STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov

Continuing Education Course Approval Checklist

Title: The Latest in Corneal Cross Linking and Presbyopic IOLs

Provider Name: Turner Eye Institute c/o Mr. Tony Gomez

☑Completed Application
Open to all Optometrists? ☑Yes ☐No
Maintain Record Agreement? ☑Yes ☐No

☑Correct Application Fee

☑Detailed Course Summary

☑Detailed Course Outline

☑PowerPoint and/or other Presentation Materials

☑Advertising (optional)

☑CV for EACH Course Instructor

☑License Verification for Each Course Instructor
Disciplinary History? ☐Yes ☑No

OPTOMETRY

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CONTINUING EDUCATION COURSE APPROVAL APPLICATION

$50 Mandatory Fee

Pursuant to California Code of Regulations (CCR) § 1536, the Board will approve continuing education (CE) courses after receiving the applicable fee, the requested information below and it has been determined that the course meets criteria specified in CCR § 1536(g).

In addition to the information requested below, please attach a copy of the course schedule, a detailed course outline and presentation materials (e.g., PowerPoint presentation). Applications must be submitted 45 days prior to the course presentation date.

Please type or print clearly.

Course Title	**Course Presentation Date**
THE LATEST IN CORNEAL CROSS LINKING AND PRESBYOPIC IOL'S.	06/08/2017

Course Provider Contact Information

Provider Name Tony Gomez 800-339-2733

CHIRAG PATEL R.
(First) (Last) (Middle)

Provider Mailing Address

Street 276 DOLORES AVE City SAN LEANDRO State CA Zip 94577

Provider Email Address TGOMES@TURNEREYE.COM

Will the proposed course be open to all California licensed optometrists?	☑ YES ☐ NO
Do you agree to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as the Board requires, for a period of at least three years from the date of course presentation?	☑ YES ☐ NO

Course Instructor Information

Please provide the information below and attach the curriculum vitae for each instructor or lecturer involved in the course. If there are more instructors in the course, please provide the requested information on a separate sheet of paper.

Instructor Name

CHIRAG PATEL R.
(First) (Last) (Middle)

License Number A122718	**License Type** MD - Ophthalmology
Phone Number (510) 614-1515	**Email Address** CPATEL@TURNEREYE.COM

I declare under penalty of perjury under the laws of the State of California that all the information submitted on this form and on any accompanying attachments submitted is true and correct.

Signature of Course Provider *Date* 4/20/2017

TURNER EYE INSTITUTE

www.turnereye.com • 800.339.2733

2 hours Free CE (Pending)

06:30-07:00: Registration and Dinner

CE Presentation: 07:00 - 09:00 PM

Thursday, May 08th, 2017

San Leandro Public Library

300 Estudillo Ave

San Leandro, CA 94577

Speaker:

Chirag R. Patel, MD

Cornea, Refractive & Cataract Surgeon

- **The latest in Corneal Cross Linking**
- **The latest in Presbyotic IOL's**

276 Dolores Ave
San Leandro, CA 94577
800-339-2733
www.turnereye.com
www.helpkeratoconus.com

RSVP by email to tgomes@turnereye.com or fax to: 510-357- 6330

Name: _____ Ph #:_____

Email: _____

Seating is limited. Please RSVP no later than 1 week prior to each meeting.

TURNER EYE INSTITUTE

Cornea Cross Linking Avedro:

This presentation has the goal of educating attendees on the latest FDA approved Corneal Cross Linking (CXL) technology and keratoconus surgical options in general. What we know from experience and what the FDA data shows. We'll present several cases studies. This presentation will provide doctors with the knowledge to diagnose and educate patients on the latest treatments for keratoconus. We'll discuss patient selection and co-management.

Tecnis Symfony IOL:

This presentation has the goal of educating attendees on the latest presbyopic FDA approved IOL. Doctors will be presented with the FDA data as well as our own experience using this lens. We'll go over patient selection and co-management. Doctors will be better prepared to have educated discussions about this technology with their own patients and will have the knowledge to determine who might be a good candidate for this lens.

This course will be open for all license optometrists in the State of CA.

Course Outline

The latest in Presbyopic IOL's

1. Tecnis Symfony & Tecnis Synfony Toric
    a. Instroduction

2. The Technology
    a. Design
    b. Material
    c. Optics
        i. Aberrations
        ii. Contrast Sensitivity

3. Vision, Functionality, Sustainability.
    a. Range
    b. Tolerance to decentration
    c. Halos & Glare
    d. Pupil size affect

4. Outcomes and Patient Results

Course Outline

Title: The Latest is Corneal Cross Linking

1. Corneal Cross Linking: Mechanism of action
    a. Early Studies
    b. What is involved
    c. How it works
    d. What does it do

2. Where do Cross-Links occur?

3. Avedro: FDA Approved Products
    a. Photrexa Viscous, Photrexa and KXL System
    b. Indications and usage
    c. Contraindications
    d. Warnings and precautions
    e. Adverse reactions

4. Dosage and administration

5. US Clinical Study Date Review
    a. Phase II study design
    b. Efficacy Analysis
        i. Progressive Keratoconus
        ii. Corneal Ectasia following refractive surgery
        iii. Mean change from baseline KMAX, CXL and SHAM

6. Treatment Emergent Adverse Side Affects (TEAES)

7. Patient Education and Co-management

8. Patient Background and Previously Unmet Medical Need

9. Patient Selection/Treatment Criteria

10. Use in Specific Populations

11. Post-operative Management

12. Pre-operative Patient Education

13. Post-operative Patient Counseling

14. Summary

Course Outline

The latest in Presbyopic IOL's

1. Tecnis Symfony & Tecnis Synfony Toric
    a. Instroduction

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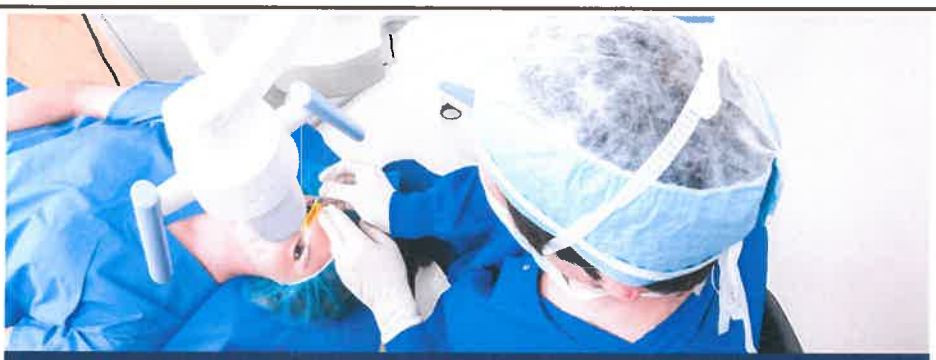
4. Outcomes and Patient Results



Photrexa® Viscous
(riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%
Photrexa®
(riboflavin 5'-phosphate ophthalmic solution) 0.146%
and the KXL® System

Corneal Cross-linking for Progressive Keratoconus and Corneal Ectasia Following Refractive Surgery

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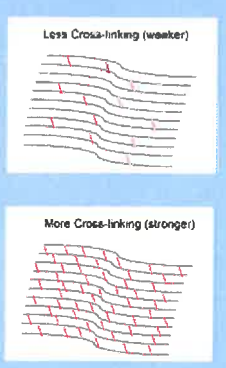
CORNEAL CROSS-LINKING: MECHANISM OF ACTION

- First studied in Europe at the University of Dresden in the late 1990s
- Corneal collagen cross-linking is a medical procedure that combines the use of ultra-violet (UV) light and riboflavin (vitamin B2) drops
- The absorption of UVA by riboflavin generates radical riboflavin and singlet oxygen to form cross-links[1]
- Cross-linking[2]:
  - Creates new corneal collagen cross-links
  - Results in a shortening and thickening of the collagen fibrils
  - Leads to the stiffening of the cornea



[1]Kamaev P, Friedman MD, Sherr E, Muller D. Photochemical kinetics of corneal cross-linking with riboflavin. Invest Ophthalmol Vis Sci. 2012;53:2360–7.
[2]Beshtawi IM, O'Donnell C, Radhakrishnan H. Biomechanical properties of corneal tissue after ultraviolet-A-riboflavin crosslinking. J Cataract Refract Surg. 2013;39(3):451–62.

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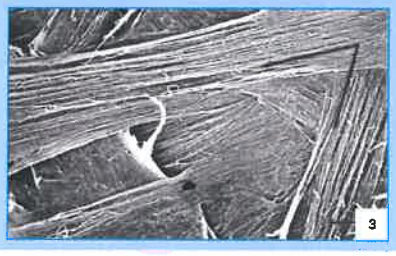
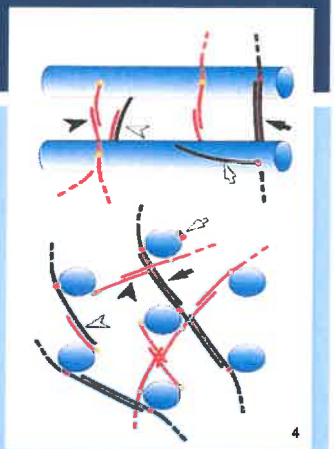
WHERE DO CROSS-LINKS OCCUR?

- Collagen fibrils within lamellae are regulated by an interconnecting network of proteoglycans.[1]
- Cross-linking with UVA/riboflavin has no effect on any collagen structural parameter measured by x-ray scattering except uniformity of nearest neighbor interfibrillar spacing.[2]
- Therefore, it is believed that cross-links are formed predominantly at fibril surfaces and within the protein network surrounding the collagen.[2]





1. Meek, K.M. & Boote, C., 2009. The use of X-ray scattering techniques to quantify the orientation and distribution of collagen in the corneal stroma. *Progress in Retinal and Eye Research*, 28(5), p.369-392.
2. Meek, K.M. & Hayes, S., 2013. Corneal cross-linking - a review. *Ophthalmic and Physiological Optics*, 33(2), p.78-93.
3. Meek, K.M. et al., 2005. Changes in collagen orientation and distribution in keratoconus corneas. *Investigative Ophthalmology and Visual Science*, 46(6), p.1948-1956.
4. Lewis, P.N. et al., 2010. Structural Interactions between Collagen and Proteoglycans Are Elucidated by Three-Dimensional Electron Tomography of Bovine Cornea. *Structure*, 18(2), p.239-245.

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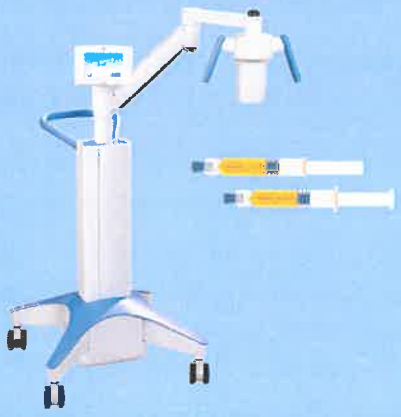
AVEDRO FDA APPROVED PRODUCTS



Photrexa Viscous, Photrexa and the KXL System are the First and Only FDA-approved Therapeutic Treatment for Progressive Keratoconus and Corneal Ectasia Following Refractive Surgery

Photrexa Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%
Photrexa (riboflavin 5'-phosphate ophthalmic solution) 0.146%

avedro

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AVEDRO FDA APPROVED PRODUCTS

INDICATION AND USAGE
Photrexa Viscous and Photrexa are photoenhancers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery.

CONTRAINDICATIONS None

WARNINGS AND PRECAUTIONS
Ulcerative keratitis can occur. Patients should be monitored for resolution of epithelial defects. The safety and effectiveness of CXL has not been established in pediatric patients below the age of 14 years. Photrexa Viscous and Photrexa should be used with the KXL System only.

ADVERSE REACTIONS
In progressive keratoconus patients, the most common ocular adverse reactions in any CXL treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision. In corneal ectasia patients, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision.

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DOSAGE AND ADMINISTRATION

- 9 mm epithelium removal
- Photrexa Viscous: 1 drop topically every 2 min for 30 min
- Check for riboflavin flare in anterior chamber
  - If yellow flare not detected, add 1 drop of Photrexa Viscous every 2 minutes for an addl 2 to 3 drops. Recheck for flare.
  - Repeat as necessary.
- Ultrasound pachymetry:
  - If <400 µm, 2 drops Photrexa every 5-10 sec until ≥400 µm.
  - Irradiation should not be performed unless 400 µm is met
- 30 minutes UV exposure with KXL System
  - 365 nm UV, 3mW/cm^2
  - Continue Photrexa Viscous every 2 min

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US CLINICAL STUDY DATA OVERVIEW

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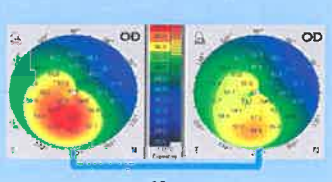
PHASE III STUDY DESIGN

- Avedro's NDA submission encompassed data from three prospective, randomized, parallel-group, open-label, placebo-controlled, 12-month trials conducted in the United States to evaluate the safety and effectiveness of riboflavin ophthalmic solution/UVA irradiation for performing corneal collagen cross-linking.
- The trials included:
  - 205 patients with progressive keratoconus.
  - 179 patients with corneal ectasia following refractive surgery.
- Schedule of Assessments:
  - Screening/baseline, Day 0 (randomization/treatment day), 1 day, 1 week, and 1, 3, 6 and 12 months after treatment.
- Primary Endpoint was K_{max}, as measured by keratometry



K_{max}

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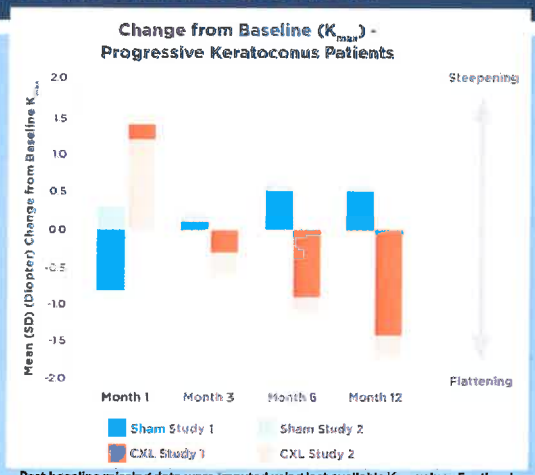
EFFICACY ANALYSIS:
PROGRESSIVE KERATOCONUS

- In clinical studies, the CXL-treated eyes showed increasing improvement in K_{max} from month 3-12,while in untreated, Sham eyes, K_{max} demonstrated steepening.
- Progressive keratoconus patients had an average K_{max} reduction of 1.4 diopters in Study 1 and 1.7 diopters in Study 2 at Month 12 in the CXL treated eyes while the sham eyes had an average increase of 0.5 diopter in Study 1 and 0.6 diopter in Study 2 at Month 12.



Post-baseline missing data were imputed using last available K_{max} value. For the sham study eyes that received CXL treatment after baseline, the last K_{max} measurement recoded prior to receiving CXL treatment was used in the analysis for later time points.

Patients should be monitored for resolution of epithelial defects as ulcerative keratitis can occur.

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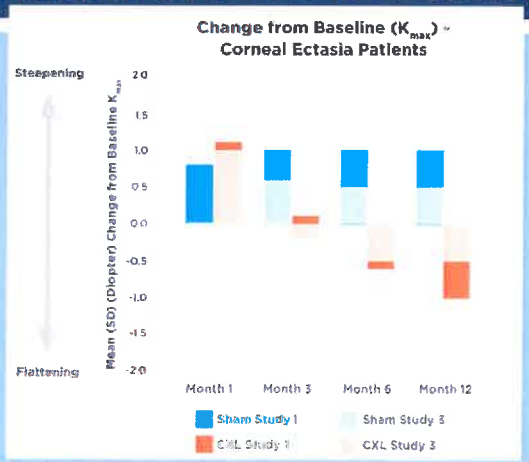
EFFICACY ANALYSIS:
CORNEAL ECTASIA FOLLOWING REFRACTIVE SURGERY

- In clinical studies, the CXL-treated eyes showed increasing improvement in K_{max} from month 3-12,while in untreated, Sham eyes, K_{max} demonstrated steepening.
- For corneal ectasia patients, at Month 12, the CXL-treated eyes had an average Kmax reduction of 1.0 diopter in Study 1 and 0.5 diopter in Study 3 while the sham eyes had an average increase of 1.0 diopter in Study 1 and 0.5 diopter in Study 3.



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Patients should be monitored for resolution of epithelial defects as ulcerative keratitis can occur.

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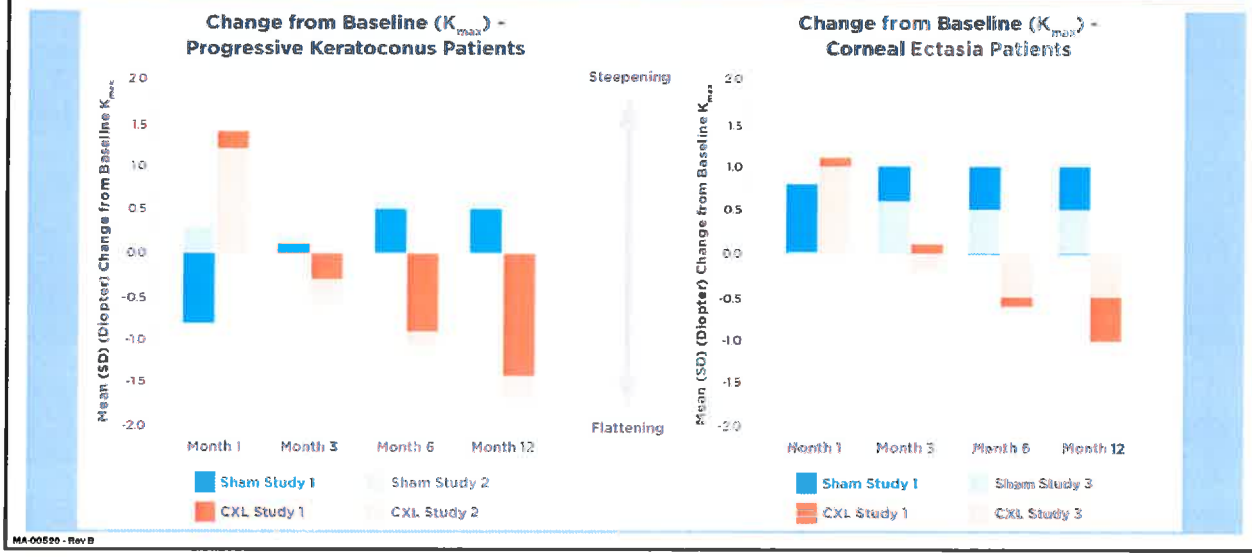
EFFICACY ANALYSIS:
MEAN CHANGE FROM BASELINE KMAX, CXL AND SHAM



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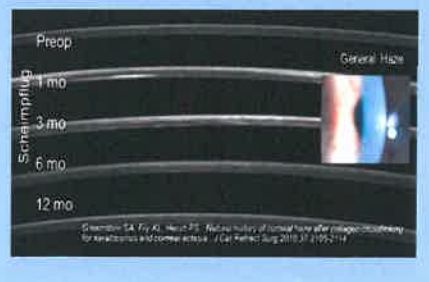
TREATMENT EMERGENT ADVERSE EVENTS (TEAES)

- In progressive keratoconus patients, the most common ocular adverse reactions in any CXL-treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision.
- In corneal ectasia patients, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision.
- The majority of adverse events reported resolved during the first month
- Corneal epithelium defect, corneal striae, punctate keratitis, photophobia, dry eye and eye pain, and decreased visual acuity took up to 6 months to resolve. Corneal opacity or haze took up to 12 months to resolve
- In 1-2% of patients, corneal epithelium defect, corneal edema, corneal opacity and corneal scar continued to be observed at 12 months



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PATIENT EDUCATION & CO-MANAGEMENT

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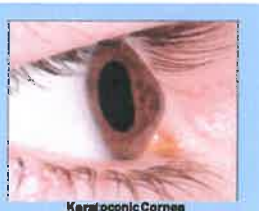
PATIENT BACKGROUND AND PREVIOUSLY UNMET MEDICAL NEED

- Keratoconus is a bilateral, progressive corneal ectasia resulting in irregular astigmatism and loss of visual function, with onset in teenage years[1]
- Affects 1 in 2000 people[2]
  - CXL for the treatment of keratoconus granted orphan designation in the US by FDA due to rare nature.
- Corneal ectasia, a non-inflammatory condition marked by progressive corneal steepening and thinning, is a rare but serious complication of vision correction procedures.
  - Granted orphan designation in the US by FDA due to rare nature.
- Alternative Treatment options include:
  - Rigid or Specialty Contact Lens
  - Intra-corneal ring segments
  - Corneal Transplant
- Predicted 73% of grafts fail within 20 years; 98% at 30 years[3]
  - Potential for multiple transplants
- Eye Bank Association of America noted >6,900 transplants/year in patients with keratoconus (16% total penetrating keratoplasty in U.S.)[4]



Keratoconic Cornea

Corneal Transplant

[1] Olivares JL, Guerrero JC, Bermudez FR. Keratoconus: age of onset and natural history. Optom Vis Sci 1997;74:147-151.
[2] National Eye Institute, National Institutes of Health. http://www.nei.nih.gov/health/cornealdisease/fm.
[3] Bordenie VM, Boelle PY, Touzeau O, et al. Predicted long-term Outcome of corneal transplantation. Ophthalmology 2009;2354-2360
[4] Eye Bank Association of America Statistical Report. 2014

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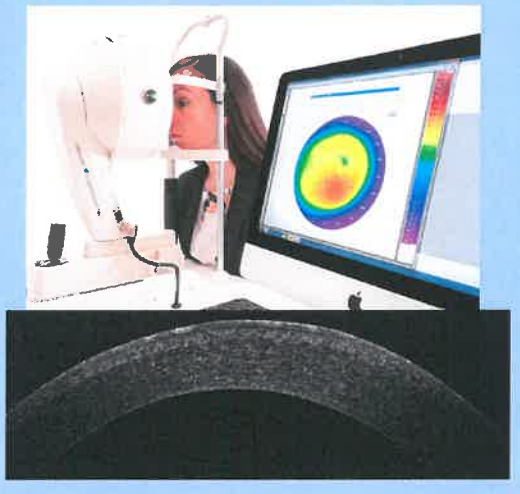
PATIENT SELECTION/ TREATMENT CRITERIA



- Screening exams for early diagnosis to identify patients and monitor for progression of keratoconus or development of corneal ectasia following refractive surgery
- Pediatric Use
  - 14 years of age and older
- Geriatric Use
  - No subjects enrolled in the clinical studies were 65 years of age or older

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USE IN SPECIFIC POPULATIONS

Pregnancy Risk Summary

Animal development and reproduction studies have not been conducted with the PHOTREXA VISCOUS/PHOTREXA/KXL™ system. Since it is not known whether the corneal collagen cross-linking procedure can cause fetal harm or affect reproduction capacity, it should not be performed on pregnant women.

Lactation Risk Summary

There are no data on the presence of PHOTREXA VISCOUS or PHOTREXA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for the PHOTREXA/KXL corneal collagen crosslinking procedure and any potential adverse effects on the breastfed child from the PHOTREXA/KXL corneal collagen cross-linking procedure or from the underlying maternal condition.

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POST-OPERATIVE MANAGEMENT

- Post-operative Care
  - Post-operative regimen similar to care after PRK
  - Care of epithelial debridement
  - Bandage contact lens
- Expected outcomes
  - Initial steepening followed by gradual flattening
- Contact Lens Refitting

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PRE-OPERATIVE PATIENT EDUCATION

- Set the expectation that cross-linking is not refractive surgery
  - Contact lenses and/or spectacles still required
- Educate patients regarding the time course of the post-operative healing process.
  - On average, steepening of Kmax is observed at 1 month postoperatively, followed by flattening through 12 months.
  - In 1-2% of patients, corneal epithelium defect, corneal edema, corneal opacity and corneal scar continued to be observed at 12 months

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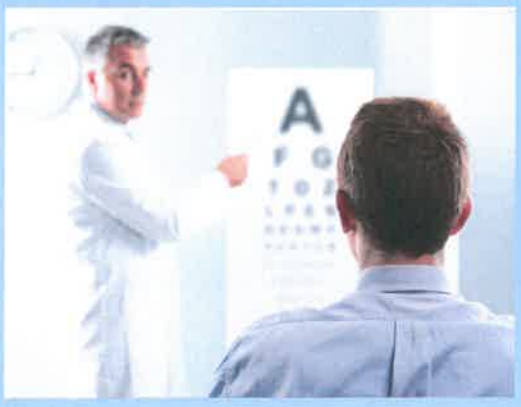
POST-OPERATIVE PATIENT COUNSELING



- Patients should be advised not to rub their eyes for the first five days after their procedure.
- Patients may be sensitive to light and have a foreign body sensation. Patients should be advised that there may be discomfort in the treated eye and that sunglasses may help with light sensitivity.
- If patients experience severe pain in the eye or any sudden decrease in their vision, they should be advised to contact their physician immediately.
- If the bandage contact lens that was placed on the patient's eye on the day of treatment falls out or becomes dislodged, the patient should be advised not to replace it and to contact their physician immediately.

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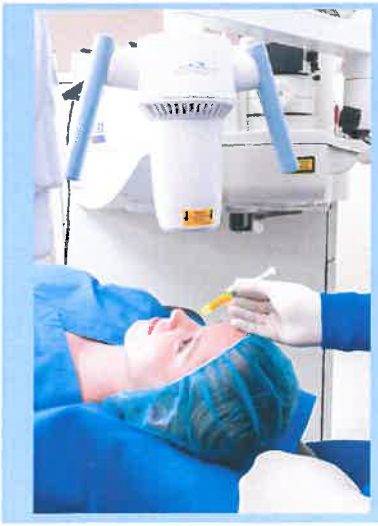
SUMMARY



- Avedro products and protocol:
  - First and Only FDA-approved Therapeutic Treatment for Progressive Keratoconus and Cornea Ectasia Following Refractive Surgery
- Clinical Outcomes Review
- Typical Adverse Events
- Proper Patient Selection
- Pre and Post Op Counseling

Thank you!

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Appendix A:
Full Prescribing Information

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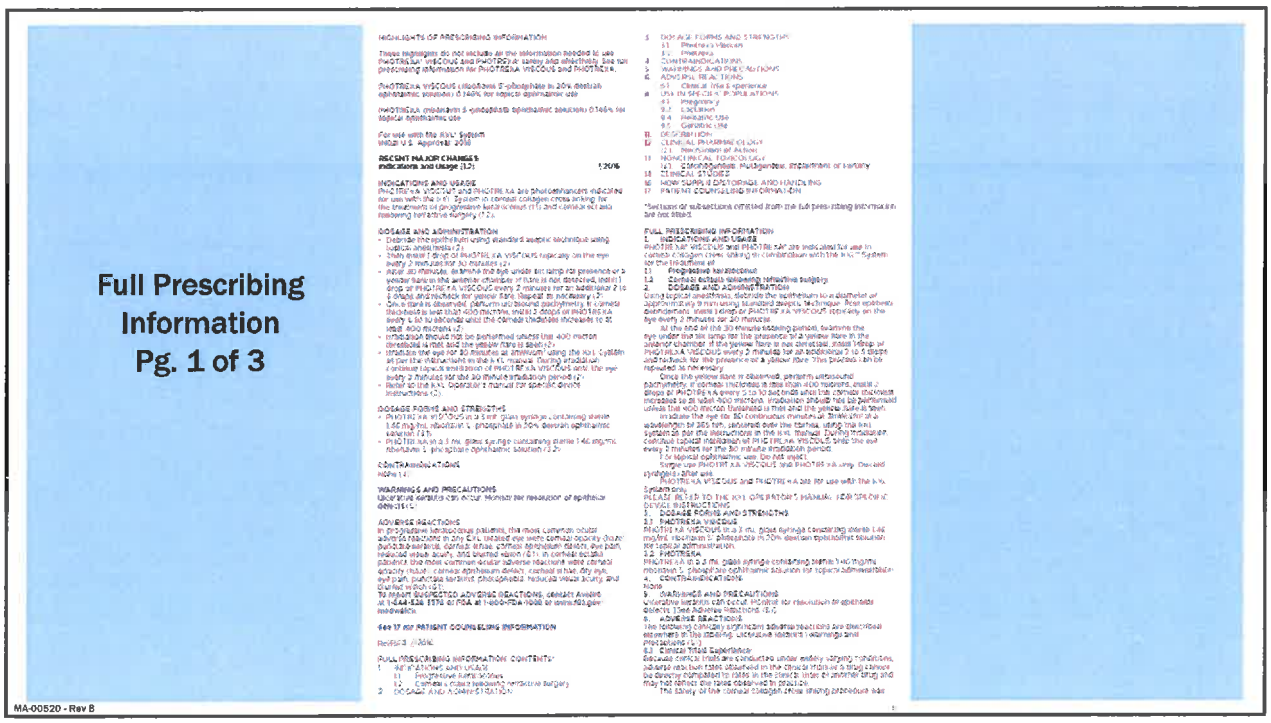
Full Prescribing Information Pg. 1 of 3



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PHOTREXA® VISCOUS and PHOTREXA® safely and effectively. See full prescribing information for PHOTREXA VISCOUS and PHOTREXA.

PHOTREXA VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% for topical ophthalmic use

PHOTREXA (riboflavin 5'-phosphate ophthalmic solution) 0.146% for topical ophthalmic use

For use with the KXL® System
Initial U.S. Approval: 2008

RECENT MAJOR CHANGES
Indications and Usage (1.2) 1/2016

INDICATIONS AND USAGE
PHOTREXA® VISCOUS and PHOTREXA are photosensitizers indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive keratoconus (1.1) and corneal ectasia following refractive surgery (1.2).

DOSAGE AND ADMINISTRATION
- Debride the epithelium using standard aseptic technique using bulbar anesthesia (2.)
- Apply exactly 1 drop of PHOTREXA VISCOUS topically on the eye every 2 minutes for 30 minutes (2.)
- After 30 minutes, examine the eye under slit lamp for presence of a yellow flare in the anterior chamber. If there is not detected, instill 1 drop of PHOTREXA VISCOUS every 2 minutes for an additional 2 to 5 times, and recheck for yellow flare. Repeat as necessary (2.)
- On a flare is observed, perform ultrasound pachymetry. If corneal thickness is less than 400 microns, instill 2 drops of PHOTREXA every 2 to 10 seconds until the corneal thickness increases to at least 400 microns (2.)
- Irradiation should not be performed unless the corneal thickness is at least 400 microns (2.)
- Irradiate the eye for 30 minutes at a minimum using the KXL System at the wavelength of 370 nm. Maintain the irradiance at the corneal surface between 9 mW/cm² and 45 mW/cm² (2.)
- Continue topical instillation of PHOTREXA VISCOUS onto the eye every 2 minutes for the 30 minute irradiation period (2.)
- Refer to the KXL System 2 manual for specific device instructions (2.)

DOSAGE FORMS AND STRENGTHS
- PHOTREXA VISCOUS is 5 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution (3.1).
- PHOTREXA is a 5 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate ophthalmic solution (3.2).

CONTRAINDICATIONS
None (4.)

WARNINGS AND PRECAUTIONS
Ulcerative keratitis can occur. Monitor for resolution of epithelial defects (5.)

ADVERSE REACTIONS
In prospective randomized trials, the most common ocular adverse reactions in the CXL treated eyes were corneal opacity (haze), photophobia/miosis, diplopia, ptosis, corneal epithelium defect, dry eye, reduced visual acuity, and blurred vision (6.1). In corneal ectasia patients the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision (6.1).
TO REPORT SUSPECTED ADVERSE REACTIONS, contact Avedro at 1-844-438-3376 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 1/2016

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION
1. INDICATIONS AND USAGE
PHOTREXA® VISCOUS and PHOTREXA® are indicated for use in corneal collagen cross-linking in combination with the KXL® System for the treatment of:
1.1 Progressive keratoconus
1.2 Corneal ectasia following refractive surgery
2. DOSAGE AND ADMINISTRATION
Using topical anesthesia, debride the epithelium to a diameter of approximately 9 mm using standard aseptic technique. Post epithelial debridement, apply 1 drop of PHOTREXA VISCOUS topically on the eye every 2 minutes for 30 minutes.
At the end of the 30 minute soaking period, examine the eye under the slit lamp for the presence of a yellow flare in the anterior chamber. If the yellow flare is not detected, instill 1drop of PHOTREXA VISCOUS every 2 minutes for an additional 2 to 5 drops and recheck for the presence of a yellow flare. This process can be repeated as necessary.
Once the yellow flare is observed, perform ultrasound pachymetry. If corneal thickness is less than 400 microns, instill 2 drops of PHOTREXA every 2 to 10 seconds until the corneal thickness increases to at least 400 microns. Irradiation should not be performed unless that 400 micron thickness is met and the yellow flare is seen.
Irradiate the eye for 30 continuous minutes at 3mW/cm² at a wavelength of 365 nm, delivered over the cornea, using the KXL System as per the instructions in the KXL manual. During irradiation, continue topical instillation of the PHOTREXA VISCOUS onto the eye every 2 minutes for the 30 minute irradiation period.
For topical ophthalmic use. Do not inject.
Surge use PHOTREXA VISCOUS and PHOTREXA only. Discard if solution is after use.
PHOTREXA VISCOUS and PHOTREXA are for use with the KXL System only.
PLEASE REFER TO THE KXL OPERATOR'S MANUAL FOR SPECIFIC DEVICE INSTRUCTIONS.
3. DOSAGE FORMS AND STRENGTHS
3.1 PHOTREXA VISCOUS
PHOTREXA VISCOUS is a 5 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution for topical administration.
3.2 PHOTREXA
PHOTREXA is a 5 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate ophthalmic solution for topical administration.
4. CONTRAINDICATIONS
None.
5. WARNINGS AND PRECAUTIONS
Ulcerative keratitis can occur. Monitor for resolution of epithelial defects. (See Adverse Reactions (6.))
6. ADVERSE REACTIONS
The following clinically significant adverse reactions are described elsewhere in the labeling: Ulcerative Keratitis (Warnings and Precautions (5.))
6.1 Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
The safety of the corneal collagen cross-linking procedure was

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evaluated in 3 randomized, parallel-group, open-label, sham-controlled trials: patients were followed up for 12 months. Study 1 enrolled patients with progressive keratoconus or corneal ectasia following refractive surgery. Study 2 enrolled only patients with progressive keratoconus, and Study 3 enrolled only patients with corneal ectasia following refractive surgery. In each study, only one eye of each patient was designated as the study eye. Study eyes were randomized to receive one of the two study treatments (CXL or sham) at the baseline visit and were followed up at Day 1, Week 1, and Months 1, 3, 6, and 12. At Month 3 or later, sham study eyes and non-study eyes had the option of receiving CXL treatment, and were followed-up for 12 months from the time of receiving CXL treatment. Each CXL treated eye received a single course of CXL treatment only.

Safety data were obtained from: 193 randomized CXL study eyes (102 keratoconus, 91 corneal ectasia), 191 control eyes, and 319 nonrandomized CXL non-study eyes (191 keratoconus, 128 corneal ectasia). Overall, 512 eyes (293 keratoconus, 219 corneal ectasia) in 364 patients received CXL treatment.

In progressive keratoconus patients, the most common ocular adverse reactions in any CXL-treated eye were corneal opacity (haze), punctate keratitis, corneal striae, corneal epithelium defect, eye pain, reduced visual acuity, and blurred vision (Table 1).

In corneal ectasia patients, the most common ocular adverse reactions were corneal opacity (haze), corneal epithelium defect, corneal striae, dry eye, eye pain, punctate keratitis, photophobia, reduced visual acuity, and blurred vision. These events are expected sequelae following epithelial corneal debridement and occurred at a higher incidence than observed in control patients, who did not undergo debridement or exposure to UVA light (Table 1).

Adverse events reported in non-study, non-randomized CXL treated were similar in terms of preferred terms and frequency to those seen in randomized study eyes.

The majority of adverse events reported resolved during the first month, while events such as corneal epithelium defect, corneal striae, punctate keratitis, photophobia, dry eye and eye pain, and decreased visual acuity took up to 6 months to resolve and corneal opacity or haze took up to 12 months to resolve. In 1-2% of patients, corneal epithelium defect, corneal edema, corneal opacity and corneal scar continued to be observed at 12 months. In 6% of corneal ectasia patients, corneal opacity continued to be observed at 12 months.

Table 1: Most Common (≥1%) Ocular Adverse Reactions in CXL-Treated Study Eye in the Pooled Randomized Safety Population – N (%)

Preferred Term	Progressive Keratoconus Studies CXL Group (N=102)[1]	Progressive Keratoconus Studies Control Group (N=103)[1]	Corneal Ectasia Studies CXL Group (N=91)[1]	Corneal Ectasia Studies Control Group (N=88)[1]
Anterior chamber cell	2 (2)	0	2 (2)	1 (1)
Anterior chamber flare	4 (4)	0	5 (6)	2 (2)
Asthenopia	1 (1)	1 (1)	2 (2)	0
Blepharitis	0	0	0	1 (1)
Corneal disorder	3 (3)	1 (1)	3 (3)	0
Corneal epithelium defect	24 (24)	1 (1)	26 (29)	3 (3)
Corneal oedema	3 (3)	0	3 (3)	0
Corneal opacity[2]	65 (64)	9 (9)	65 (71)	8 (9)
Corneal striae	24 (24)	12 (12)	8 (9)	6 (7)
Corneal thinning	1 (1)	2 (2)	0	0
Diplopia	2 (2)	1 (1)	1 (1)	0
Dry eye	6 (6)	2 (2)	13 (14)	4 (5)
Eye complication associated with device	2 (2)	0	1 (1)	0
Eye discharge	2 (2)	1 (1)	0	0
Eye oedema	7 (7)	0	0	0
Eye pain	17 (17)	3 (3)	24 (26)	0
Eye pruritus	2 (2)	0	0	0
Eyelid oedema	5 (5)	0	5 (6)	1 (1)
Foreign body sensation in eyes	15 (15)	1 (1)	13 (14)	2 (2)
Glare	4 (4)	1 (1)	2 (2)	0
Halo vision	1 (1)	0	2 (2)	0
Keratitis	1 (1)	0	3 (3)	0
Lacrimation increased	5 (5)	0	9 (10)	1 (1)
Meibomian gland dysfunction	1 (1)	1 (1)	[illegible] (3)	2 (2)
Ocular discomfort	0	0	8 (9)	0
Ocular hyperaemia	14 (14)	2 (2)	7 (8)	4 (5)
Photophobia	11 (11)	0	17 (19)	0
Punctate keratitis	25 (25)	9 (9)	18 (20)	3 (3)
Vision blurred	16 (16)	2 (2)	15 (17)	4 (5)
Visual acuity reduced	10 (10)	9 (9)	10 (11)	1 (1)
Visual impairment	3 (3)	2 (2)	4 (4)	1 (1)
Vitreous detachment	2 (2)	0	0	0

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1) Results are presented as the number (%) of patients with an event from baseline to Month 3.
2) Almost all cases of corneal opacity were reported as haze.

Headache was reported in between 4 to 8% of treated patients.

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Risk Summary

Animal development and reproduction studies have not been conducted with the PHOTREXA® VISCOUS/PHOTREXA®/KXL® System. Since it is not known whether the corneal collagen cross-linking procedure can cause fetal harm or affect reproduction capacity, it should not be performed on pregnant women.

8.2. Lactation

Risk Summary

There are no data on the presence of PHOTREXA VISCOUS or PHOTREXA in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for the PHOTREXA/KXL corneal collagen cross-linking procedure and any potential adverse effects on the breastfed child from the PHOTREXA/KXL corneal collagen cross-linking procedure or from the underlying maternal condition.

8.4. Pediatric Use

The safety and effectiveness of corneal collagen cross-linking has not been established in pediatric patients below the age of 14 years.

8.5. Geriatric Use

No patients enrolled in the clinical studies were 65 years of age or older.

11. DESCRIPTION

PHOTREXA VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% and PHOTREXA (riboflavin 5'-phosphate ophthalmic solution) 0.146% are intended for topical ophthalmic administration as part of corneal collagen cross-linking with the KXL System.

PHOTREXA VISCOUS and PHOTREXA are supplied as:

- PHOTREXA VISCOUS in a 3 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution for topical administration.
- PHOTREXA in a 3 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate ophthalmic solution for topical administration.

PHOTREXA VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% is a yellow sterile buffered viscous solution containing 1.46 mg/mL riboflavin 5'-phosphate and 20% dextran 500. The pH of the solution is approximately 7.1 and the osmolality is 301-339 mOsm/kg. Each 1 mL of solution contains 1.53 mg of riboflavin 5'-phosphate sodium (equivalent to 1.20 mg riboflavin). Riboflavin 5'-phosphate sodium USP is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin diphosphates. The inactive ingredients are dibasic sodium phosphate, dextran, monobasic sodium phosphate, sodium chloride, and water for injection.

PHOTREXA (riboflavin 5'-phosphate ophthalmic solution) 0.146% is a yellow sterile buffered solution containing 1.46 mg/mL riboflavin 5'-phosphate. The pH of the solution is approximately 7.1 and the osmolality is 157-177 mOsm/kg. Each 1 mL of solution contains 1.53 mg of riboflavin 5'-phosphate sodium (equivalent to 1.20 mg riboflavin). Riboflavin 5'-phosphate sodium USP is a mixture of the sodium salts of riboflavin, riboflavin monophosphates, and riboflavin diphosphates. The inactive ingredients are dibasic sodium phosphate, monobasic sodium phosphate, sodium chloride, and water for injection.

The chemical formula for riboflavin 5'-phosphate sodium (Vitamin B2) is $C_{17}H_{20}N_4NaO_9P$ with a molecular mass of 478.33 g/mol.

Please refer to the KXL System Operator's Manual for a specific device description and instructions.

12. CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

Riboflavin 5'-phosphate sodium (Vitamin B2) is the precursor of two coenzymes, flavin adenine dinucleotide and flavin mononucleotide, which catalyze oxidation/reduction reactions involved in a number of metabolic pathways.

Under the conditions used for corneal collagen cross-linking, riboflavin 5'-phosphate functions as a photoenhancer and generates singlet oxygen which is responsible for the cross-linking.

13. NONCLINICAL TOXICOLOGY

13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to determine the carcinogenic potential of photoexcited riboflavin. Photoexcited

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riboflavin has been shown to be genotoxic in the Ames Salmonella reverse mutation assay and in the SOS-umu test system.

The genotoxicity of riboflavin, in the absence of photoexcitation, has been examined in vitro in bacterial reverse mutation assays, sister chromatid exchange assay, chromosomal aberration assays and in vivo in a mouse micronucleus study. The overall weight of evidence indicates that riboflavin, in the absence of photoexcitation, is not genotoxic.

Animal studies to determine the effects of the PHOTREXA/KXL corneal collagen cross-linking procedure on fertility were not conducted.

14. CLINICAL STUDIES

Three prospective, randomized, parallel group, open-label, sham-controlled trials were conducted to evaluate the safety and effectiveness of riboflavin ophthalmic solution/UVA irradiation for performing corneal collagen cross-linking. These trials were sham-controlled for the first 3 months and had a total duration of 12 months for safety and efficacy evaluations. Study 1 enrolled 58 patients with progressive keratoconus and 49 patients with corneal ectasia following refractive surgery. Study 2 enrolled 147 patients with progressive keratoconus, and Study 3 enrolled 130 patients with corneal ectasia following refractive surgery. In each study, patients had one eye designated as the study eye and were randomized to receive one of two study treatments (CXL or sham) in their study eye at the baseline visit. The patients were evaluated at Day 1, Week 1 and Months 1, 3, 6, and 12. At Month 3 or later, patients had the option of receiving CXL treatment in both the sham study eyes and non-study eyes and were followed up for 12 months from the time of receiving CXL treatment.

Approximately 56% and 88% of the sham study eyes in patients with progressive keratoconus received CXL treatment by Month 3 and Month 6, respectively. The average age of keratoconus patients was 31 years. The average baseline K_{max} value was 61 diopters. For corneal ectasia patients in Study 1 and Study 3, approximately 60% and 80% of the sham study eyes received CXL treatment by Month 3 and Month 6, respectively. The average age of corneal ectasia patients was 43 years and the average baseline K_{max} was 55 diopters. A majority (93%) of the corneal ectasia patients had LASIK only, 5 (4%) patients had photorefractive keratectomy (PRK) only, and 5 (4%) patients had both LASIK and PRK.

In each study, the maximum corneal curvature (K_{max}) was assessed at baseline, Months 1, 3, 6, and 12. The CXL treated eyes showed increasing improvement in K_{max} from Month 3 through Month 12 (Figure 1). Progressive keratoconus patients had an average K_{max} reduction of 1.4 diopters in Study 1 and 1.7 diopters in Study 2 at Month 12 in the CXL-treated eyes while the sham eyes had an average increase of 0.5 diopter in Study 1 and 0.6 diopter in Study 2. At Month 12 the difference (95% CI) between the CXL and sham groups in the mean change from baseline K_{max} were -1.9 (-3.4, -0.3) diopters in Study 1 and -2.3 (-3.5, -1.0) diopters in Study 2.

For corneal ectasia patients, at Month 12, the CXL treated eyes had an average K_{max} reduction of 1.0 diopter in Study 1 and 0.5 diopter in Study 3 while the sham eyes had an average increase of 1.0 diopter in Study 1 and 0.5 diopter in Study 3. The treatment difference between the CXL and sham groups was -2.0 (-3.0, -1.1) diopters in Study 1 and -1.1 (-1.9, -0.3) diopters in Study 3.

Study 1: Progressive Keratoconus

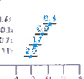
Visit	Sham (N=29)	CXL (N=29)	Difference (95% CI)
Baseline	63 (10.1)	61 (7.8)	
Month 1	0.8 (2.4)	1.4 (2.7)	2.2 (0.8, 3.5)
Month 3	0.1 (2.0)	-0.3 (2.2)	-0.5 (-1.3, 0.9)
Month 6	0.6 (2.0)	-0.9 (2.6)	-1.4 (-2.6, -0.1)
Month 12	0.5 (3.0)	-1.4 (2.6)	-1.9 (-3.4, -0.3)

Study 2: Progressive Keratoconus

Visit	Sham (N=74)	CXL (N=73)	Difference (95% CI)
Baseline	60 (9.2)	61 (8.9)	
Month 1	0.3 (2.2)	1.2 (3.4)	0.9 (0.1, 1.8)
Month 3	0.2 (2.4)	-0.6 (4.4)	-0.7 (-1.9, 0.4)
Month 6	0.6 (2.8)	-1.1 (3.5)	-1.7 (-3.0, -0.5)
Month 12	0.6 (2.9)	-1.7 (3.7)	-2.3 (-3.5, -1.0)

Study 1: Corneal Ectasia

Visit	Sham (N=25)	CXL (N=24)	Difference (95% CI)
Baseline	55 (5.5)	56 (6.5)	
Month 1	0.6 (1.7)	1.1 (2.1)	0.5 (-0.8, 1.6)
Month 3	1.0 (2.7)	0.5 (1.8)	-0.5 (-1.8, 0.8)
Month 6	1.0 (2.7)	-0.6 (1.6)	-1.7 (-2.6, -0.7)
Month 12	1.0 (3.2)	-1.0 (1.7)	-2.0 (-3.0, -1.1)



Study 3: Corneal Ectasia

Visit	Sham (N=63)	CXL (N=63)	Difference (95% CI)
Baseline	55 (6.9)	55 (7.1)	
Month 1	0.0 (1.1)	1.0 (1.9)	1.0 (0.4, 1.5)
Month 3	0.4 (1.9)	-0.3 (2.4)	-0.8 (-1.6, 0.0)
Month 6	0.5 (2.3)	-0.5 (2.0)	-1.0 (-1.8, -0.3)
Month 12	0.5 (2.1)	-0.5 (2.2)	-1.1 (-1.9, -0.3)

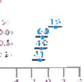


Figure 1: Mean (SD) (Diopter) Baseline K_{max} and Change from Baseline K_{max}

Post-baseline missing data were imputed using last available K_{max} value. For the sham study eyes that received CXL treatment after baseline, the last K_{max} measurement recorded prior to receiving CXL treatment was used in the analysis for later time points. In Study 3, four patients in the CXL group had missing baseline K_{max} value and were excluded from the analysis.

16. HOW SUPPLIED/STORAGE AND HANDLING

PHOTREXA® VISCOUS and PHOTREXA® are provided in a bulk pack of 10 (ten) single-use foil pouches. Each foil pouch contains a 3 mL glass syringe of PHOTREXA VISCOUS or PHOTREXA contained within a Tyvek® pouch.

The entire bulk pack should be stored at 15°-25°C (59°-77°F) and care should be taken to minimize exposure of the syringe to light once removed from its protective packaging. Discard syringe after use.

For topical ophthalmic use.

PHOTREXA VISCOUS and PHOTREXA should be used with the KXL System only.

17. PATIENT COUNSELING INFORMATION

- Patients should be advised not to rub their eyes for the first five days after their procedure.
- Patients may be sensitive to light and have a foreign body sensation. Patients should be advised that there may be discomfort in the treated eye and that sunglasses may help with light sensitivity.
- If patients experience severe pain in the eye or any sudden decrease in their vision, they should be advised to contact their physician immediately.
- If the bandage contact lens that was placed on the patient's eye on the day of treatment falls out or becomes dislodged, the patient should be advised not to replace it and to contact their physician immediately.

PHOTREXA® VISCOUS (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146%, PHOTREXA® (riboflavin 5'-phosphate ophthalmic solution) 0.146% and the KXL® System are marketed by Avedro, 230 Third Avenue, Waltham, MA 02451

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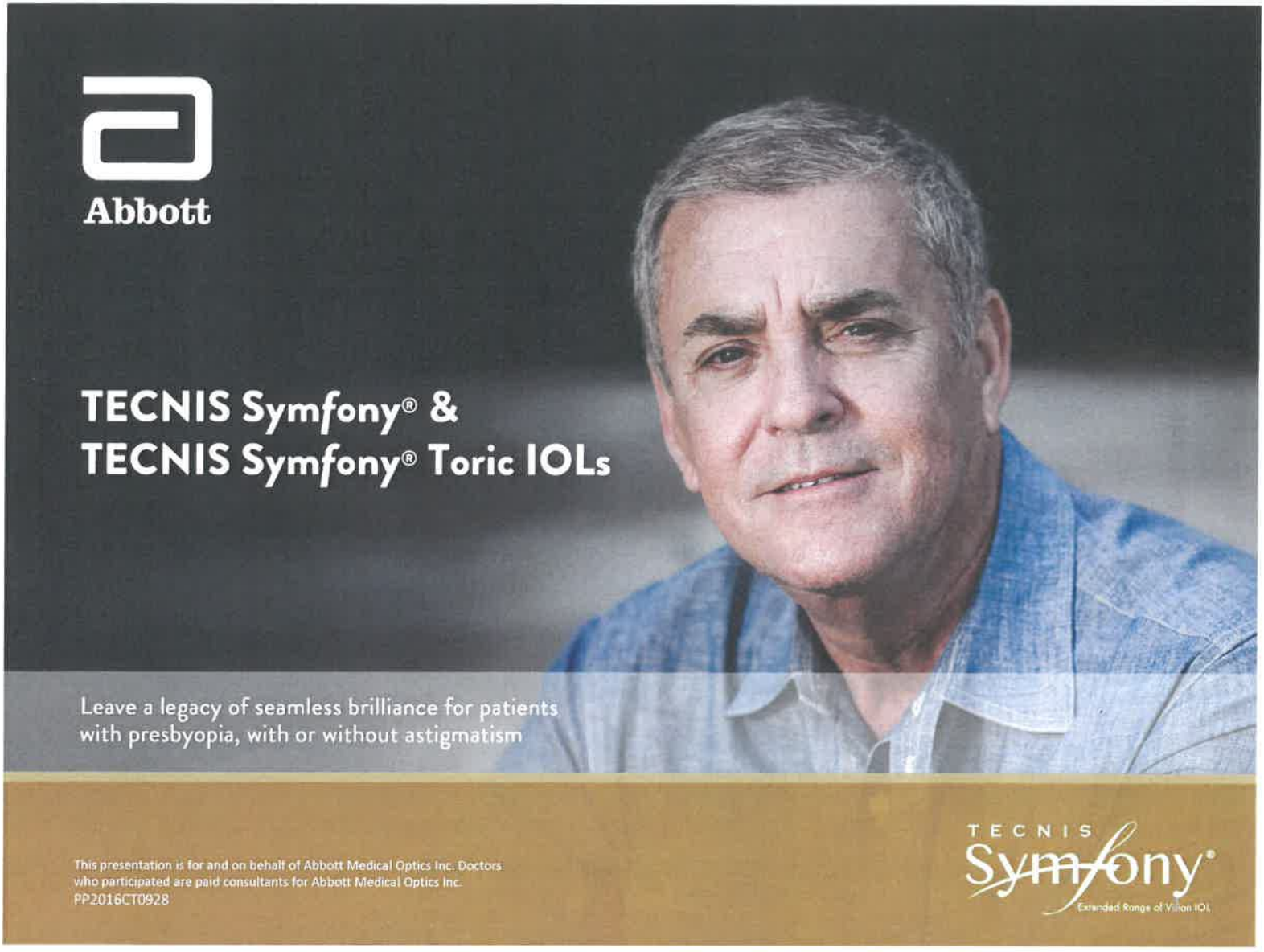
Abbott
TECNIS Symfony® &
TECNIS Symfony® Toric IOLs
Leave a legacy of seamless brilliance for patients
with presbyopia, with or without astigmatism
This presentation is for and on behalf of Abbott Medical Optics Inc. Doctors
who participated are paid consultants for Abbott Medical Optics Inc.
PP2016CT0928
TECNIS
Symfony®
Extended Range of Vision IOL

INTRODUCING:

The first and only Extended Depth of Focus (EDOF) Presbyopia-Correcting IOL for patients with and without Astigmatism

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® TORIC Extended Range of Vision IOL

INDICATIONS: 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.

INDICATIONS: 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.

See safety information on slides 28-33

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PROPRIETARY TECHNOLOGY

TECNIS Symfony®
Extended Range of Vision IOL

TECNIS Symfony® IOL Merges Two Complementary Enabling Technologies

Proprietary Echelette Design
Extends the depth of focus

Proprietary Achromatic Technology
Corrects chromatic aberration for enhanced image contrast[1]

1. TECNIS® Symfony® IOL DFU

DIFFRACTIVE TECHNOLOGY

TECNIS Symfony
Extended Range of Vision IOL

- Diffractive technology has been associated with multifocal IOLs, but it can be used in different ways
- Other industries use diffractive lenses (cameras, telescopes, microscopes) to optimize optical performance under constrained conditions

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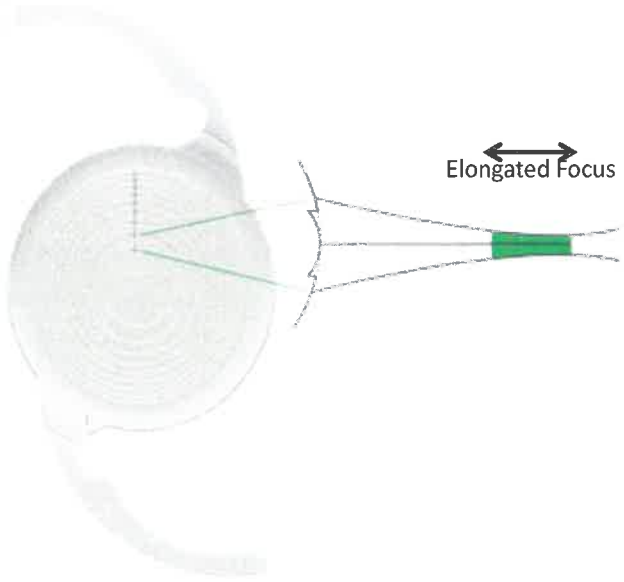
EXTENDED DEPTH OF FOCUS

TECNIS Symfony®
Extended Range of Vision IOL



The proprietary echelette design introduces a novel pattern of light diffraction that elongates the focus of the eye[1]

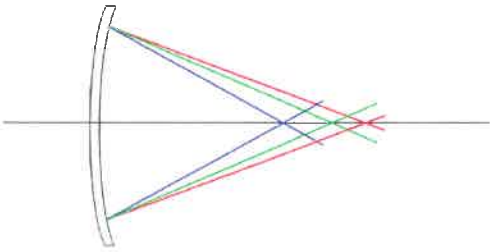
- The echelette is the relief or profile of the lens (height differential) within each ring
- The height, spacing, and profile of the echelettes are optimized to create a diffractive pattern for an elongated focus

1. TECNIS® Symfony® IOL DFU

ACTIVE CORRECTION OF CHROMATIC ABERRATION

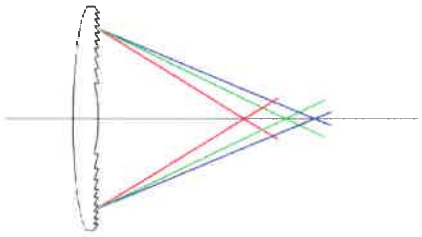
TECNIS Symfony
Extended Range of Vision IOL

Cornea



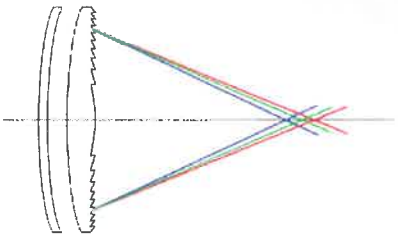
All corneas have a similar amount of chromatic aberration

Lens with Achromatic Technology



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

Cornea+ Lens with Achromatic Technology



The net result is reduced chromatic aberration

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TECNIS SYMFONY® IOL

TECNIS Symfony
Extended Range of Vision IOL

Sharpest Vision

Enhanced Functionality

Long-Term Sustainability

PP2016CT0928

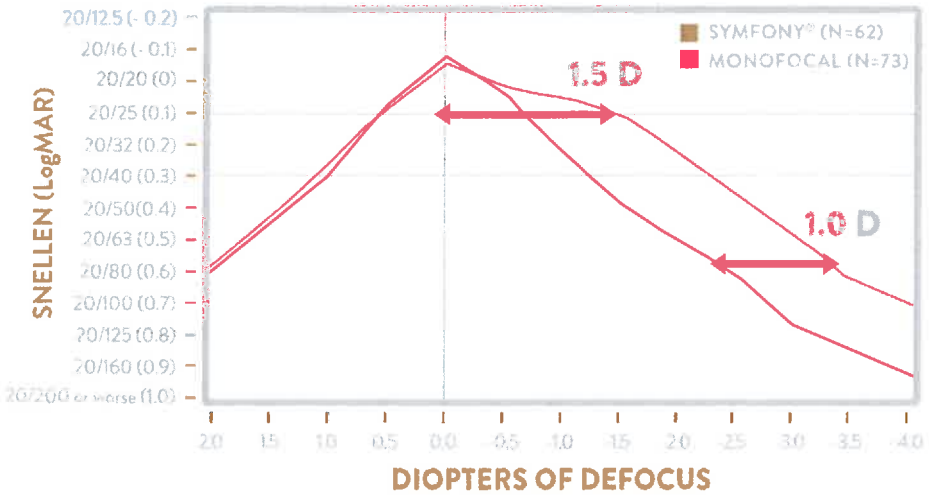
SHARPEST VISION

CONTINUOUS VISION

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® IOL provides continuous, high-quality vision at all distances

BINOCULAR DEFOCUS CURVE AT 6 MONTHS



TECNIS Symfony® IOL delivers:

- Sustained mean visual acuity of 20/25 or better through 1.5 D of defocus
- Increase of 1.0 D range of vision throughout the defocus curve compared to a monofocal

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1. TECNIS® Symfony® IOL DFU

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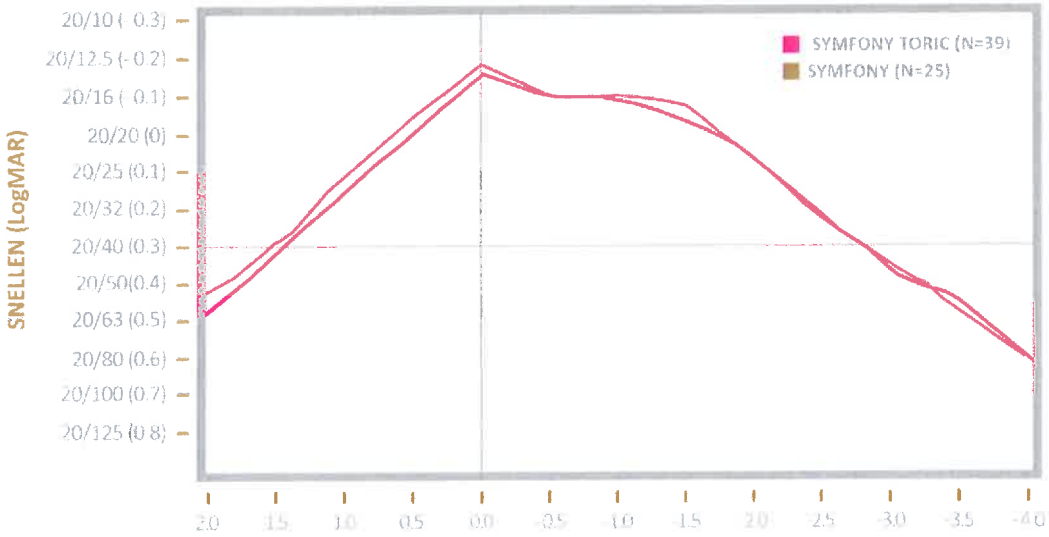
CONTINUOUS VISION

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® Toric IOL delivers the same continuous range of vision as the TECNIS Symfony® IOL

BINOCULAR DEFOCUS CURVE AT 6 MONTHS

Best-Corrected Distance Defocus Curve at 6 Months Adjusted Data
Bilateral Subjects with the Same Study IOL (Toric vs. Non-Toric)



1. TECNIS Symfony® NZ Study final data

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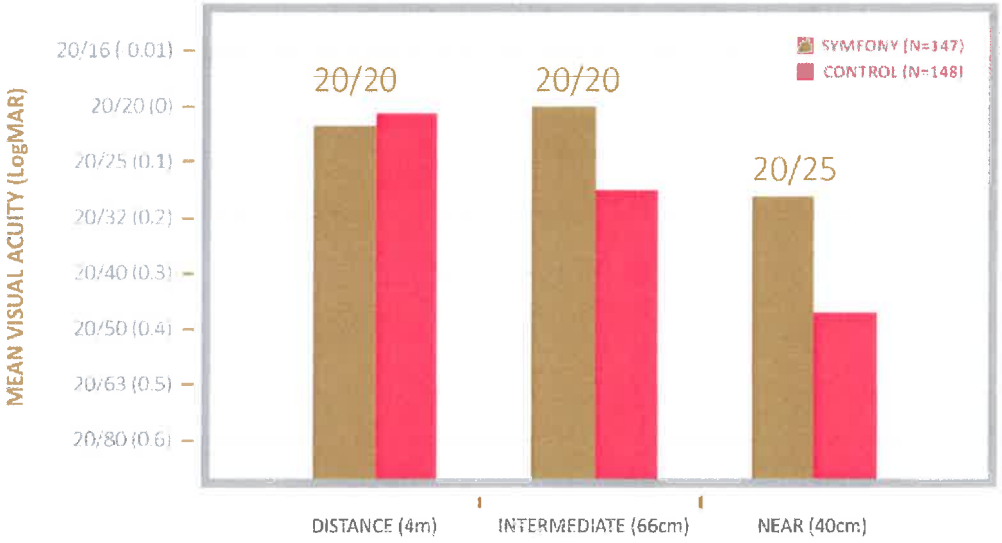
EXCELLENT VISION AT ALL DISTANCES

TECNIS Symfony®

TECNIS Symfony® IOL delivers excellent uncorrected visual acuity at all distances[1]

UNCORRECTED BINOCULAR VISUAL ACUITY AT 6 MONTHS POSTOPERATIVE



- Monocular Distance Corrected vision with TECNIS Symfony® IOL improved 2.4 lines for intermediate vision and 2.2 lines for near vision compared to the monofocal control.[1]

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1. TECNIS® Symfony® IOL DFU

PP2016CT0928

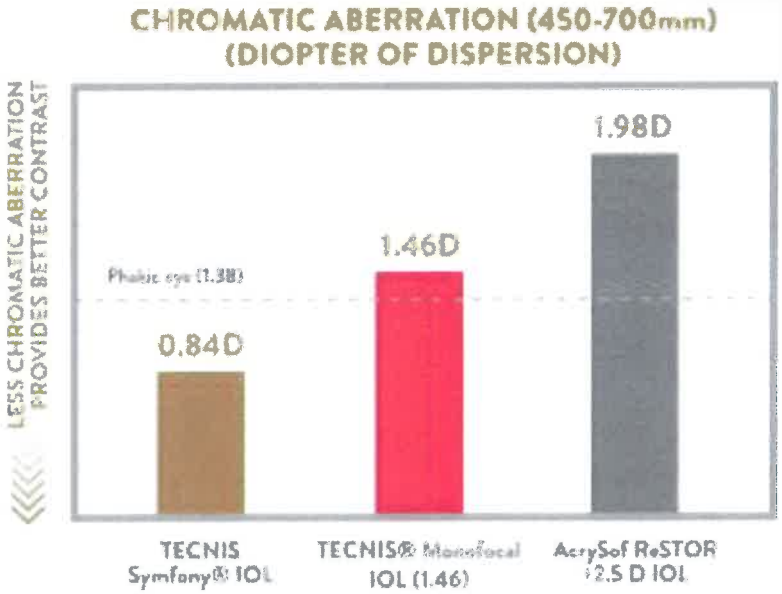
CHROMATIC ABERRATION CORRECTION

TECNIS Symfony®

Extended Range of Vision IOL

TECNIS Symfony® IOL actively corrects chromatic aberration[1]

- TECNIS material minimizes chromatic aberration
- In addition the **ACCEL™** Achromatic Technology of TECNIS Symfony® IOL actively corrects the chromatic aberration of the eye[1]
- AcrySof® IQ ReSTOR® IOLs induce chromatic aberration of the eye[1]



1. DOF2015CT0018_Chromatic Aberration of the TECNIS Symfony IOL

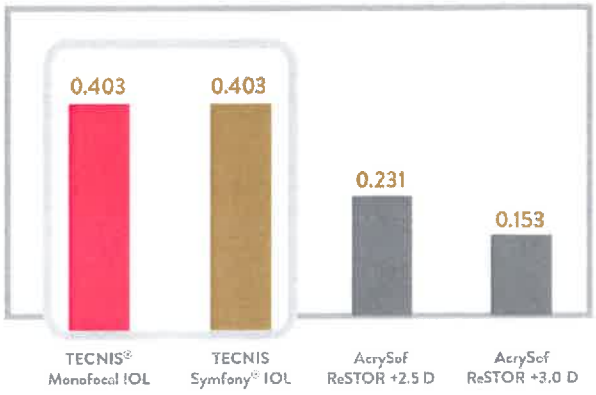
PP2016CT0928

CONTRAST SENSITIVITY

TECNIS Symfony® Extended Range of Vision IOL

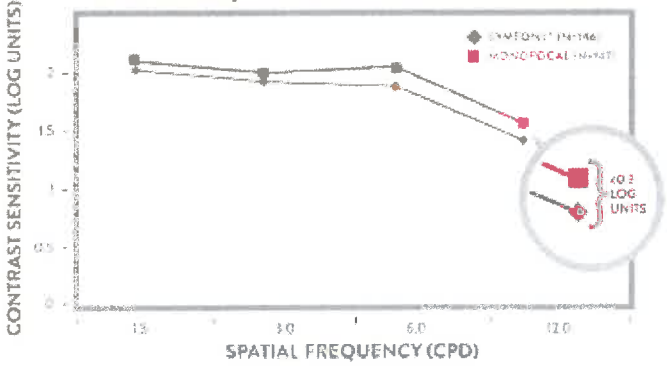
TECNIS Symfony® IOL delivers contrast sensitivity with no clinically significant difference compared to a monofocal IOL

MTF50 FAR 5MM IN ACE EYE MODEL[1]



TECNIS Symfony® IOL maintained image contrast comparable to that of the TECNIS® Monofocal IOL (at 5 mm aperture)

CONTRAST SENSITIVITY MEASURED AT MULTIPLE SPACIAL FREQUENCIES MESOPIC WITHOUT GLARE[2]



None of the differences exceeded 0.3 log units at two or more spatial frequencies

Significant loss in contrast sensitivity has been linked to increased incidence of crashes and increased risk of falls[3,4]

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

1. DOF2015CT0020_MTF of TECNIS Symfony IOL, and other lens models. 2. TECNIS® Symfony DFU 3. Owsley, McGwin. Vision Impairment and Driving. Survey of Ophthalmology. 43:6:535-550. 1999 4. Dhital. Pey and Stanford. Visual loss and falls: a review. Nature Eye. 24:1437-1446, 2010.

PP2016CT0928

TECNIS SYMFONY® TORIC IOL: SHARPEST VISION FOR PATIENTS WITH ASTIGMATISM

TECNIS Symfony® Extended Range of Vision IOL

92% of patients achieved ≤ 0.50 D of residual refractive cylinder[1]

STUDY DESIGN: Evaluate the clinical outcomes of far, intermediate and near visual acuities of patients implanted with the TECNIS Symfony® Toric IOL

- 6-month, prospective, bilateral, open-label clinical investigation, at 2 sites in New Zealand
- TECNIS Symfony® Toric IOL n=39

POST-OP CYLINDER CORRECTION RESULTS:

Mean*

0.32 D

SD 0.34D

92%

of patients have ≤ 0.5 D

WARNING: 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.

*First Eye Data

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1. DOF2016CT0025 TECNIS Symfony Toric Results

PP2016CT0928

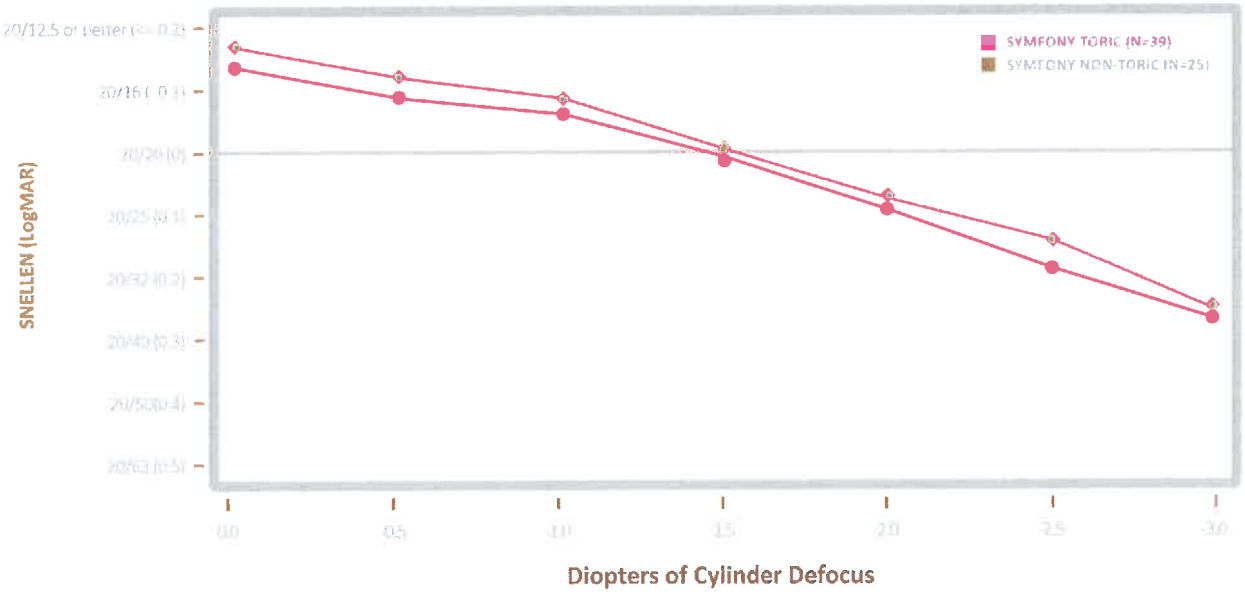
ENHANCED FUNCTIONALITY

TOLERANCE TO ASTIGMATISM

TECNIS Symfony

TECNIS Symfony® IOLs delivers 20/20 vision even in the presence of astigmatism[1, 2]

BINOCULAR MANIFEST CYLINDER DEFOCUS CURVES AT 6 MONTHS



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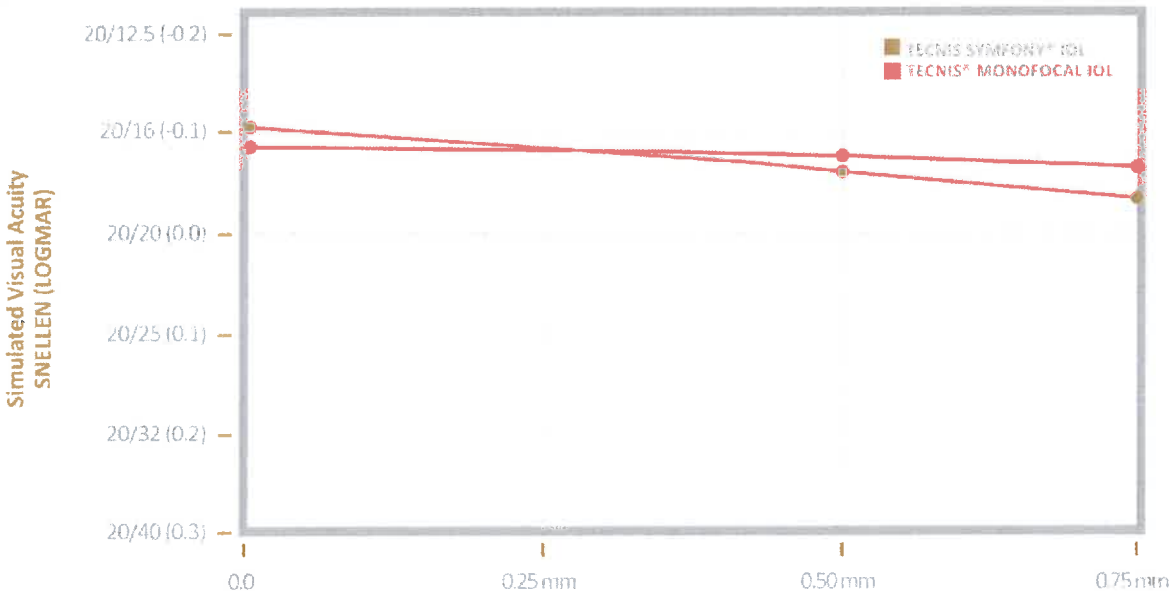
1. DOF2016CT0025 TECNIS Symfony Toric Results, 2. SC2016OTH004 Preclinical Evaluation of Tolerance to Astigmatism with an ERV IOL

PP2016CT0928

TOLERANCE TO DECENTRATION

TECNIS Symfony®
Extended Range of Vision IOL

TECNIS Symfony® IOL maintains image quality throughout 0.75 mm of decentration[1]



These calculations were performed with theoretical calculations.[1]
In the US Clinical Trial there was no report of decentration at 6 months.[2]

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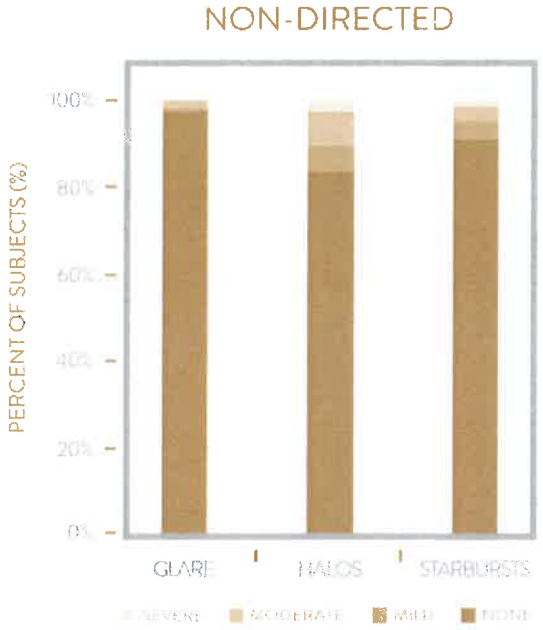
1. DOF2016CT0023 TECNIS Symfony® IOL Tolerance to decentration. 2. TECNIS Symfony® IOL DFU

PP2016CT0928

LOW INCIDENCE OF HALO AND GLARE

TECNIS Symfony® Extended Range of Vision IOL

Less than 3% of patients spontaneously reported incidence of severe night vision symptoms



WARNING: 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.

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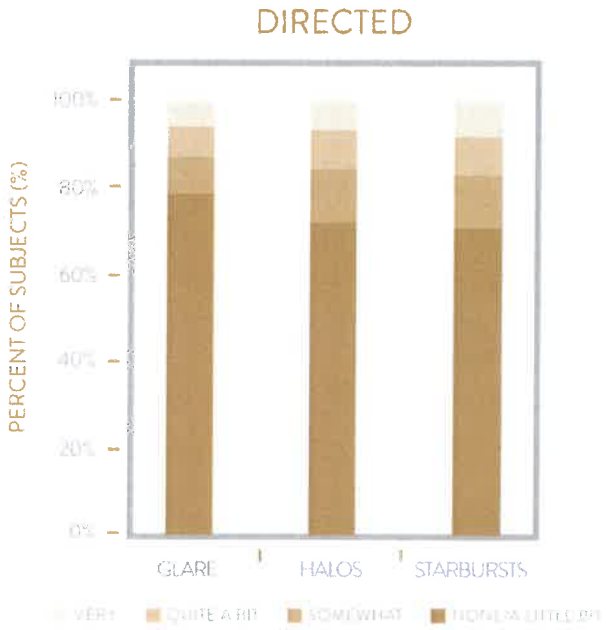
1. TECNIS® Symfony® IOL DFU

PP2016CT0928

LOW INCIDENCE OF HALO AND GLARE

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® IOL demonstrated a low incidence of halo and glare



WARNING: 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.

1. TECNIS Symfony® IOL DFU

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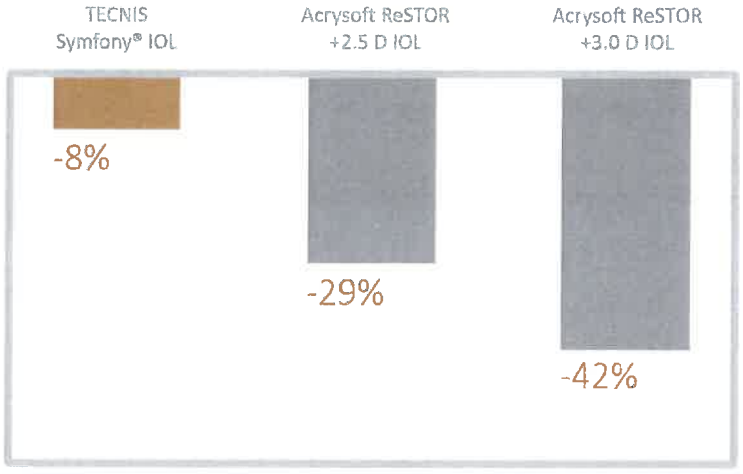
PUPIL INDEPENDENT LENS PERFORMANCE

TECNIS Symfony®

TECNIS Symfony® IOL pupil independence enables optimal performance in all lighting conditions[1,2]

MTF LOSS WHEN THE PUPIL OPENS FROM 3mm TO 5mm



Distance MTF at 50 c/mm in white light

Less MTF loss provides better contrast under low-light conditions

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1. TECNIS Symfony® IOL DFU 2. DOF2015CT0020_MTF of TECNIS Symfony IOL, and other lens models.

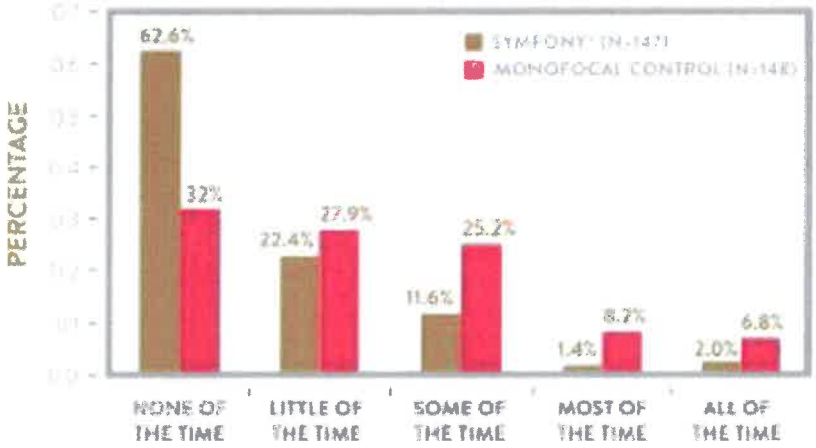
PP2016CT0928

LOW SPECTACLE WEAR

TECNIS Symfony® Extended Range of Vision IOL

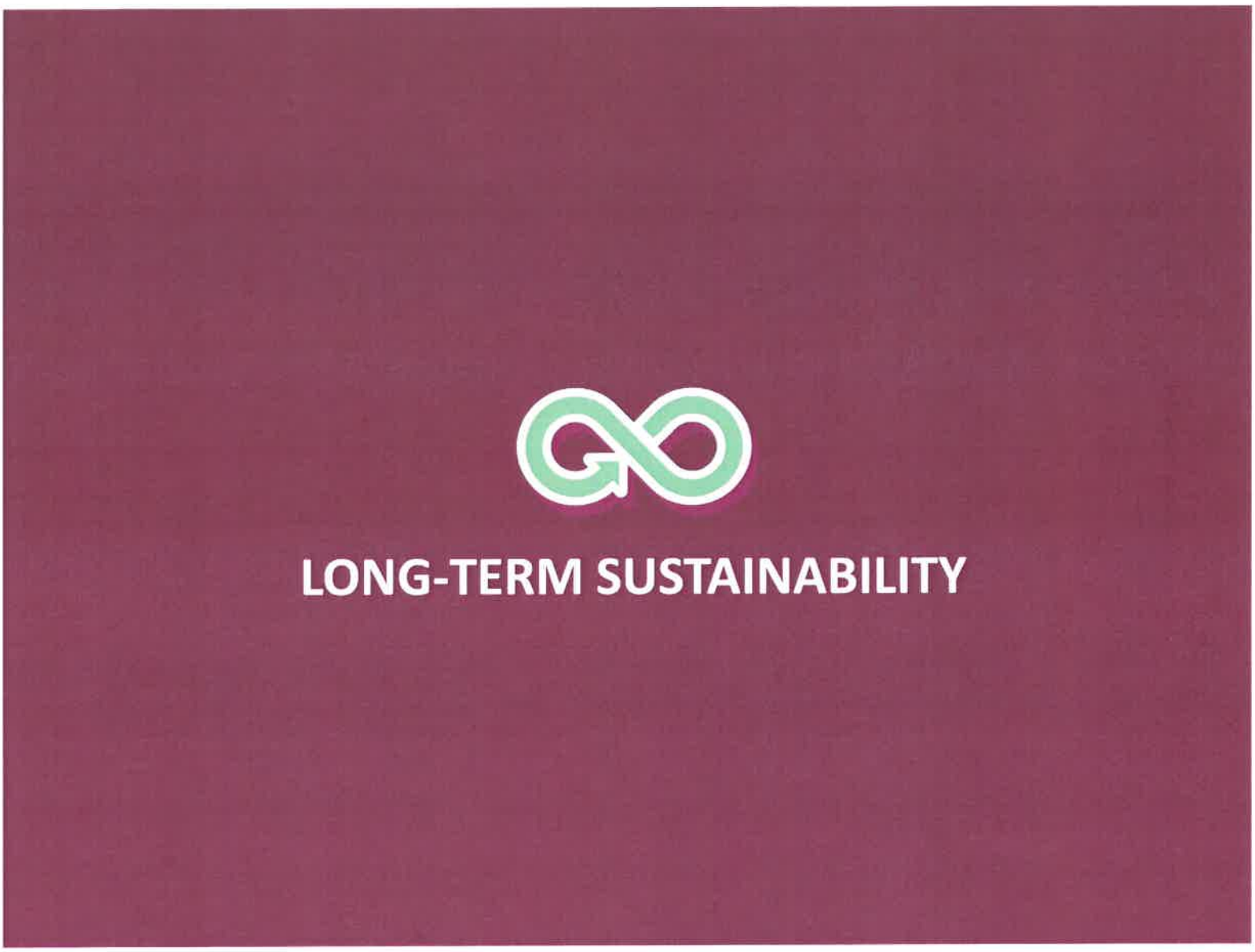
85% of TECNIS Symfony® IOL patients wore glasses none or a little bit of the time*

FREQUENCY OF GLASSES / CONTACTS WEAR DURING LAST 7 DAYS, ASKED AT 6 MONTH VISIT



*Although the questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence, data showed that the Symfony IOL achieved the secondary effectiveness endpoint of reduced overall spectacle wear compared to the control monofocal IOL

1. TECNIS Symfony® IOL DFU


LONG-TERM SUSTAINABILITY

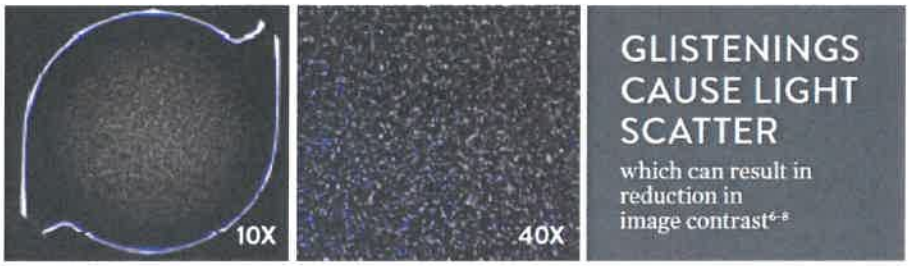
LONG-TERM SUSTAINABILITY

TECNIS Symfony® Extended Range of Vision IOL

TECNIS® IOL MATERIAL
is not associated with glistenings[1]

VS

AcrySof® IOLs have glistenings[2-5]



DARK FIELD IMAGES OF AcrySof® LENS[9]

1. Data on File 150_Sensar not associated with glistenings – Literature analysis. Abbott Medical Optics, Inc., 2013. REF2014OTH0002 2. Christiansen G, et al. Glistenings in the AcrySof® intraocular lens: Pilot study. *JCRS* 2001; 27:728-733. REF2014MLT0005. 3. Colin J, et al. Incidence of glistenings with t.he latest generation of yellow-tinted hydrophobic acrylic intraocular lenses. *JCRS* 2012; 38:1140-1146. REF2014MLT0006. 4. Gunenc U, et al. Effects on visual function of glistenings and folding marks in AcrySof® intraocular lenses. *JCRS* 2001; 27:1611-1614. REF2014MLT0011. 5. Nagata M, et al. Clinical evaluation of the transparency of hydrophobic acrylic intraocular lens optics. *JCRS* 2010; 36:2056-2060. REF2015CT0080. 6. Bousquet M, PhD, Health Canada. Intraocular lenses and the development of glistenings. Canadian Adverse Reaction Newsletter 2013. REF2015CT0254. 7. Miyata A, Yaguchi S. Equilibrium water content and glistenings in acrylic intraocular lenses. *JCRS* 2004; 30:1768-1772. REF2014OTH0032. 8. van der Mooren, et al. Explanted multifocal intraocular lenses. *JCRS* 2015; 41:873-877. REF2015OTH0117. 9. Van der Mooren M, et al. Effects of glistenings in intraocular lenses. *Biomedical Optics Express*.11 July 2013:1294-1304. REF2014OTH0139.

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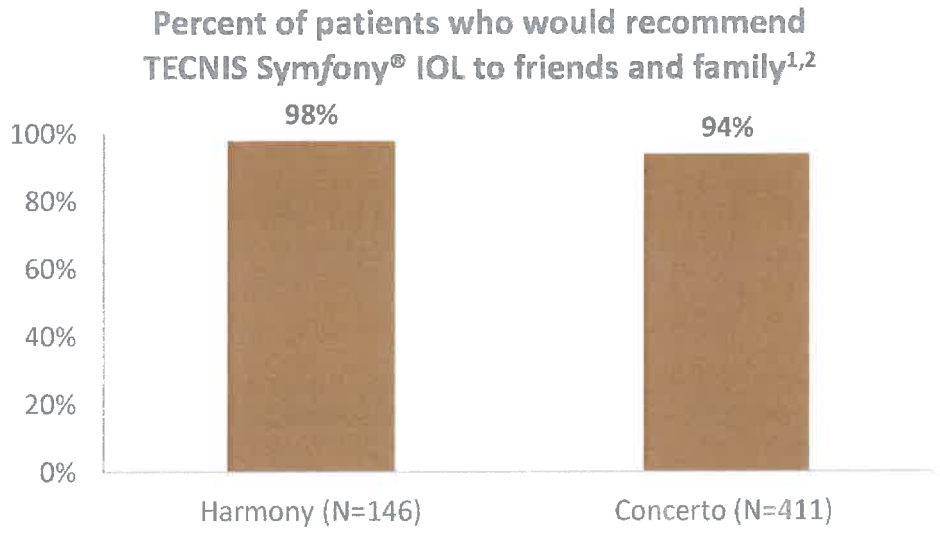
PATIENT SATISFACTION

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® IOL delivers high patient satisfaction



1.. DOF2016CT0024 Concerto Study Report, 2. DOF2015OTH0009 Symfony Harmony Observational Study

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PP2016CT0928

TECNIS SYMFONY® IOL

TECNIS Symfony® Extended Range of Vision IOL

First and only Extended Depth of Focus Presbyopia-Correcting IOL

Sharpest Vision

High-quality continuous vision at all distances[1]

- Proprietary echelette design delivers an sustained mean visual acuity of 20/25 or better through 1.5 D of defocus
- Excellent uncorrected visual acuity at all distances[1]
- Proprietary achromatic technology actively corrects chromatic aberration for improved image contrast[1,5]

Enhanced Functionality

Forgiving lens

- Tolerance to astigmatism[2,3]
- Tolerance to decentration[4]

Excellent overall performance in any lighting condition

- Low incidence of halo and glare[1]
- Pupil independent lens performance[1,5]

Low spectacle wear

- 85% of patients wore glasses *None* or *A little bit* of the time[1]

Long-Term Sustainability

TECNIS® IOL material is not associated with glistenings[6]

- Glistenings cause light scatter resulting in reduction in image contrast[11-13]
- AcrySof® IQ ReSTOR® IOLs have glistenings[7-10]

High Patient Satisfaction

>94% of patients would recommend the lens to family and friends[14,15]

TECNIS Symfony® Toric IOL provides continuous, high-quality vision at all distances for patients with astigmatism

- TECNIS Symfony Toric patients experience all the benefits of the TECNIS Symfony IOL[2]
- 92% of TECNIS Symfony® Toric IOL patients achieved ≤0.50 diopters of residual refractive cylinder[2]

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REFERENCES FOR SUMMARY SLIDES

1. TECNIS Symfony DFU
2. DOF2016CT0025 TECNIS Symfony Toric Results
3. SC20160TH004 Preclinical Evaluation of Tolerance to Astigmatism with an ERV IOL
4. DOF2016CT0023 TECNIS Symfony® IOL Tolerance to decentration.
5. DOF2015CT0018_MTF of TECNIS Symfony IOL, and other lens models
6. Data on File 150_Sensar not associated with glistenings – Literature analysis. Abbott Medical Optics, Inc., 2013.
7. Christiansen G, et al. Glistenings in the AcrySof® intraocular lens: Pilot study. *JCRS* 2001; 27:728-733. REF2014MLT0005.
8. Colin J, et al. Incidence of glistenings with the latest generation of yellow-tinted hydrophobic acrylic intraocular lenses. JCRS 2012; 38:1140-1146. REF2014MLT0006.
9. Gunenc U, et al. Effects on visual function of glistenings and folding marks in AcrySof® intraocular lenses. *JCRS* 2001; 27:1611-1614. REF2014MLT0011.
10. Nagata M, et al. Clinical evaluation of the transparency of hydrophobic acrylic intraocular lens optics. *JCRS* 2010; 36:2056-2060. REF2015CT0080.
11. Bousquet M, PhD, Health Canada. Intraocular lenses and the development of glistenings. Canadian Adverse Reaction Newsletter 2013. REF2015CT0254.
12. Miyata A, Yaguchi S. Equilibrium water content and glistenings in acrylic intraocular lenses. *JCRS* 2004; 30:1768-1772. REF2014OTH0032.
13. van der Mooren, et al. Explanted multifocal intraocular lenses. *JCRS* 2015; 41:873-877. REF2015OTH0117.
14. DOF2016CT0024 Concerto Study Report
15. DOF2015CT0028 Symfony Harmony Observational Study

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

TECNIS Symfony® Extended Range of Vision IOL

Caution:

- Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Indications for use:

- The TECNIS® Symfony Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only.

- The TECNIS® Symfony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.

Warnings:

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

1. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight:
    a. Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.
    b. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
    c. Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).
    d. A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
    e. Circumstances that would result in damage to the endothelium during implantation.
    f. Suspected microbial infection.
    g. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
    h. Children under the age of 2 years are not suitable candidates for intraocular lenses.
    i. Congenital bilateral cataracts.
    j. Previous history of, or a predisposition to, retinal detachment.
    k. Patients with only one good eye with potentially good vision.
    l. Medically uncontrollable glaucoma.
    m. Corneal endothelial dystrophy.
    n. Proliferative diabetic retinopathy.

PP2016CT0928

Warnings (cont):

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:

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

TECNIS Symfony® Extended Range of Vision IOL

Precautions (cont.):

Before Surgery

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

During Surgery

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

PP2016CT0928

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

TECNIS Symfony® Extended Range of Vision IOL

Precautions (cont.):

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 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.
14. 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.
15. 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.
16. 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.

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

TECNIS Symfony® Extended Range of Vision IOL

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 TECNIS® 1-Piece IOL

TECNIS Symfony® Extended Range of Vision IOL

Rx Only

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

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

PRECAUTIONS
Do not reuse, resterilize, or autoclave.

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

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

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WORK/EDUCATION:

2012-present **Turner Eye Institute (San Leandro, CA)**
Medical Director
Cornea, Anterior Segment, and Refractive Surgeon

2015-present **Tissue Banks International San Francisco Eye Bank (Richmond, CA)**
Medical Director

2011-2012 **The New York Eye and Ear Infirmary (New York, NY)**
Cornea, External Disease, and Refractive Surgery Fellowship

2008---2011 **Vanderbilt Eye Institute (Nashville, TN)**
Ophthalmology Resident Physician Chief
Resident 2010---2011

2007-2008 **St. Mary's Medical Center (San Francisco, CA)**
Preliminary Internal Medicine Internship

2002-2007 **University of California, San Diego (UCSD) School of Medicine (La Jolla, CA)**
M.D.

1997-2001 **University of California, Berkeley (Berkeley, CA)**
B.A. Molecular and Cell Biology (with Emphasis in Immunology)

HONORS, AWARDS, & DISTINCTIONS:

2010-2011 **Chief Resident, Vanderbilt Eye Institute**

2009-2010 **Outstanding Oculoplastics Award, Vanderbilt Eye Institute**

2009---2011 **Organizer, Vanderbilt Eye Institute/Tilganga Eye Center (Kathmandu, Nepal) International Elective**

2008-2011 **Resident Representative, Haiti Outreach Program, Vanderbilt Eye Institute**

2007---2008 **Outstanding Clinical Intern Award, St. Mary's Medical Center (San Francisco, CA)**

2003 **NIH Research Training Grant, University of California, San Diego**

2002---2007 **President, American Association of Physicians of Indian Origin (AAPI), UCSD Chapter**

2002-2007 **UCSD School of Medicine**
- Honors in Pharmacology course, Laboratory Medicine course, & Family Medicine Clerkship
- Academic Distinction in Anatomy course and in Medicine, Pediatrics, Neurology, Psychiatry, & OB/GYN clerkships

2001 **Phi Beta Kappa Honor Society**

1997-2001 **High Honors, University of California, Berkeley**

1997–2001	**Dean's List, University of California, Berkeley**
1997---2001	**Pre---Medical Honor Society, University of California, Berkeley**
1997	**Regents Scholarship Nominee, University of California**

RESEARCH:

2014–present **Reduction in the Bacterial Load on the Skin in a Clincal Setting**
Co-Authors: David W. Stroman, OD, Keri Mintun, OD, Arthur B. Epstein, OD, Crystal Brimer, OD, James D. Branch, M.D., Katy Najafi-Tagol, M.D.

2011–present **Long–Term Graft Survival Rates in Descemet's Stripping Endothelial Keratoplasty**
The New York Eye and Ear Infirmary (New York, NY)
Co-Authors: John A. Seedor, M.D., David C. Ritterband, M.D., & Elaine Wu, M.D.

2011–present **Outcomes with Deep Anterior Lamellar Keratoplasty (DALK)**
The New York Eye and Ear Infirmary (New York, NY)
Co-Authors: John A. Seedor, M.D., David C. Ritterband, M.D., & Elaine Wu, M.D.

2010–2011 **Incidence of and Risk Factors for Chronic Uveitis Following Cataract Surgery**
Vanderbilt Eye Institute (Nashville, TN)
Department of Veterans Affairs Medical Center (Nashville, TN) Co-Authors: Stephen J. Kim, M.D. & Amy Chomsky, M.D.

2009---2011 **Endophthalmitis Rates Following Anti---VEGF Intravitreal Injection**
Department of Veterans Affairs Medical Center (Nashville, TN)
Vanderbilt Eye Institute (Nashville, TN)
Co-Authors: Amy Chomsky, M.D. & Janice C. Law, M.D.

2006–2007 **Detection of Glaucoma Using Scanning Laser Polarimetry**
Long–term Predictive Value of a Glaucoma Risk Calculator
UCSD School of Medicine Department of Ophthalmology (La Jolla, CA) Co-Authors: Robert N. Weinreb, M.D. & Felipe Medeiros, M.D., Ph.D.

2002–2007 **Association of Peripheral Arterial Disease with Mortality**
UCSD School of Medicine Dept. of Family & Preventative Medicine (La Jolla, CA)
Co-Authors: Michael H. Criqui, M.D., MPH
Supported by National Institute of Health (NIH) Research Training Grant

1999–2001 **The Role of TRAIL in Apoptosis of Neoplastic Cells**
University of California, Berkeley Dept. of Molecular & Cell Biology (Berkeley, CA)
Co-Authors: Astar Winoto, Ph.D.

PRESENTATIONS:

Patel C. Monday Morning Quarterback: Anterior Segment Triage and Treatments. (*Presented at 2014 UCBSO Berkeley Practicum, Berkeley, CA*)

Patel C. Corneal Surgery: Past, Present, and Future. (*Presented at 2013 ACCCOS Annual Meeting, Walnut Creek, CA*)

Patel C, Chomsky A, Kim SJ. Incidence of and Risk Factors for Chronic Uveitis Following Cataract Surgery. (*Presented at 2011 Vanderbilt Eye Institute Resident Day Research Symposium*)

Patel C, Law JC, Chomsky A. Retrospective Review of Anti---Vascular Endothelial Growth Factor Intraocular Injection Use and Post---Injection Endophthalmitis Rates Within the Medical Facilities of the United States Department of Veterans Affairs. (*Presented at 2010 Vanderbilt Eye Institute Resident Day Research Symposium*)

Patel C. Cataract Surgery in the Developing World. (*Presented at 2007 Sankara Eye Foundation Gift of Vision Banquet, Santa Clara, CA*)

Patel C, Yue HH, Diehl G, Chang A, Winoto A. The Role of TRAIL in Apoptosis of Neoplastic Cells. (*Presented at 2001 University of California, Berkeley Department of Molecular and Cell Biology Honors Thesis Symposium*)

ABSTRACTS:

Stroman DW, Mintun K, Epstein AB, **Patel C**, Brimer C, Branch JD, Najafi-Tagol K. Reduction in the Bacterial Load on the Skin in a Clinical Setting. (To be p*resented at 2016 ARVO Annual Meeting*)

Patel C, Chomsky A, Kim SJ. Incidence of and Risk Factors for Chronic Uveitis Following Cataract Surgery. (*Presented at 2011 Association for Research in Vision and Ophthalmology Annual Meeting*)

Patel C, Law JC, Chomsky A. Retrospective Review of Anti---Vascular Endothelial Growth Factor Intraocular Injection Use and Post---Injection Endophthalmitis Rates Within the Medical Facilities of the United States Department of Veterans Affairs. (*Presented at 2010 Association for Research in Vision and Ophthalmology Annual Meeting*)

Patel C, Denenberg JO, Langer RD, Criqui MH. Twenty---year Mortality Rates in Patients with Isolated Small Vessel Peripheral Arterial Disease. (*Presented at 2003 NIH Research Training Grant Poster Session)*

PUBLICATIONS:

Patel C, Kim SJ, Chomsky A, Saboori M. Incidence and Risk Factors for Chronic Uveitis Following Cataract Surgery. (*accepted for publication in Ocular Immunology & Inflammation*)

Patel C, Law JC, Chomsky A. Retrospective Review of Anti---Vascular Endothelial Growth Factor Intraocular Injection Use and Post---Injection Endophthalmitis Rates Within the Medical Facilities of the United States Department of Veterans Affairs. (*Manuscript in preparation*)

Medeiros FA, Bowd C, Zangwill LM, **Patel C**, Weinreb RN (2007). Detection of glaucoma using scanning laser polarimetry with enhanced corneal compensation. Investigative ophthalmology & visual science, 48(7), 3146---3153.

COMMUNITY INVOLVEMENT:

2002--2006 **UCSD Student-Run Free Clinic Project (San Diego, CA)**
Diabetes Clinic Director
Medical Student Volunteer

2002--2003 **UCSD Doc for a Day (La Jolla, CA)**
Medical Student Mentor

1999--2001 **University of California, San Francisco Medical Center (San Francisco, CA)**
Melanoma Clinic Volunteer

INTERNATIONAL WORK:

2011 **Tilganga Eye Center (Kathmandu, Nepal)**
Clinical Rotation

- Provided free care to underserved patients and performed small incision extracapsular cataract surgery

2005--2006 **Sankara Eye Centre (Coimbatore, Tamil Nadu, India)**
Clinical Internship

- Aided with rural eye camp administration and with screening of patients

PROFESSIONAL ASSOCIATIONS:

American Board of Ophthalmology (Board Certified Ophthalmologist)
American Academy of Ophthalmology (AAO)
Association for Research in Vision and Ophthalmology (ARVO)
The American Society of Cataract and Refractive Surgery (ASCRS)
The Cornea Society