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The future of cell therapy.



OpRegen® Program Update 2021 ARVO Annual Meeting

May 3, 2021

Forward-Looking Statements

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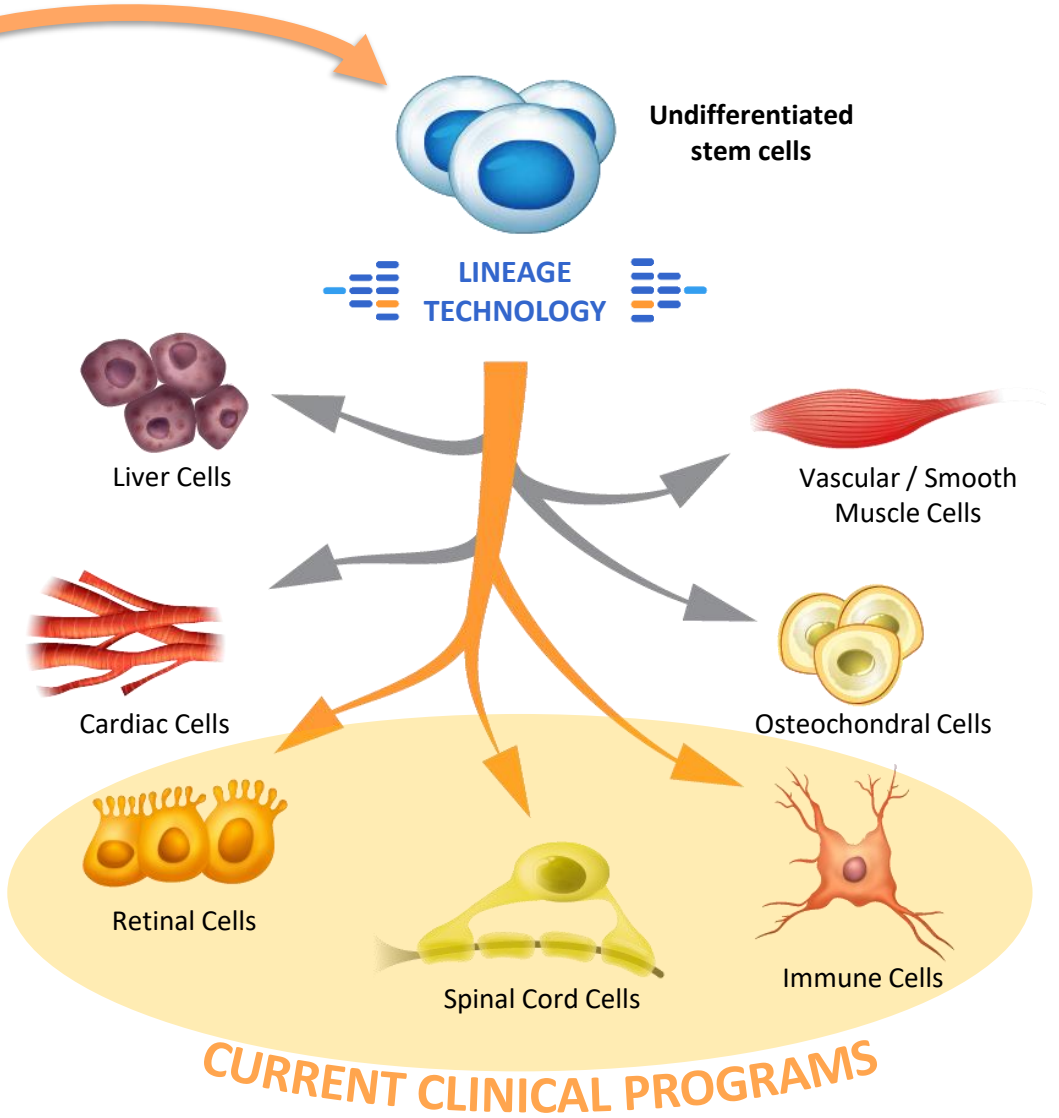
"We aim to pioneer a new branch of medicine, based on transplanting specific cell types into the body"

Business Overview

Lineage Technology Platform – Allogeneic Cell Transplants

- **The Lineage Platform starts with a frozen vial of *self-renewing stem cells***
- **These pluripotent cells can become *any* cell type in the body**
- **Lineage's proprietary processes create *only* the cell type which is desired**
- **No alterations are made to the cell's DNA**
- **Commercial-scale production occurs from a single vial of cells**



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Pipeline and Validating Partnerships

Clinical Programs	Financial Support Received	Phase 1	Phase 2a	Next Steps
OpRegen® (RPE Cells) Dry AMD with Geographic Atrophy (GA)	רשות החדשנות Israel Innovation Authority **$16M**	→		Enrollment completed
OPC1 (Oligodendrocytes) Spinal Cord Injury (SCI)	CIRM CALIFORNIA'S STEM CELL AGENCY **$14M**	→		Data collected; planning for Phase 2b/3
VAC2 (Dendritic Cells) Non-Small Cell Lung Cancer (NSCLC)	CANCER RESEARCH UK **$10M**	→		1 patient left to enroll

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AMD is the leading cause of irreversible vision loss in the US

Source: aao.org

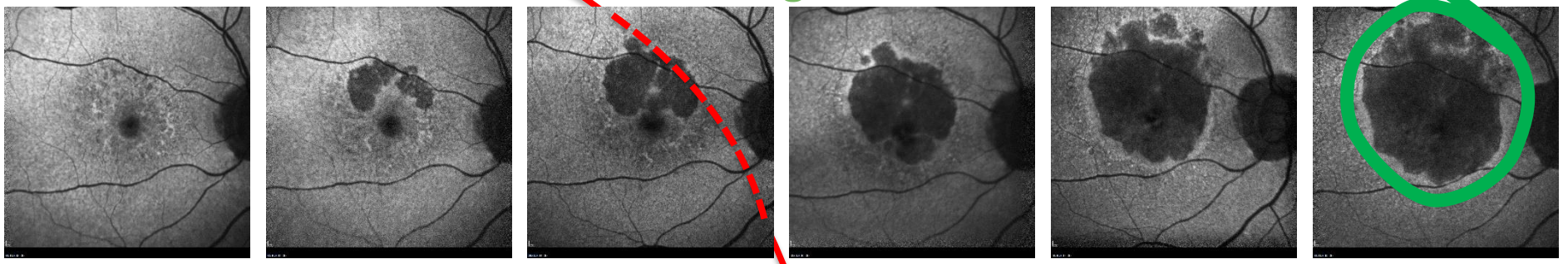
OpRegen®: RPE Cell Transplants to Treat Dry AMD

Dry AMD Can Lead Rapidly to Blindness

Visual acuity over time…

20/20 (normal)

The area of geographic atrophy or "GA" grows larger as retinal cells die



2012 2013 2014 2015 2017 2019

20/200 (legally blind in 3 years)

20/640

Dry AMD involves the progressive loss of retina cells, which can lead rapidly to blindness

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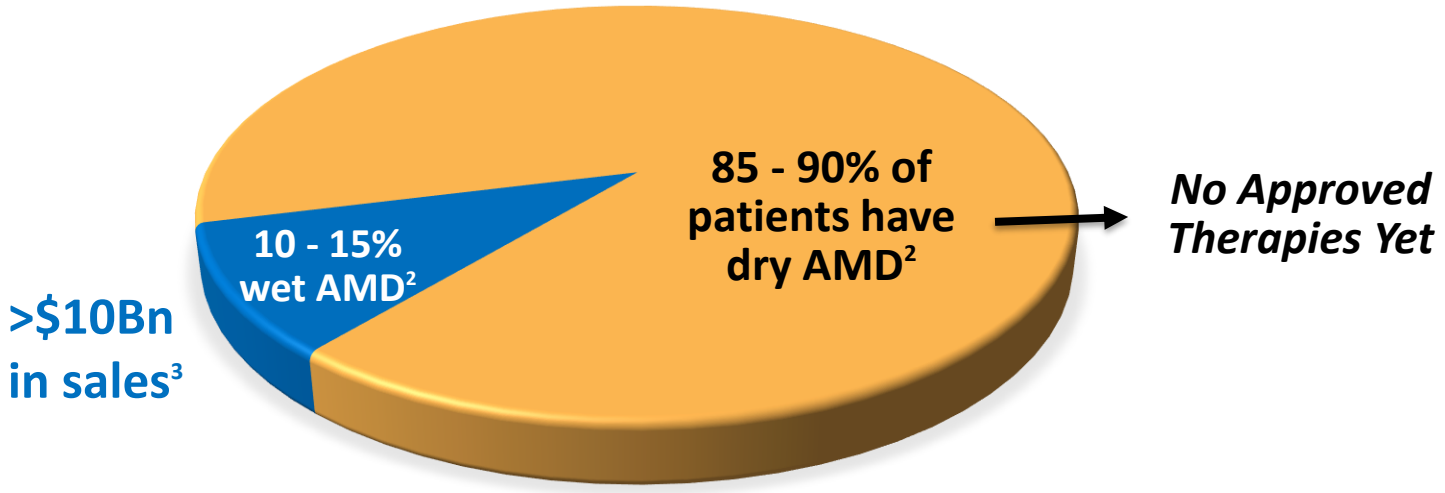
Image courtesy of Jordi Monés, MD, PhD

Multi-Billion Dollar Market Opportunity in the U.S.

Age-related Macular Degeneration (AMD) (all forms) afflicts ~11 million people in the United States

Type of AMD	% of AMD Cases	FDA Approved Therapies
Wet AMD	10 – 15%	Lucentis & Eylea ($10 Billion in annual sales)
Dry AMD	**85 – 90%**	**None**



Sources: (1) Bright Focus Foundation. Macular Degeneration Facts & Statistics: Bright Focus Foundation. http://www.brightfocus.org/macular/about/understanding/facts.html; (2) JM Seddon, Epidemiology of age-related macular degeneration. (AP Schachat, S Ryan eds.) Retina, 3rd ed. St. Louis, MO: Mosby; 2001;1039-50; (3) 2018 product sales summary based on publicly reported revenue figures for Lucentis and Eylea.

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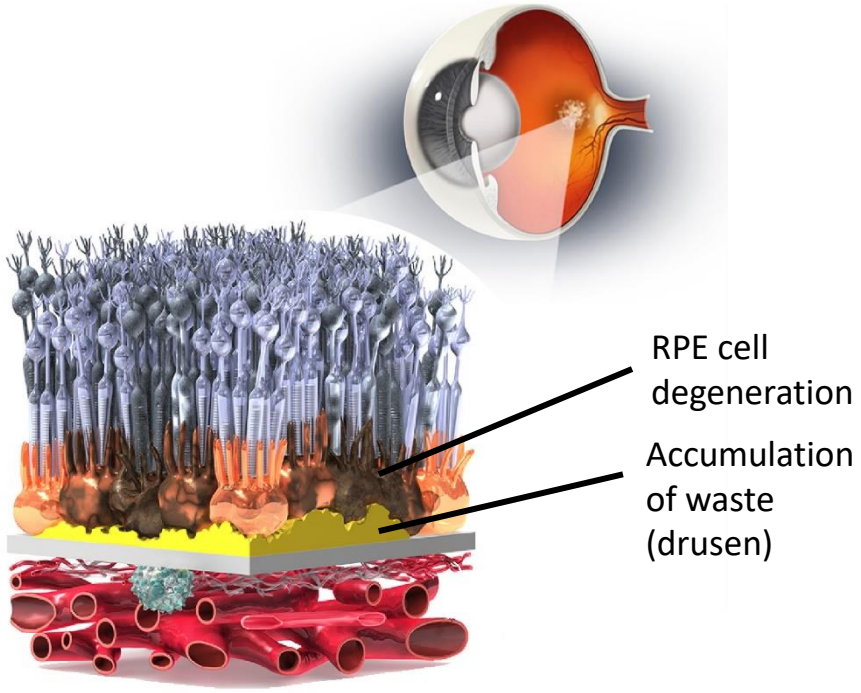
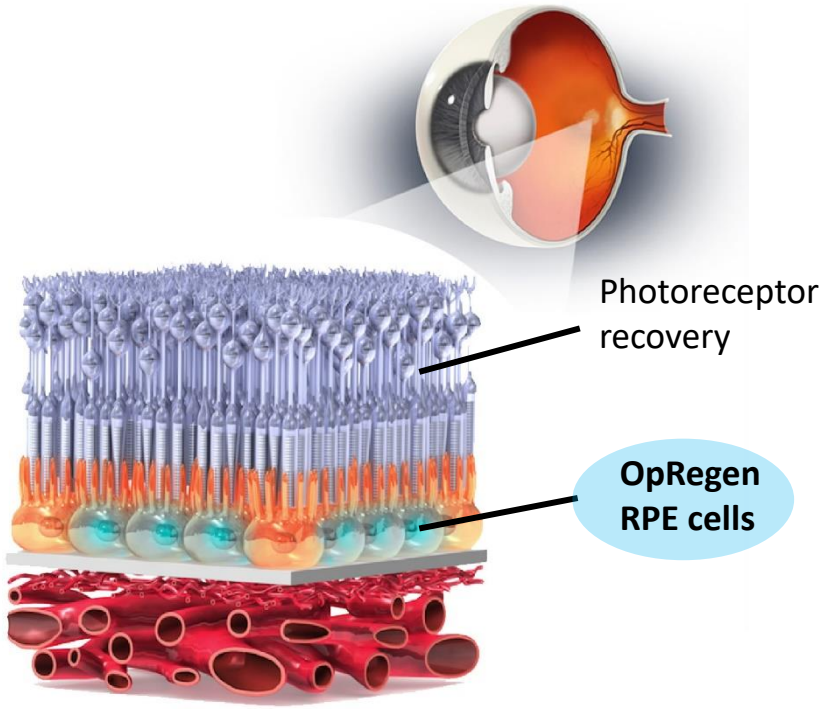
Lineage Approach – OpRegen, an RPE Cell Transplant

- **Dry AMD involves the loss of retina cells, creating an area of geographic atrophy (GA), which causes impaired vision and blindness**



Pre-Transplant

- **OpRegen is an injection of RPE cells beneath the retina, to replace lost retinal cells, recover function, and preserve or improve vision**



Post-Transplant

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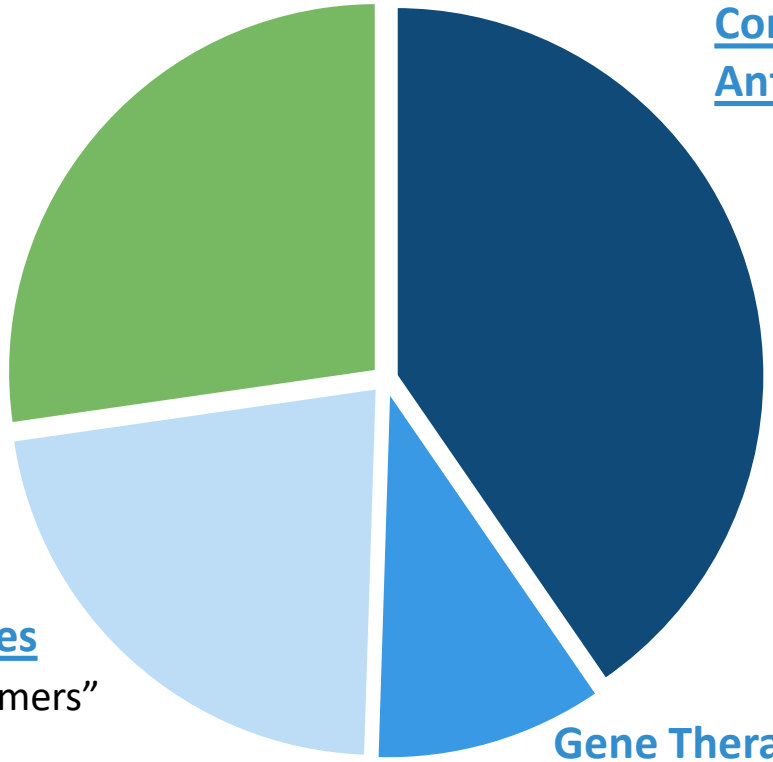
Image adapted from scienceofamd.org

Dry AMD Competitive Landscape

<u>Only</u> cell therapy or gene therapy can offer infrequent dosing
-and-
<u>Only</u> Lineage has shown clinical evidence of retinal restoration



Cell Therapy

- **Lineage Cell (Ph1/2)**
- Astellas (Ph1/2)*
- Regen. Patch (Ph1/2)
- jCyte/Santen (Preclinical)

Via acquisition of Ocata Therapeutics for $379M

Complement Inhibition/ Anti-Inflammatory MOA

- Apellis (Ph3)
- Iveric (Ph3)
- Roche (Ph2)
- Annexon (Ph 2)
- NGM (Ph1)
- Biogen (Preclinical)
- ONL Therapeutics (Preclinical)

Oxidative Stress Approaches

- Alkeus (Ph3), Vitamin A “dimers”
- Allegro (Ph2), integrins
- Stealth Bio (Ph2), mitochondria
- Boehringer (Ph1), inflammasome

Gene Therapy

- Gyroscope (Ph1/2)
- Hemera/Janssen (Ph1)
- Novartis (Preclinical)†

†Via acquisition of VedereBio for $280M

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Commercial-Scale Manufacturing Capabilities

- **OpRegen consists of >99% pure RPE cells**
  - Uses NIH-approved line was established >20 years ago
  - Extensive characterization and karyotyping performed on each batch
  - No genetic modifications are made to the cells

- **Immediate-use "thaw and inject" formulation**
  - No dose preparation is required
  - From frozen cells to injection device in 5 minutes

- **Current production scale is 5 billion cells per 3-liter bioreactor**
  - Equal to 2,500 clinical doses/batch
  - Further scale-up can be performed in larger or parallel reactors

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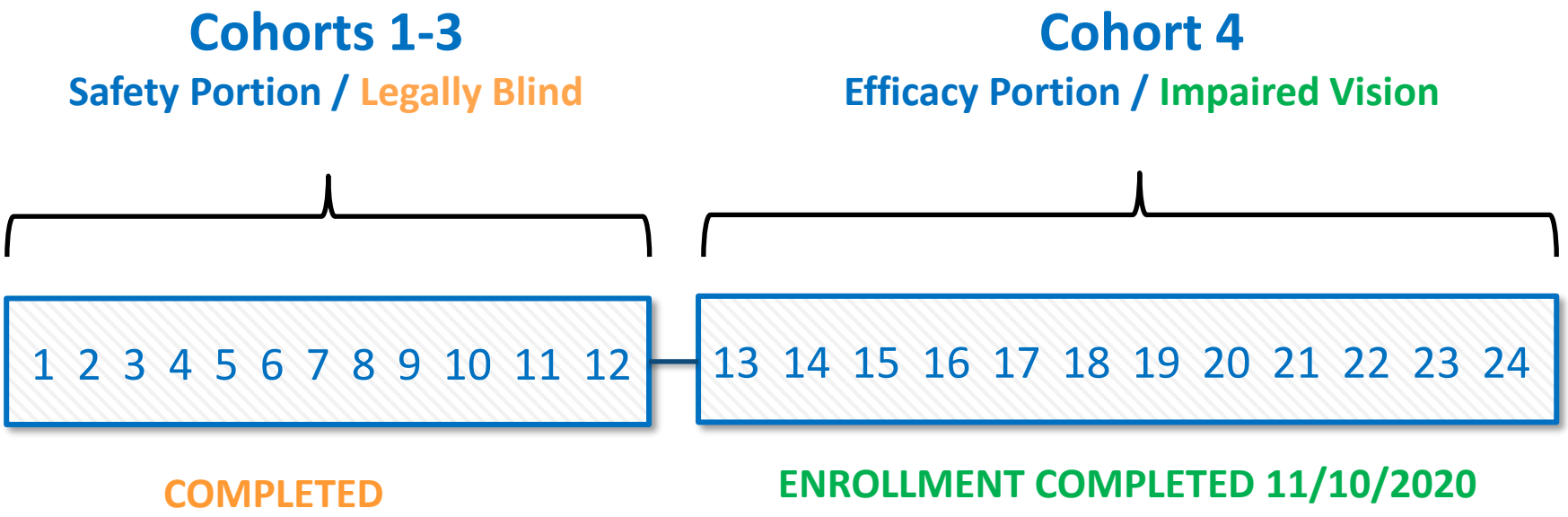
Phase I/IIa Clinical Trial of Transplanted Allogeneic Retinal Pigmented Epithelium (RPE, OpRegen) Cells in Advanced Dry Age-Related Macular Degeneration (AMD): Interim Results

2021 ARVO Annual Meeting Data Summary

Ongoing Phase 1/2a Clinical Trial of OpRegen for Dry AMD



Purpose:	**To evaluate the safety and efficacy of transplanted RPE cells in patients with dry AMD with geographic atrophy (GA)**
Design:	**Open label, single arm, international, multi-center**
Dose and Administration:	**One 50-100 ul dose of cells injected into the subretinal space**

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Phase I/IIa Clinical Trial Objectives

- **Primary Objective**
  - To evaluate the safety and tolerability of subretinally transplanted hESC - derived RPE cells (OpRegen) in patients with advanced dry age-related macular degeneration (AMD) and geographic atrophy (GA)
- **Secondary Objective**
  - To evaluate survival and possible effects of OpRegen treatment by assessing changes in retinal structure and function
- **Exploratory Objective**
  - Evaluate safety in Cohort 4 participants who receive a subretinal injection of OpRegen "thaw and inject" (TAI) preparation using the Orbit™ Subretinal Delivery System (Orbit SDS)*

** Orbit and Orbit SDS are trademarks of Gyroscope Therapeutics Limited (Gyroscope)*

As presented at 2021 ARVO Meeting

Phase I/IIa Clinical Trial Design, Population, Management

Parameter	Cohorts 1-3 (legally blind) n = 12 of 12 planned (*complete*)	Cohort 4 (better BCVA) n = 12 of 12 planned *(complete)*
Phase / design	Phase I-IIa; staggered design; IND (NCT02286089)	
Duration	Screening up to 8 Weeks; short term F/U – 1 year; long term F/U – 4 years	
Management	Central reading/central labs/Independent DSMB/Advisory Committees	
Treated disease	Advanced Dry AMD and GA	
Subretinal Dose (delivered via PPV and retinotomy {n = 17} or SDS {n = 7})	Cohort 1: 50K cells Cohorts 2-3: up to 200K cells	Up to 200K cells
BCVA	≤ 20/200	≤ 20/64 and ≥ 20/250
GA size – Central Reading assessment	≥ 1.25mm^2 and ≤ 17 mm^2	≥ 4 mm^2 and ≤ 11 mm^2
Historical Growth of GA	N/A	SQRT per year of > 0.25 mm
Cataract status	Not defined	Pseudophakic or phakic w/ Orbit SDS
Significant concomitant diseases exclusion (systemic / ocular)	Defined *a priori*	
Immunosuppression	PO tacrolimus from 1 week prior to Sx until 6 weeks post-op PO mycophenolate from 1 week prior to Sx to at least 3 months post-op	

Phase I/IIa Clinical Trial Status and Baseline Characteristics

	Cohorts 1 - 3 (legally blind) Recruitment complete (n = 12)	**Cohort 4 (better VA)** Recruitment complete (n = 12)	
	Pars plana vitrectomy (PPV) and retinotomy	**PPV and retinotomy** (n = 5)	**Orbit SDS** (n = 7)
n (%) subjects dropout	2 (17%) (2 medical illness)	1 (12.5%) (Withdrawal of consent/COVID)	0
Age: mean (SD / min - max), yrs	78.3 (± 8.2 / 64.8 - 92.2)	78.1 (± 2.8 / 74.6 - 81.0)	74.2 (± 10.4 / 60.9 - 88.5)
ETDRS BCVA: mean (SD / min - max)	23.7 (± 11.7 / 0 - 39) letters [24 letters ≈ 20/400]	49.6 (± 3.8 / 45 - 54) letters [50 letters ≈ 20/100]	41.4 (± 8.9 / 28 - 55) letters [41 letters ≈ 20/160]
GA area: mean (SD / min - max)	12.7 (± 6.7 / 6 - 30) mm^2	6.2 (± 2.8 / 1.4 - 8) mm^2	8.2 (± 2.9 / 4 - 11) mm^2
Post-op cumulative F/U period	45 years	9.7 years	6.9 years
Mean F/U (days)	1369 days (SE ± 159)	711 days (SE ± 204)	361 days (SE ± 74)

Phase I/IIa Clinical Trial Primary Endpoint Overview

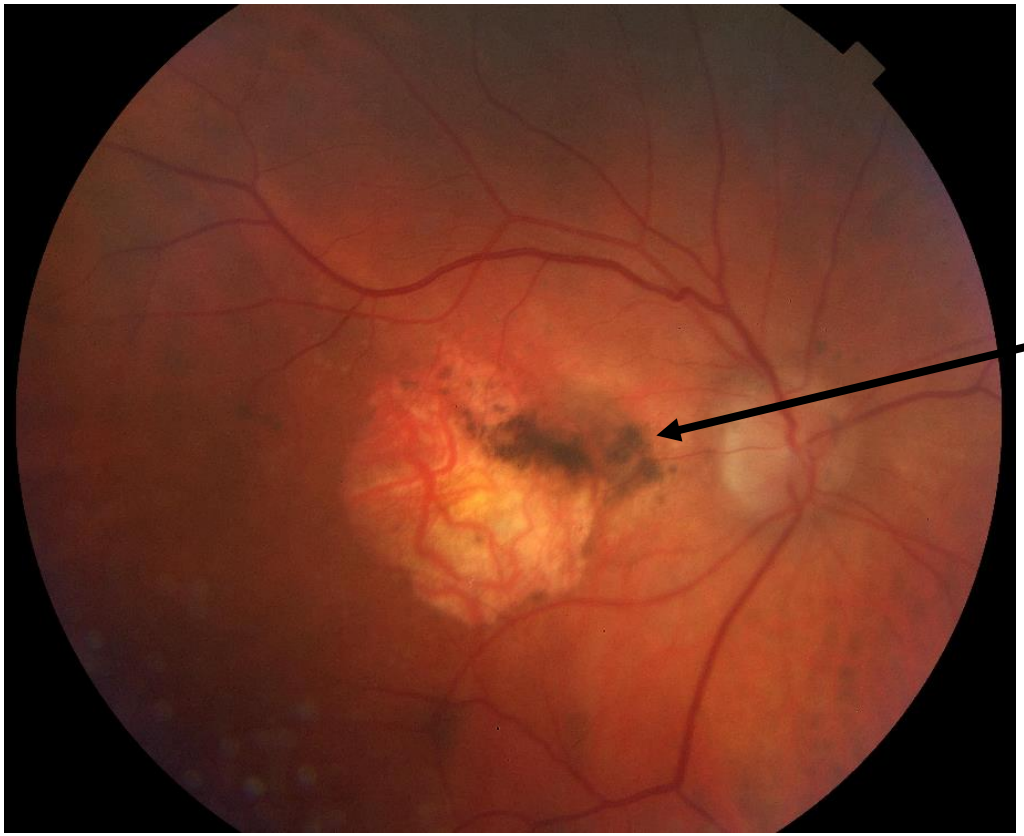
- **In Cohort 1-3 patients (legally blind at baseline), visual acuity (VA) reductions occurred as expected due to progressive GA;**
- **In Cohort 4 patients (smaller areas of GA and higher baseline BCVA), improved or sustained BCVA has been observed in 10/12 (83%) patients as of their last visit prior to this update (range of -7 to +19 ETDRS letters);**
- **OpRegen continues to be well-tolerated in all treated patients (N = 24)**
- **No acute or delayed inflammation and no sustained increased intraocular pressure (IOP) have been observed;**
- **While all patients reported at least one adverse event (AE), the majority of AEs were mild (87%);**
- **AEs in Eye Related Disorders System (n = 165 events):**
  - n = 136 in PPV treated patients (n = 17 patients; 54.7 years F/U),
  - n = 29 in Orbit SDS treated patients (n = 7 patients; 6.9 years F/U).

Phase I/IIa Clinical Trial Primary Endpoint: Systemic and ocular safety and tolerability (*continued*)

AE Term	PPV / Retinotomy Treated (n = 17)	Orbit SDS Treated (n = 7)
Conjunctival Hemorrhage	9 / 17	6 / 7
Limited Subretinal Hemorrhage	1 / 17 (asymptomatic & auto resolved)	4 / 7 (asymptomatic & auto resolved)
Any form of Macular Fibrosis (ERM)	15 / 17	1 / 7
Subretinal Pigmentation	10 / 17 (potentially a positive finding)	2 / 7 (potentially a positive finding)
Subretinal Fluid, persisting >24h	4 / 17 (all resorbed within 72h)	4 / 7 (2 of 4 resorbed <72h) One (1) patient had persistent SRF for 3 months until complete resorption without treatment
CNV	1 / 17 (began >2 yrs post-procedure) – continues to undergo regular anti-VEGF therapy and is responsive	3 / 7 - One (1) Type 2 CNV – 6M post-op at choroidal puncture site, successfully treated with single administration of an anti-VEGF, 2 others at area of GA occurred <6M post-op and have received one anti-VEGF, appear responsive
Lamellar or macular hole	2 / 17 (associated with ERM)	1 / 7 (resolved without treatment or sequelae)
Retinoschisis	2 / 17 (associated with ERM)	1 / 7
Retinal tear	2 / 17	0 / 7

Ocular SAEs	PPV Treated (n = 17) - *5 events in 4 patients*	Orbit SDS Treated (n = 7)
ERM	3/17, clinically significant, severe ERM requiring surgical peel, all successful	0 / 7
Retinal Detachment	2/17 (2 weeks post-procedure; not related to the study medication/RPE cells; considered to be related to surgical procedure/PPV and/or due to peripheral retinal tear/hole, 1 RD was successfully repaired, 1 failed to recover)	0 / 7

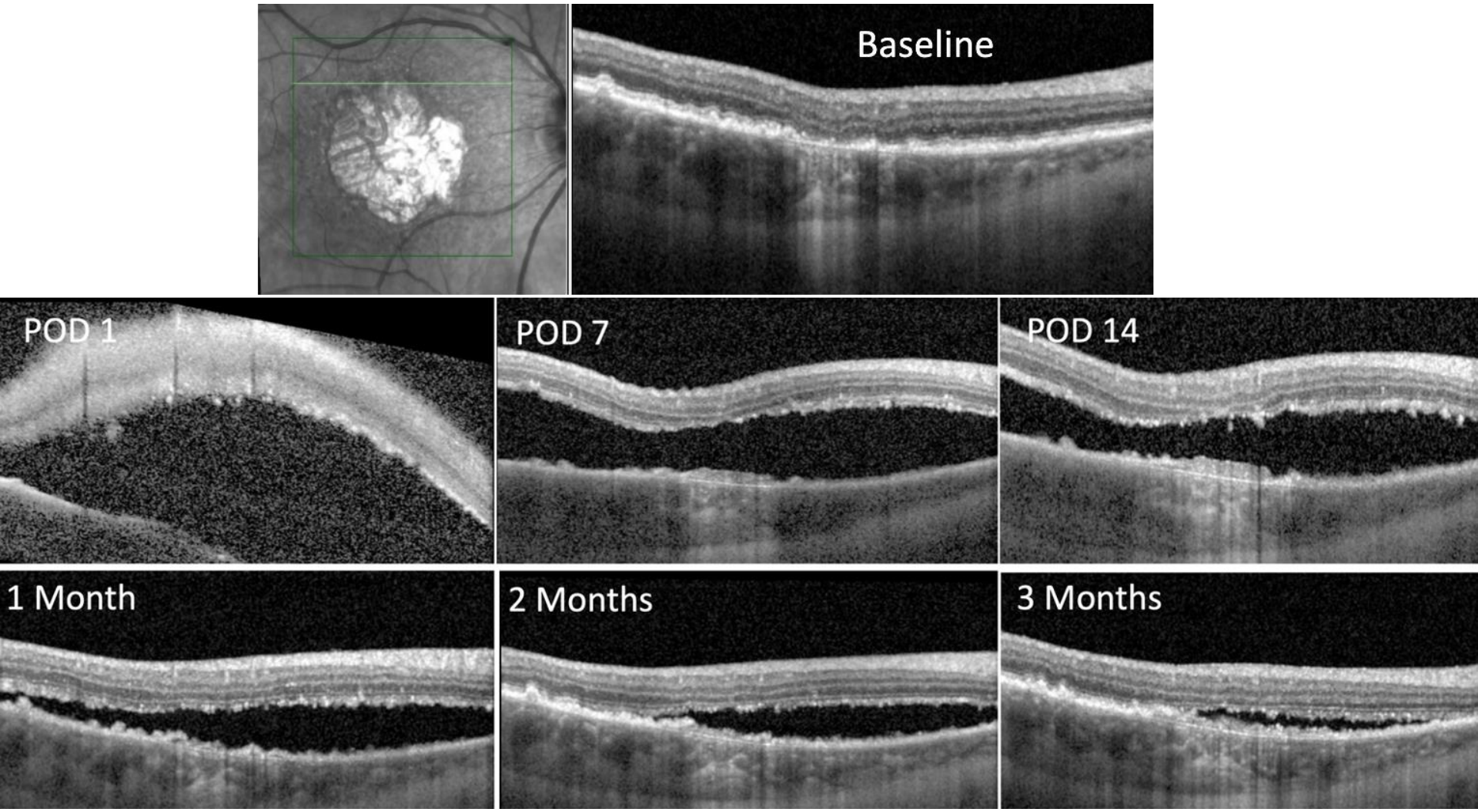
Case Study (Patient #18) – 9 Months Post-op



OpRegen TAI / Orbit SDS Treated

Area of transplant and evidence of continued presence of RPE cells 9M post-transplant

Case Study (Patient #18) – Subretinal Fluid, Resolved w/o Intervention



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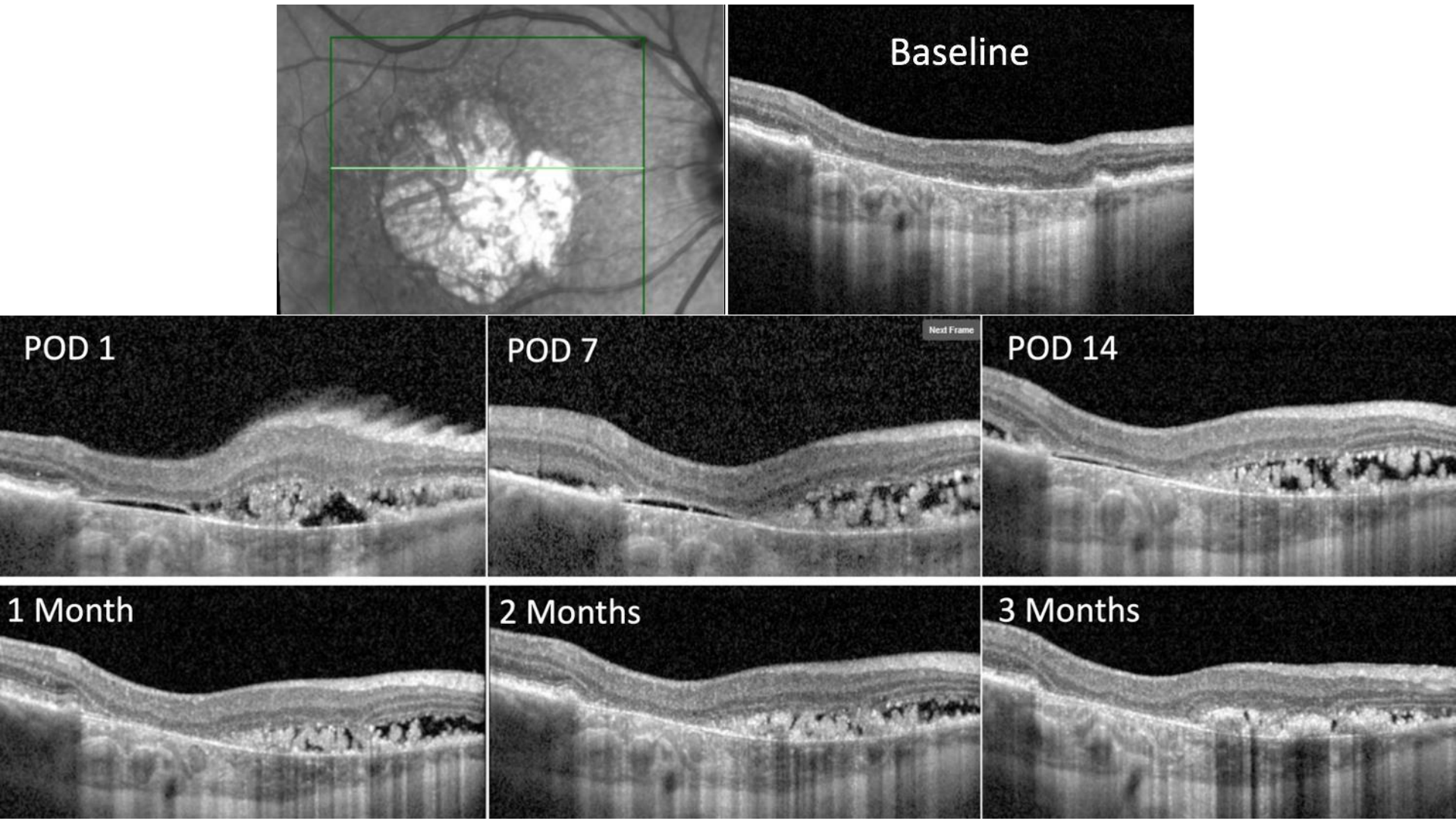
Case Study (Patient #18) – Subretinal Fluid, Resolved w/o Intervention



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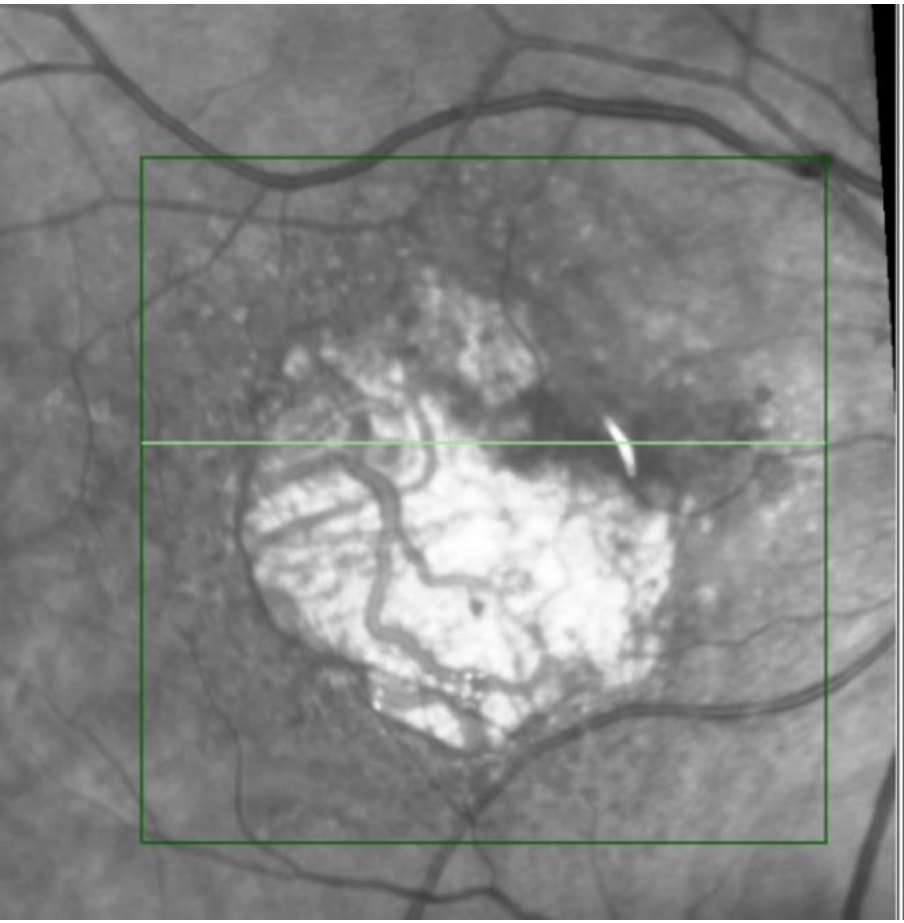
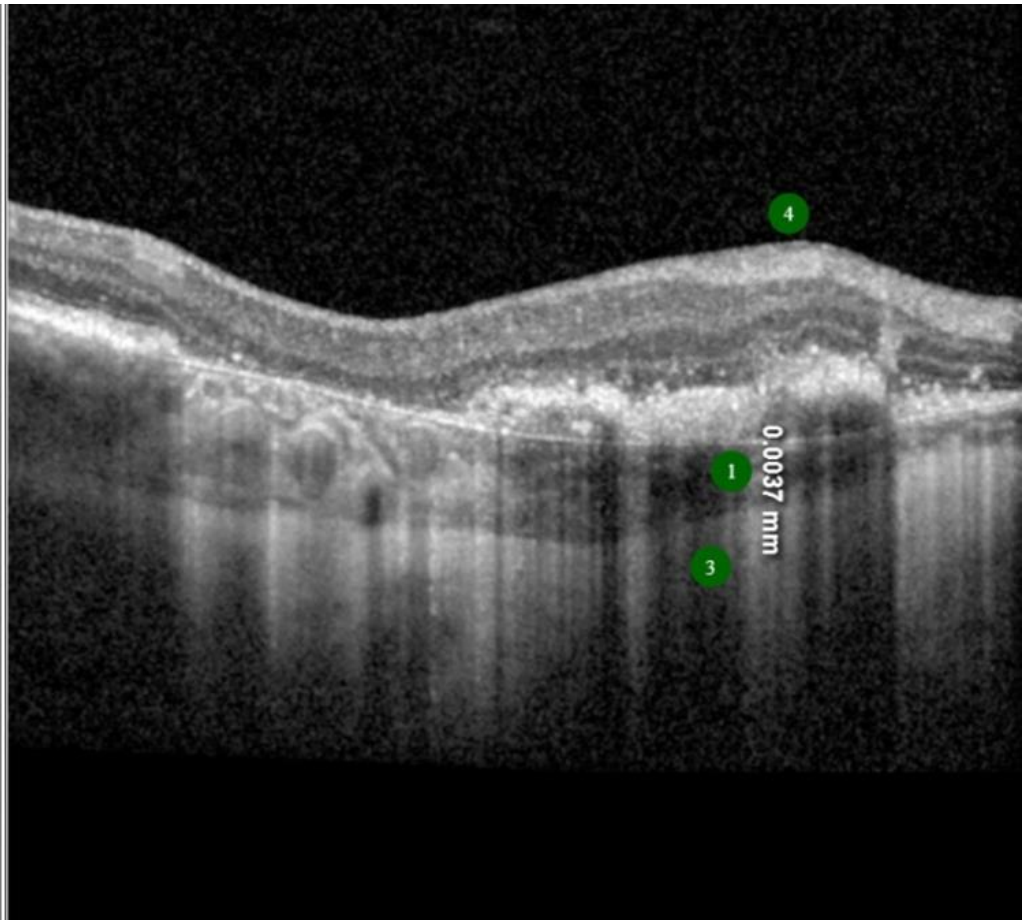
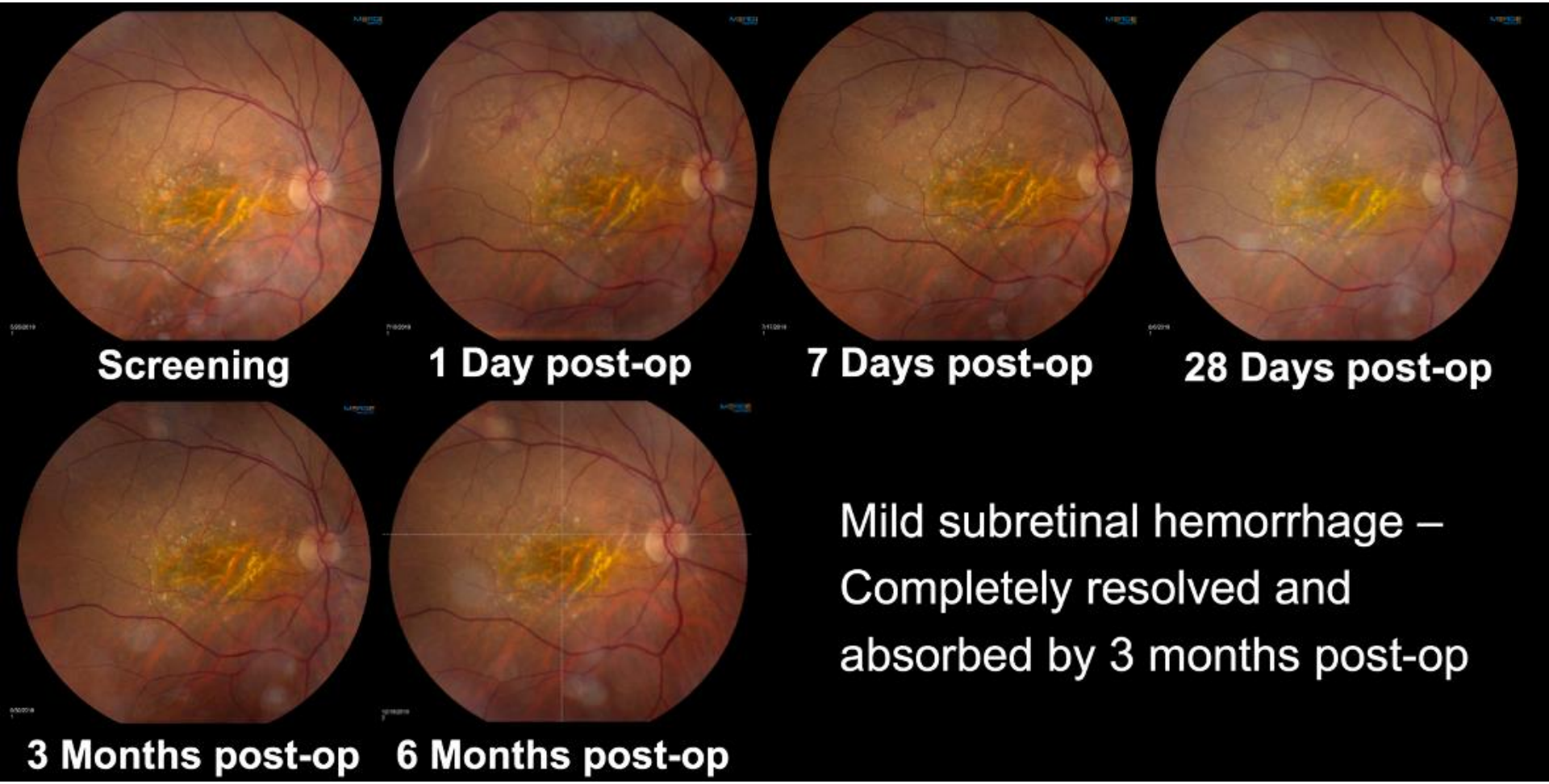
Case Study (Patient #18) – CNV 6 months post-operative

New area of CNV, not in area of needle penetration, noted at 6M post-op, anti-VEGF therapy initiated; patient appears responsive as of last study visit





Case Study (Patient #16) – Mild Subretinal Hemorrhage, Resolved



OpRegen TAI / Orbit SDS Treated

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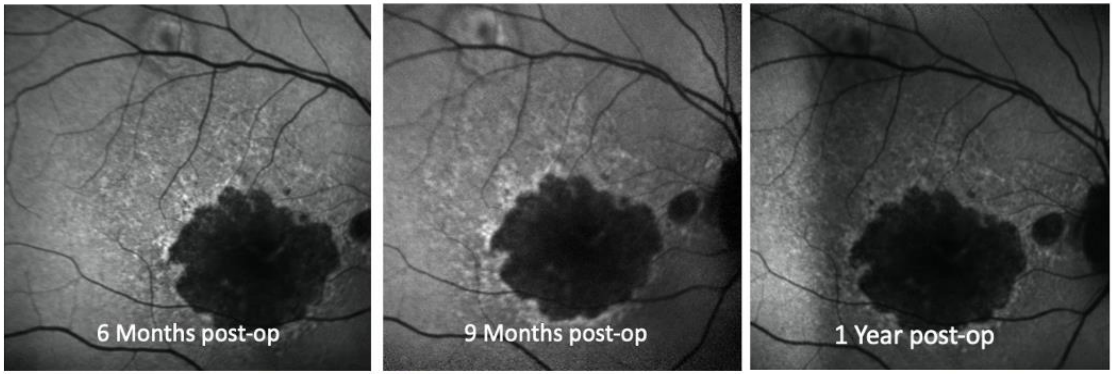
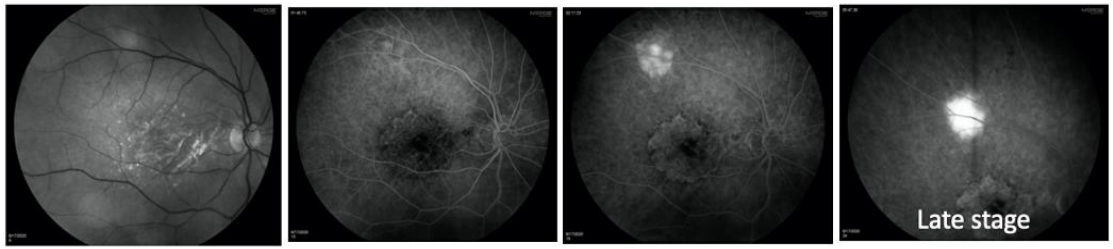
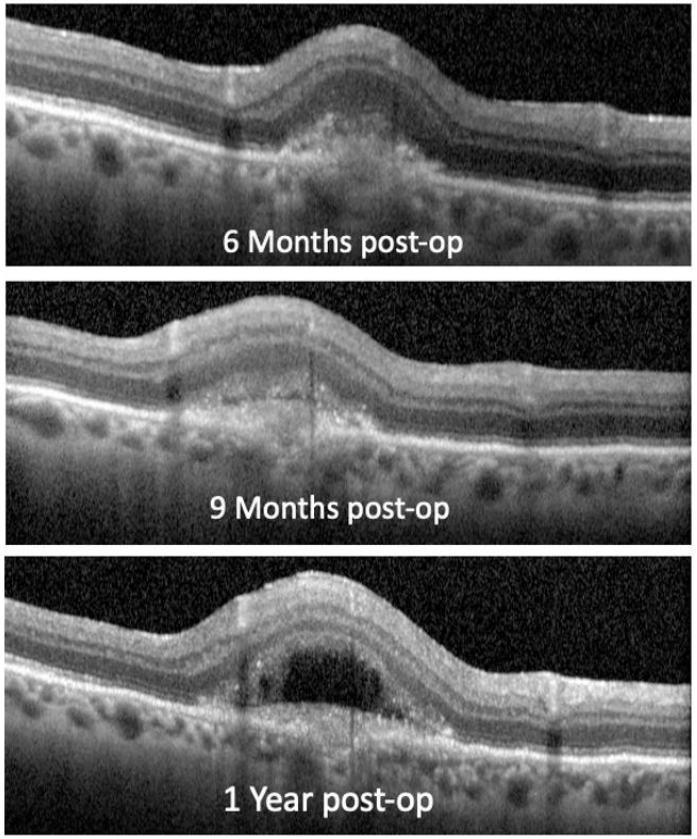
Case Study (Patient #16)– Type 2 CNV Successfully Treated with anti-VEGF



9M post-op - formation of fibrosis with early de-pigmentation in the area of Orbit SDS needle penetration, which had expanded at 1-year post-op with SRF



On FA, the lesion filling begins in the arteriovenous and venous stage, with max staining at late stage – also suggesting choroidal pathology – Type 2 CNV



OpRegen TAI / Orbit SDS Treated

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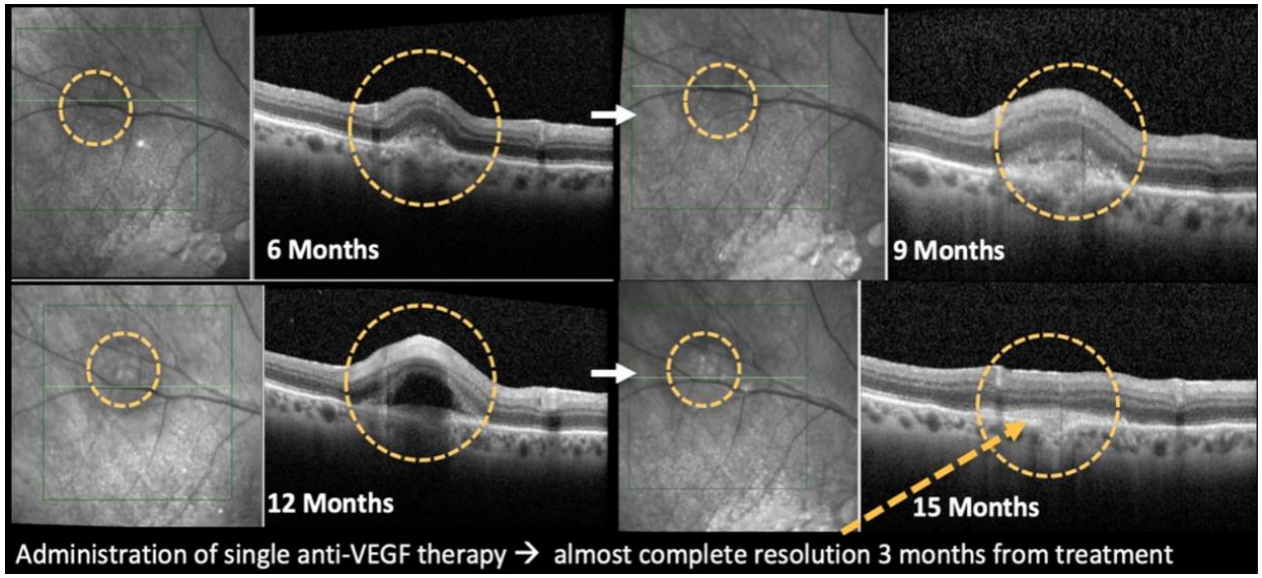
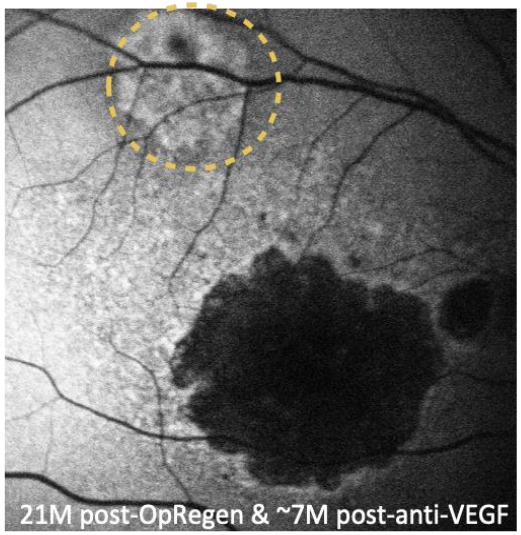
Case Study (Patient #16)– Type 2 CNV Successfully Treated with anti-VEGF

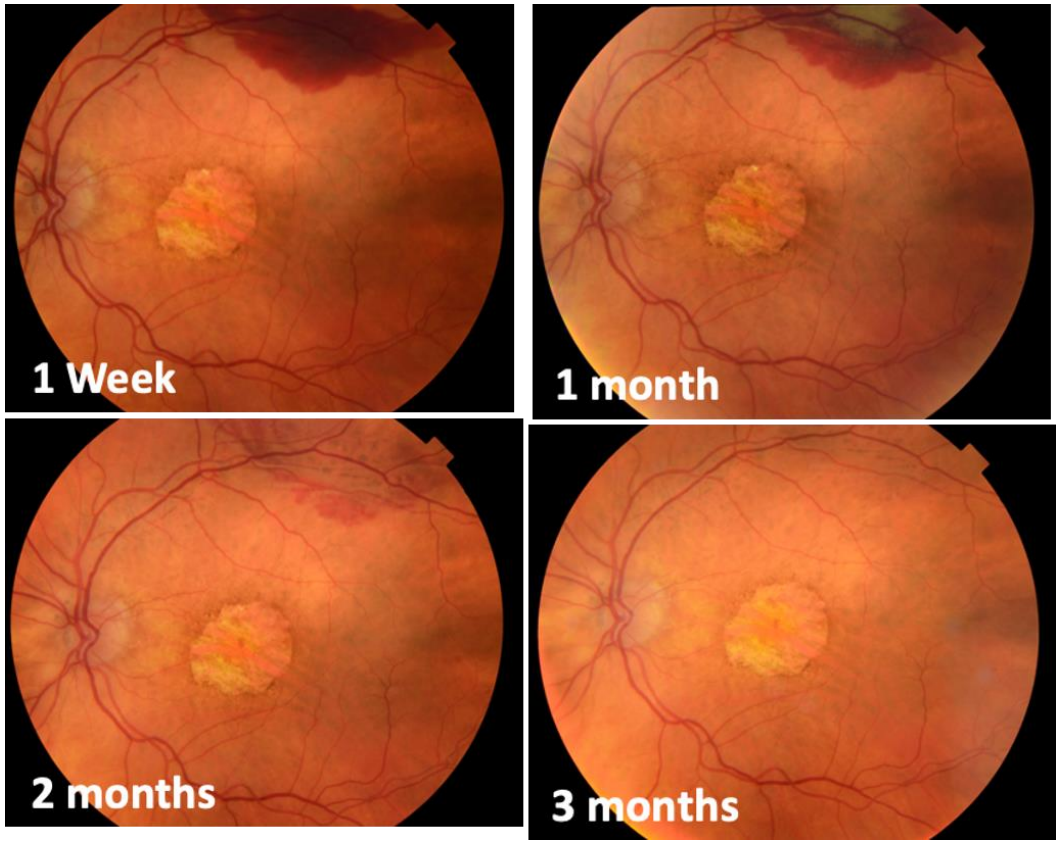




- **Subsequent recheck approximately 21M post-OpRegen (7 months post-anti-VEGF) show no evidence of recurrence or fluid and no clinical indication for additional anti-VEGF**
- **There appears to be some area of asymptomatic scarring, likely at site of needle penetration, most clearly visible via FAF**

OpRegen TAI / Orbit SDS Treated

Case Study (Patient #24) – Subretinal hemorrhage



- **Long procedure with surgical access problems**
- **Subretinal hemorrhage noted 1 day post-op**
- **Auto-resolved 3 months post-op**
- **Without intervention**
- **No adverse sequelae**

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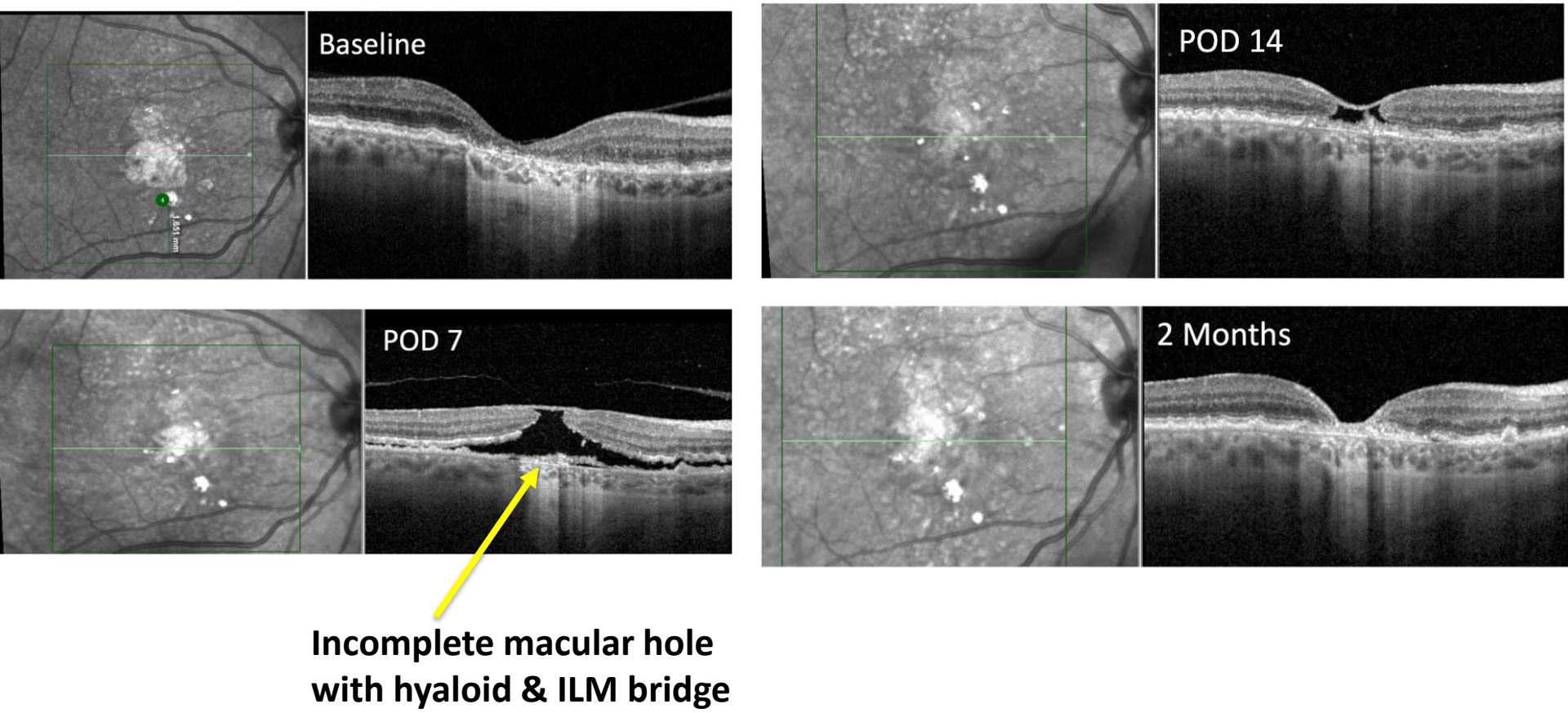
Case Study (Patient #22) – Auto-resolving Incomplete Macular Hole



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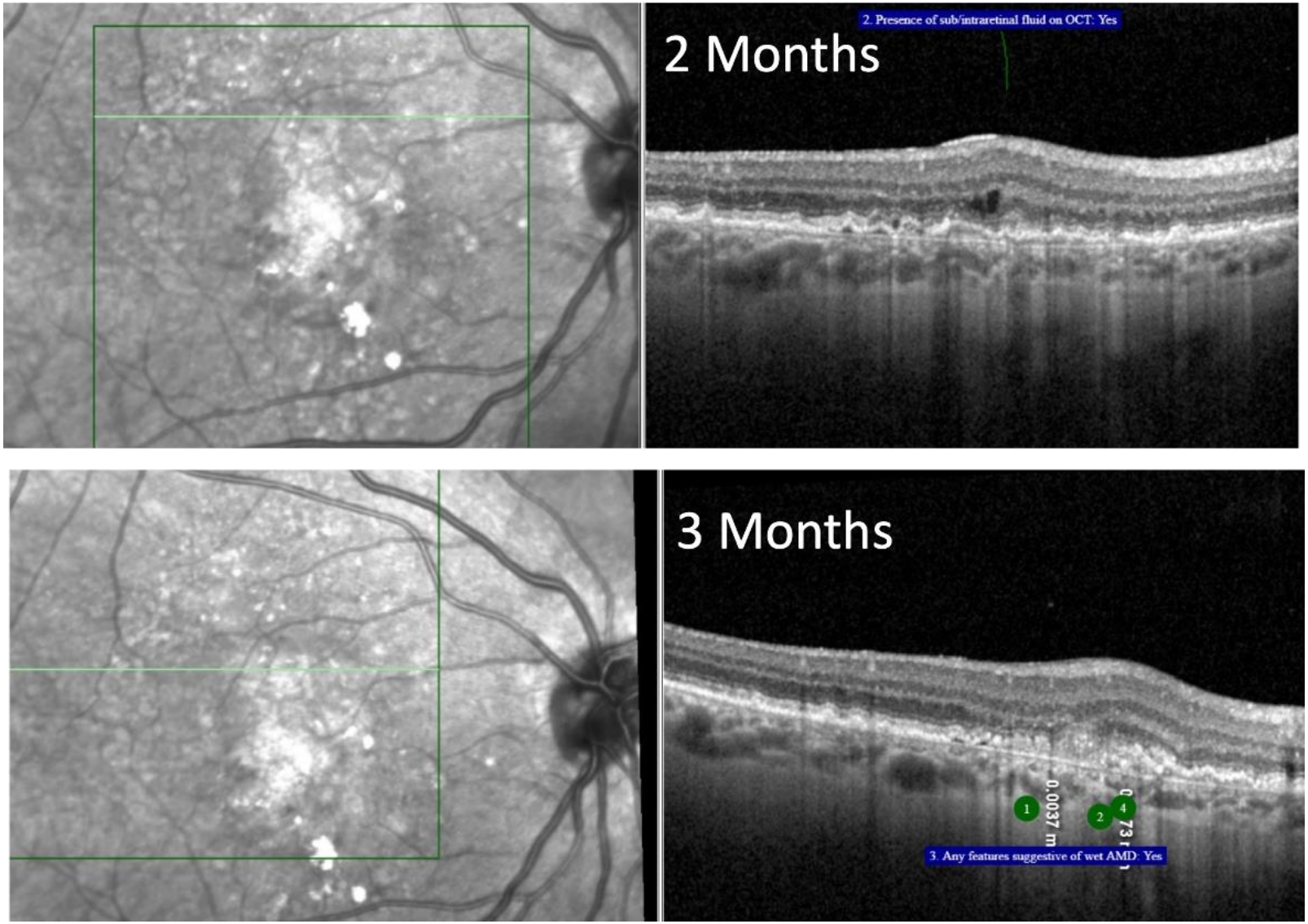
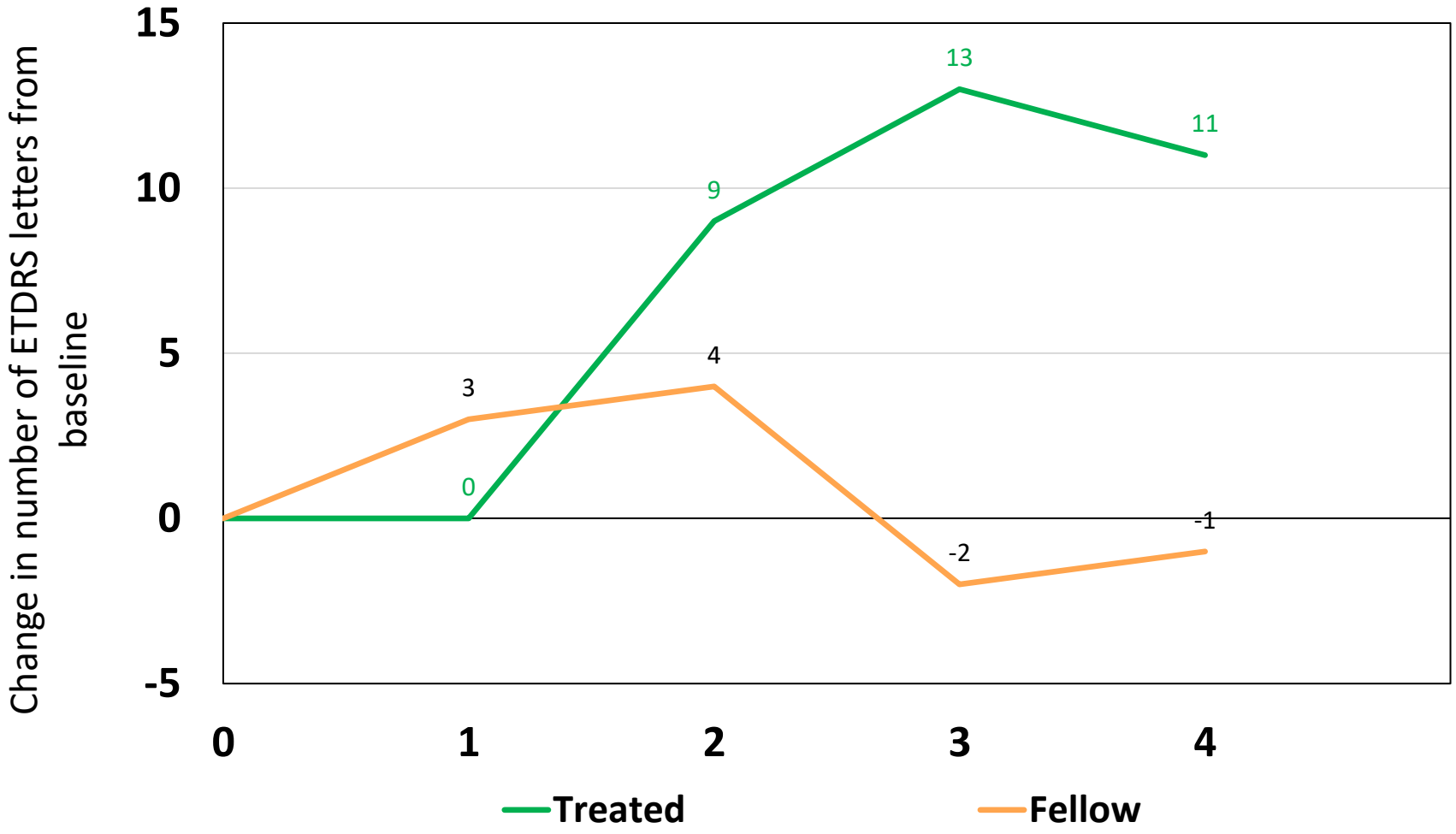
Case Study (Patient #22) – Potential New CNV



OpRegen TAI / Orbit SDS Treated

Case Study (Patient #22) Vision in Treated Eye Drastically Improved

BCVA Changes (via Orbit SDS) Treated vs. Fellow Eye



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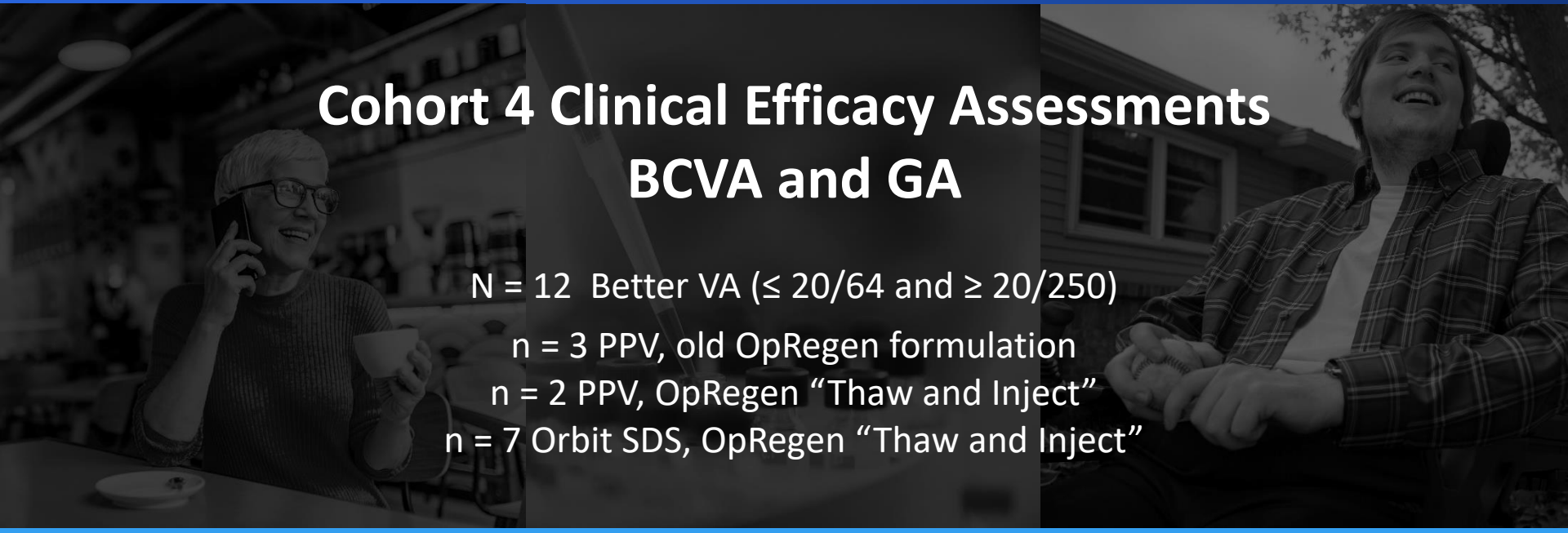


Cohort 4 Clinical Efficacy Assessments BCVA and GA

N = 12 Better VA (≤ 20/64 and ≥ 20/250)

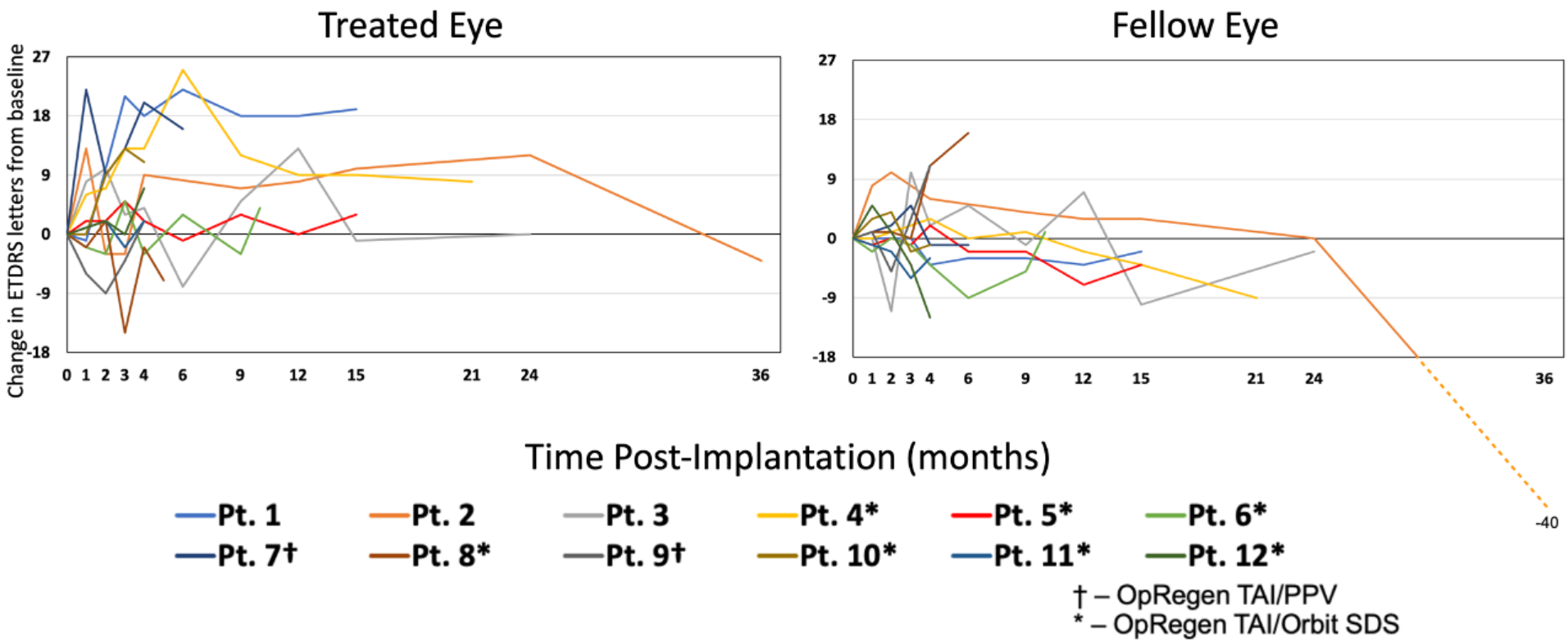
n = 3 PPV, old OpRegen formulation

n = 2 PPV, OpRegen “Thaw and Inject”

n = 7 Orbit SDS, OpRegen “Thaw and Inject”

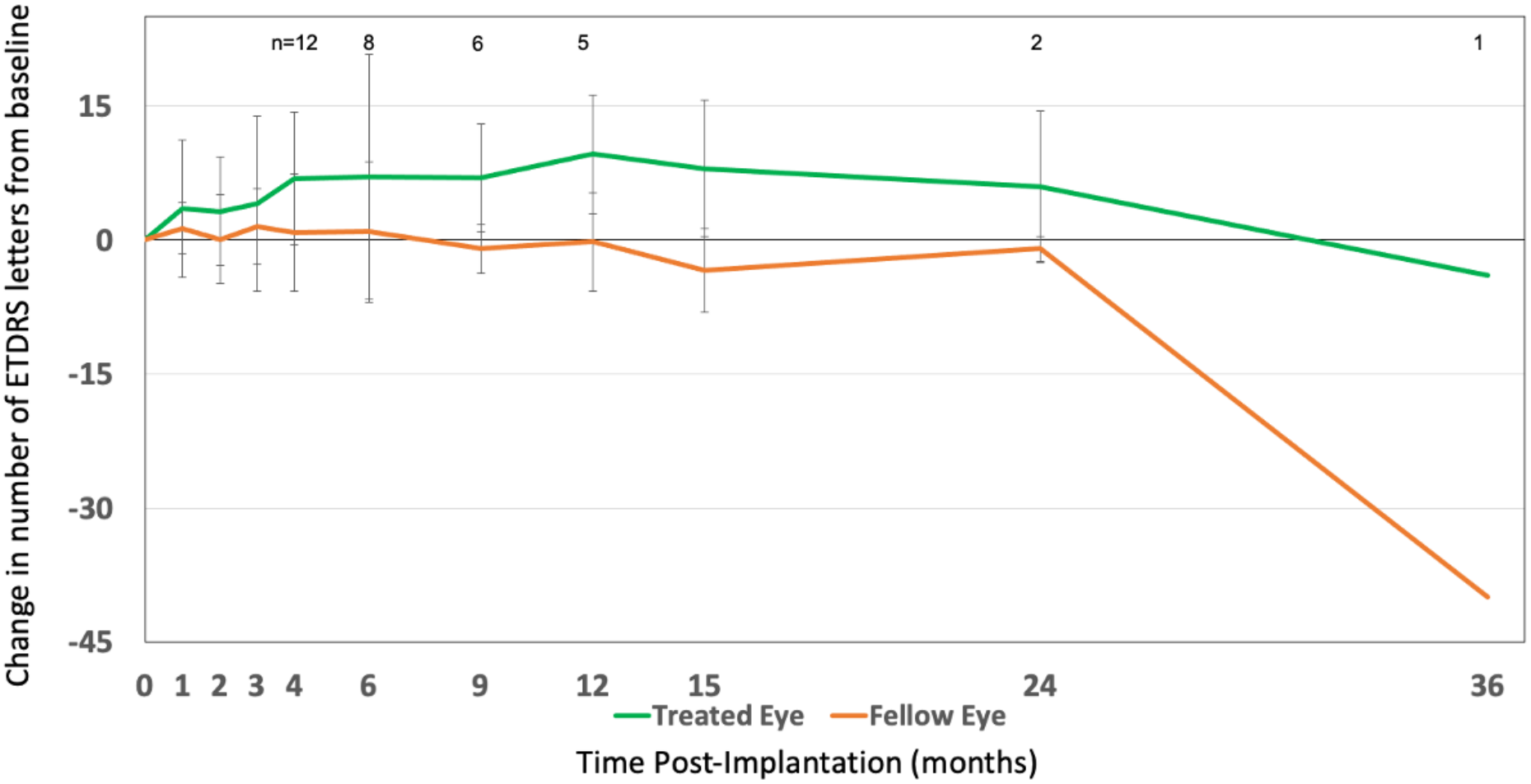
Improvements in Visual Acuity Observed

Cohort 4 BCVA – Individual Changes in Number of ETDRS Letters Read from Baseline



Improvements in Visual Acuity Observed

Mean Change in Cohort 4 BCVA – Treated and Fellow Eye



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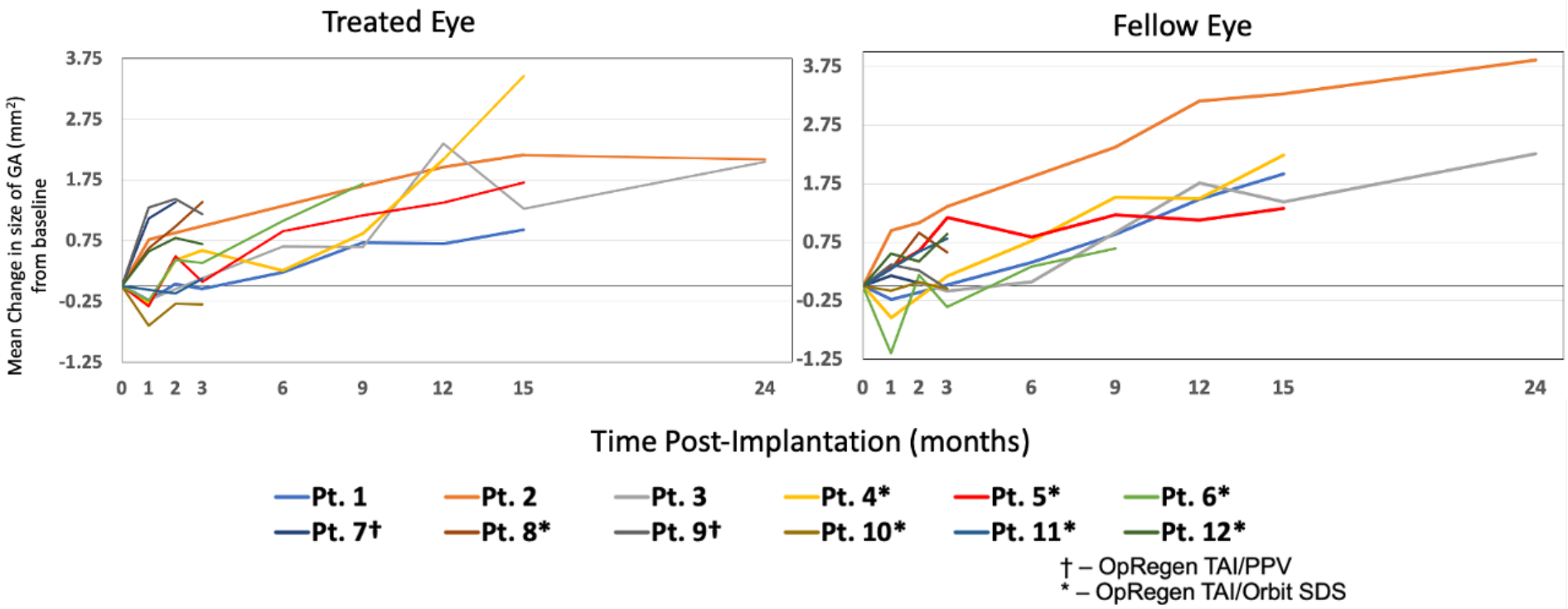
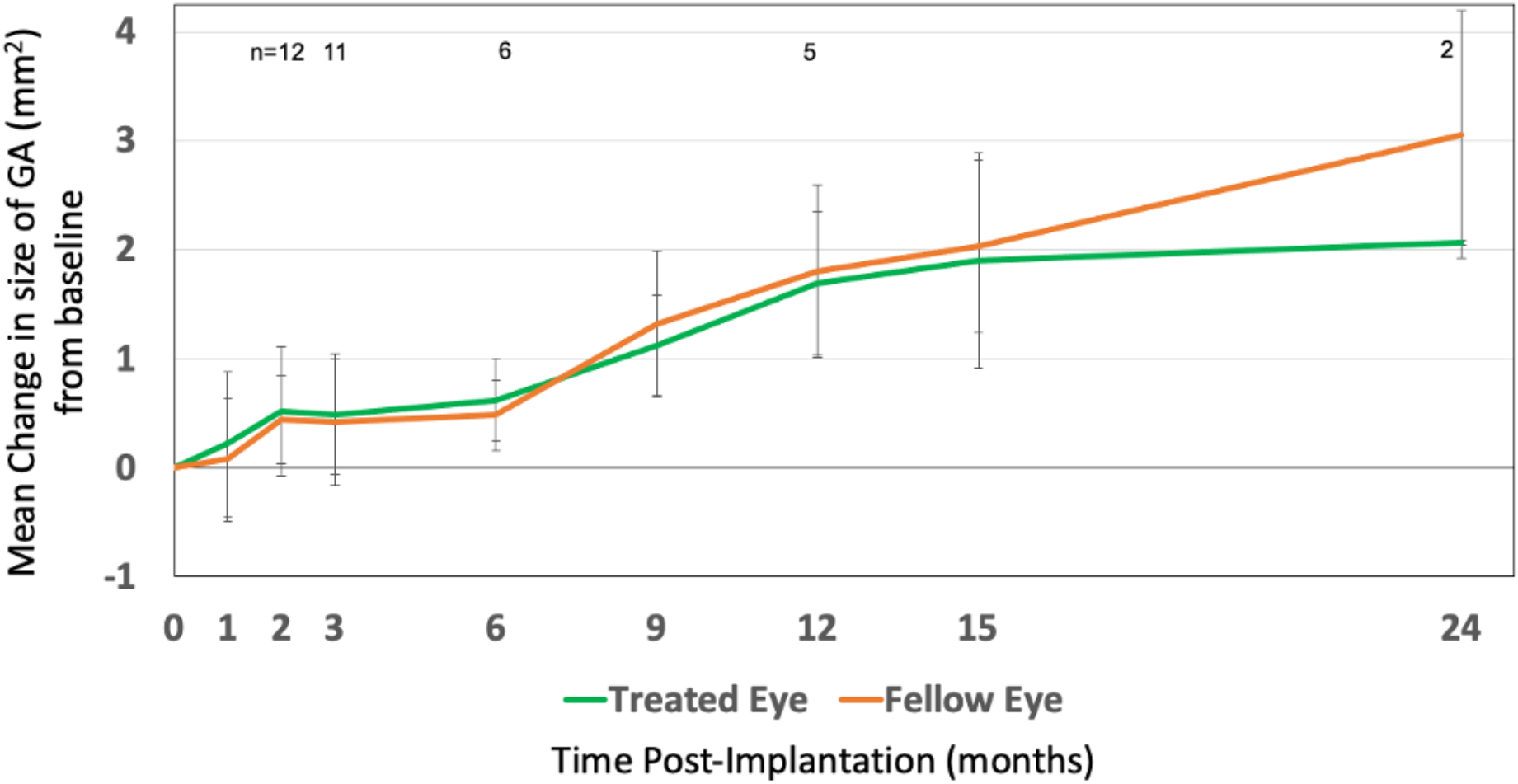
A Trend Towards Slower Atrophy Growth Observed

Individual Changes in Cohort 4 GA (mm^2)



A Trend Towards Slower Atrophy Growth Observed

Mean Change in Cohort 4 GA (mm^2) – Treated and Fellow Eye



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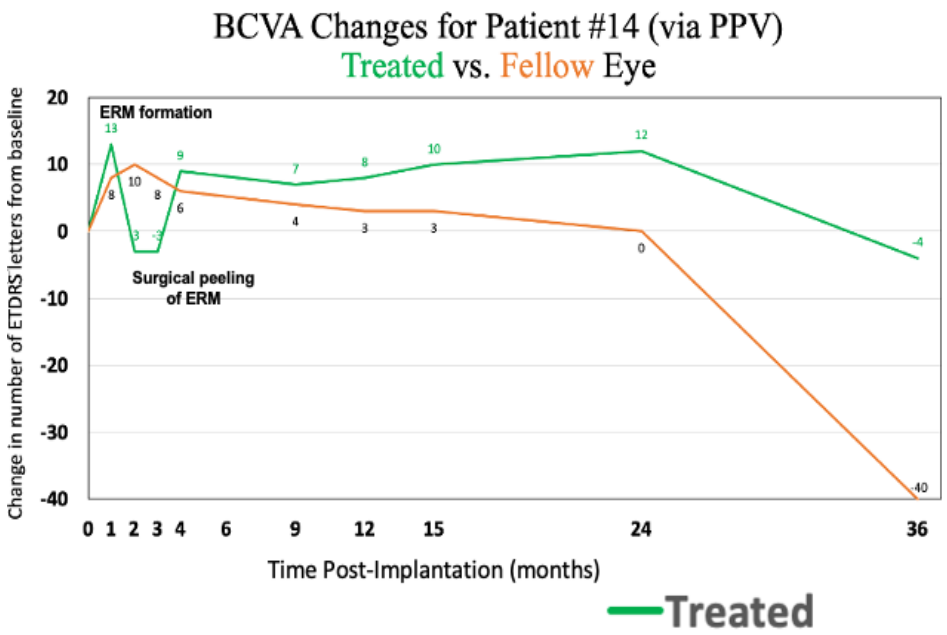
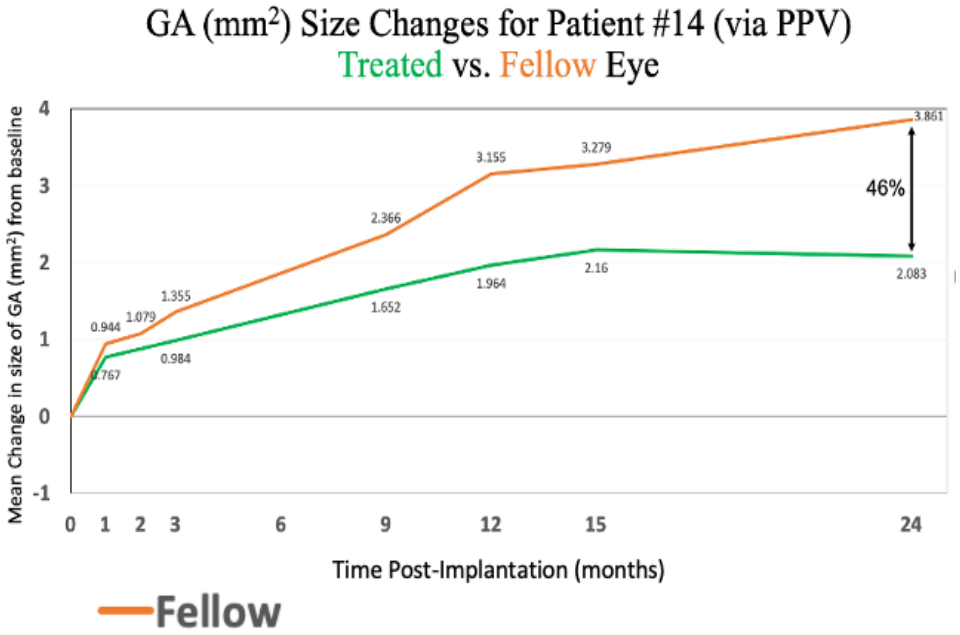
Individual Responder with Durable Improvements

BCVA and GA (mm^2) Changes for Patient #14
Treated vs. Fellow Eye





Time point	Fellow (OD)	Treated (OS)
Baseline	61 letters read (20/63)	54 letters read (20/80)
3 years post-op	21 letters read (20/400)	50 letters read (20/100)

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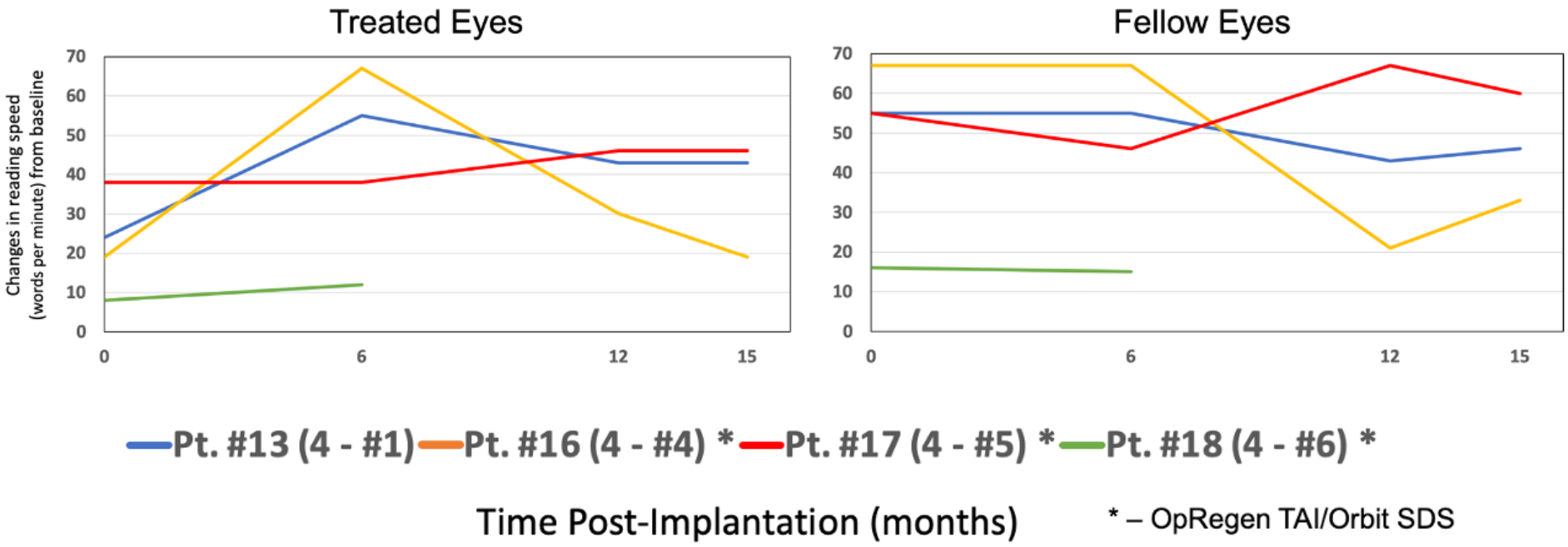
Reading Speed Appears Improved in Treated Eyes

Cohort 4 Reading Speed (MNRead) – Individual Changes in All Eyes with Post-Baseline Assessment



Positive Patient-Reported Outcomes (Quality of Life Questionnaire)

- **National Eye Institute (NEI) Visual Function Questionnaire (VFQ-25)**
- **25 vision-related questions reported across 11 constructs**
- **Improvement occurred in 9 of 11 categories and remained unchanged in one category in Cohort 4 patients**

	Category	N (%) Change from Screening to Year 1 (n=5 available to date)
1.	General Vision	4/5 (80%) patients reported improvement
2.	Ocular Pain	2/5 (40%) patients reported improvement
3.	Near Activities	5/5 (100%) patients reported improvement
4.	Distance Activities	3/5 (60%) patients reported improvement
5.	Vision Specific: Social Functioning	3/5 (60%) patients reported improvement
6.	Vision Specific: Mental Health	5/5 (100%) patients reported improvement
7.	Vision Specific: Role Difficulties	4/5 (80%) patients reported improvement
8.	Vision Specific: Dependency	3/5 (60%) patients reported improvement
9.	Driving	0/5 (0%) patients reported improvement (only 2 subjects were driving at screening)
10.	Color Vision	0/5 (0%) no change from screening (all patients previously reported highest possible score, no improvement possible)
11.	Peripheral Vision	2/5 (40%) patients reported improvement

Previously Reported Study Observations Continue

- **OpRegen continues to be well-tolerated in all treated patients (N = 24);**
  - Even in 2 patients with less immunosuppression (COVID or other health conditions)
- **Sustained subretinal pigmentation continues to suggest OpRegen durability;**
- **Improved anatomy and function in some patients continues to be observed:**
  - Reduction in drusen
  - Restoration of photoreceptor and RPE layers in some patients.
  - Localized slowing of GA progression in treated areas and a trend towards slower GA growth in treated versus fellow eyes continue to be observed.
  - Better visual acuity, VFQ-25 scores, and reading speed have been observed in some early Cohort patients and most Cohort 4 patients.
- **Earlier intervention in less severely affected patients and more central placement of the transplanted OpRegen cells may increase likelihood of a clinically beneficial effect;**

Study Conclusions and Discussion

- **Post-treatment surgical interventions occurred in four cases (5 events in 4 patients);**
  - Three epiretinal membranes (ERM) were surgically peeled. Mild to moderate ERM were observed in an additional 12 of 17 PPV operated patients. Most ERMs were clinically insignificant.
  - Retinal detachment (RD) was observed in 2 out of 17 patients receiving cells via PPV and retinotomy, neither of which appears to be attributable to OpRegen or any study related medications:
    - The first case of RD, in a Cohort 3 patient, was an unsuccessful repair of a post-surgical retinal tear; visual acuity did not regain baseline levels;
    - The second case of RD, in a Cohort 4 patient, was successfully repaired; post-surgical visual acuity has remained higher than baseline.
- **No Orbit SDS patient has required reoperation to date; multiple devices were utilized in 5 out of 7 patients;**
- **CNV was observed in 3 out of 7 patients receiving OpRegen via the Orbit SDS, all of whom received treatment with an approved anti-VEGF;**

Study Conclusions and Discussion (*continued*)

- **OpRegen TAI formulation delivered was utilized in 7 Orbit SDS and 2 PPV-treated patients;**
- **Slow resorption of subretinal fluid, without sequelae, was observed in Orbit SDS / TAI treated patients;**
- **Enrollment is complete, follow-up is ongoing;**
- **Ongoing assessments of clinical benefit are utilizing detailed OCT analyses in addition to standard FAF measurements;**
- **Due to the slow progressive nature of dry AMD with GA, patients will be followed for further evaluation of reductions in growth rate of GA.**

Promising Results (ARVO 2021 Summary)

- **83% of all Cohort 4 patients (the intended commercial population) have experienced increased BCVA**
- **Visual acuity continues to decline in the majority (83%) of untreated eyes**
- **Positive interim patient-reported outcomes reported on NEI Visual Function Questionnaire**
- **OpRegen cell transplant has been well tolerated with no cases of rejection**
- **Immunosuppressive regimen has been reduced from 1 year to ~90 days**
- **A trend towards slower GA growth has continued**
- **Encouraging findings across unrelated assessments; various patients have exhibited evidence for one or more of:**
  1. **Reduced growth of geographic atrophy**
  2. **Improved visual acuity, reading speed, and/or retina structure**
  3. **Reductions in waste material (drusen)**
  4. **Stable engraftment of cells (5+ years and counting)**
  5. **Previously reported evidence of retinal restoration has persisted to month 35 (continuing to monitor)**

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OpRegen – Positioned for Commercial Success

OpRegen has been designed to capture a more than billion-dollar opportunity:

- **Transplanting RPE cells may provide benefits other approaches cannot**
- **Market opportunity is not limited to monogenic deficiencies (e.g. gene therapy)**
- **Treatment to date has been well-tolerated**
- **Some patients have exhibited clinically meaningful improvements in clinically-relevant metrics such as visual acuity, GA growth, and reading speed**
- **Potential for recurring revenues, but with multiple treatments years apart**
- **May have application in other retinal diseases (example: Stargardt's Disease)**
- **Issued patents cover aspects of production, characterization, and formulation**
- **Fast Track designation from FDA**
- **Exclusive option to evaluate alternate delivery device**
- **Opportunities for strategic partnerships for late-stage development**

Our Goal is to Provide Life-Changing Cell Therapies to Patients

Lineage Cell Therapeutics: Bringing the Promises of Cell Therapy into Clinical Reality

3 clinical-stage programs with billion-dollar potential and partnership opportunities

World class in-house process development and GMP manufacturing

One of the largest patent portfolios in cell therapy

Funded well into 2023 with cost-efficient business model

Leader in the emerging field of regenerative medicine

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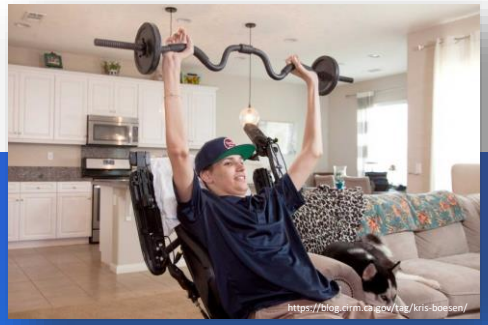
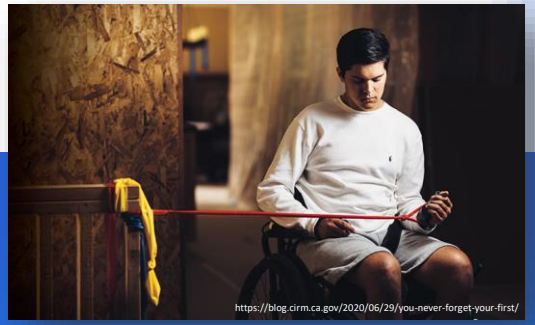
The Patients Are Our Inspiration.
View their stories at **lineagecell.com/media/#patients**

OPC1 SCiStar Study Participants

Lucas Lindner
"There's no reason to not look forward in the same way now that I had before all of this happened. I'm looking forward to driving again… it's a bright future."



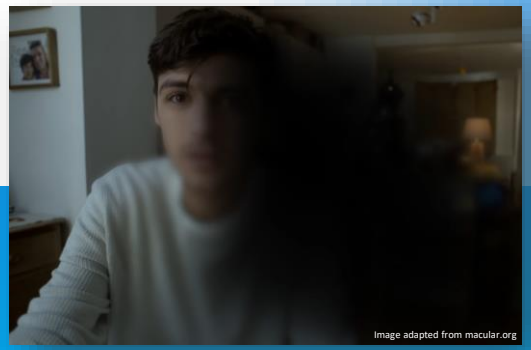
Kris Boesen
"I couldn't drink, couldn't feed myself, couldn't text or pretty much do anything, I was basically just existing. I wasn't living my life, I was existing."



Jake Javier
"Even though it's a completely different perspective, I can still lead that way. I can just try to be the best I can and to persevere the best I can."
Diablo Magazine, Feb. 16, 2017

The Millions Worldwide Suffering from Dry AMD Vision Loss

"Macular degeneration is a very frustrating condition which can greatly affect your day-to-day life."
- Macular Society



Courtesy of CIRM, American Macular Degeneration Foundation, and Macular Society