

Caution
Federal law restricts this device to sale by or on the order of a physician.

Indications
TECNIS 1-piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction.

Precautions
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.

Adverse Events

The most frequently reported adverse event that occurred during the clinical trial of the 1-Piece lens was macular edema, which occurred at a rate of 3.3%. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

Avoidance

Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

References


14. Zhao H, Piers PA, Mainster MA. The additive effects of different optical design elements contributing to contrast loss in pseudophakic eyes implanted with different acrylic IOLs. Invest Ophthalmol Vis Sci. 2006;47:3533-43.