

The Unintended Consequences of High Myopia

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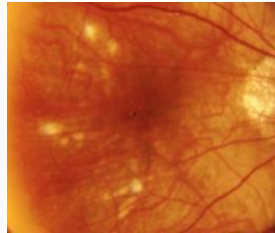
Mark Dunbar: Disclosure 2025-2026

- Optometry Consultant/Advisory Board
 - Carl Zeiss
 - Tarsus
 - Orasis
 - Astella
 - Apellis
 - Azura
 - Sun
 - B&L
 - Topcon
 - Visus
 - Sydnexis
 - Cloudbreak
 - Tenpoint

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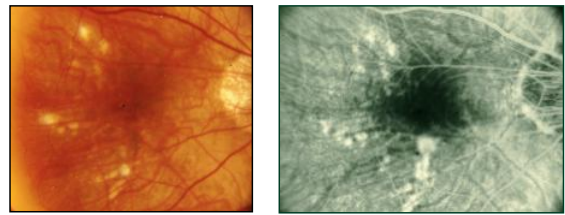
38-y-old White Female Executive with Vision Change in Right Eye (her only seeing eye)

- History of high myopia
 - ≈ -15.00 D range
- RGP contact lens wearer
- Good vision in right eye
- Previous laser (left eye) 5 y ago
 - No VA improvement
- Noted blur and metamorphopsia in right eye 1 week ago
 - She knew she had mCNV and did not want to be treated



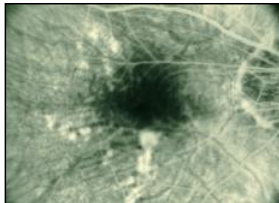
RGP, rigid gas permeable

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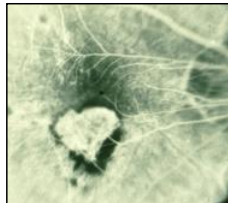


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Initial Presentation



2 Months Later



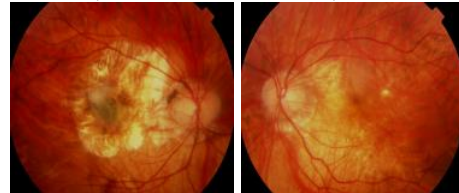
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33-year-old Hispanic Woman Blurred Vision in Left Eye

April 16, 2002 18 weeks pregnant

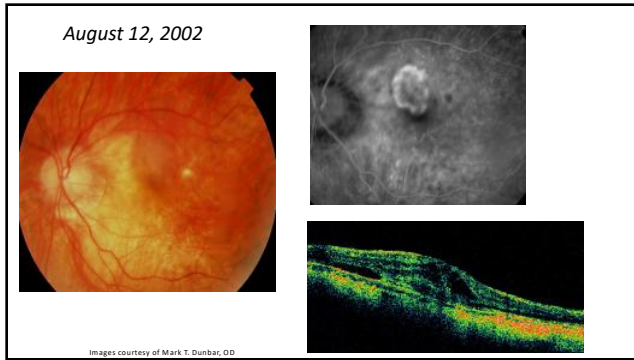
20/800 vision

20/40 vision



Images courtesy of Mark T. Dunbar, OD

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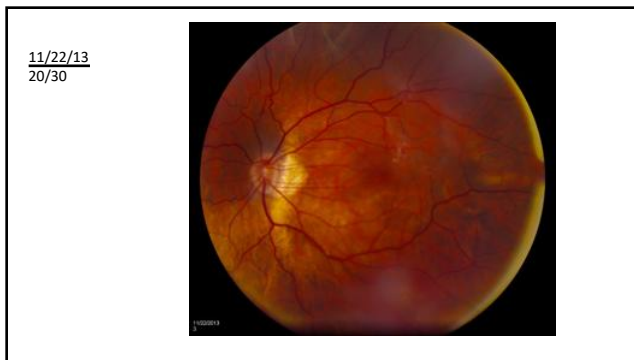


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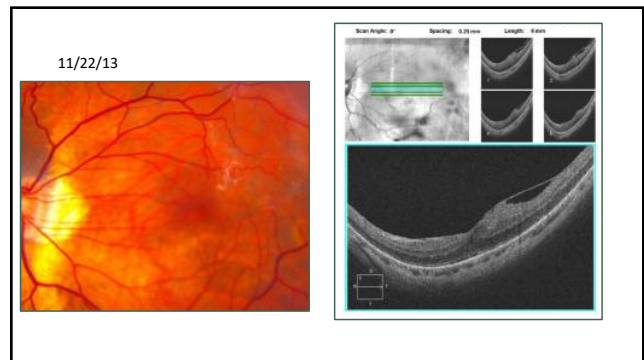
Jeff: mid-50's Attorney, High Myopia
Hx of RD Repair in both eyes: RE: 1985 LE 1989

- Never recovers vision in the RE
- He is followed through the 90's with a progressive NS and declining Va ~ 20/70
 - 1 eyed patient and reluctant to have CE
- Eventually has CE/IOL 90's-early 2000's and does well
 - VA 20/25 low refractive error

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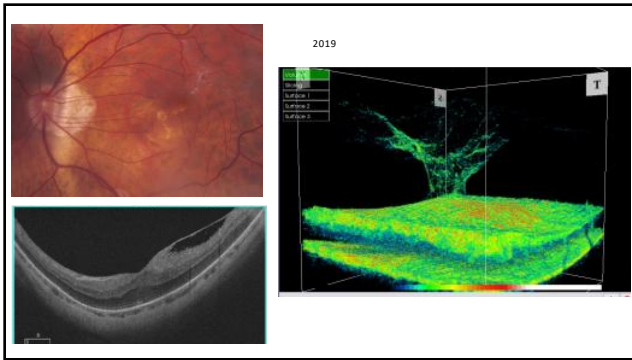
Jeff: High Myopia and VMT

3/11/19

- Feels Vision is slightly worse, increase in distortion

| Base Eye Exam | |
|----------------------------------|-------|
| Visual Acuity (Snellen - Linear) | |
| Right | Left |
| Dist cc | IP |
| Tonometry (Tonopen, 12:04 PM) | |
| Right | Left |
| Pressure | 14 15 |

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Jeff: (66 yo) High Myopia, Pseudophakia and VMT

5/11/20

- Notes a paracentral defect in the LE X 2 weeks
 - Starting to invade the central vision: VA: 20/150

 A composite of two ophthalmic images. The left is a fundus photograph. The right is a cross-sectional OCT scan showing a paracentral defect.

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6 weeks later

9/27/2021: Vision is better: 20/50

 A cross-sectional OCT scan showing a vitreous macular traction (VMT) defect.

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7/28/24

Cirrus

Spectralis

 Two cross-sectional OCT scans. The top one is labeled '7/28/24' and 'Cirrus'. The bottom one is labeled 'Spectralis'. A small fundus photograph is visible on the right side.

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What is going to happen?
 Will he progress to macular hole
 Would he benefit from a vitrectomy?

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Is Myopia a Disease...or Just a Refractive Condition?

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WSJ December 28, 2025

Smartphones and the Childhood Epidemic of Myopia
 Time indoors looking at screens can cause eyeballs to elongate, leading to nearsightedness.

WSJ OPINION

The FDA claimed it wasn't persuaded by the data, though the European Union and U.S. approved Synvisc[®] drug this year. The U.S. is a global outlier, as there are approved versions of low-dose atropine in all other major markets. China approved a home-grown pharmaceutical company's low-dose atropine drops last year.

This hydroxyapatite fits an FDA pattern this year of blinding companies by arbitrarily changing standards for approval. Chief Medical Officer Vinay Prasad has taken the short-sighted view that many medications that slow disease progression aren't worth their cost to the healthcare system.



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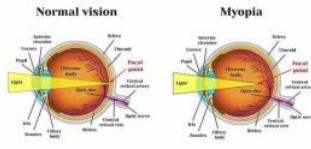
Classification of Myopia

- Simple Myopia
 - Normal chance variation in refractive error
- Congenital myopia
 - Tend to be stationary, nonprogressive
- Degenerative (Pathologic) myopia
 - > -6 D, increased axial length (> 26 mm)
 - Progressive choroidal degeneration in post pole

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Physiologic Myopia


- Each component of refraction lies in its normal distribution
- Postnatal development is normal
 - Correlation fault between the total refractive power (cornea/lens) and axial length
- Onset typically in older children
- Fundus is frequently normal



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Intermediate Myopia


- Excessive enlargement of the posterior segment
- Clinical changes can be seen in the fundus
 - Crescent formation at the disc as the posterior segment enlarges
 - Straightening of the vessels
 - Tessellation of the fundus
- Good visual function
- Higher incidence of glaucoma



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What is Myopic Degeneration?

- Subgroup of myopia characterized by progressive stretching of the eye that results in characteristic changes to the retina, choroid and RPE
- Defined as "high myopia with any posterior myopia-specific pathology from axial length elongation"

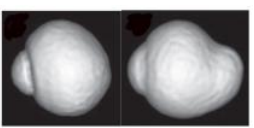


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Pathologic Myopia

(Also Known as "Degenerative Myopia" or "Myopic Degeneration")

- Prevalence up to 3%¹
 - Responsible for up to 31% of cases of low vision
 - Leading cause of blindness in Japan²
- Prevalence varies across populations of different regions and ethnicities
 - More common in Asia, especially in Chinese ethnicity
 - Higher in urban areas
- Excessive/progressive elongation of globe¹
- Stretching /thinning of choroid and RPE layers¹
- Posterior segment deformity¹



3D MRI of emmetropic eye (left) and highly myopic eye (right)

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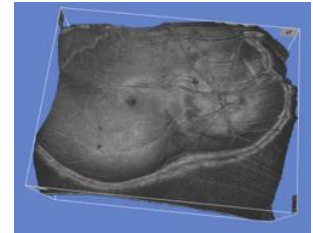
Myopic Degeneration

- Pathogenesis is not clearly understood
- Is it “biomechanical” process caused by progressive expansion of the scleral coats?
- Genetically determined: hereditary factors?
- Aging is an important factor
 - Posterior staphyloma rarely seen < 40 yo
 - Myopic chorioretinal atrophy rarely seen < 20

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Clinical Features of Pathologic Myopia

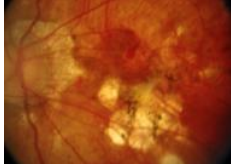
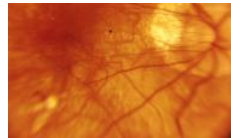
- Peripapillary scleral crescent
- Posterior staphyloma
- RPE atrophy
- Fuchs spot
- Tilted disc
- Retinal degeneration
- Lacquer cracks



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Pathologic Myopia Sequela

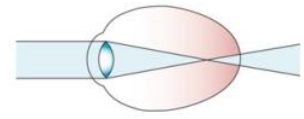
- Glaucoma
- Retinal detachments and retina tears
- PVD
- Choroidal neovascularization
 - 3rd most common cause of CNV
- Myopic Tractional Maculopathy (MTM), myopic schisis
- ERM



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Pathologic Myopia Risk Factors

- Greater axial length (>26.5 mm)
- ≥ -6 D
- Larger optic disc area
- Female gender
- Family history
- East Asian ethnicity



Wong TY et al. Am J Ophthalmol. 2014;157:9-25.

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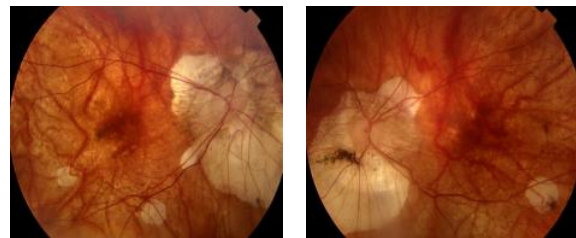
Clinical Features of Pathologic Myopia

- | | |
|---|--|
| <ul style="list-style-type: none"> • Peripapillary scleral crescent • RPE atrophy • Visible choroidal vessels and sclera • Fuchs spot • Posterior staphyloma • mCNV | <ul style="list-style-type: none"> • Tilting/temporal flattening of optic nerve • Retinal degeneration • Lacquer cracks (4.2% of eyes with axial length >26.5 mm) • Macular tractional maculopathy (MTM), myopic foveal retinoschisis |
|---|--|

Raecker ME et al. EyeNet. April 2015. www.aao.org/eyenet/article/agnosis-treatment-of-cnv-in-myopic-macular-degen. Accessed February 6, 2016.

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Pathologic Myopia



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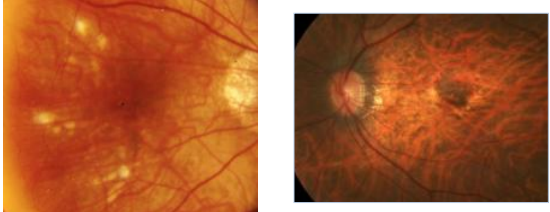
Posterior Staphylomas

- Pathognomonic of degenerative myopia
- Localized posterior pole ectasia involving the sclera, choroid, and RPE
- Usually present early in life, and increases with age
- Clinically underestimated: 10% vs 35% histopathology



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Myopic Choroidal Neovascularization (mCNV)



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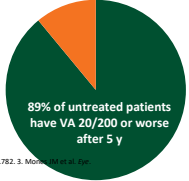
Myopic Choroidal Neovascularization (mCNV)

- 2nd most common disease associated w CNV
 - Used to be 4th most common
- CNV associated with myopic degeneration occurs in 10% of high myopia patients
 - 60-75% subfoveal

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mCNV: The Most Prevalent, Vision-Threatening Complication of Pathologic Myopia¹

- Affects 5%–10% of highly myopic eyes¹
 - Most (~60%) aged <50 y
- Causes acute deterioration central VA²
- 30% will have mCNV in their other eye within 8 y³



Untreated mCNV leads to legal blindness⁴

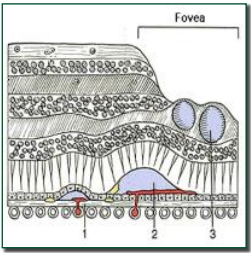
89% of untreated patients have VA 20/200 or worse after 5 y

1. Neelam K et al. Prog Retin Eye Res. 2012;31:495-525. 2. Willis JJ et al. Ophthalmology. 2016;123:1771-1782. 3. Moshirfar M et al. Eye. 2009;23:1275-1281. 4. Ohno-Matsui K et al. Retina Today. July/Aug 2011.

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CNV Growth Patterns

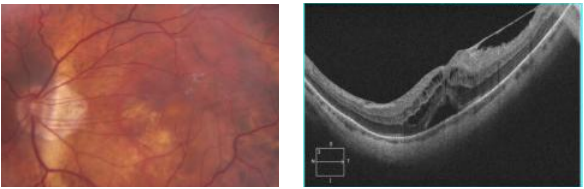
- mCNV, typically type 2 (classic)
 - Usually subfoveal¹
- Can occur at any degree of myopia²
- ↓ incidence, ↑ post staphyloma
- Need preserved CC for CNV to develop?
- Different dynamics with age
 - Older, ↑ leakage
 - Younger, ↓ leakage



1. Adamba FA et al. Ophthalmology. 2015;60:204-215. 2. Wong TY et al. Br J Ophthalmol. 2015;99(1):289-296.

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Jeff: (66 yo) High Myopia, Pseudophakia and VMT



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Myopic Macular Schisis Traction Maculopathy (MTM)

- ◆ Also known as myopic myopic traction maculopathy (MTM) or myopic macular schisis, foveoschisis,
- ◆ **Seen in 8-34% of highly myopic eyes with posterior staphyloma**
- ◆ Results from perifoveal and tangential traction on the macula
- ◆ Factors that may contribute:
 - Rigidity of ILM that induces traction from the vitreous
 - Stiff retinal vasculature

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Myopic Macular Schisis

- Progression in up to 30-43% of eyes
 - Up to 50% progress to macular hole formation or macular detachment within 2 years
- Often necessitates PPV with membrane peel
- Indications for surgery
 - Macular hole or retinal detachment
 - VA worse than 20/50


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MTM Staging

- Stage 1: inner/outer maculoschisis
- Stage 2: predominantly outer maculoschisis
- Stage 3: maculoschisis/macular detachment
- Stage 4: macular detachment

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June 2024



Retinal and Vitreous Changes Associated with Spontaneous Improvement in Myopic Macular Schisis

Mahilde Goudar, MD,¹ Aude Courrier, MD, PhD,¹ William Beament, MD,¹ Alain Ghaib, MD,¹ Ramon Tadayoni, MD, PhD,^{1,2} Elise Philippakis, MD^{1,2}

Results: In a cohort of 74 nonoperated eyes with MMS, MMS improved in 14 eyes (19%) after a mean follow-up of 55 ± 38 months (range, 8–138). In these improved cases, the mean decrease in CFT was 153 ± 166 μm (range, 24–635; P = 0.005) and a complete resolution of MMS was observed in 9 eyes (64%). In 9 eyes (64%), the improvement was associated with visible vitreous changes in the macular area on the OCT scans. The mean visual acuity, which was already good at baseline (20/50, 0.4 ± 0.2 logarithm of the minimum angle of resolution), increased at the last visit (20/40, 0.3 ± 0.3 logarithm of the minimum angle of resolution) but without reaching significance.

Conclusions: This long-term follow-up analysis showed that almost 20% of MMS in eyes without indication for surgery could improve over time. In most cases, the improvement was associated with an apparent resolution of vitreous tensions.

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Can we prevent or slow down the progression of myopia?




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Foundational Studies For Myopia Control

ATOM (Atropine for the Treatment of Myopia) demonstrated atropine's ability to slow axial elongation and refractive progression, highlighted dose-dependent response, and established atropine as a credible therapy (2012)

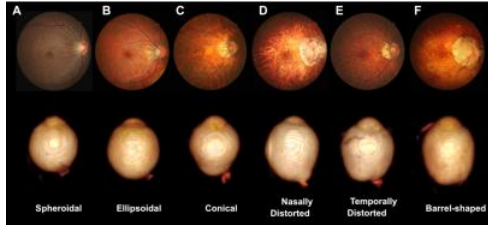
LAMP (Low-Concentration Atropine for Myopia Progression) again showed clear dose-dependent effectiveness across 0.05%, 0.025%, and 0.01% concentrations, shaping practical dosing strategies (2018)

LAMP-II provided multi-year continuation data, confirming sustained benefits, long-term tolerance, and reinforcing atropine's role in multi-year myopia management (2020)



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Will slowing down progression stop retinal degenerative myopia changes from occurring?



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STAR (Study of Atropine for the Reduction of Myopia Progression) Trial

- Largest global clinical program completed to date in pediatric myopia
- 847 children aged 3-14 at treatment initiation
- Myopia -0.50 diopters (D) to -6.00D with a mean baseline progression of -2.65D were enrolled across the U.S. and Europe, and randomized (1:1:1)
 - Vehicle (placebo), SYD-101 0.01%, or SYD-101 0.03%
- Primary efficacy endpoint was proportion of patients with confirmed progression of -0.75D
 - This endpoint proposed by FDA and a key secondary endpoint was annual progression rate

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STAR (Study of Atropine for the Reduction of Myopia Progression) Trial

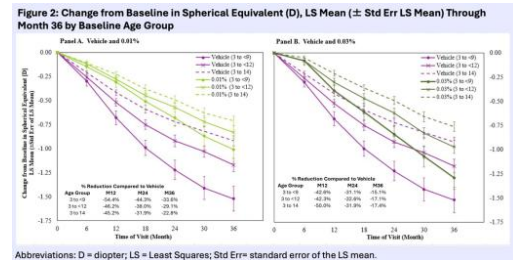
- SYD-101 0.01% successfully met both the primary and key secondary endpoints
 - Progression of > 0.75: 139 Vehicle vs 111 patients 0.01%; p=0.0226

| Confirmed Progression At or Below Month 36 | Vehicle (N=282) | 0.01% (N=282) | 0.03% (N=282) |
|--|-----------------|---------------|---------------|
| Participants with progression n (%) | 139.9 (49.26) | 111.4 (39.50) | 122.0 (43.11) |
| 95% CI percentage with progression | 43.0, 55.5 | 33.4, 45.6 | 37.0, 49.2 |
| CI95% p-value, difference to Vehicle | – | 0.0226 | 0.1319 |

- SYD-101 was well tolerated with no unexpected atropine-related adverse events

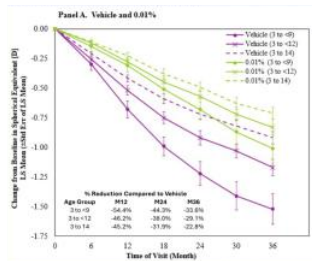
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Change from Baseline in Spherical Equivalent (D), LS Mean (± Std Err LS Mean) Through Month 36 by Baseline Age Group



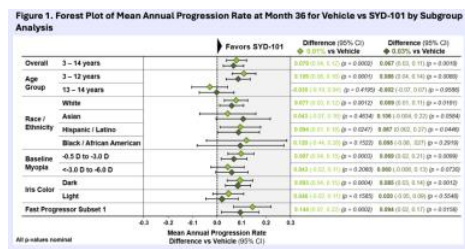
52

Change from Baseline in Spherical Equivalent (D), LS Mean (± Std Err LS Mean) Through Month 36 by Baseline Age Group



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Mean Annual Progression Rate at Month 36 for Vehicle vs SYD-101 by Subgroup



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STAR: Clinical Benefit in Younger Patients 3-12 yo

- The magnitude of clinical effect of change in spherical equivalent was even larger in younger patients (3-12 years old), with both doses demonstrating nominal statistical significance
 - Vehicle -1.07 D
 - 0.01% -0.77 D (p=0.0002)
 - 0.03% -0.85 D (p=0.0065)



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Effect of Age on Myopia Reduction

| Study Dose | 3 to <9-year-olds | 3 to 12-year-olds | 3 to 14-year-olds (FAS) |
|------------|--------------------|--------------------|-------------------------|
| Vehicle | -1.52 D | -1.07 D | -0.92 D |
| 0.01% | -1.01 D (p=0.0034) | -0.77 D (p=0.0002) | -0.71 D (p=0.0022) |
| 0.03% | -1.29 D (p=0.1855) | -0.85 D (p=0.0065) | -0.76 D (p=0.0158) |

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STAR (Study of Atropine for the Reduction of Myopia Progression) Trial

Subgroup of fast progressors [more than -0.5D/yr progression prior to the study] at 36 months

- In these patients with low to moderate myopia (-0.50 D to -3.00D) at study initiation: SYD-101 0.01% reduced the progression by more than 50%
 - Vehicle: -1.18 D
 - 0.01%: -0.51D (p=0.0004)
 - 0.03%: -0.92 D (p=0.1505)
- Highlights the importance of early disease modifying intervention in childhood myopia

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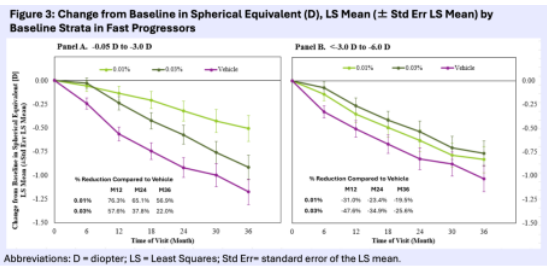
Effect of Prior Myopia Progression on Myopia Reduction

| Fast Progressors | Fast Progressors |
|-------------------------------------|---------------------------------------|
| Month 36 – Subgroup (-0.5 to -3.0D) | Month 36 – Subgroup (<-3.0D to -6.0D) |
| • Vehicle: -1.18 D | • Vehicle: -1.03 D |
| • 0.01%: -0.51 D (p=0.0004) | • 0.01%: -0.83 D (p=0.2715) |
| • 0.03%: -0.92 D (p=0.1505) | • 0.03%: - 0.77 D (p=0.1442) |

Figure 3: Change from Baseline in Spherical Equivalent (D), LS Mean (± Std Err LS Mean) by Baseline Strata in Fast Progressors

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Change From Baseline in Spherical Equivalent



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STAR (Study of Atropine for the Reduction of Myopia Progression) Trial

- Of note: 36% of patients who were between 16-18 yo when the study ended – not likely to get progression by that time
 - With 1/3 of the total population not significantly progressing – It becomes scientifically very difficult to show large differences in progression reduction when the base is not actively progressing
 - SYD-101 still hit its primary and key secondary efficacy endpoints (suggested by the FDA) in the full data set

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October 2025

FDA Rejects Commercial SYD 101

The agency's view is that the data do not support the effectiveness of low-dose atropine in children with myopia. No deficiencies were noted related to safety or product quality of SYD-101.

The FDA wrote in its complete response letter that although the drug met its primary efficacy endpoint in a phase 3 study, and no safety or quality deficiencies were noted, the data did not support the effectiveness of low-dose atropine in pediatric myopia, according to a Sydnexis press release. The study's efficacy endpoint, the proportion of patients who progressed ≥ 0.75 D, was "preposed by" the FDA, Sydnexis said in another press release.

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Greater Risk of Glaucoma with High Myopia

- Blue Mountains Eye Study found a strong relationship between POAG and myopia
 - Odds ratio of 2.3 in eyes with low myopia (between -1.0 and -3.0D) and 3.3 in eyes with moderate-to-high myopia ($> -3.0D$)
- Barbados Eye Study, a myopic refraction was one of several risk factors for POAG in adult black people
- Beaver Dam Eye Study showed that patients with myopia were 60% more likely to have glaucoma than those with emmetropia
- Singapore Malays Eye Study showed an association between moderate or high myopia (worse than -4 D) and POAG
 - Moderate or high myopia had an almost 3 X higher risk of POAG vs emmetropia
- Beijing Eye Study in China myopia of >6 D was a risk factor for glaucoma

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Challenges in Diagnosing/Recognizing Glaucoma in Myopic Degeneration

- Already anomalous optic nerves
 - Extensive PPA
 - Tilted discs
 - Cup can be indistinguishable
 - Often large discs
- Challenges in utilizing normative data bases

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66 yo Hispanic Female: 2nd Opinion on Glaucoma

On Latanoprost qhs OU: Ta 18 OU

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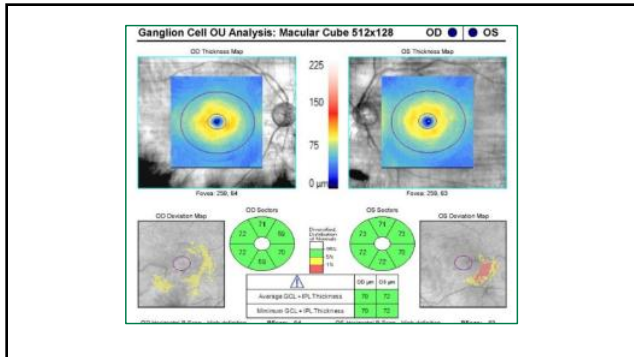
Using OCT RNFL Data in Pathologic Myopia

- Useful images may be difficult to capture due to extensive PPA and anomalous ON's
- You can't really utilize normative data
- But with good reliable imaging you may be able to utilize the data to monitor for progression
- GCC data may also be helpful

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Be careful to make decisions on what is normal for patients who do not fit into the normative data base

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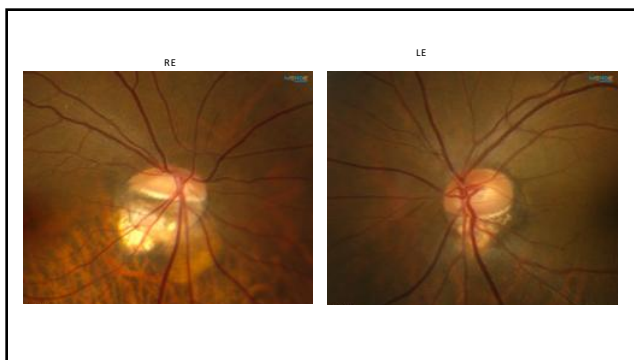
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51 yo Asian Female: June 2017

- Diagnosed with glaucoma 10 years ago
 - Treated with latanoprost OU and timolol bid OU
- Father with glaucoma
- History of LASIK
- Tmax (according to patient) ~ 24

- VA: RE 20/30; LE 20/25
- Ta: 12/13
- Gonio: CBB 360 OU

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Unintended Consequences of High Myopia: Summary

- Myopia is occurring at epidemic proportions
 - By 2050 1 in 2 will have myopia
- The science supports that we can slow down the progression of myopia
 - Lifestyle changes, Pharmacologic treatments, Optical/CL
- Can we slow it down enough to prevent some of the visually devastating complications of pathologic myopia?

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