

What I Am Doing Now That I Was Not Doing One Year Ago

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Case Presentation #1

- 19 y/o female with progressive vision loss left > right eye x several years. Has difficulty with reading, near work activities and distance focus. Unable to complete DMV school due to vision; impacting school work

Case Presentation #1

- POH: Congenital cataracts
- SH: College- art major
- Exam:
- Va OD 20/25
OS 20/30
- Lens: 3mm central opacity OU



Case Presentation #1

- Imp : Visually significant congenital cataract OU
- Plan: Cataract surgery both eyes- general anesthesia – left eye 1st
- IOL options reviewed – Symfony IOL was chosen
- IOL SE target : -0.25
- Surgeries done one week apart over Christmas holiday

Case Presentation #1- Postop

- One month Postop :

- Vasc OD 20/25 ; J3

OS 20/25 ; J1

10 months Postop:

Vasc OD 20/25 ; J2

OS 20/25 ; J2

OU 20/20+3; J1+

What I Am Doing Now That I Was Not Doing One Year Ago

- Using ED IOLs as my primary “Premium” IOL of choice
- Using miLOOP device to manually bisect nucleus in dense “ high risk” cataract surgeries
- Cypass device for patients with mild-moderate glaucoma undergoing cataract surgery
 - Started and stopped!
- Using the IMT in pseudophakic patients
 - IMT-TES study

ED IOLs are now my primary “Premium” IOL of choice

- Account for about 85% of my premium IOL usage
 - Symphony & Symphony Toric IOLs

Symphony IOL

Ideal Candidates:

- **Strong desire for reading ability without glasses without significant compromise of night vision**
- **Great for “working age population”**
- **Don't mind OTC readers for small print*****
- **Consider much wider age range vs multifocal IOL**

Usage pearls:

- **Lens has some “flexibility of focus”, allowing undercorrection of astigmatism**
- **IOL target : -0.25 sphere**

INTRODUCING:

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

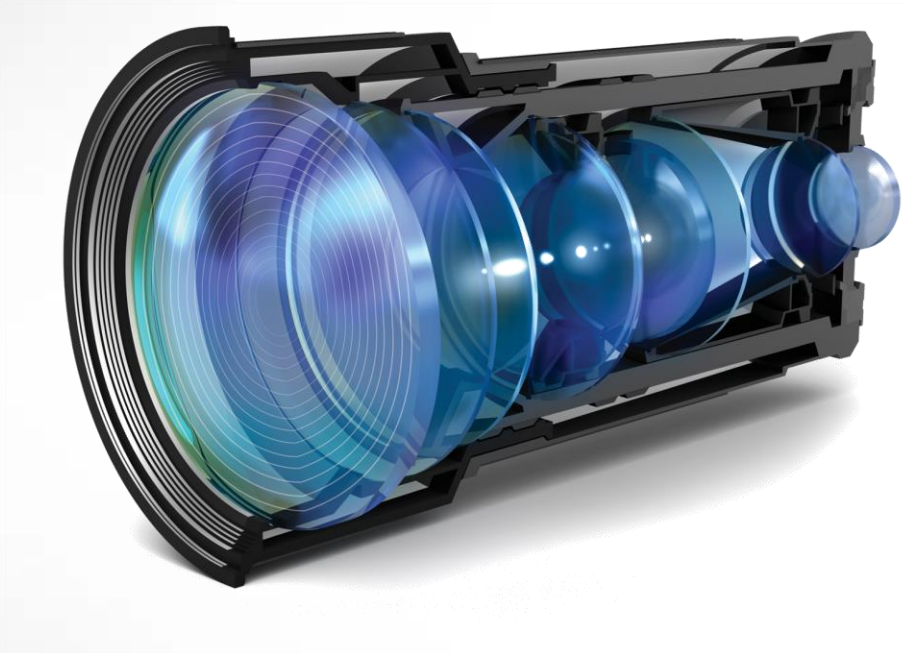


INDICATIONS: The TECNIS® Symphony Extended Range of Vision IOL, Model ZXR00, is indicated for primary implantation for the visual correction of aphakia, in adult patients with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the 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.

See safety information on slides 28-33



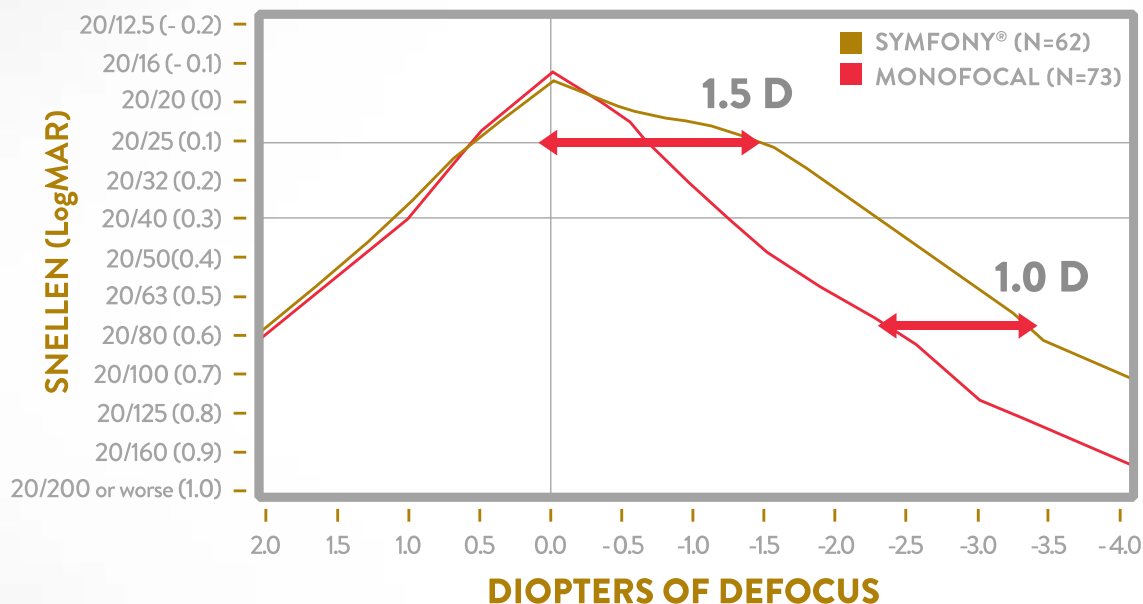
INDICATIONS: The TECNIS® Symphony Toric Extended Range of Vision IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter 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.



- 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

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

BINOCULAR DEFOCUS CURVE AT 6 MONTHS

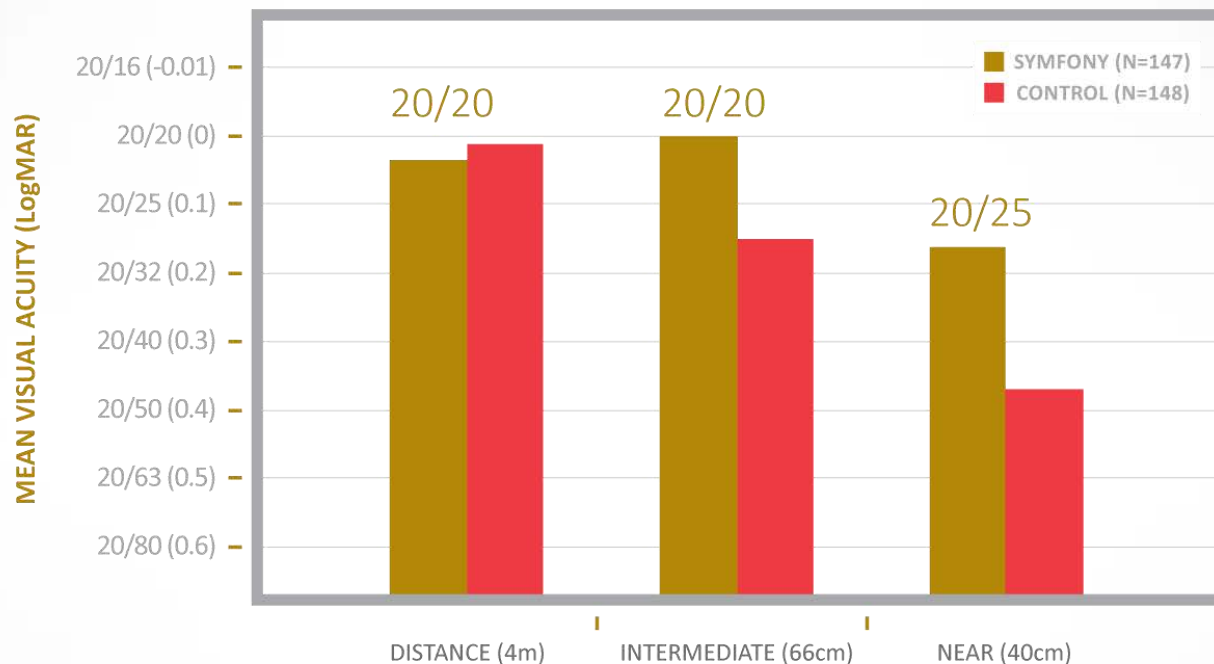


TECNIS Symfony® IOL delivers:

- 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

TECNIS Symfony[®] IOL delivers excellent uncorrected visual acuity at all distances¹

UNCORRECTED BINOCULAR VISUAL ACUITY AT 6 MONTHS POSTOPERATIVE

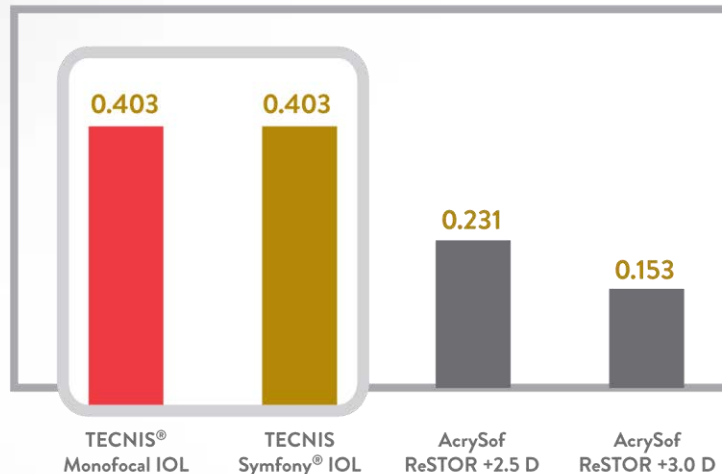


- Monocular Distance Corrected vision with TECNIS Symfony[®] IOL improved 2.4 lines for intermediate vision and 2.2 lines for near vision compared to the monofocal control.¹

CONTRAST SENSITIVITY

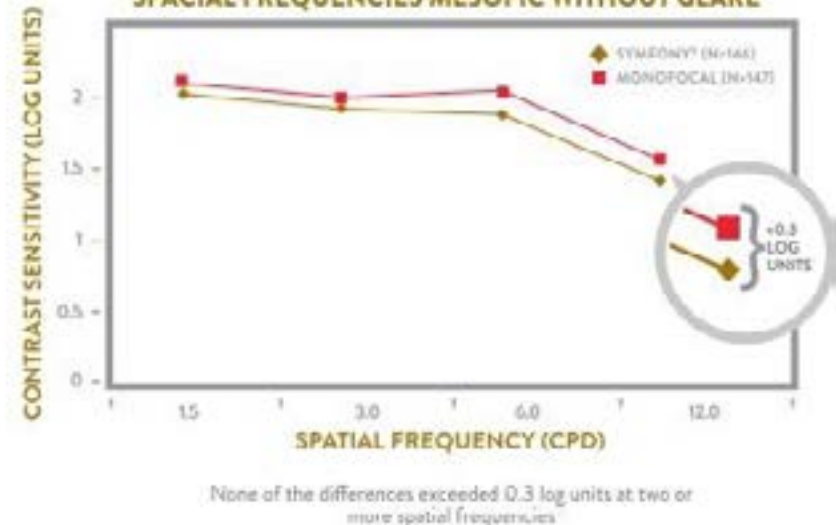
TECNIS Symphony® IOL delivers contrast sensitivity with no clinically significant difference compared to a monofocal IOL

MTF50 FAR 5MM IN ACE EYE MODEL¹



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

CONTRAST SENSITIVITY MEASURED AT MULTIPLE SPATIAL FREQUENCIES MESOPIC WITHOUT GLARE²



Significant loss in contrast sensitivity has been linked to increased incidence of crashes and increased risk of falls^{3,4}

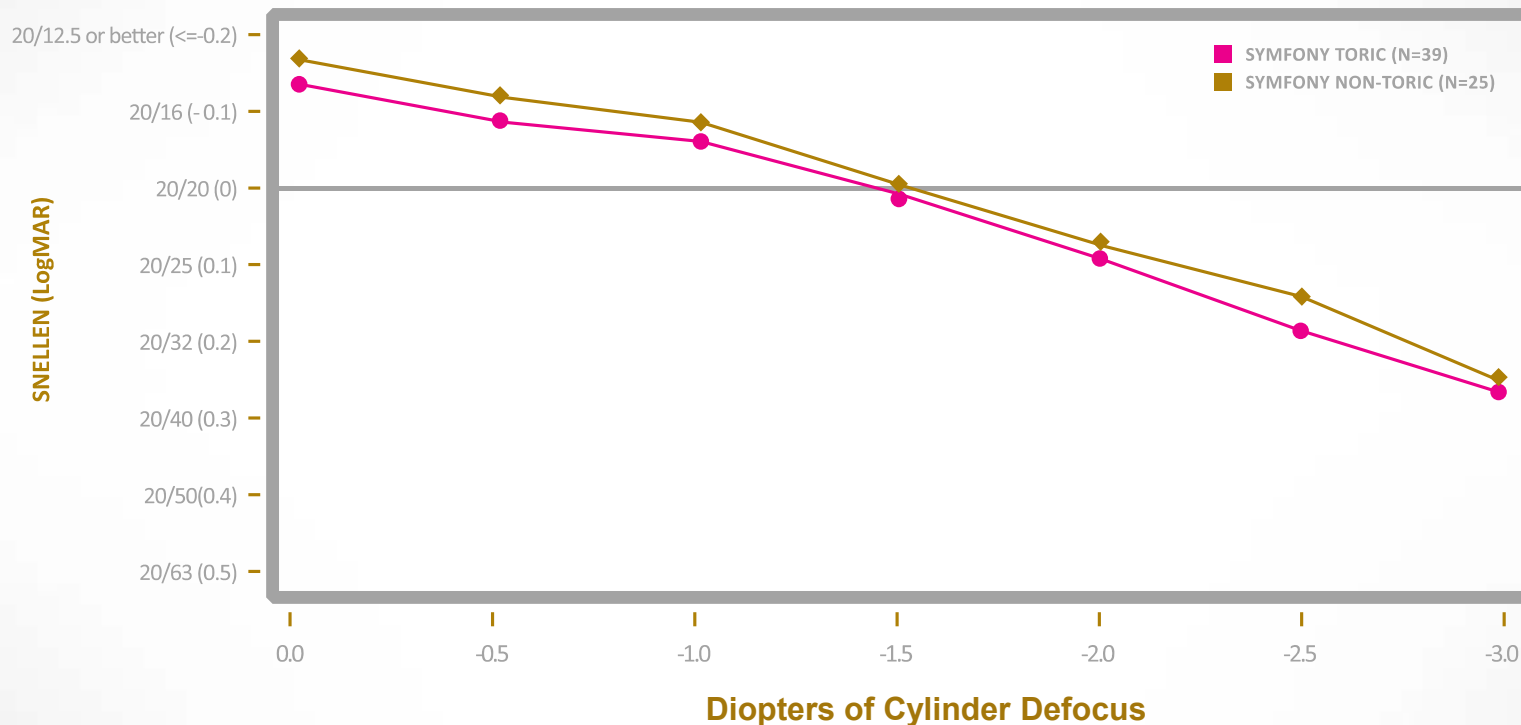
WARNING: The TECNIS® Symphony IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast 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 Symphony IOL, and other lens models. 2. TECNIS® Symphony 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.

TECNIS Symfony® IOLs delivers 20/20 vision even in the presence of astigmatism^{1, 2}

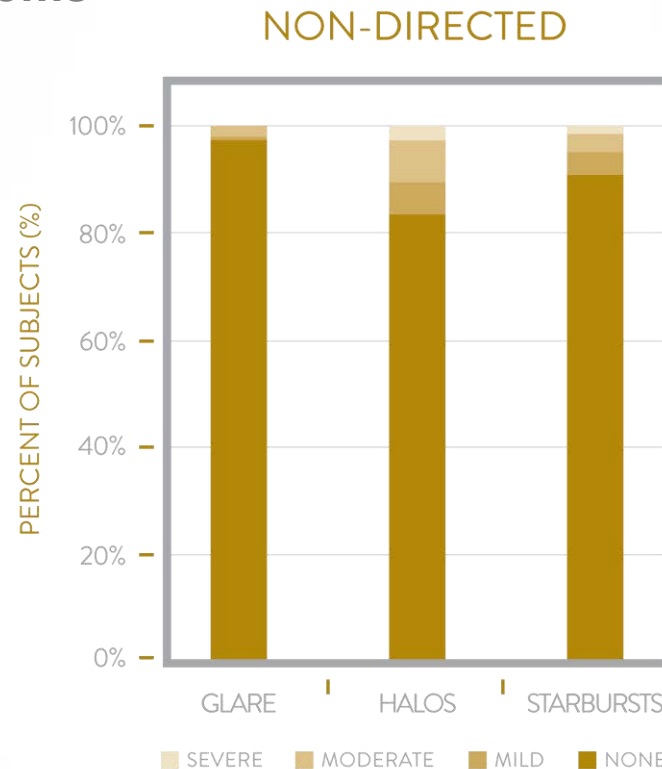
BINOCULAR MANIFEST CYLINDER DEFOCUS CURVES AT 6 MONTHS



LOW INCIDENCE OF HALO AND GLARE

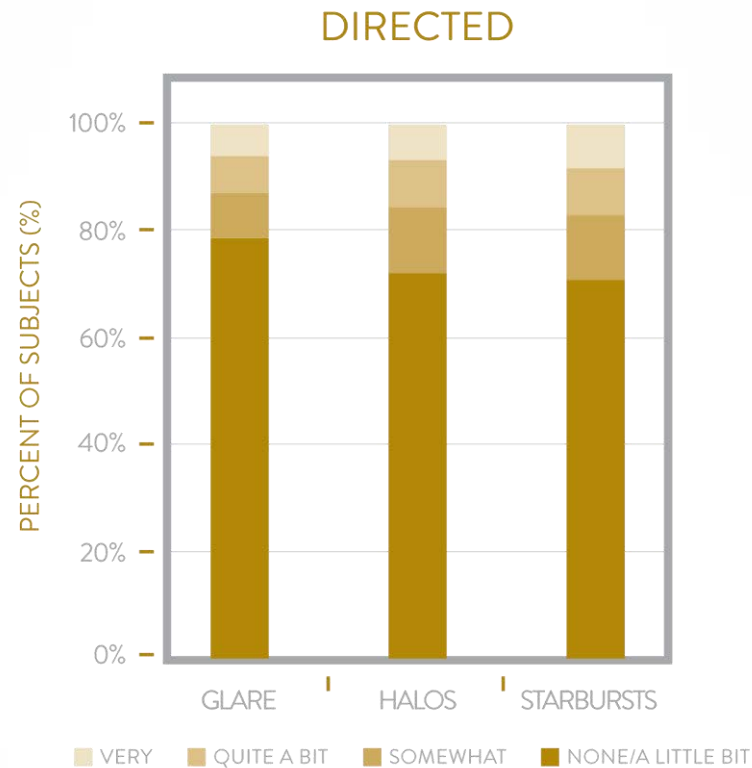


Less than 3% of patients spontaneously reported incidence of severe night vision symptoms



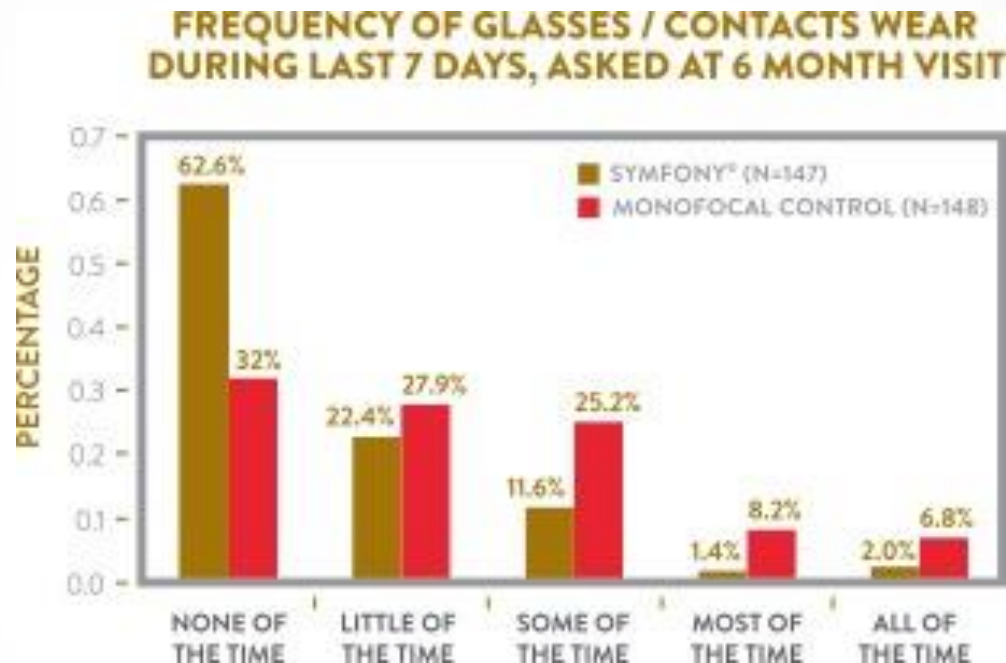
WARNING: Some visual effects associated with the TECNIS® Symphony IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome 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.

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.

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



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

Rauser- Premium IOL Choice Summary

- ED IOLs
 - working age population
 - Post LASIK patients
 - **Don't mind +1.00 readers for small print**
- Multifocal IOLs
 - Usually > age 70 with normal macula and optic N function
 - Desire fine reading ability without glasses
 - Minimal night driving needs
- Toric IOLs
 - Desire eyeglass independence at distance
 - **Don't mind near vision correction**

Case Presentation #2

- 49 y.o.male here presents for a cataract evaluation. Referred by another ophthalmologist . Patient complains of worsening vision right eye over a period of several year(s), causing problems with Reading, Near work activities, Seeing steps, curbs, and Watching TV.
- POH: h/o PPV right eye in April 2015 for IOFB after eye trauma (Dec 2014).

Case Presentation #2

- Exam right eye
- Va HM
- C- Scar at nasal limbus
- AC – OD D&Q
- I – dilates to 4 mm ; iris defect at 3:30
- Lens: +4 NS; diffuse ASC

Case Presentation #2

- Imp: Traumatic cataract right eye- high risk case due to:
 1. Advanced cataract
 2. Small pupil
 3. h/o eye trauma
 4. h/o PPV
- Surgical plan: CE right eye
 - Retrobulbar anesthesia
 - Iris hooks
 - Vision blue dye
 - miLOOP usage

miLOOP

- What is miLOOP?
- Manual surgical device that can be used to bisect the lens nucleus, avoiding the need for phaco energy or manual chopping to achieve this surgical task
- Nucleus bisection = most important step of phaco surgery

Why miLOOP?

- Phaco is an incredible technology that has evolved over 50 years...
...and uses ultrasonic energy to fragment the lens during cataract surgery
- Surgeons and industry have worked hard to reduce the energy required during surgery
 - Example: Torsional phaco
- Certain patient groups benefit from less or zero energy used to fragment the lens
 - *Energy* and *prolonged surgical time* to fragment the lens creates additional risk of complications during and following cataract surgery
- miLOOP helps mitigate this risk with certain patient groups

Impact of a “Dense” or “Complex” Cataract

- The denser the cataract, the more energy required (when using Phaco)
- The more complex the case, the longer it takes to perform surgery
- **Longer cases can easily throw off the day's surgery schedule**
- Each extra minute has an associated cost:
 - Costs to run an operating room are:
 - \$40-80 per minute for an ASC
 - \$80-\$120 per minute for a hospital
- Surgeons can routinely underestimate the density of the cataract prior to surgery

miLOOP - Improved Phaco Efficiency

1. Zero energy lens fragmentation
2. 100% endocapsular
3. Cataract grade independent
4. Consistent, full-thickness

Micro-Interventional Approach

1. Super-elastic
2. Memory Shaped
3. Micro-thin Nitinol filament



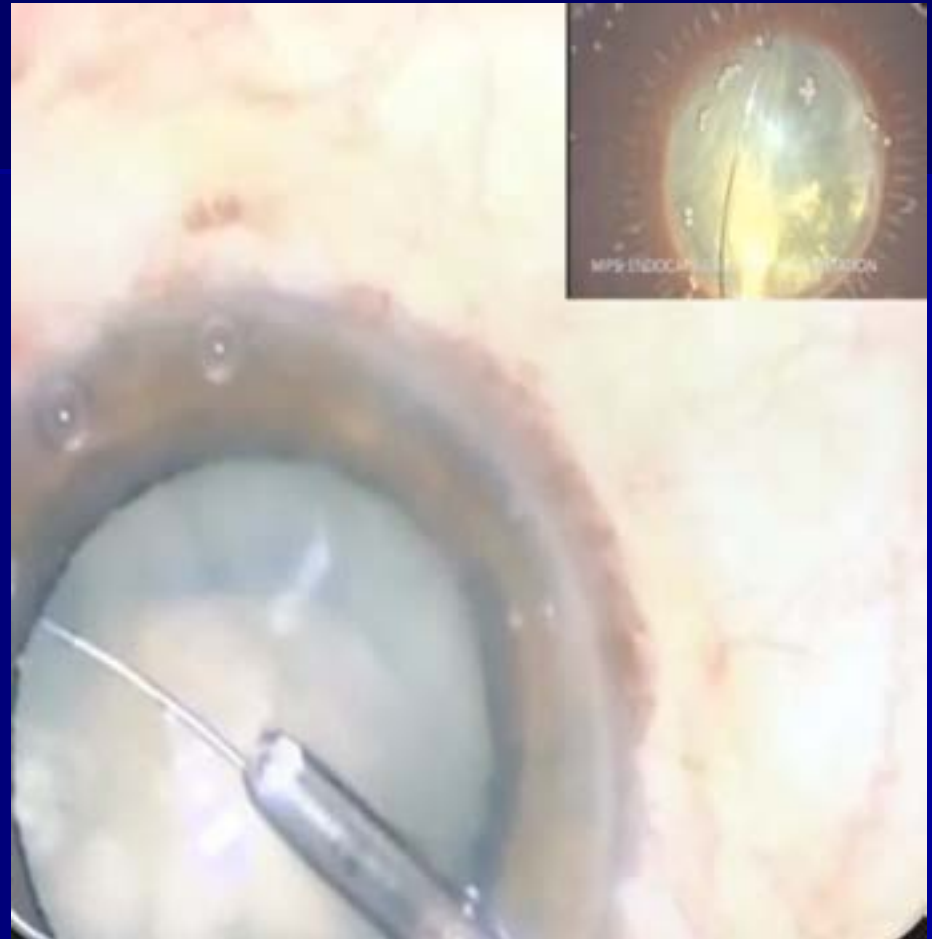
MiLoop

- No ultrasonic energy required
- Centripetal vs centrifugal lens sectioning
- Viscoelastic chamber control and protection (no I/A , no phaco)
- Single instrument chopping



miLOOP

- Smooth unfolding and tracking
- Cortical sweep and release
- Minimal capsule tension out-in cutting



Video of miLOOP Use



Patients Who May Benefit From miLOOP Use

% of US cataract patients with...

Corneal
Dystrophies
2%

Diabetes
25%

Grade 3+ density
4%

Pseudo
exfoliation
5%

Premium IOLs
14%

Younger than 65¹
20%

Complex
cataracts
10%

Retinal injections
(4MM/yr)
??%

miLOOP Case Presentation Follow-Up

- Uneventful surgery – able to bisect nucleus and remove cataract successfully
- 2 week POV- 20/30 sc
- 4 week POV- 20/25 sc

miLOOP summary

- Useful addition to the cataract surgeon's " toolbox" to reduce the risk of intraoperative complications
- Cost / benefit best for "high risk " cataract surgeries
- Helpful in cases that require minimal phaco energy
 - Fuch's corneal dystrophy

Case Presentation #3

- 72y/o male with progressive vision loss right eye x several months. Has difficulty with reading and driving
- POH: Peripheral Iridotomy OU; Ahmed tube shunt surgery left eye ; CE OS
- Meds : Dorzolamide 2% BID OD, Timolol BID OD and Latanoprost qhs OD

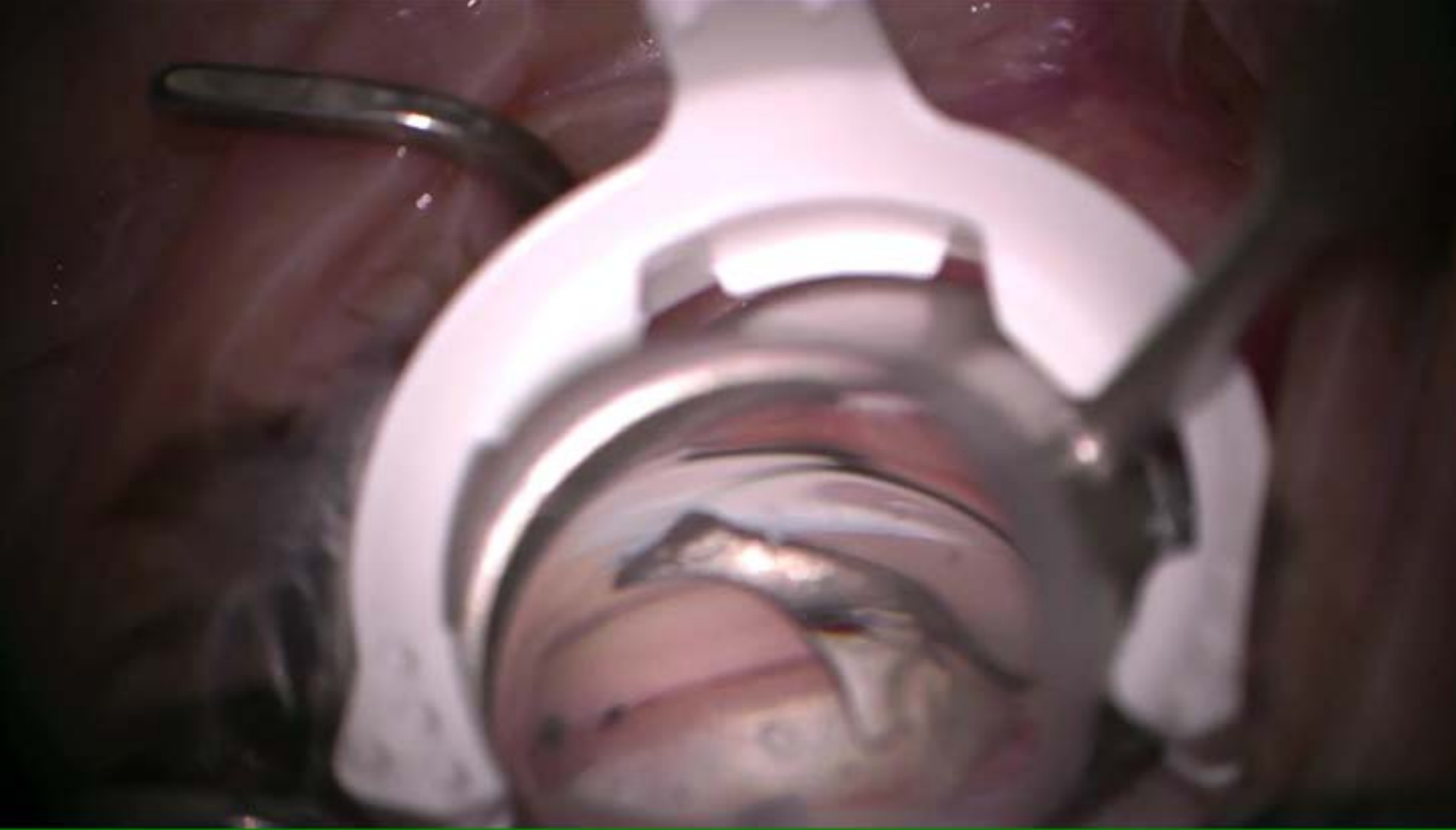
Case Presentation #3

- Exam:
- Va OD 20/200 ph 20/40
- OS; 20/50 ph 20/30
- IOP 19/ 20
- AC – OD D&Q
- OS – ST tube in place
- I – patent PI OU
- Lens: +3 NS right eye ; PCIOL left eye

Case Presentation #3

- Fundus : c/d 0.75 OD ; 0.7 +1 pallor OS
- Imp: Moderate POAG OU- IOP stable
- Visually significant cataract right eye
- Plan: CE with IOL / Cypass placement right eye

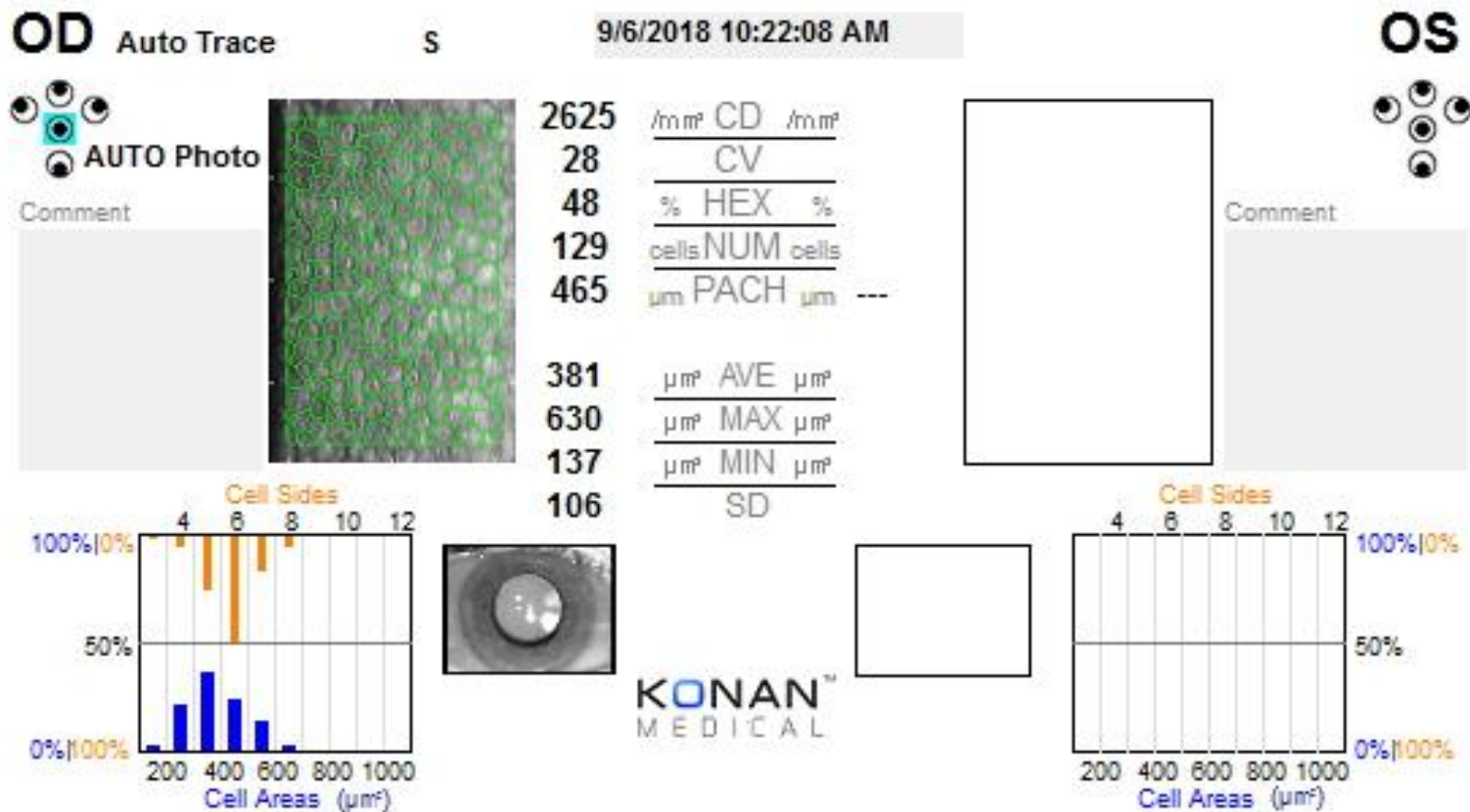
Cypass Insertion Video



Case Presentation #3- postop

- 3 weeks Postop right eye:
- Va 20/20 sc
- IOP 11
- Normal Anterior segment with PCIOL
- Off all glaucoma drops

Postop ECC – 2625mm/2



Cypass Device

- Approved in July 2016 for use in conjunction with cataract surgery in patients with mild-moderate open angle glaucoma
- Placed in the supraciliary space to facilitate uveoscleral outflow
- 6.35mm long with external opening of 510um; retention rings

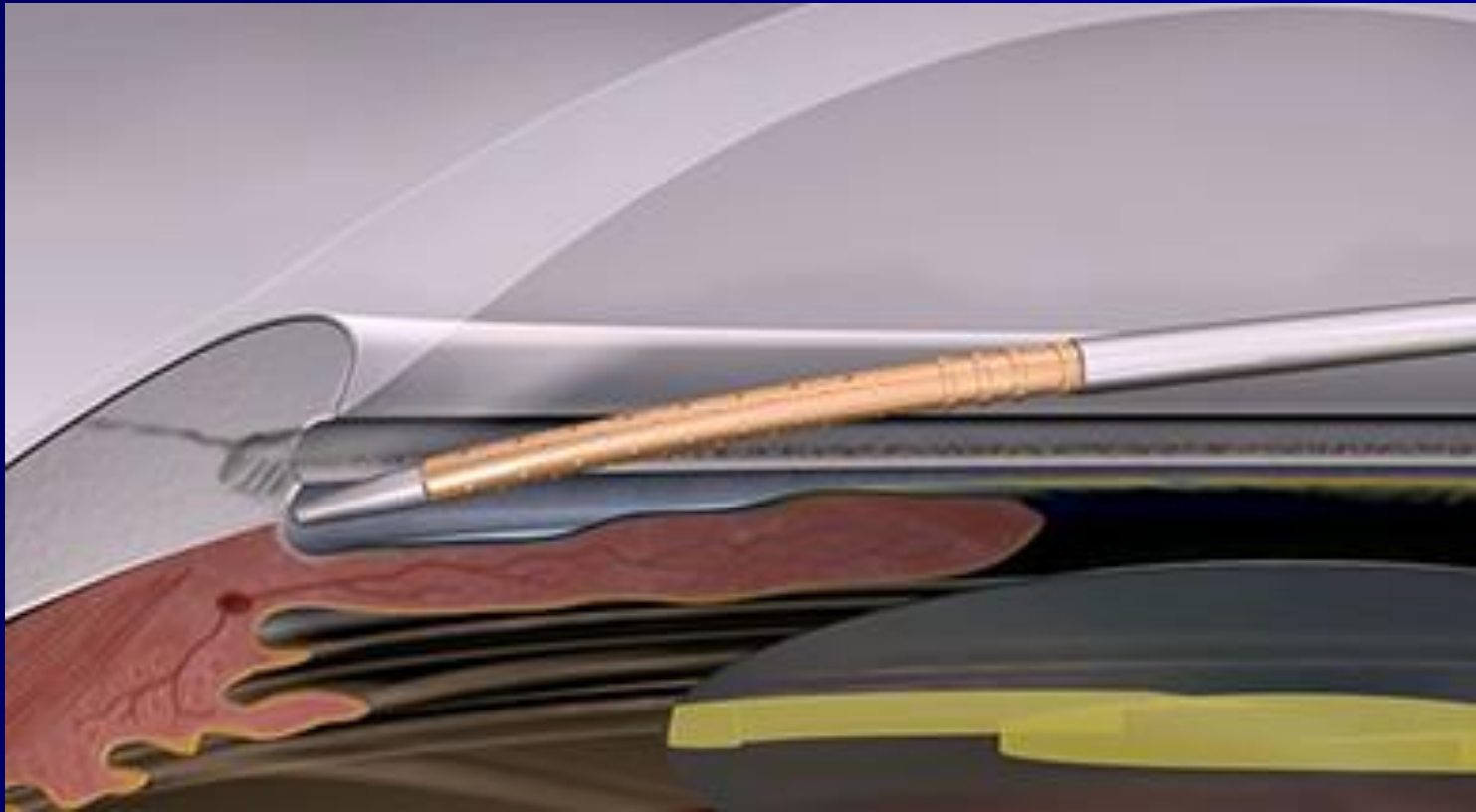
Cypass device

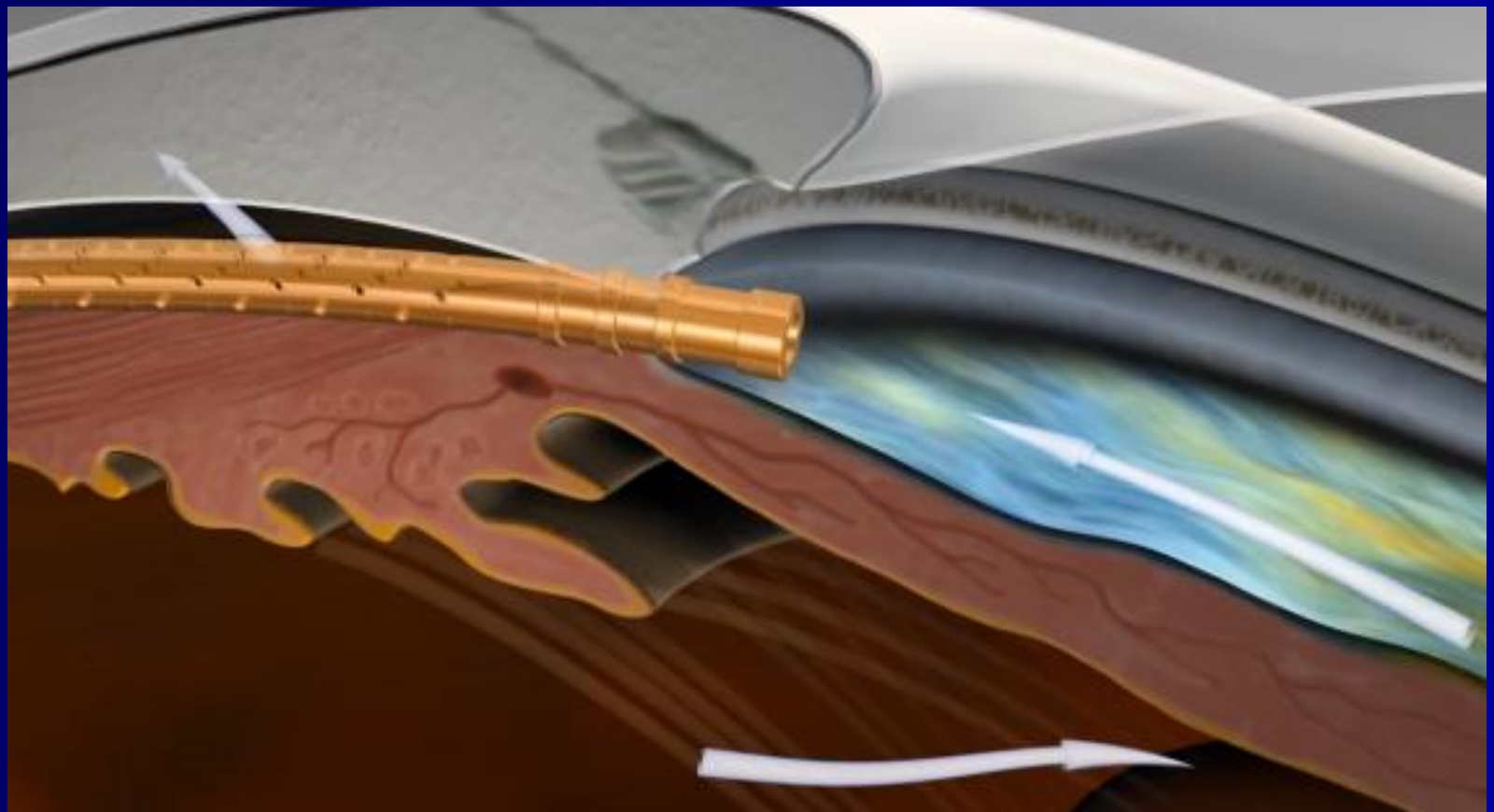


Cypass device

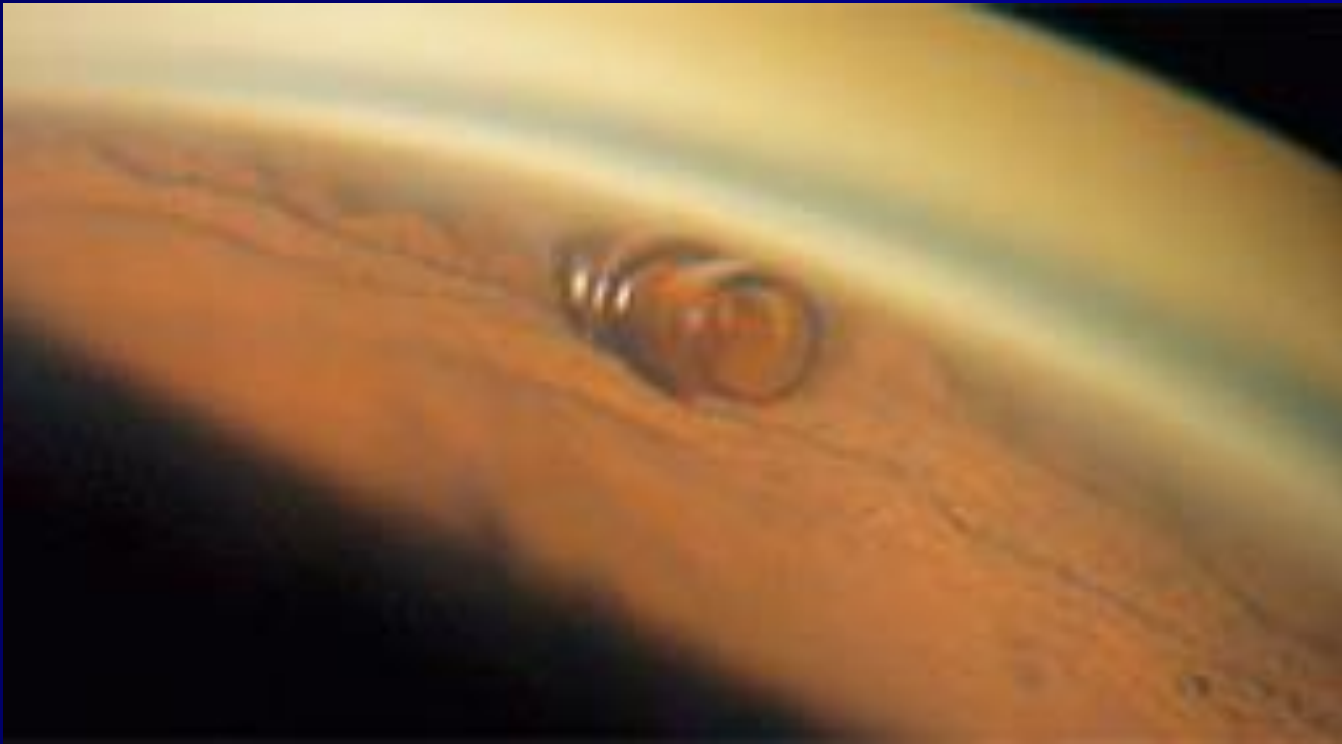


Cypass insertion





Cypass – Gonio view



Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts

Steven Vold, MD,¹ Iqbal Ike K. Ahmed, MD,² E. Randy Craven, MD,^{3,4} Cynthia Mattox, MD,⁵
Robert Stamper, MD,⁶ Mark Packer, MD,⁷ Reay H. Brown, MD,⁸ Tsontcho Ianchulev, MD, MPH,^{9,10}
for the CyPass Study Group*

Purpose: We evaluated 2-year safety and efficacy of supraciliary microstenting (CyPass Micro-Stent; Transcend Medical, Inc., Menlo Park, CA) for treating mild-to-moderate primary open-angle glaucoma (POAG) in patients undergoing cataract surgery.

Design: Multicenter (24 US sites), interventional randomized clinical trial (RCT) (ClinicalTrials.gov identifier, NCT01085357).

Participants: Subjects were enrolled beginning July 2011, with study completion in March 2015. Subjects had POAG with mean diurnal unmedicated intraocular pressure (IOP) 21–33 mmHg and were undergoing phacoemulsification cataract surgery.

Methods: After completing cataract surgery, subjects were intraoperatively randomized to phacoemulsification only (control) or supraciliary microstenting with phacoemulsification (microstent) groups (1:3 ratio). Microstent implantation via an ab interno approach to the supraciliary space allowed concomitant cataract and glaucoma surgery.

Main Outcome Measures: Outcome measures included percentage of subjects achieving $\geq 20\%$ unmedicated diurnal IOP lowering versus baseline, mean IOP change and glaucoma medication use, and ocular adverse event (AE) incidence through 24 months.

Results: Of 505 subjects, 131 were randomized to the control group and 374 were randomized to the microstent group. Baseline mean IOPs in the control and microstent groups were similar: 24.5 ± 3.0 and 24.4 ± 2.8 mmHg, respectively ($P > 0.05$); mean medications were 1.3 ± 1.0 and 1.4 ± 0.9 , respectively ($P > 0.05$). There was early and sustained IOP reduction, with 60% of controls versus 77% of microstent subjects achieving $\geq 20\%$ unmedicated IOP lowering versus baseline at 24 months ($P = 0.001$; per-protocol analysis). Mean IOP reduction was $\downarrow 7.4$ mmHg for the microstent group versus $\downarrow 5.4$ mmHg in controls ($P < 0.001$), with 85% of microstent subjects not requiring IOP medications at 24 months. Mean 24-month medication use was 67% lower in microstent subjects ($P < 0.001$); 59% of control versus 85% of microstent subjects were medication free. Mean medication use in controls decreased from 1.3 ± 1.0 drugs at baseline to 0.7 ± 0.9 and 0.6 ± 0.8 drugs at 12 and 24 months, respectively, and in the microstent group from 1.4 ± 0.9 to 0.2 ± 0.6 drugs at both 12 and 24 months ($P < 0.001$ for reductions in both groups at both follow-ups vs. baseline). No vision-threatening microstent-related AEs occurred. Visual acuity was high in both groups through 24 months; $> 98\%$ of all subjects achieved 20/40 best-corrected visual acuity or better.

Conclusions: This RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication use after microinterventional surgical treatment for mild-to-moderate POAG. *Ophthalmology* 2016;123:2103-2112 © 2016 by the American Academy of Ophthalmology.



*Supplemental material is available at www.aaojournal.org.

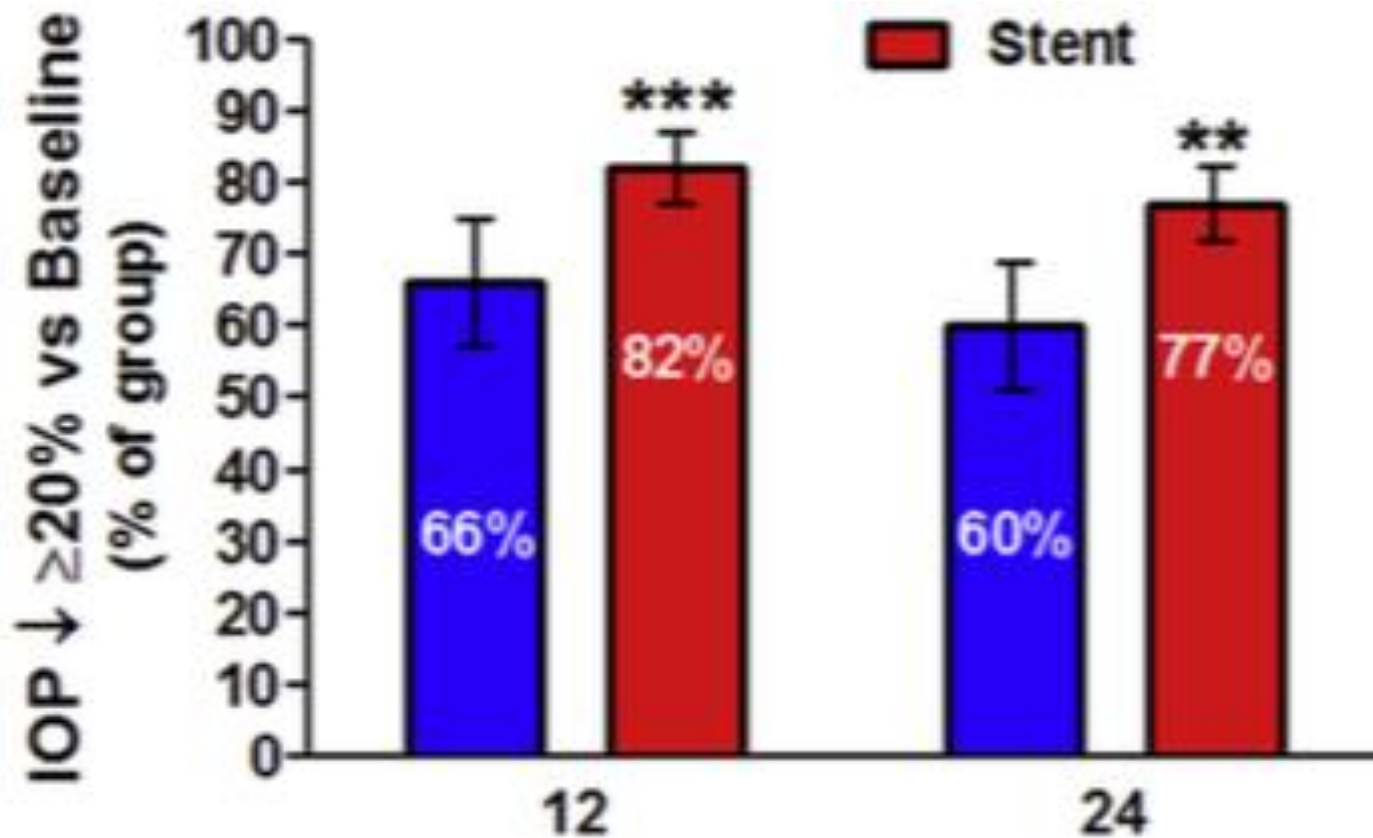
Glaucoma is a progressive optic neuropathy that remains the second leading cause of blindness globally,¹ affecting 64.3 million persons.² In North America, the 2015 estimated glaucoma prevalence was 3.3 million people of the population aged ≥ 40 years.³ The only treatment for glaucoma is lowering intraocular pressure (IOP) to

reduce optic nerve damage progression. Medical therapy is the first-line glaucoma treatment,⁴ but lifelong hypotensive eye drop administration fails in $> 50\%$ of patients who require multiple medications and may eventually progress to conventional filtering glaucoma surgery.^{5–7}

Two Year Compass Trial results

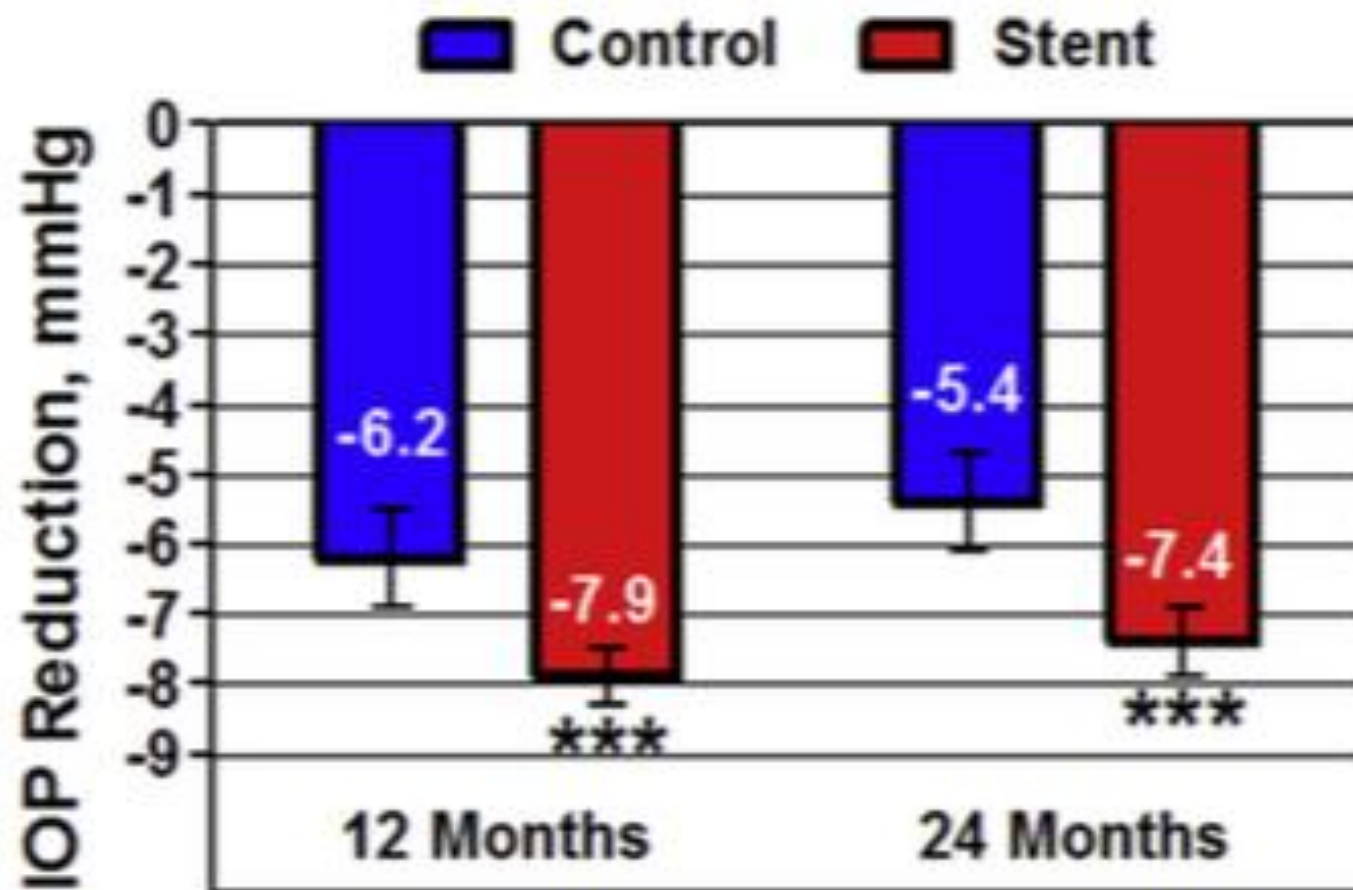
- Inclusion criteria:
 - Age 45 years and above
 - diagnosed or confirmed POAG (Shaffer grade 3 in all quadrants of the study eye) within 90 days of screening;
 - Screening medicated IOP 25 mmHg or unmedicated IOP between 21 and 33 mmHg;
 - Baseline unmedicated diurnal IOP between 21 and 33 mmHg, and 3 mmHg higher than screening IOP; and
 - age-related cataract with best-corrected visual acuity (BCVA), or acuity testing with a Brightness Acuity Meter, of 20/40 or worse that was eligible for phacoemulsification cataract surgery with IOL implantation.

20% decrease in IOP vs Baseline

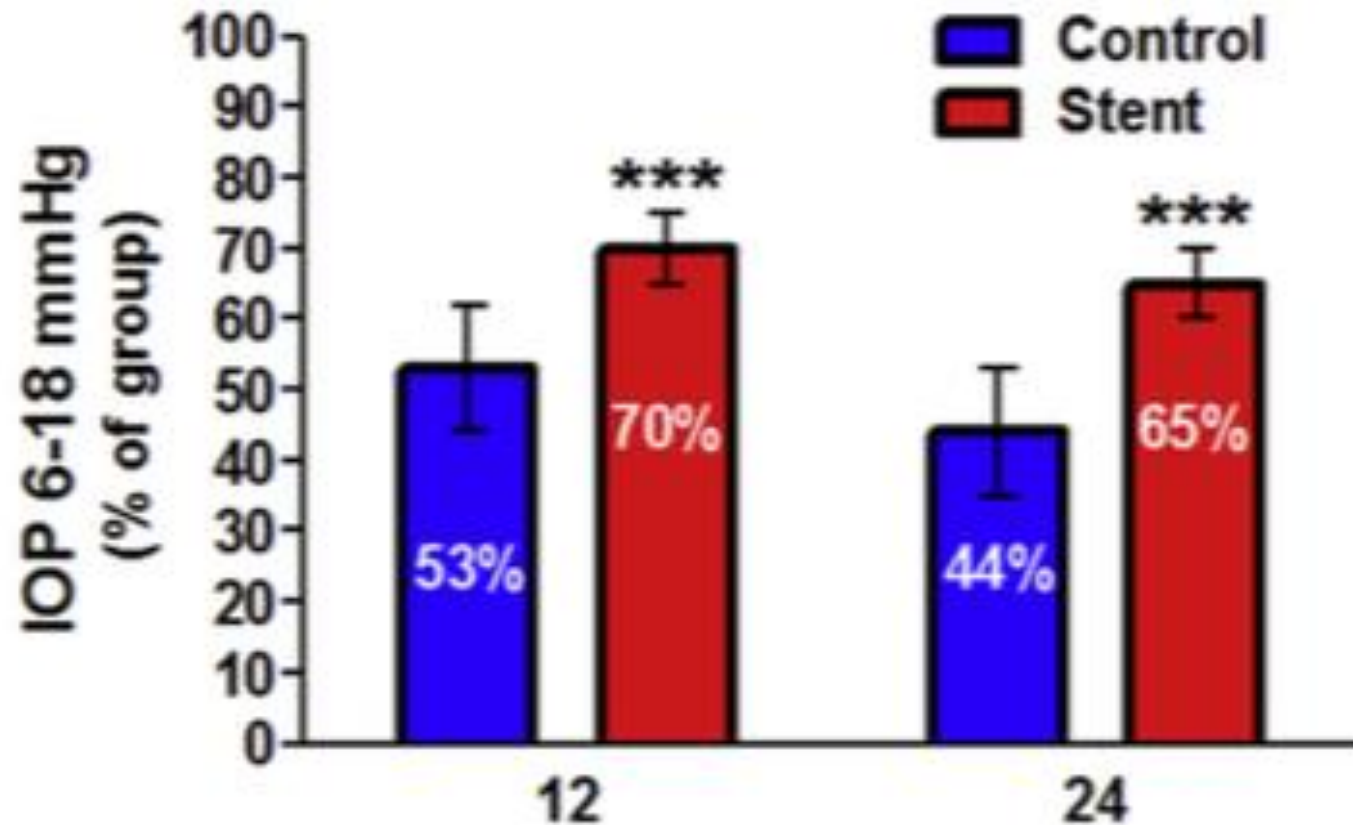


Unmedicated IOP

D



Unmedicated IOP between 6-18



Ocular Adverse Events – none Statistically Significant

Table 2. Ocular Adverse Events through 24 Months of Follow-up

AE	Stent (n = 374)	Control (n = 131)
BCVA loss ≥ 10 letters	33 (8.8%)	20 (15.3%)
Corneal abrasion	7 (1.9%)	2 (1.5%)
Corneal edema	13 (3.5%)	2 (1.5%)
Conjunctivitis	4 (1.0%)	3 (2.3%)
Cyclodialysis cleft >2 -mm circumference	7 (1.9%)	0 (0.0%)
Hyphema, transient intraoperative	10 (2.7%)	0 (0.0%)
Iritis	32 (8.6%)	5 (3.8%)
Hypotony (IOP <6 mmHg)	11 (2.9%)	0 (0%)
IOP ≥ 10 mmHg over baseline	16 (4.3%)	3 (2.3%)
Maculopathy, cystoid edema	6 (1.3%)	1 (0.8%)
Stent obstruction	8 (2.1%)	N/A
Subconjunctival hemorrhage	6 (1.6%)	1 (0.8%)
Secondary ocular surgical intervention	20 (5.5%)	7 (5.3%)
Visual field loss progression, confirmed	25 (6.7%)	13 (9.9%)

August 29, 2018 Announcement from Alcon

Alcon announces voluntary global market withdrawal of CyPass Micro-Stent for surgical glaucoma

Aug 29, 2018

- Decision based on five-year data from COMPASS-XT long-term safety study
- Alcon advises ophthalmic surgeons to cease further implantation



The COMPASS-XT study was designed to collect safety data on the subjects who participated in the COMPASS study for an additional three years, with analysis of the completed data set at five years post-surgery. At five years, the CyPass Micro-Stent group experienced statistically significant endothelial cell loss compared to the group who underwent cataract surgery alone.

“We believe that withdrawing the CyPass Micro-Stent from the market is in patients’ best interest and is the right thing to do,” said Dr. Stephen Lane, Chief Medical Officer, Alcon. “Although we are removing the product from the market now out of an abundance of caution, we intend to partner with the FDA and other regulators to explore labeling changes that would support the reintroduction of the CyPass Micro-

CyPass Micro-stent Background

INDICATIONS

Europe (CE mark 2008)

- For use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with **mild to moderate** primary open-angle glaucoma.
- For use in conjunction with cataract surgery or in a **standalone** procedure for the reduction of IOP in adult patients with primary open-angle glaucoma **where previous medical treatments have failed**.

USA (approved July 29, 2016)

- Indicated for implantation in conjunction with cataract surgery, for the reduction of intraocular pressure (IOP) in subjects with **mild to moderate** primary open-angle glaucoma (POAG)

•COMPASS clinical study:

- N = 505 subjects randomized ~3:1 to cataract surgery + CyPass vs cataract surgery alone
- 24 month follow-up

•COMPASS XT

- Post Approval Study with follow-up of 5 years with original study cohort
 - Primary (*Safety*)
- Rate of sight-threatening adverse events
 - Secondary (*Safety*)

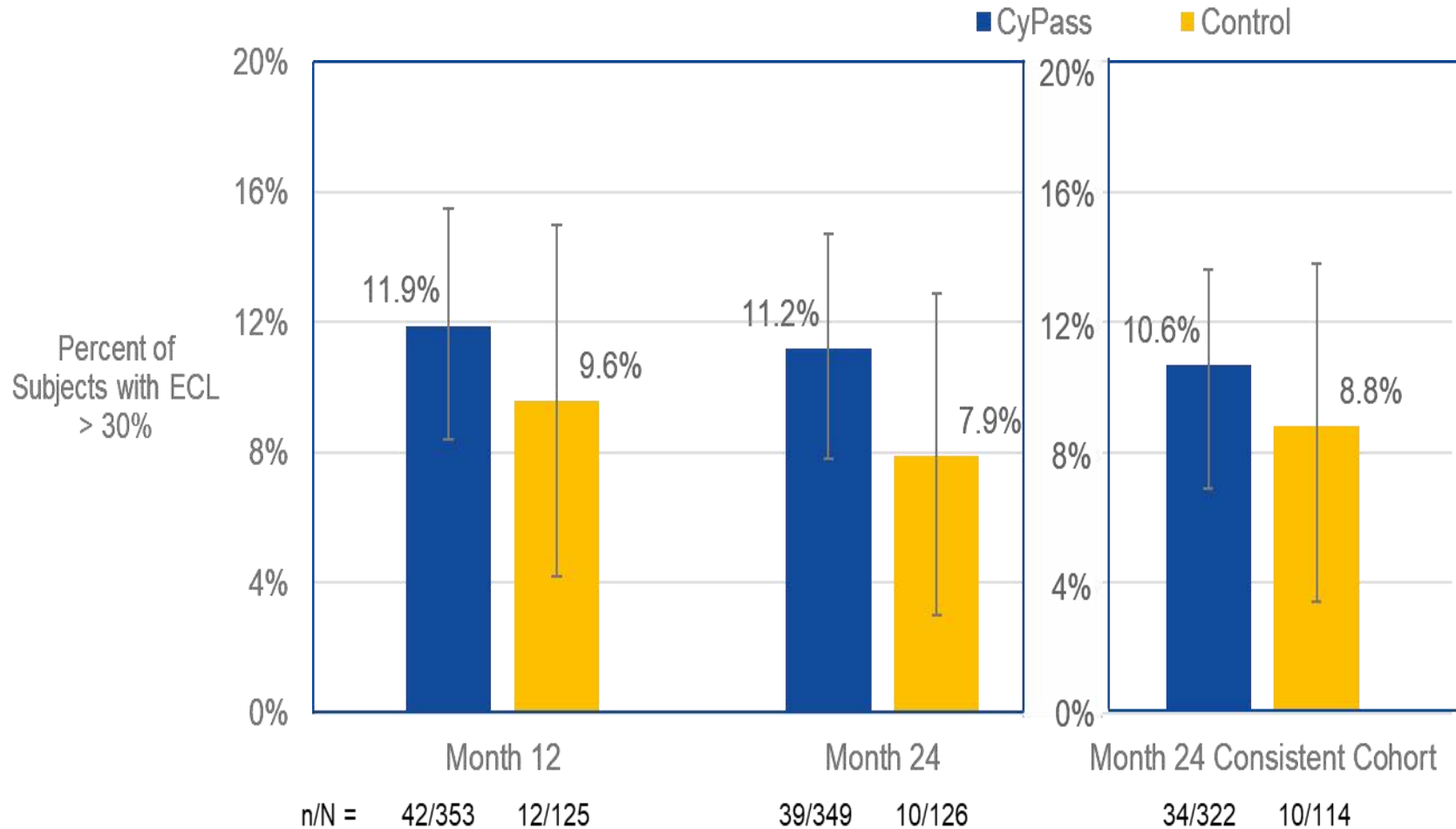


- BCVA; ocular AEs; slit-lamp, gonioscopy, and fundus findings; VF mean deviation; CCT; **central corneal endothelial density**; CyPass malposition, dislodgement, or movement

COMPASS Study Results through Month 24

Effectiveness Outcomes	CyPass N=374	Control N=131	Mean Difference	p-value
1 ^o % of Patients Achieving $\geq 20\%$ Mean DIOP	72.5%	58.0%	14.2%	0.0030
2 ^o Mean DIOP Reduction vs. Baseline	-7.0	-5.3	1.7	<0.0001
Safety Outcomes				
2 ^o DIOP ≥ 6 mmHg and ≤ 18 mmHg	61.2%	43.5%	17.7%	0.0005
<p>CyPass safety in conjunction with cataract surgery in subjects with mild to moderate glaucoma</p> <ul style="list-style-type: none"> • Low overall incidence of adverse events • Little difference in endothelial cell density or visual acuity observed between CyPass and Control groups • No safety observations raising a concern for the CyPass Micro-Stent, when implanted in conjunction with cataract surgery 				

No Statistical Difference in Percent of Subjects with ECL > 30% Between CyPass and Control Through Month 24

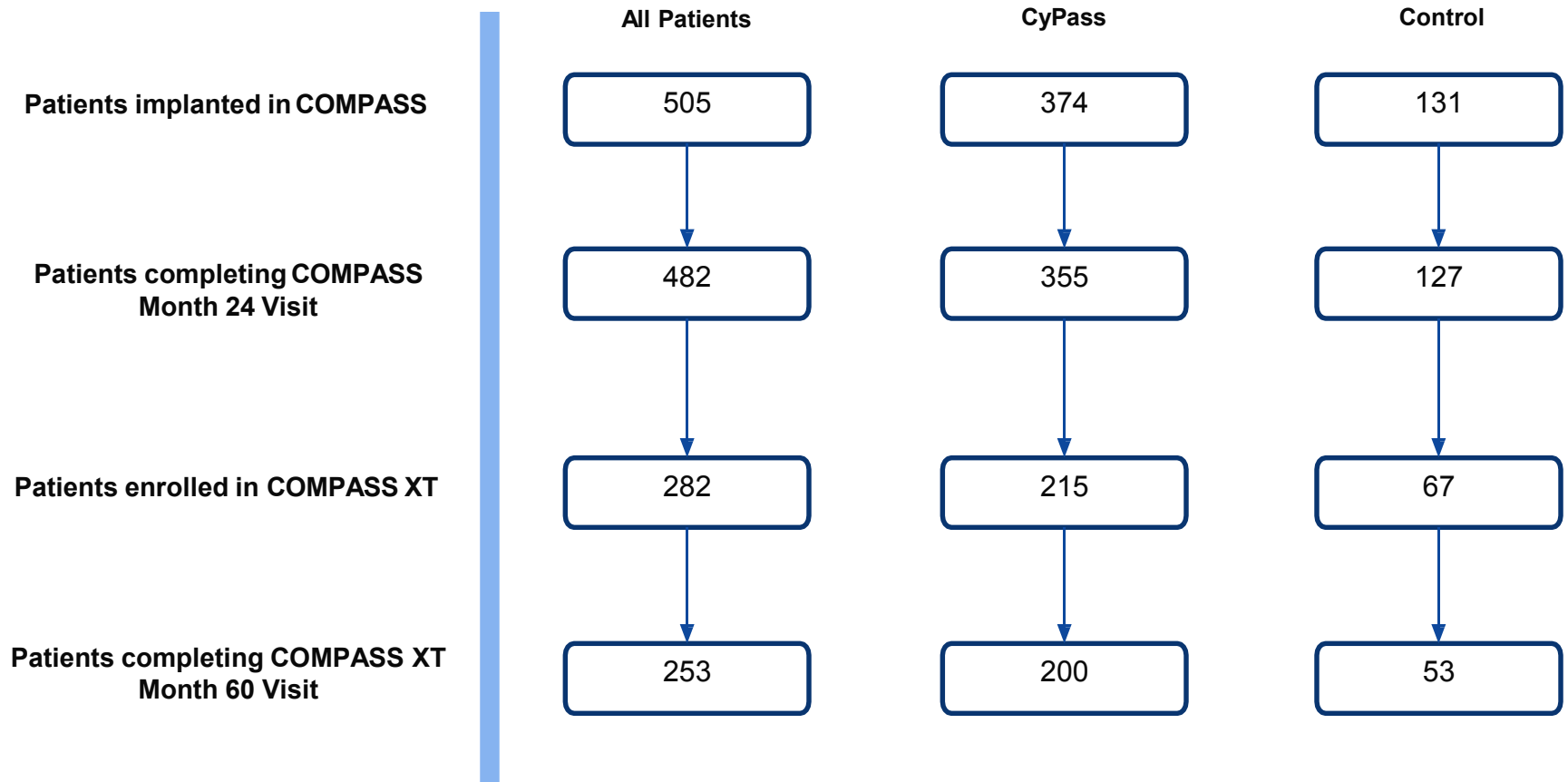


All available data from safety population. Error bars represent 95% confidence intervals.

Post-Approval Extension Study: COMPASS XT

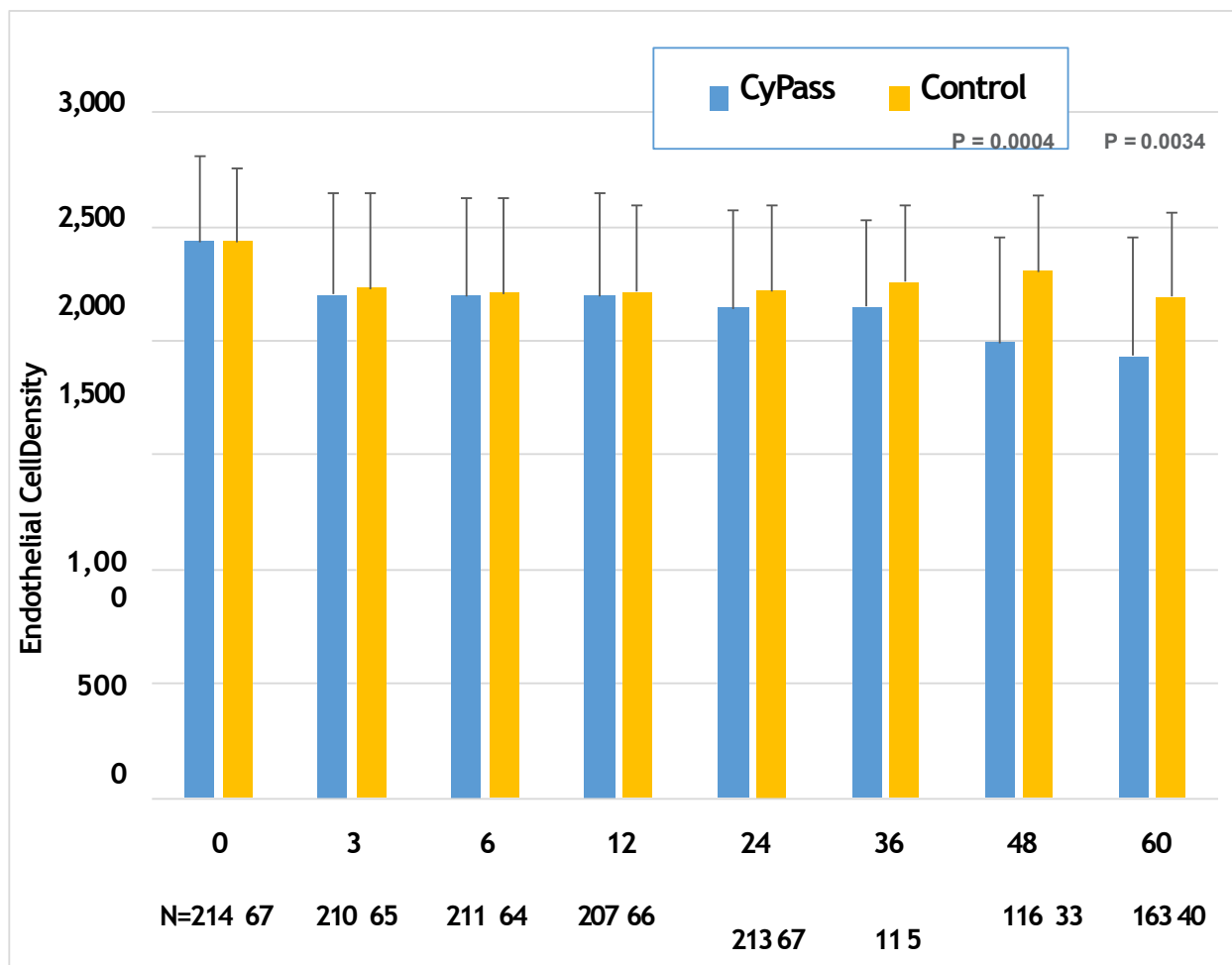
Long-Term Safety Findings: Endothelial Cell Loss

Patient Enrollment in COMPASS and COMPASS XT Studies

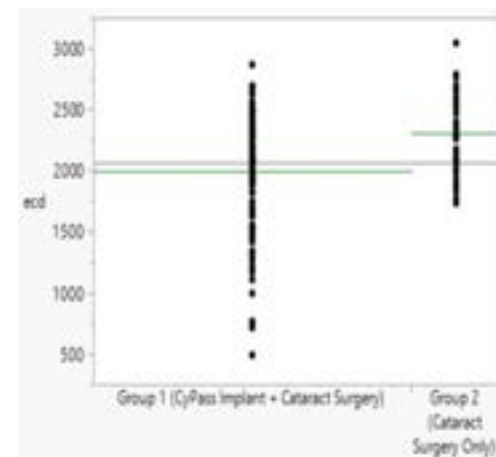


Note: Patient enrollment in COMPASS-XT initiated during FDA review of CyPass PMA, but after many patients had passed the Month 36 and Month 48 visit windows.

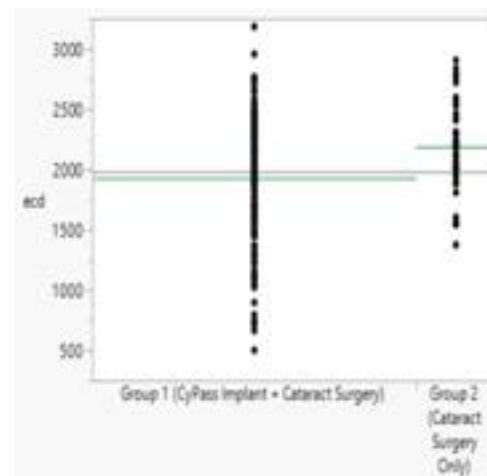
Statistically Significant Difference in ECD between CyPass and Control at Months 48 and 60



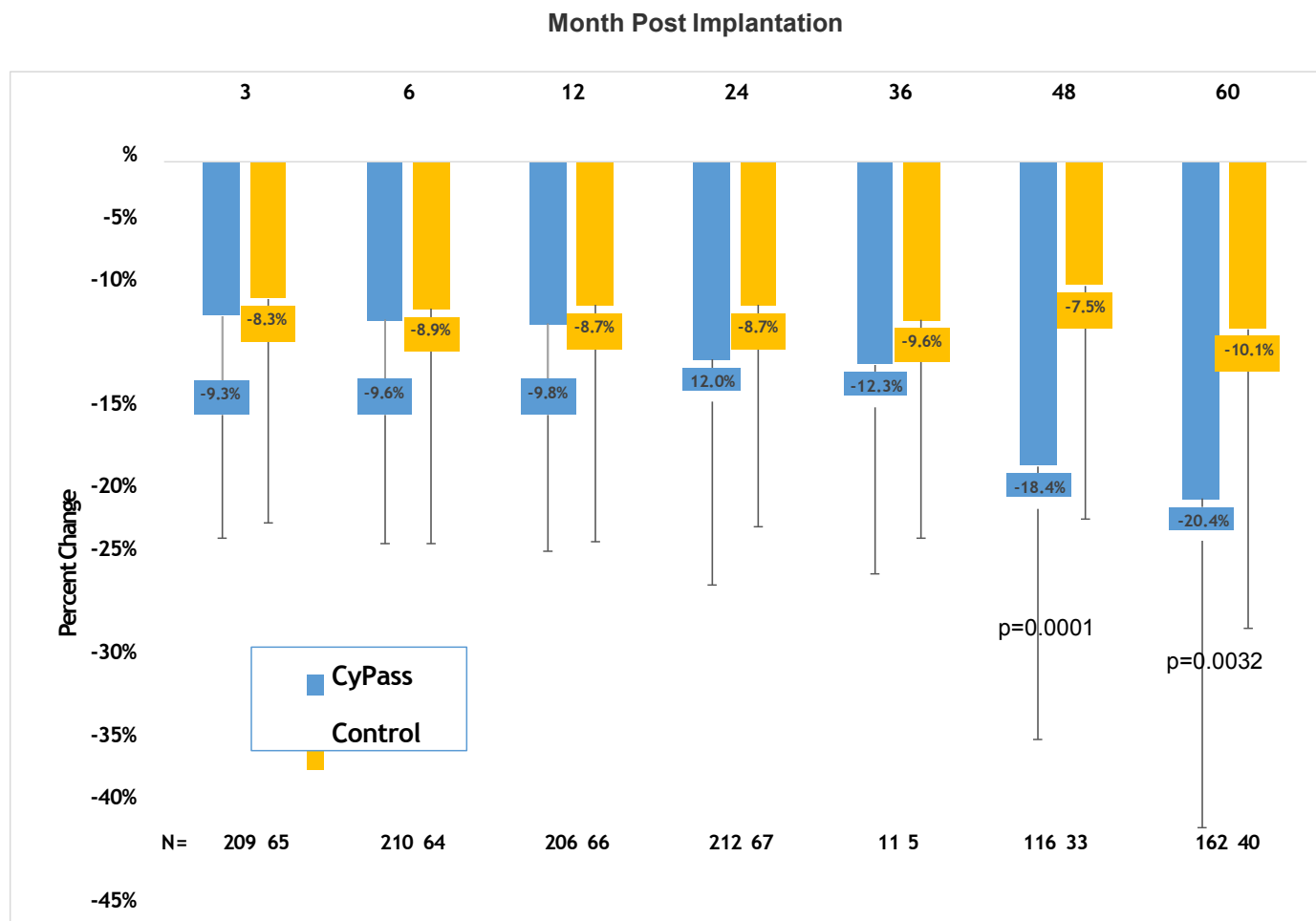
Month 48



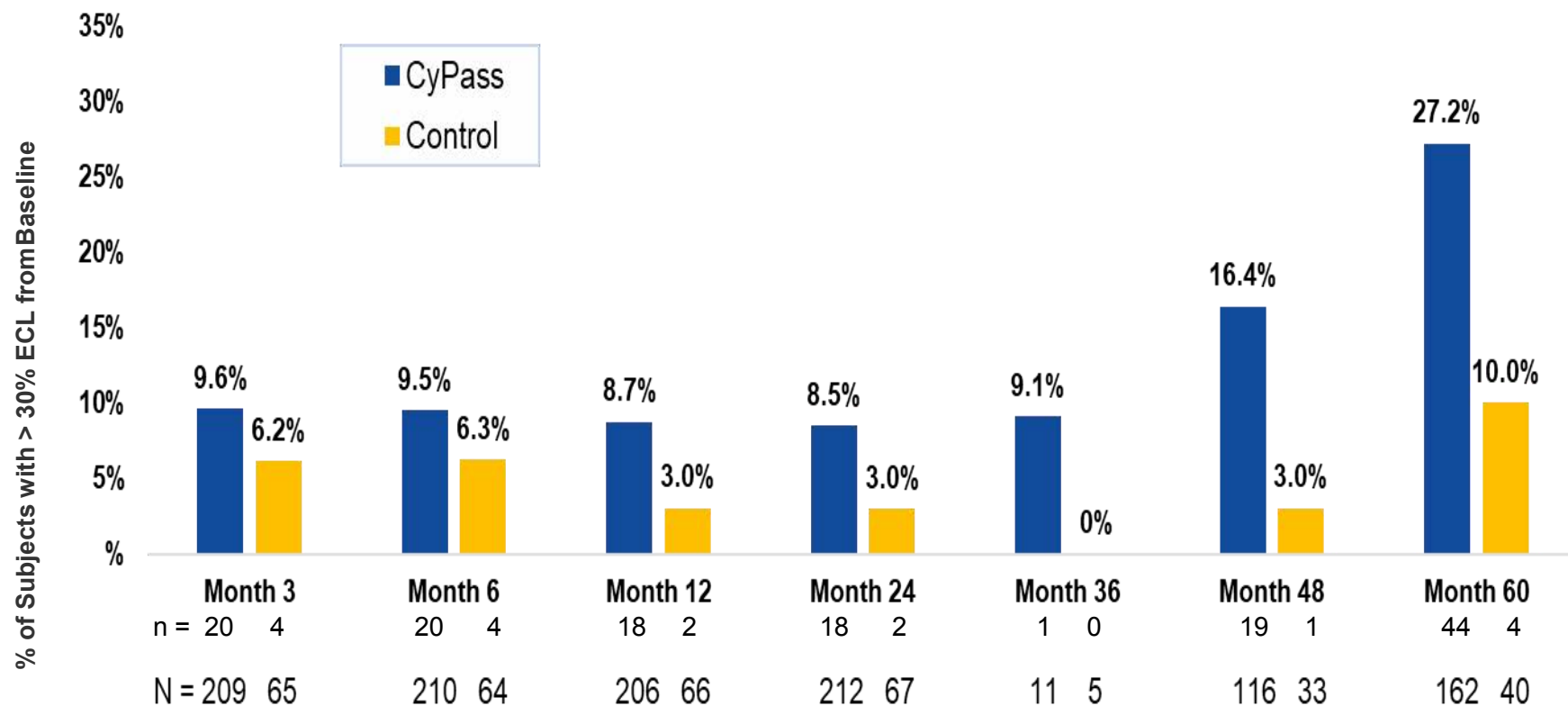
Month 60



Statistically Significant Difference in ECL between CyPass and Control at Months 48 and 60

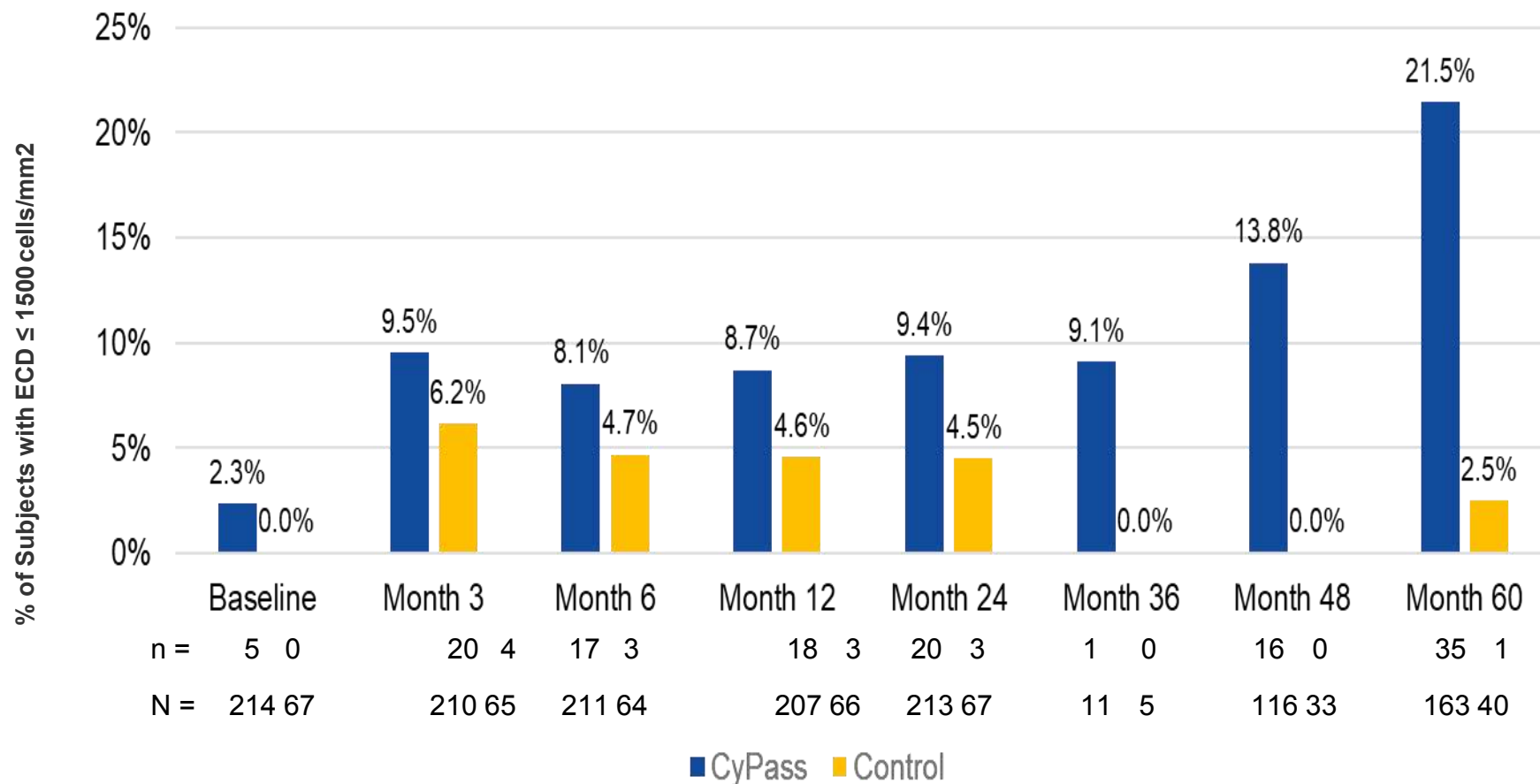


Increase in Percent of CyPass Subjects with > 30% ECL at 48 and 60 Months



30% ECL is identified in ANSI Z80:27 as a meaningful threshold

Increase in Percent of CyPass Subjects with ECD ≤ 1500 cells/mm² at 48 and 60 Months



Subjects with ECL > 30%: No Impact on Corneal Health Observed

- 44/162 (27.2%) of subjects at Month 60 had ECL > 30% from baseline
 - 31/44 (70.5%) also had < 1500 cells/mm²
 - 7/44 (15.9%) also had < 1000 cells/mm²
- All subjects had clear corneas, except for one case of corneal edema
 - Observed at 51 months
 - Assessed as mild by the Investigator, considered to be related to CyPass – endothelial touch. Trimming of device successfully performed 4 months later.
 - Edema resolved at study completion (Month 60).

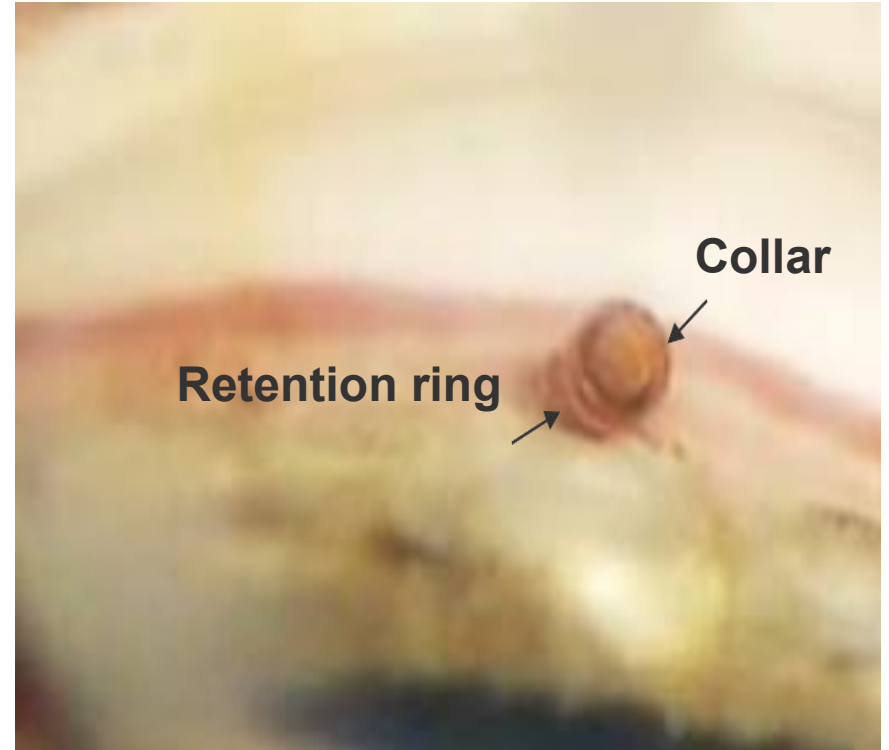
Only Device Position was Strongly Correlated with Increased ECL through 60 Months in the Clinical Study

- Analysis of Subjects with Significant ECL for Potential Covariates
 - Age
 - Baseline ECD
 - Study Site
 - Movement of the device after placement
 - Device position
- Only device position was strongly correlated with increased ECL through 60 months
 - Baseline ECD was weakly correlated

Example of CyPass MicroStent Position

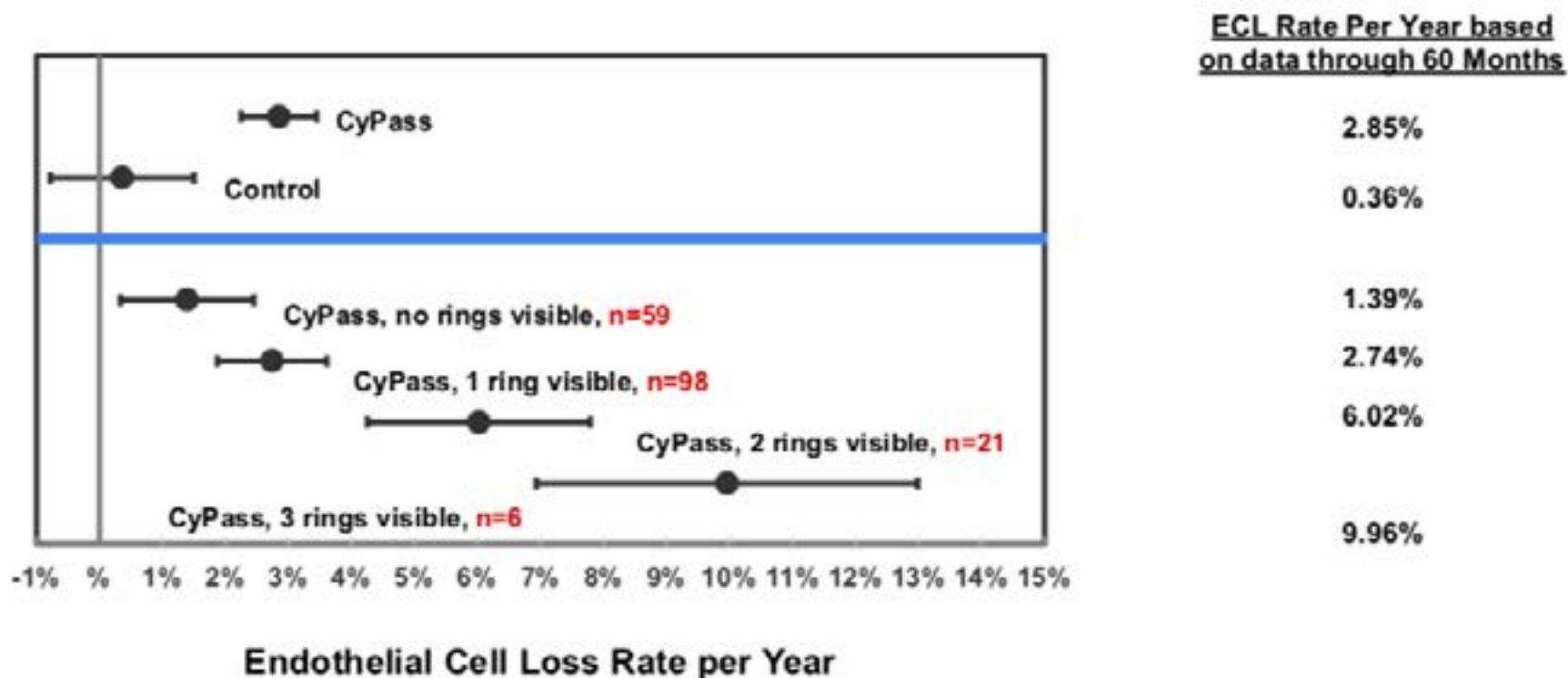


3 rings



1 ring

Annualized ECL Rate Increases with Number of Visible Rings



Annual Endothelial Cell Loss Rates ($\pm 95\%$ CI) (starting at 6 months after surgery)
 Per DFU, 1 ring visible is "optimal position"

COMPASS XT

OVERALL SAFETY

Post-operative AEs (Slide 1 of 2)

Adverse Events (COMPASS XT PAS)	Cataract Surgery with CyPass (N=215)	Cataract Surgery Only (N=67)
CyPass device obstruction by iris, vitreous, lens, fibrous overgrowth, fibrin or blood	10 (4.7%)	N/A
2-pt worsening of questionnaire report to Severe/Very Severe, not assoc. w/pre-existing condition	4 (1.9%)	0 (0.0%)
CyPass trimming	4 (1.9%)	N/A
Macular edema (as defined in the protocol)	3 (1.4%)	1 (1.5%)
Other maculopathy	3 (1.4%)	1 (1.5%)
Choroidal folds	2 (0.9%)	0 (0.0%)
CyPass device malposition, dislodgement or movement	2 (0.9%)	N/A
Ocular symptom questionnaire report of Severe or Very Severe (as defined in the protocol)	2 (0.9%)	0 (0.0%)
Other retinal complications	2 (0.9%)	0 (0.0%)

Post-operative AEs (Slide 2 of 2)

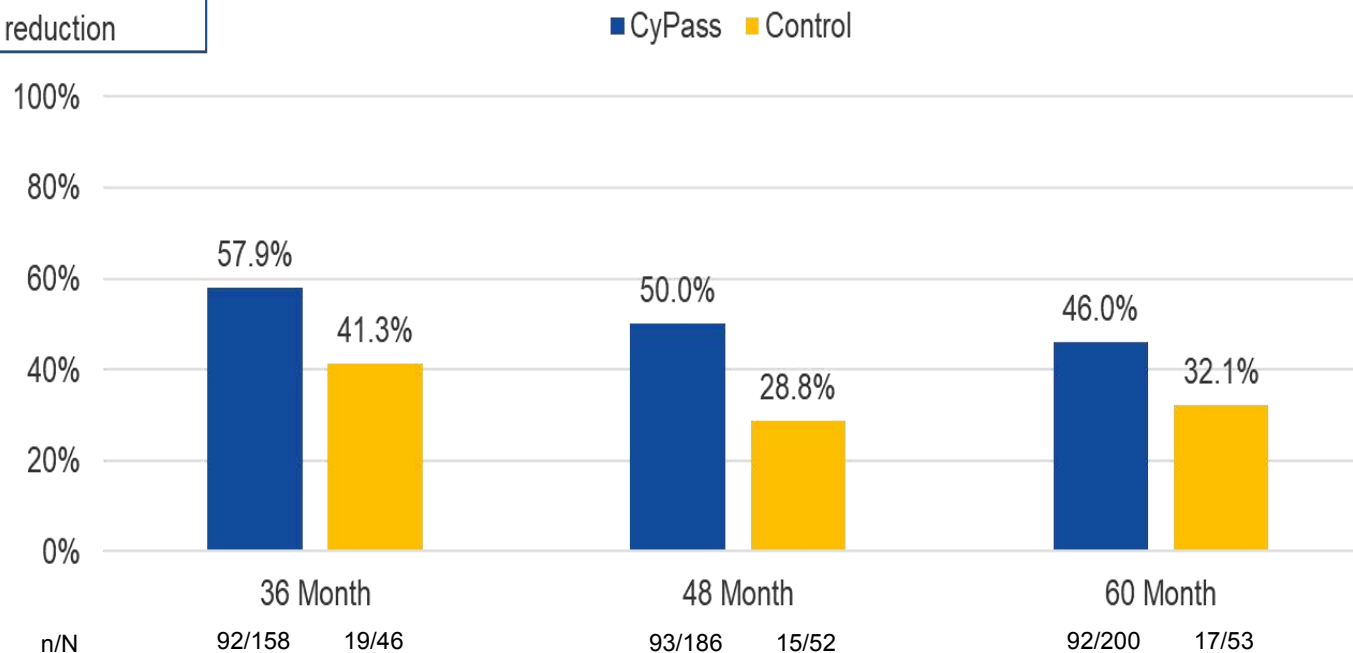
Adverse Events (COMPASS XT PAS)	Cataract Surgery with CyPass (N=215)	Cataract Surgery Only (N=67)
Treatment of elevated IOP that is not satisfactorily managed using ocular hypotensive medication	1 (0.5%)	1 (1.5%)
Chronic anterior uveitis (as defined in the protocol)	1 (0.5%)	0 (0.0%)
Corneal edema	1 (0.5%)	0 (0.0%)
Increase in C:D ratio of ≥ 0.3 units compared to COMPASS 24 Month C:D ratio	1 (0.5%)	0 (0.0%)
Mean or median IOP ≥ 10 mmHg higher than COMPASS baseline mean unmedicated diurnal IOP	0 (0.0%)	1 (1.5%)
Retinal detachment	0 (0.0%)	1 (1.5%)
Significant foreign body sensation	1 (0.5%)	0 (0.0%)
Vitreous hemorrhage	1 (0.5%)	0 (0.0%)

COMPASS XT

EFFECTIVENESS

COMPASS XT - EFFECTIVENESS

Percent of patients not using medications AND with $\geq 20\%$ IOP reduction



CyPass arm had greater proportion of patients who were responders through month 60

Note: Responder rate definition was different between COMPASS and COMPASS XT Studies

COMPASS

- $\geq 20\%$ reduction from baseline at the washed-out 24-month visit

COMPASS XT

- $\geq 20\%$ reduction from baseline AND
- Not using ocular hypotensive meds

COMPASS XT Summary

- ECL
 - Meaningful and statistically significant difference between ECL for CyPass and Control arms at 48 and 60 months
 - Increased ECL rate correlated with device position
 - Greater number of rings exposed is associated with higher long-term rate of ECL
- Other Safety Endpoints
 - No issues identified with the primary endpoint or any of the other secondary endpoints
- IOP
 - Study was not designed or powered to show long-term effectiveness
 - Responder analysis favors CyPass + cataract compared to cataract surgery alone

So What Do We Do Now?

- **Preliminary ASCRS CyPass Withdrawal Consensus Statement:**
- Notification of patients
- Risk assessment
 - Gonioscopy : Cypass device positioning, depth (rings visible)
 - Corneal exam : Edema, guttata
 - Corneal pachymetry & Endothelial cell counts
- If corneal decompensation develops and >1 ring of the device is visible, the surgeon may consider CyPass repositioning, removal, or proximal end trimming.

Conclusions

- New devices and IOLs are available to assist cataract surgeons in achieving optimal refractive outcomes, while minimizing surgical complications
- MIGS continues to evolve and improve, allowing better long term IOP control with devices implanted at the time of cataract surgery.
 - Long term data is important!