

**Hawaiian Eye and Retina 2025, Kauai, Hawaii, January 18–24, 2025**

# **Pooled Functionality Data of Revakinagene Taroretcel in Patients With Macular Telangiectasia Type 2**

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and the MacTel Study Investigators

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# Financial Disclosures

- W. Lloyd Clark has the following disclosures:
  - Consultant (Amgen, Bayer, Cardinal Health, Genentech/Roche, Neurotech, Ocular Therapeutix, Regeneron); Grant Support (Bayer, Eyepoint, Genentech/Roche, Kodiak, Notal Vision, Ocular Therapeutix, Oculis, Outlook, Regeneron); Speakers Bureau (Genentech/Roche, Regeneron)
- These trials were funded by Neurotech Pharmaceuticals
- This study includes research conducted on human subjects. Institutional Review Board approval was obtained prior to study initiation

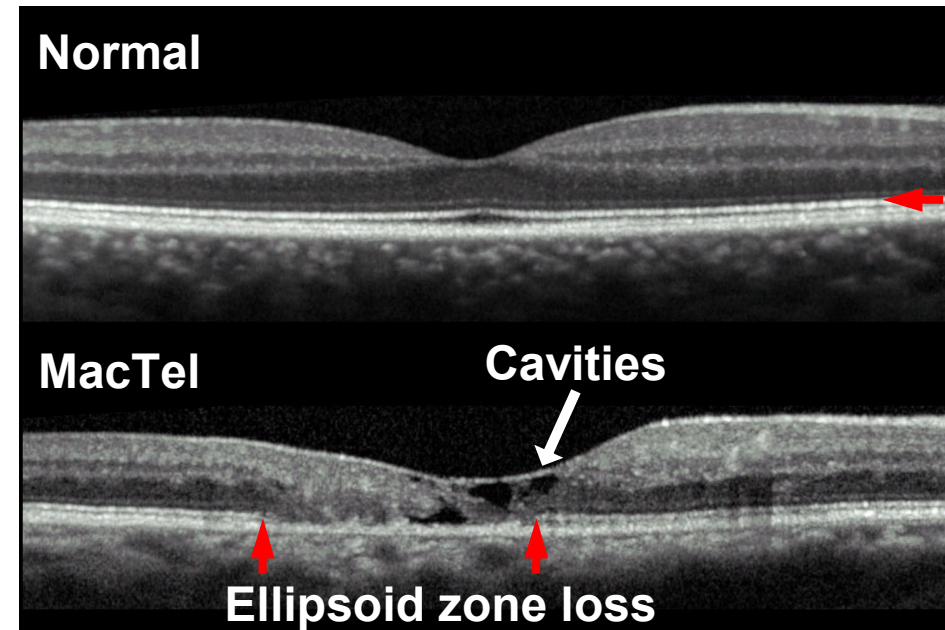
# Take Home Points

- NT-501 conferred both **anatomic and visual function benefits** across three randomized, sham-controlled studies
- Relative to sham, NT-501 demonstrated a:
  - preservation of anatomy
    - 36% reduction in photoreceptor loss
  - preservation of function
    - 68% reduction in reading speed loss
    - 35% reduction in retinal sensitivity loss<sup>a</sup>

# Macular Telangiectasia Type 2 (MacTel) Is a Neurodegenerative Disease That Leads to Vision Loss<sup>1,2</sup>

- MacTel is a bilateral, progressive retinal neurodegenerative disease
  - Leads to vision loss and functional impairment<sup>1,2</sup>
  - Associated with abnormalities in Müller glia, retinal pigment epithelium, and photoreceptors in the central retina<sup>3,4</sup>
  - Characterized by progressive loss of the ellipsoid zone on SD-OCT<sup>3</sup>

## SD-OCT



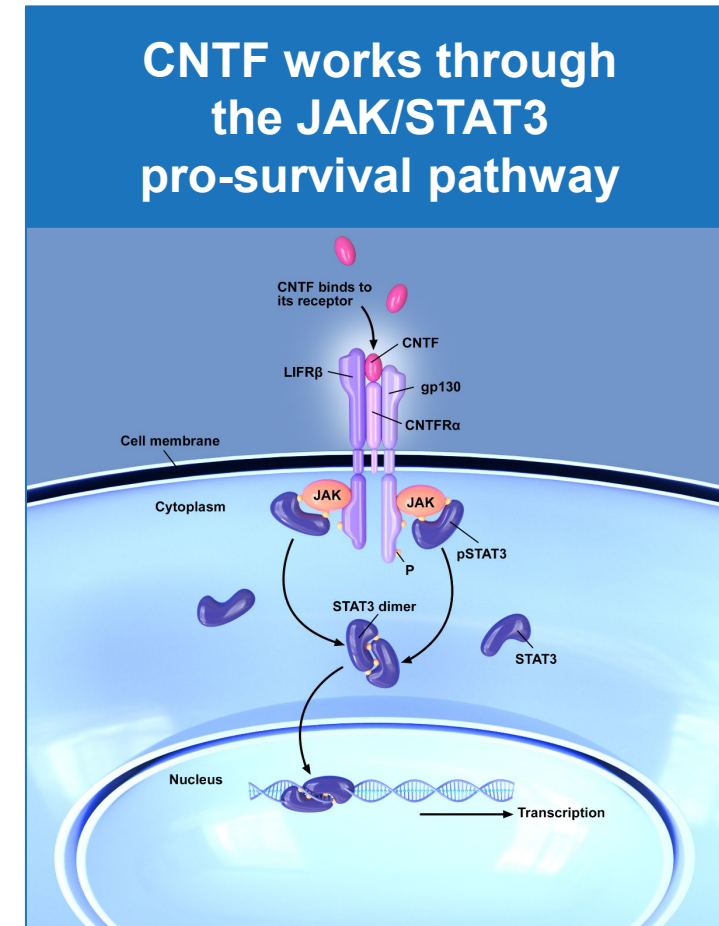
MacTel, macular telangiectasia; SD-OCT, spectral-domain optical coherence tomography.

1. Charbel Issa P, et al. *Prog Retin Eye Res.* 2013;34:49-77. 2. Heeren TFC, et al. *Ophthalmology.* 2020;127:1539-48. 3. Heeren TFC, et al. *Retina.* 2018;38(suppl 1):S20-S26.

4. Kedariseti KC, et al. *Clin Ophthalmol.* 2022;16:3297-309.

# CNTF Is a Potent Neuroprotectant<sup>1-3</sup>

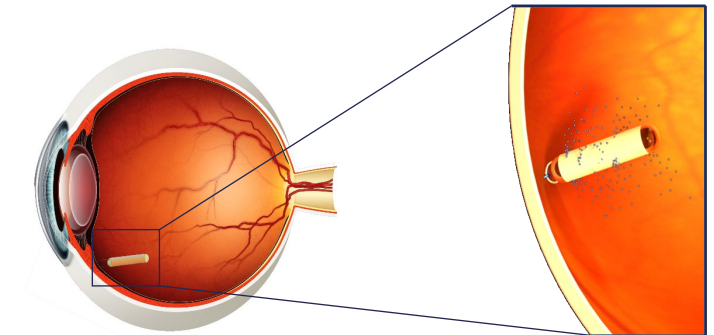
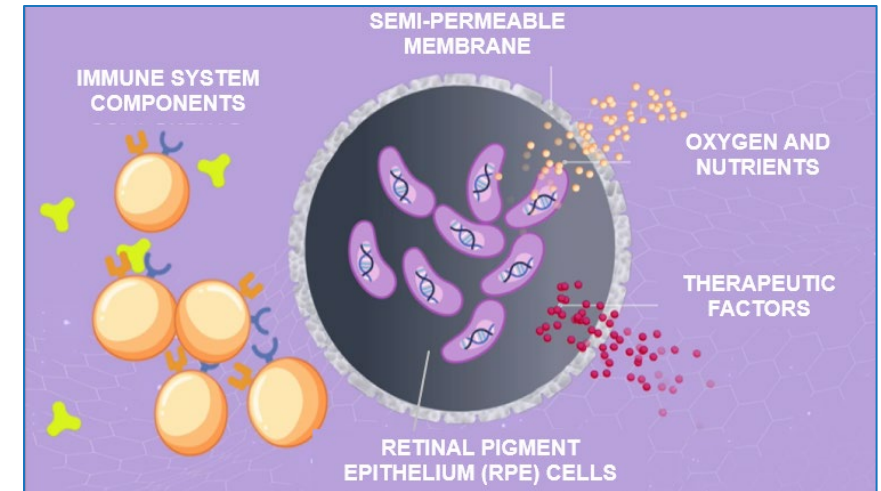
- In response to injury, Müller glial cells release the neuroprotective factor CNTF<sup>1</sup>
- **CNTF protects and preserves photoreceptors<sup>2-4</sup>**
- In preclinical models of retinal degeneration, photoreceptors can be rescued with intravitreal injection of CNTF<sup>2,4</sup>





# Encapsulated Cell Therapy Is Designed to Deliver Sustained Levels of CNTF

- NT-501 is a first-in-class encapsulated cell therapy<sup>1-3</sup>
  - Houses NTC-201-6A cells<sup>1</sup>
  - Allogenic retinal pigment epithelial cells with a unique expression vector for CNTF release<sup>1</sup>
  - Surgically implanted into the vitreous cavity<sup>2</sup> and stably anchored to the sclera<sup>4</sup>
  - Developed to produce long-term sustained levels of CNTF<sup>2</sup>
  - The FDA has set a PDUFA date of March 18, 2025



# NT-501 Has Been Studied Across 3 Randomized, Sham-controlled Clinical Trials

	NTMT-02 <sup>a</sup> 67 participants 99 eyes <sup>d</sup> All-treated population	NTMT-03A <sup>b</sup> 115 participants 115 eyes All-treated population	NTMT-03B <sup>c</sup> 113 participants 113 eyes All-treated population
Key inclusion criteria	Aged >21 to <80 years; Diagnosis of MacTel		
	<ul style="list-style-type: none"><li>• EZ break between 0.16 mm<sup>2</sup> and 4.00 mm<sup>2</sup></li><li>• BCVA of ≥64 ETDRS letters</li></ul>	<ul style="list-style-type: none"><li>• EZ break between 0.16 mm<sup>2</sup> and 2.00 mm<sup>2</sup></li><li>• BCVA of ≥54 ETDRS letters</li></ul>	
Randomization	NT-501: 16 participants <sup>d</sup> Sham: 19 participants NT-501 + Sham: 32 participants	NT-501: 58 participants Sham: 57 participants	NT-501: 59 participants Sham: 54 participants
Primary endpoint	Change from baseline in EZ area loss at Month 24	Rate of change from baseline in EZ area loss through Month 24	
Secondary endpoints	Reading speed, aggregate retinal sensitivity (microperimetry), BCVA (safety)		
Each study lasted 24 months			

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; EZ, ellipsoid zone; MacTel, macular telangiectasia type 2;

NT-501, revakinagene tarorelcel.

<sup>a</sup>NCT01949324. <sup>b</sup>NCT03316300. <sup>c</sup>NCT03319849. <sup>d</sup>Participants with one eligible eye (35 participants) received NT-501 (16 eyes) or sham (19 eyes). In participants with two eligible eyes (32 participants), one eye received NT-501 (32 eyes) and one eye received sham procedure (32 eyes). If both eyes were eligible, right eye was randomized 1:1 to sham or NT-501 and left eye received other surgery.

# Rationale for a Pooled Functionality Analysis

- Rare disease
- Inherent variability of outcome measures<sup>1-3</sup>
- Similar populations and study designs
- Increase the sample size

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ARVO Annual Meeting Abstract • June 2024

# Reducing Test-Retest Variability of the E-ETDRS Test with Hierarchical Bayesian Modeling

Yuhai Zhao<sup>1</sup>, Luis A. Lerner<sup>1</sup>, Michael Dorr<sup>1</sup>, Zheng S. Li<sup>1</sup>, et al.

+ Author Affiliations & Notes

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## Clinical and Epidemiologic Research

### Test–Retest Variability of Reading Performance Metrics Using MNREAD in Patients with Age-Related Macular Degeneration

Praveen J. Patel,<sup>1</sup> Fred K. Chen,<sup>1,2</sup> Lyndon L. Allibab<sup>1</sup>

*Alibaba et al. Int J Retin Vis (2020) 6:16  
https://doi.org/10.1186/s40942-020-00217-0*

International Journal of Retina and Vitreous

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## Abstract

**Purpose:** Visual acuity (VA) is the primary endpoint in clinical trials for AMD, however, the high test-retest variability of VA signals, we designed a hierarchical Bayesian model to reduce the variability of E-ETDRS testing by gold standard ETDRS chart.

**Methods:** We initiated post-hoc analysis of the generative model of trial-by-trial probability. The model comprises two parameters required to achieve a specific per-reading VA behavior changes with increasing distance procedures were developed to testing: (1) A Bayesian Inference Procedure distribution of VABF parameters independent hierarchical Bayesian model (HBM) that parameters and hyperparameters from (2021A), and (3) A hierarchical Bayesian model computes the joint distribution of the VABF both E-ETDRS and qVA (Lesmes & Dorr, 2014). We applied to a VA dataset obtained from each of 4 Bangerter log conditions with 1000 trials. We assessed TRV1, 96-test-retest difference derived from the repeated E-ETDRS test.

**Results:** Figure 2 displays the Bland-Altman from the original E-ETDRS procedure at 0.17 for the original C, 0.19 for BIP, 0.14 for TRV1 for BIP is comparable to that of E-ETDRS by 22% and 30%, respectively.

**Conclusions:** By integrating information of the E-ETDRS tests. Integrating information tests, the HBM integrated the greatest repeat post-hoc procedures can be employed

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## Original Article

### Test–retest variability of microperimetry in geographic atrophy

A. Yasin Alibhai<sup>1</sup>, Nihal Mehta<sup>1†</sup>, Sheila Hickson-Curran<sup>2</sup>, Carlos Moreira-Neto<sup>3</sup>, Emily S. Levine<sup>1</sup>, Elias Reichel<sup>1</sup>, Jay S. Duker<sup>1</sup> and Nadia K. Waheed<sup>1\*</sup>

**Abstract**

**Purpose:** Microperimetry (MP) allows for measurement of retinal sensitivity at precise locations and is now commonly employed as a clinical trial endpoint. Test–retest reliability is important when evaluating treatment effects in patients with geographic atrophy (GA). This study aimed to determine the test–retest variability of MP in patients with moderate to severe GA using the MAIA MP device.

**Methods:** In this prospective study, patients with a confirmed diagnosis of foveal-involving GA were enrolled. Participants performed three MP assessments of a selected eye over two visits with the Macular Integrity Assessment (MAIA) 2 instrument (Centervue, Padova, Italy) utilizing a wide 30° grid, consisting of 93 stimuli (Goldmann III) using a 4–2 representation strategy, encompassing the entire area of GA and beyond. Mean retinal sensitivity (RS) was expressed as an average threshold value (dB) for the entire field tested. Coefficients of Repeatability at a 95% level (CRA95%) were calculated for Point Wise Sensitivity (PWS). Fixation stability (FS) was assessed by evaluating the area of an elliptical representation encompassing 95% of the cloud of fixation points (CFP) dataset generated by the MAIA MP known as the bivariate contour ellipse area (BCEA).

**Results:** A total of 8 subjects were enrolled (21 tests), with six subjects completing 3 MP assessments. BCVA in these patients ranged from 20/100 to 20/800. The mean area of GA was 18.7 ± 12.3 mm². The average time to complete one MP assessment was 13 min 9 s and mean BCEA95% was 35.5 ± 19.2°. The MS was 14.3 ± 4.5 dB. No significant increase in MS was noted between testing pairs 1&2 and 2&3. The preferred retinal locus was maintained in the same quadrant on successive tests. The mean CRFS for PWS were similar for testing pairs 1&2 (± 3.50 dB) and 2&3 (± 3.40 dB).

**Conclusion:** Microperimetry using a wide grid can be reliably performed in a reasonable amount of time in patients with moderate and severe vision loss secondary to GA. There was no learning effect seen between sequential assessments when analyzing MS or PWS. A change of approximately 4 dB in PWS provides a threshold for considering a true change in this patient cohort.

**Introduction**

Microperimetry (MP) is a several-decades old technology designed to test retinal sensitivity at different points on the macula. First developed in the 1980s, MP was initially deployed as part of a scanning laser ophthalmoscope system. In its early forms, MP systems were relatively difficult to use. In the last two decades, however, there has been a resurgence in development of new microperimetry systems, beginning with the Nidek MP-1 and continuing more recently with the Nidek MP-3 and Macular Integrity Assessment (MAIA) 2 systems, which are user friendly with a number of features such as eye tracking.

With newer improvements, microperimetry (MP) has gained more widespread adoption as a means of

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† Nihal Mehta and Nadia K. Waheed are co-first authors  
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# Changes From Baseline in EZ Area Loss, Reading Speed, Retinal Sensitivity, and BCVA Were Assessed

## Assessments

- Change from baseline assessments in the all-treated population in the Phase 3 and Phase 2 studies:
  - Anatomical:
    - Area of photoreceptor (ie, EZ area) loss (primary endpoint)
  - Functional:
    - Monocular reading speed
    - Aggregate retinal sensitivity (microperimetry)
  - Safety:
    - BCVA

# Baseline Demographic Characteristics, by Participant<sup>a</sup>

	Phase 2			Phase 3 (Study A)		Phase 3 (Study B)	
By participant	NT-501 (n=16)	Sham (n=19)	NT-501 + Sham (n=32)	NT-501 (n=58)	Sham (n=57)	NT-501 (n=59)	Sham (n=54)
<b>Female</b> , n (%)	9 (56)	11 (58)	21 (66)	39 (67)	40 (70)	46 (78)	36 (67)
<b>Mean age</b> , years (SD)	60.1 (10.7)	59.4 (7.6)	63.4 (8.4)	61.1 (8.0)	60.2 (8.4)	58.5 (7.6)	58.7 (8.9)
<b>Race</b> , n (%)							
White	12 (75)	16 (84)	30 (94)	50 (86)	48 (84)	55 (93)	47 (87)
Asian	0	1 (5)	0	2 (3)	3 (5)	3 (5)	1 (2)
Black or African American	0	0	1 (3)	1 (2)	2 (4)	0	0
American Indian or Alaska Native	0	0	0	0	1 (2)	0	0
Other	4 (25)	2 (11)	1 (3)	5 (9)	3 (5)	1 (2)	6 (11)
<b>Ethnicity</b> , n (%)							
Hispanic or Latino	1 (6)	0	1 (3)	1 (2)	5 (9)	4 (7)	4 (7)

**Baseline demographic characteristics were well balanced across studies and treatment arms**

# Baseline Ocular Characteristics, by Eye<sup>a</sup>

By eye	Phase 2		Phase 3 (Study A)		Phase 3 (Study B)	
	NT-501 (n=48)	Sham (n=51)	NT-501 (n=58)	Sham (n=57)	NT-501 (n=59)	Sham (n=54)
<b>EZ area loss</b> (mm <sup>2</sup> ), n	48	51	58	57	59	54
Mean (SD)	0.70 (0.42)	0.77 (0.55)	0.51 (0.48)	0.49 (0.36)	0.52 (0.31)	0.48 (0.29)
<b>EZ area category</b> , n (%)						
<0.5 mm <sup>2</sup>	18 (37.5)	20 (39.2)	41 (70.7)	40 (70.2)	31 (52.5)	33 (61.1)
≥0.5 mm <sup>2</sup>	30 (62.5)	31 (60.8)	17 (29.3)	17 (29.8)	28 (47.5)	21 (38.9)
<b>Mean BCVA</b> , ETDRS letter (SD)	77.0 (5.6)	76.2 (6.9)	70.8 (9.11)	73.3 (8.64)	74.4 (7.76)	73.6 (9.23)
Snellen equivalent	20/32	20/32	20/40	20/40	20/32	20/32
<b>Reading speed</b> (wpm), n	47	49	57	56	59	53
Mean (SD)	94.29 (46.13)	107.26 (43.17)	92.09 (43.72)	96.01 (54.01)	96.49 (47.31)	94.09 (42.81)
<b>Retinal sensitivity<sup>b</sup></b> , n	40	45	53	54	52	49
Mean (SD)	89.15 (76.15)	107.96 (106.77)	62.14 (77.58)	59.02 (62.63)	57.92 (56.94)	50.48 (58.36)

**Participants in the Phase 2 trial had greater baseline EZ area loss compared with the Phase 3 studies**

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; EZ, ellipsoid zone; NT-501, revakinagene tarorectel; SD, standard deviation; wpm, words per minute.

<sup>a</sup>Results reported for the all-treated population, unless otherwise noted. Not available in full pool. <sup>b</sup>Results reported for the per-protocol population.

# Baseline Demographic and Ocular Characteristics in Pooled Sample<sup>a</sup>

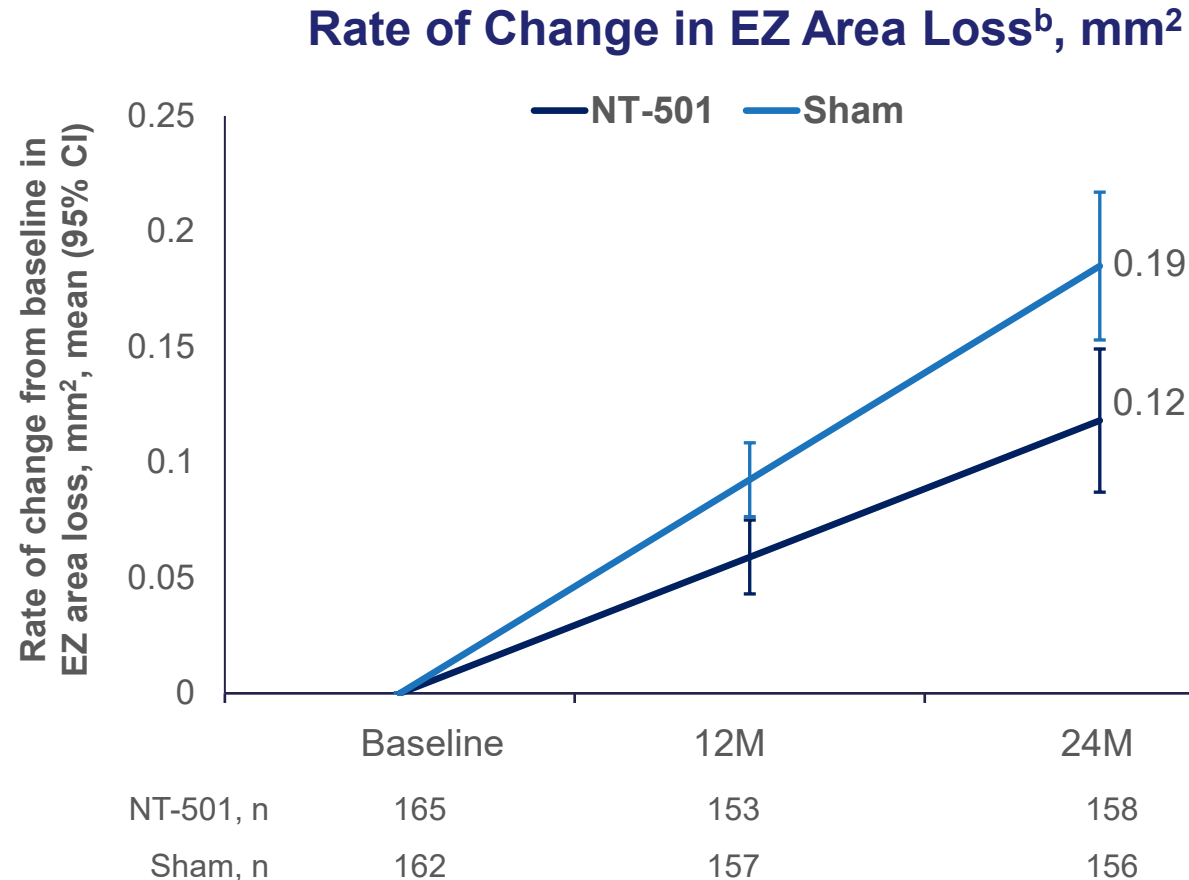
	Phase 2 and Phase 3 Pool <sup>b</sup>	
	NT-501 (n=165)	Sham (n=162)
<b>Demographic characteristics (by participant)</b>		
<b>Female</b> , n (%)	115 (69.7)	108 (66.7)
<b>Mean age</b> , years (SD)	60.5 (8.4)	60.3 (8.6)
<b>Race</b> , n (%)		
White	147 (89)	141 (87)
Asian	5 (3)	5 (3)
Black or African American	2 (1)	3 (2)
American Indian or Alaska Native	0	1 (1)
Other	11 (7)	12 (7)
<b>Ethnicity</b> , n (%)		
Hispanic or Latino	7 (4)	10 (6)
<b>Ocular characteristics (by eye)</b>		
<b>EZ area loss</b> (mm <sup>2</sup> ), n	165	162
Mean (SD)	0.57 (0.41)	0.57 (0.43)
<b>EZ area category</b> , n (%)		
<0.5 mm <sup>2</sup>	90 (54.5)	93 (57.4)
≥0.5 mm <sup>2</sup>	75 (45.5)	69 (42.6)
<b>Mean BCVA</b> , ETDRS letter (SD)	73.8 (8.2)	74.2 (8.5)
Snellen equivalent	20/40	20/32
<b>Reading speed</b> (wpm), n	163	158
Mean (SD)	94.32 (45.50)	98.86 (47.24)
<b>Retinal sensitivity<sup>c</sup></b> , n		
Mean (SD)	-	-

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; EZ, ellipsoid zone; NT-501, revakinagene taroretcel; SD, standard deviation; wpm, words per minute.

<sup>a</sup>Results reported for the all-treated population, unless otherwise noted. Not available in full pool. <sup>b</sup>Per the NTMT-02 study design, participants with two eligible study eyes received NT-501 in one eye and sham in the other eye. These 32 participants are included in both columns for the pooled summary. <sup>c</sup>Results reported for the per-protocol population.

# NT-501 Demonstrated Greater Preservation of EZ Area Over 2 Years Compared With Sham in All Treated Participants<sup>a</sup>

- A 19.3% reduction in photoreceptor loss with NT-501 compared with sham in Phase 2
- A 54.8% reduction in photoreceptor loss with NT-501 compared with sham in Phase 3, Study A
- A 30.6% reduction in photoreceptor loss with NT-501 compared with sham in Phase 3, Study B



**36.2%**  
Reduction in  
Photoreceptor  
Loss  
(p=0.003)

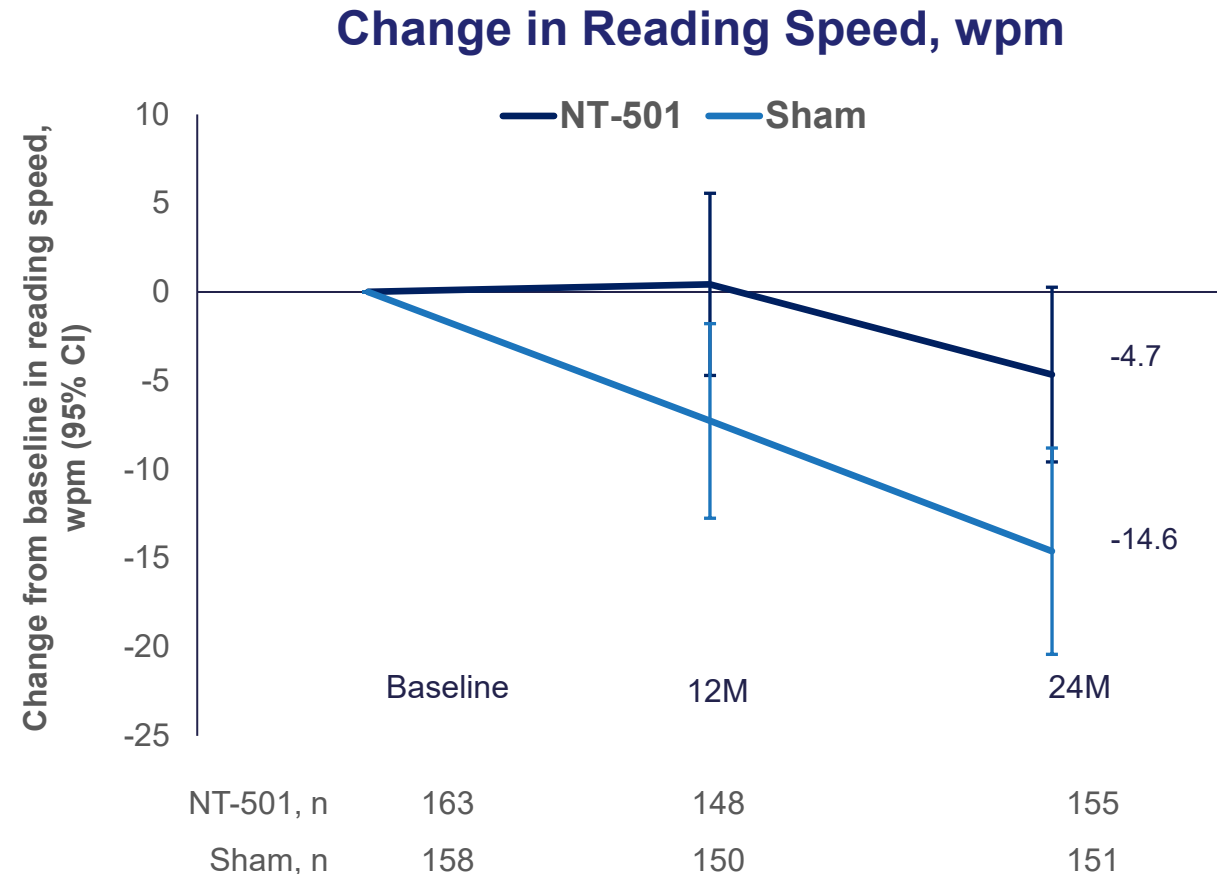
CI, confidence interval; EZ, ellipsoid zone; M, month; NT-501, revakinagene tarorectel.

<sup>a</sup>Per the NTMT-02 study design, participants with two eligible study eyes received NT-501 in one eye and sham in the other eye. These 32 participants are included in both groups for the pooled analysis, by study eye. <sup>b</sup>Rate of EZ change, difference, and CIs from a repeated measures model. The outcome variable is EZ area assessed longitudinally at baseline, Months 12, 16 (Phase 3 only), 18 (Phase 2 only), 20 (Phase 3 only), and 24. At baseline, EZ area is calculated as the mean area across two independent readers. The model includes treatment group, time (continuous), treatment\*time interaction, and participant-specific random intercepts. The difference between treatment groups in rate of EZ change is estimated at Month 12 and Month 24 based on the treatment\*time interaction term.



# NT-501 Preserved Reading Speed Over 2 Years Compared With Sham in All Treated Participants<sup>a</sup>

- A 90.7% reduction in reading speed loss with NT-501 compared with sham in Phase 2
- A 49.3% reduction in reading speed loss with NT-501 compared with sham in Phase 3, Study A
- A 69.1% reduction in reading speed loss with NT-501 compared with sham in Phase 3, Study B

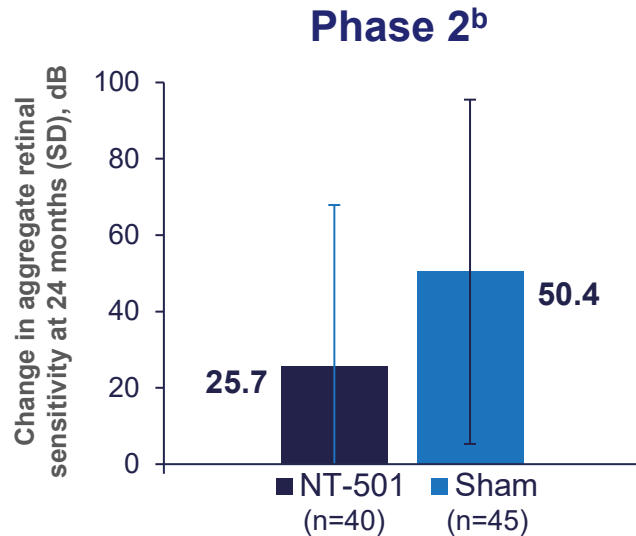


**68.1%**  
Reduction in  
Reading  
Speed Loss  
( $p=0.0104$ )

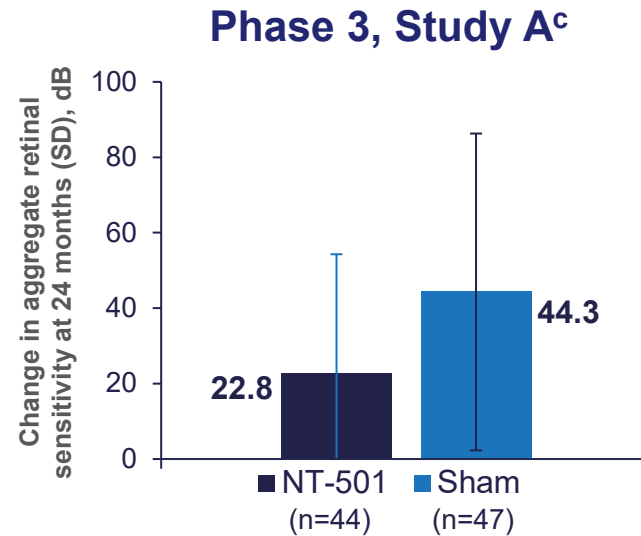
CI, confidence interval; M, month; NT-501, revakinagene tarorectel; SD, standard deviation; wpm, words per minute.

<sup>a</sup>Per the NTMT-02 study design, participants with two eligible study eyes received NT-501 in one eye and sham in the other eye. These 32 participants are included in both groups for the pooled analysis, by study eye.

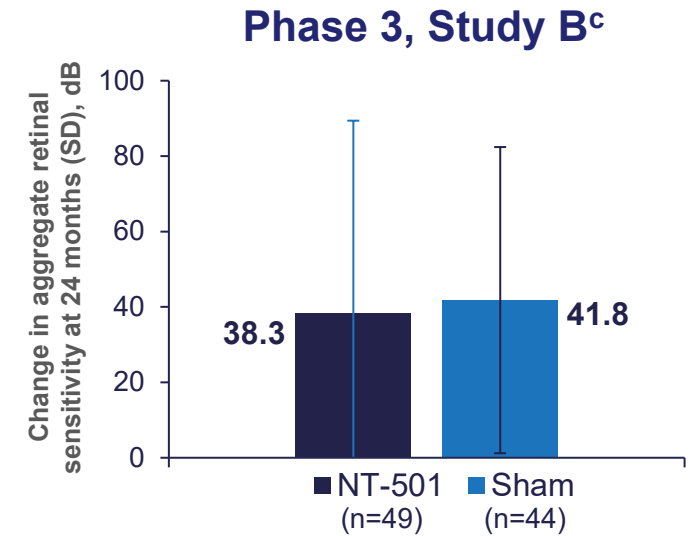
# NT-501 Preserved Aggregate Retinal Sensitivity (Microperimetry) Over 2 Years Compared With Sham<sup>a</sup>



A **49.0%** reduction in aggregate retinal sensitivity loss with NT-501 compared with sham in Phase 2



A **48.5%** reduction in aggregate retinal sensitivity loss with NT-501 compared with sham in Phase 3, Study A



An **8.4%** reduction in aggregate retinal sensitivity loss with NT-501 compared with sham in Phase 3, Study B

**34.8% Reduction in Aggregate Retinal Sensitivity Loss Across the 3 Studies<sup>d</sup>**

dB, decibel; MAIA, Macular Integrity Assessment; NT-501, revakinagene tarorectel; SD, standard deviation.

<sup>a</sup>Retinal sensitivity was measured via MAIA microperimetry. <sup>b</sup>In the Phase 2 study, retinal sensitivity is reported for the per-protocol population, which included all treated subjects who had no major protocol infractions (defined prior to unmasking of the study). Per the NTMT-02 study design, participants with two eligible study eyes received NT-501 in one eye and sham in the other eye. These 32 participants are included in both groups for the pooled analysis by study eye. <sup>c</sup>In the Phase 3 studies, the retinal sensitivity per-protocol population is reported, including all treated subjects who had a baseline and Month 24 microperimetry collected according to study protocol. <sup>d</sup>Results per study in the respective per-protocol populations were weighted by the proportion of treated eyes with non-missing data in each study and combined descriptively.

# BCVA Remained Stable for NT-501 and Sham Treatment Arms

Mean Change in BCVA, (SD)<sup>a</sup>

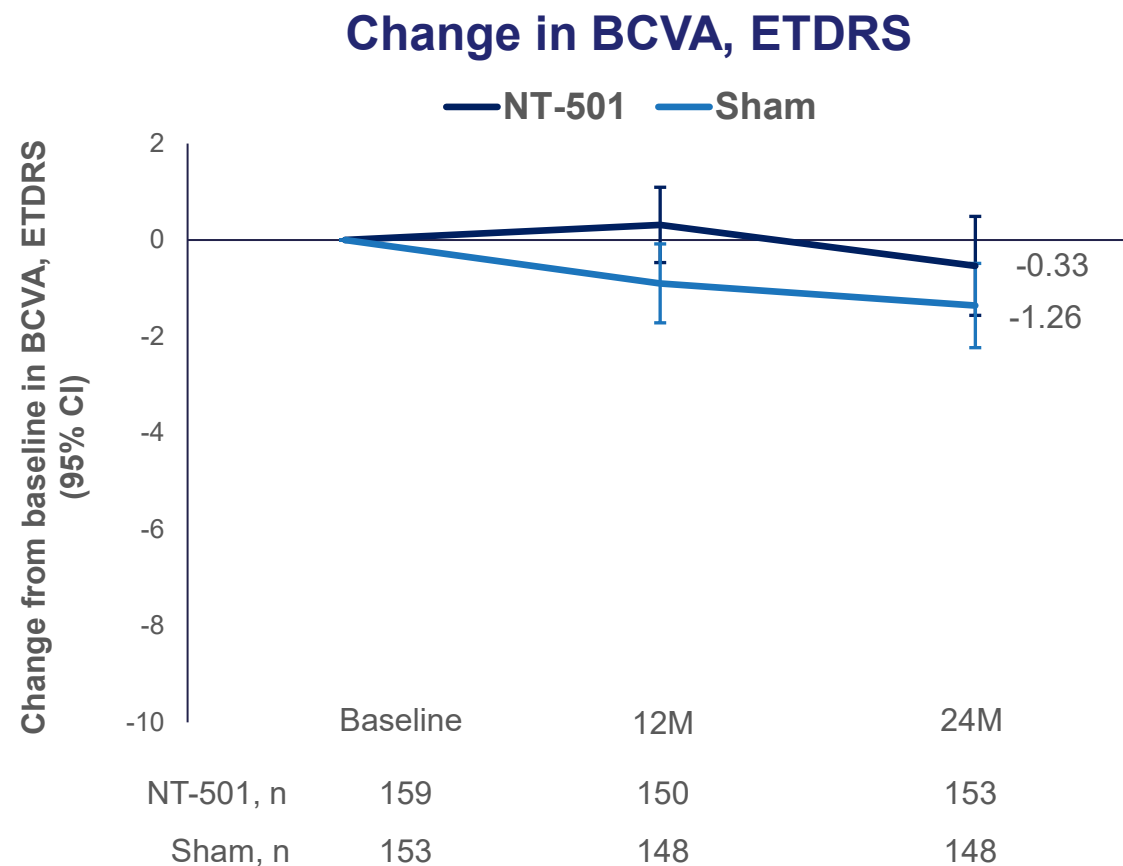
Phase 2	NT-501	Sham
Baseline	77.0 (5.61)	76.2 (6.85)
12M	-0.9 (4.87)	-1.6 (3.81)
24M	-1.9 (5.85)	-2.0 (4.28)

Mean Change in BCVA, (SD)

Phase 3, Study A	NT-501	Sham
Baseline	70.8 (9.11)	73.3 (8.64)
12M	1.0 (4.68)	-0.3 (5.36)
24M	0.2 (7.55)	-0.6 (6.30)

Mean Change in BCVA, (SD)

Phase 3, Study B	NT-501	Sham
Baseline	74.4 (7.76)	73.6 (9.23)
12M	0.6 (5.12)	-0.9 (5.81)
24M	-0.3 (6.01)	-1.7 (4.99)



BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; NT-501, revakinagene tarorectel.

<sup>a</sup>Per the NTMT-02 study design, participants with two eligible study eyes received NT-501 in one eye and sham in the other eye. These 32 participants are included in both groups by study eye.

# Take Home Points

- NT-501 conferred both **anatomic and visual function benefits** across three randomized, sham-controlled studies
- Relative to sham, NT-501 demonstrated a:
  - preservation of anatomy
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# Acknowledgements

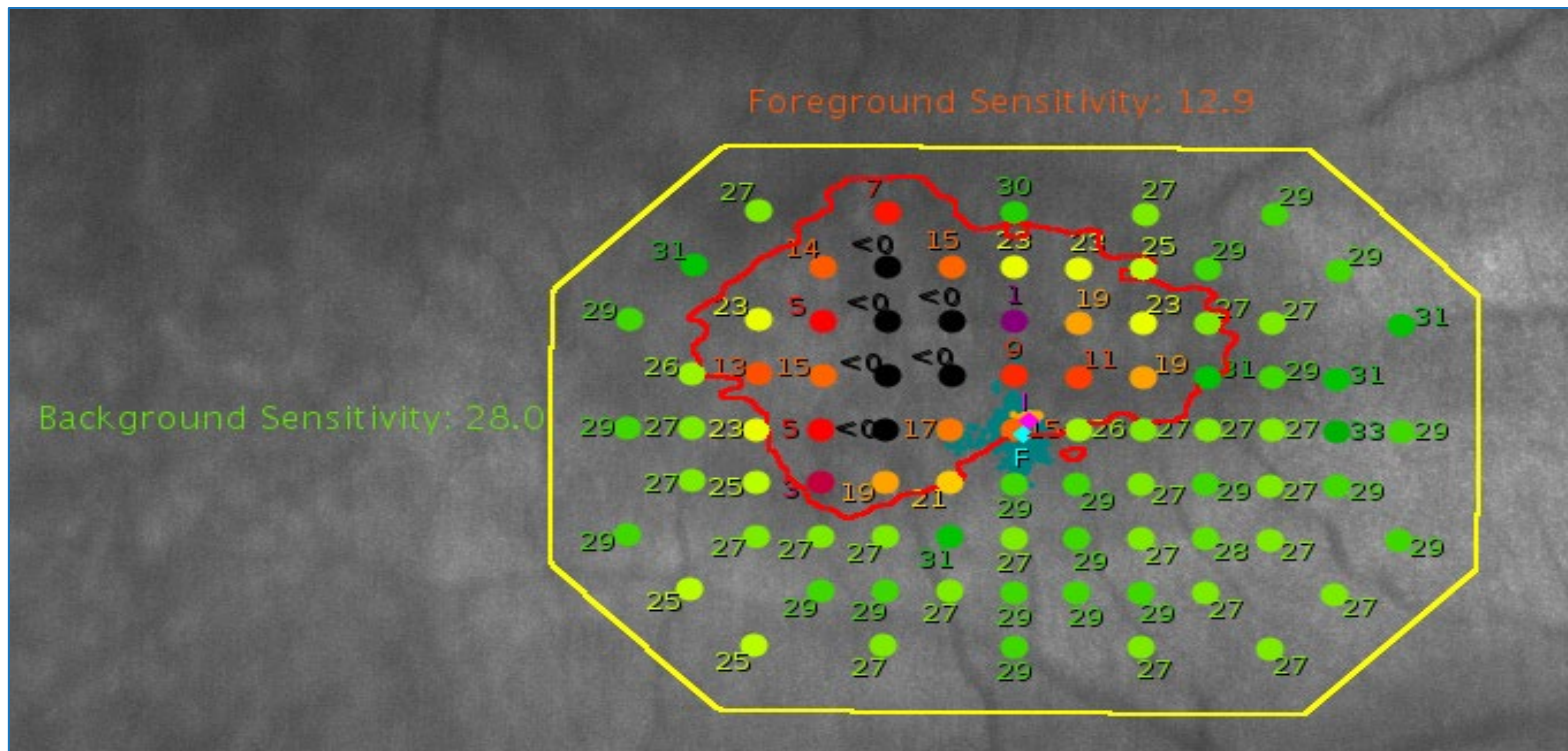
- Writing and editorial assistance was provided Elizabeth McSpiritt, MD, MPH, and Kristin Carlin, BS Pharm, RPh, of Peloton Advantage, LLC, an OPEN Health company, and was funded by Neurotech



# Appendix

# Aggregate Retinal Sensitivity Explained

The boundary in **yellow** denotes the FOV of the Microperimetry sensitivity map. All calculations are limited to the FOV only, since any extrapolation outside FOV may be subject to error<sup>1</sup>



## Calculation Overview<sup>2</sup>

1. Aggregate retinal sensitivity is calculated by summing and averaging test point values on microperimetry outside of the scotoma (considered the background retinal sensitivity)
2. Levels of retinal sensitivity within the scotoma are subtracted from this mean
3. The sum of these differences results in the value known as aggregate sensitivity

# MacTel Patient Impact

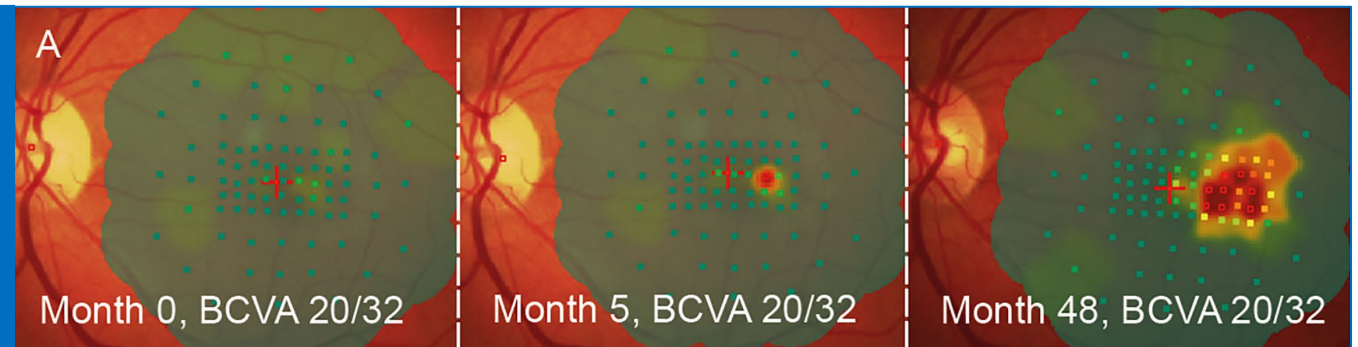
## Visual Symptoms<sup>1,2</sup>

- Patients can experience<sup>1</sup>:
  - Blurred vision
  - Distorted vision
  - Expanding Paracentral blind spots
  - Loss of central vision
- Late disease stage defined by a BCVA of 20/200 or worse<sup>3</sup>
- Visual acuity is a suboptimal measure of disease burden

## Impact on Activities of Daily Living<sup>2-6</sup>

- Reduced reading capabilities
  - Baseline reading speed for Phase 3 studies was reduced by 50% of normal
- Limitations on driving
- Loss of depth perception impacting mobility

These microperimetry images demonstrate progression of a new scotoma in a MacTel patient over 4 years





# Thank you!