Ocular Diseases Forum 2

Landscape for IRD Drug Development: Potential Endpoints in Clinical Trials

September 28, 2024

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Disclosures

VR Intellectual property licensing through the Univ. of Pennsylvania

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F.M. Kirby Foundation
Center for Advanced Retinal and Ocular Therapeutics,(CAROT),
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Research to Prevent Blindness
Pennsylvania Lions Sight Conservation & Eye Research Foundation

Clinical trial support

Atsena Therapeutics
Editas Medicine
Opus Genetics
Spark Therapeutics

Vision endpoints (including FST) in clinical trials

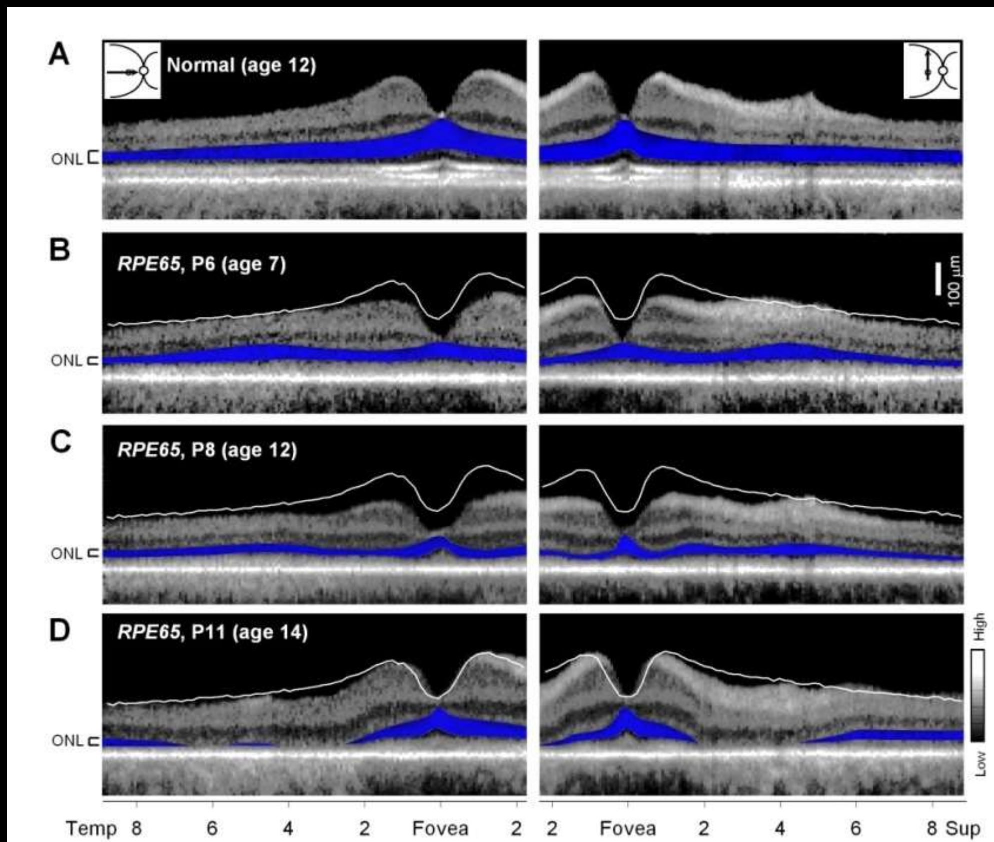
RPE65-LCA: Hauswirth, Jacobson, Roman, Cideciyan, Aleman 2008 & others (NIH)
RPE65-LCA: Banin, 2010 (MVRF)
RPE65-LCA: Bennett, 2012 & others (CHOP/Spark)
End-stage RP: Ahuja, 2013 (Second Sight)
RP: Bittner, 2014 (NIH)
MERTK-RD: Ghazi, 2016 (King Salman Center)
End-stage RP: Edwards, 2018 (Retina Implant Alpha AMS)
RLBP1-RD: Kvanta, 2024 (Novartis)
CNGA3-ACHM: Fischer, 2020 (RD-CURE)
GUCY2D-LCA: Jacobson, Cideciyan, Aleman 2021 & others (Sanofi/Atsena)
CEP290-LCA: Pierce, Aleman, Pennesi 2024 (Editas)
CEP290-LCA: Cideciyan, 2019 & others (ProQR)
LCA5-LCA: Aleman, Cideciyan, Roman et al.

RHD12-LCA
NPHP5-LCA
BCM

- **Used in 4 successfully treated forms of LCA**
- **Used in 2 waiting for treatment forms of LCA**
- **Used in specialized test for BCM awaiting Tx**

The catalyst – Leber Congenital Amaurosis Experience

Favored Tx scenario: blind spared photoreceptors



Beautiful retina but

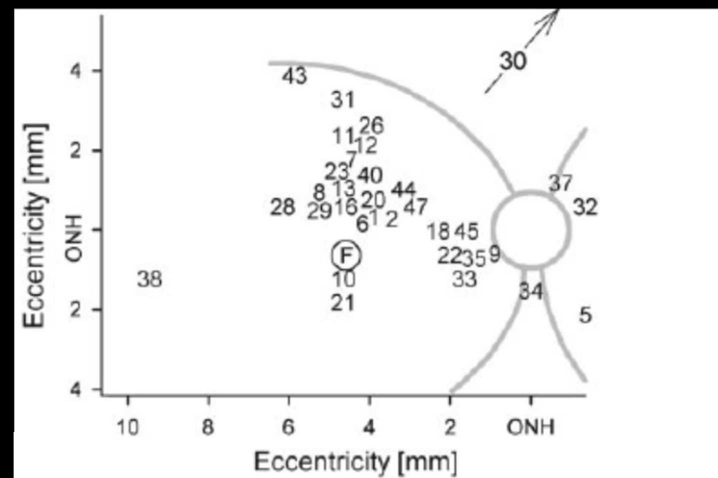
- Low vision
- Flat ERGs
- Small or no fields

Identifying photoreceptors in blind eyes caused by *RPE65* mutations: Prerequisite for human gene therapy success

Samuel G. Jacobson[*,†], Tomas S. Aleman[*], Artur V. Cideciyan[*], Alexander Sumaroka[*], Sharon B. Schwartz[*], Elizabeth A. M. Windsor[*], Elias I. Traboulsi[‡], Elise Heon[§], Steven J. Pittler[¶], Ann H. Milam[*], Albert M. Maguire[*], Krzysztof Palczewski[||], Edwin M. Stone[**], and Jean Bennett[*]

PNAS | April 26, 2005 | vol. 102 | no. 17 | 6177–6182

Visual Acuity:
The most used and trusted endpoint

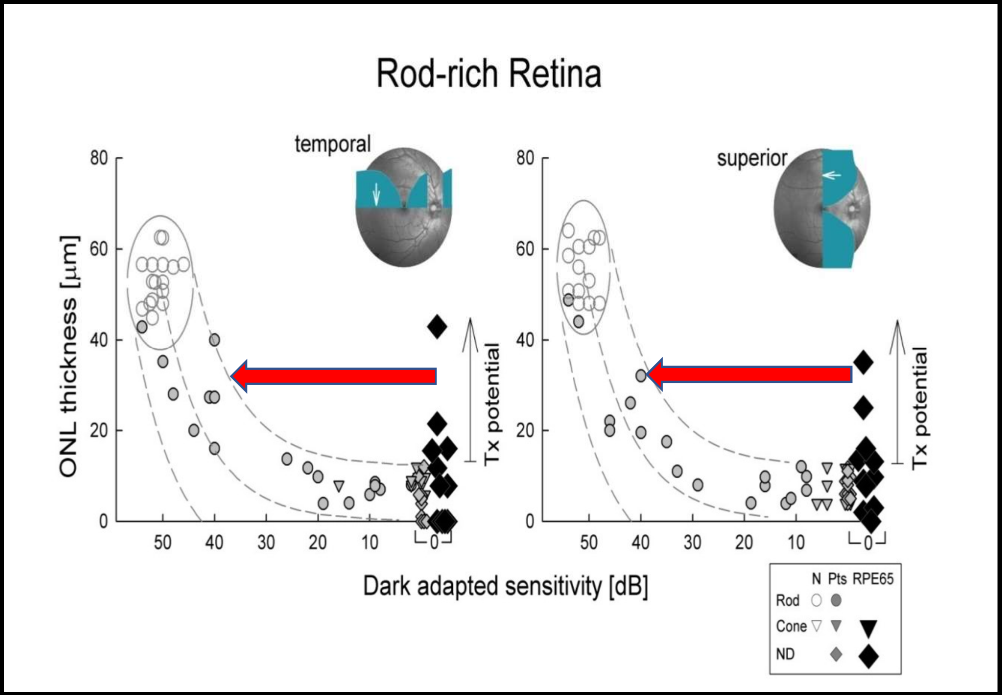


ABCA4-Associated Retinal Degenerations Spare Structure and Function of the Human Parapapillary Retina

Artur V. Cideciyan,[1] Malgorzata Swider,[1] Tomas S. Aleman,[1] Alexander Sumaroka,[1] Sharon B. Schwartz,[1] Marisa I Roman,[1] Ann H. Milam,[1] Jean Bennett,[1] Edwin M. Stone,[2] and Samuel G. Jacobson[1]

- Easy to deliver, important for quality of life but…
- May not relate well with disease severity (as commonly performed)
- Complicated in low vision
- Does NOT localize function (is a moving ‘target’ and SR gene therapy is a local Tx)
- Influenced by neurodevelopment

Patients are blind as a result of an insensitive retina
Must Measure Photoreceptor Sensitivity!



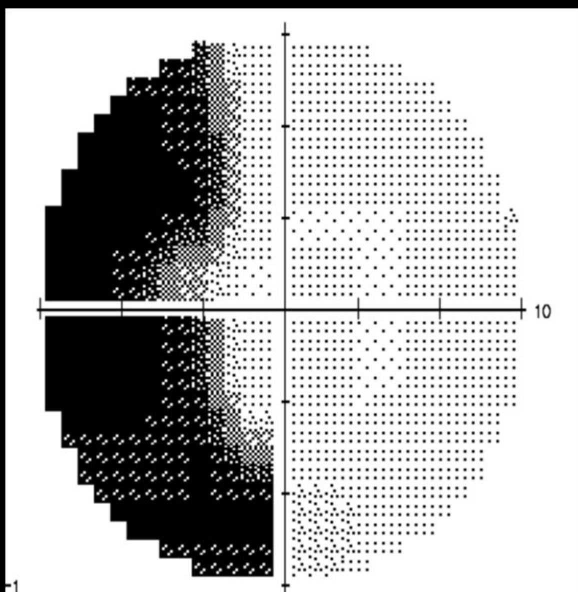
- Structural-Functional Dissociation
- Loss of vision is disproportionate to loss of photoreceptors

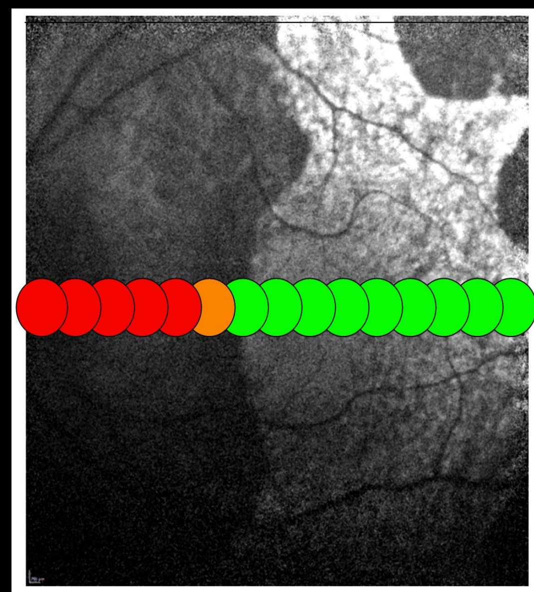
Perelman School of Medicine University of Pennsylvania

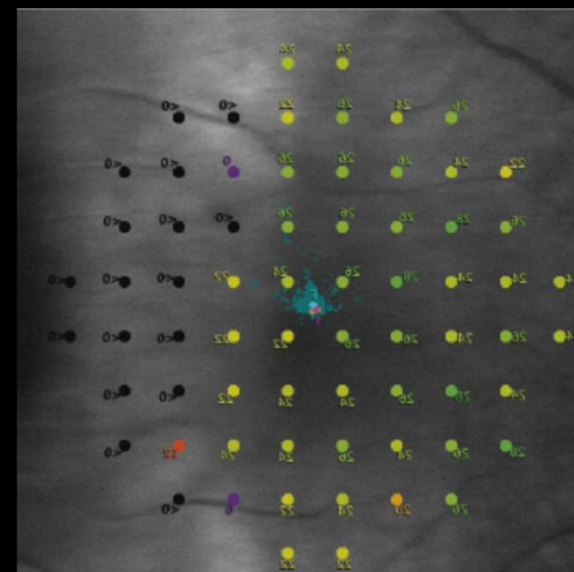
Scheie Eye Institute Penn Medicine

Must measure photoreceptor sensitivity

Static Perimetry vs Fundus Tracking Perimetry







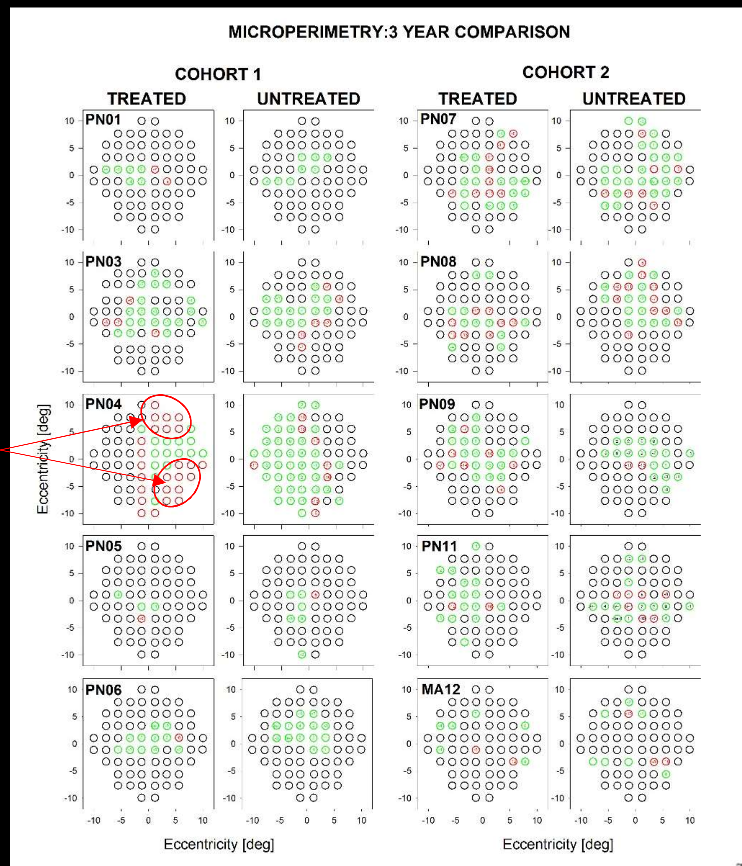
<u>Static perimetry:</u>
Widely available
Limited dynamic range
<u>Affected by fixation</u>
Not easy in children

<u>Fundus Tracking Perimetry:</u>
Widely available
<u>Limited dynamic range</u>
Not easy in children

Microperimetry as End Point in CHM

Low dose

High dose



Retinotomy scars

Stable

Worse

- Put it to the test in Upenn/Harvard Spark trial

Adeno-Associated Virus Serotype 2–*hCHM* Subretinal Delivery to the Macula in Choroideremia

Two-Year Interim Results of an Ongoing Phase I/II Gene Therapy Trial

Tomas S. Aleman, MD,[1,2,3] Rachel M. Huckfeldt, MD, PhD,[4] Leona W. Serrano, BS,[1,2] Denise J. Pearson, COMT,[1,2] Grace K. Vergilio, BS,[1,2] Sarah McCague, MS,[2,3] Kathleen A. Marshall, COT,[2,3] Manzar Ashtari, PhD,[2,3] Tu M. Doan, BS,[4] Carol A. Weigel-DiFranco, BA, MA,[4] Bethany S. Biron, BS,[4] Xiao-Hong Wen, MD, PhD,[4] Daniel C. Chung, DO,[5] Emily Liu, MS, MBA,[5] Kevin Ferenchak, MD,[4] Jessica I.W. Morgan, PhD,[1,2] Eric A. Pierce, MD, PhD,[4] Dean Eliott, MD,[4] Jean Bennett, MD, PhD,[1,2] Jason Comander, MD, PhD,[4] Albert M. Maguire, MD[1,2,3]

Early 2000s, *RPE65*-LCA Trial Approaching…
Our wish list:

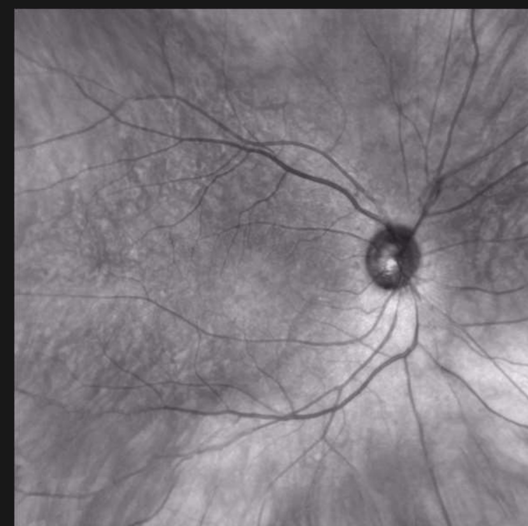
- Accommodate disease severity (wide dynamic range)
- Not affected by central disease (independent of fixation)
- Reproducible and sensitive (ability to detect change)
- Relatable to other readouts
- Ability to dissect photoreceptor mechanisms
- Easy, fast, applicable over a wide age range

FST is born

Alejandro J. Roman

Perimetry/microperimetry
(localized)

FST
(full field)



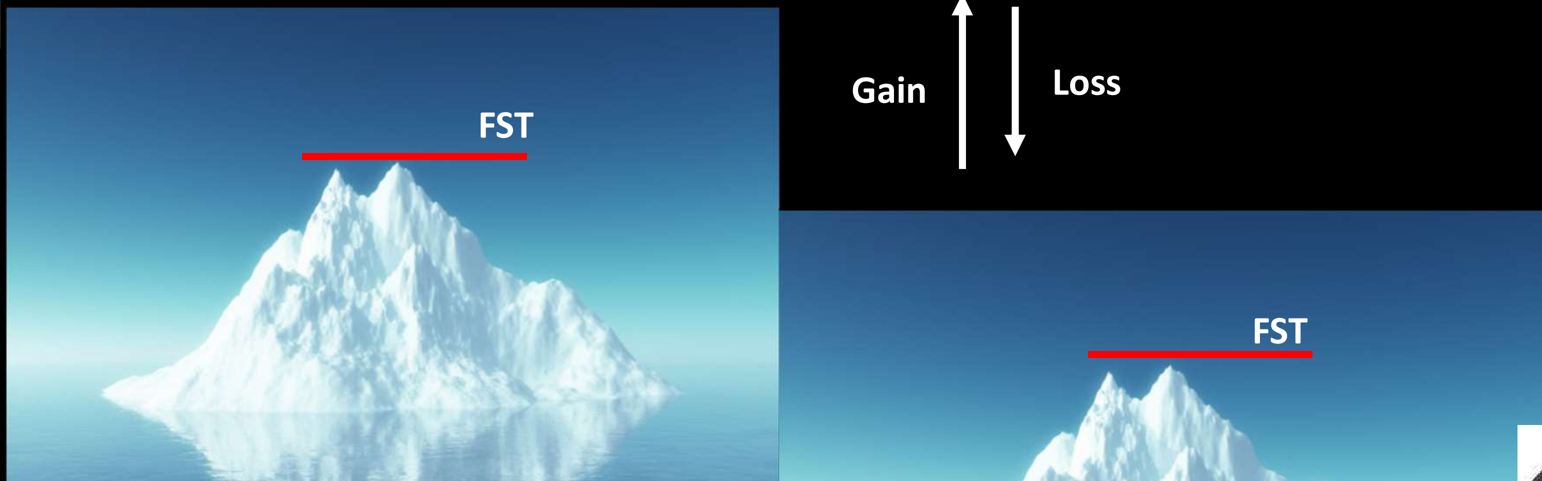
Full-field stimulus testing (FST) to quantify visual perception in severely blind candidates for treatment trials

Alejandro J Roman, Artur V Cideciyan, Tomas S Aleman and Samuel G Jacobson

Quantifying rod photoreceptor-mediated vision in retinal degenerations: dark-adapted thresholds as outcome measures

Alejandro J. Roman[1], Sharon B. Schwartz[1], Tomas S. Aleman, Artur V. Cideciyan, John D. Chico, Elizabeth A.M. Windsor, Leigh M. Gardner, Gui-shuang Ying, Elaine E. Smilko, Maureen G. Maguire, Samuel G. Jacobson*

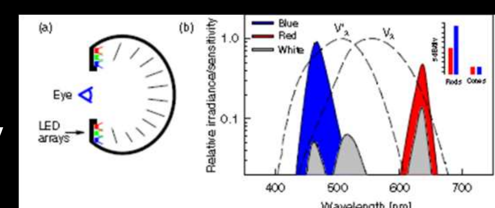
FST: virtues and limitations



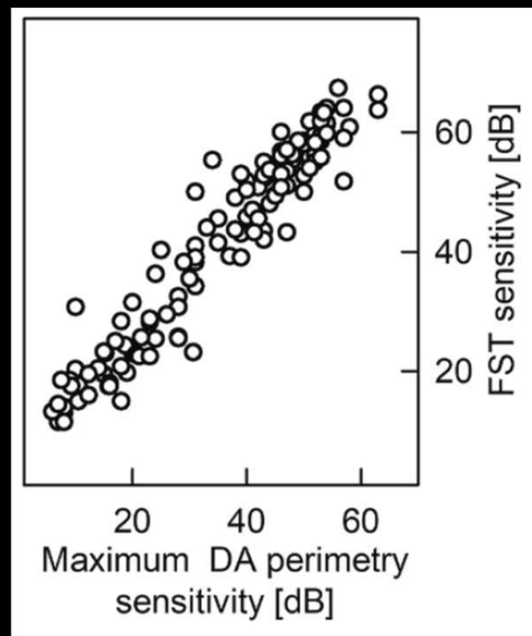
Gain

Loss

- Measures most sensitive region.
- Large dynamic range.
- Independent of fixation.
- Provides measures of photoreceptor specific function.
- Confusing in patients with intraretinal variability in disease severity



Relationship with Dark Adapted Perimetry



- Relates nicely with the maximum dark adapted sensitivity by automatic static perimetry


Contents lists available at ScienceDirect
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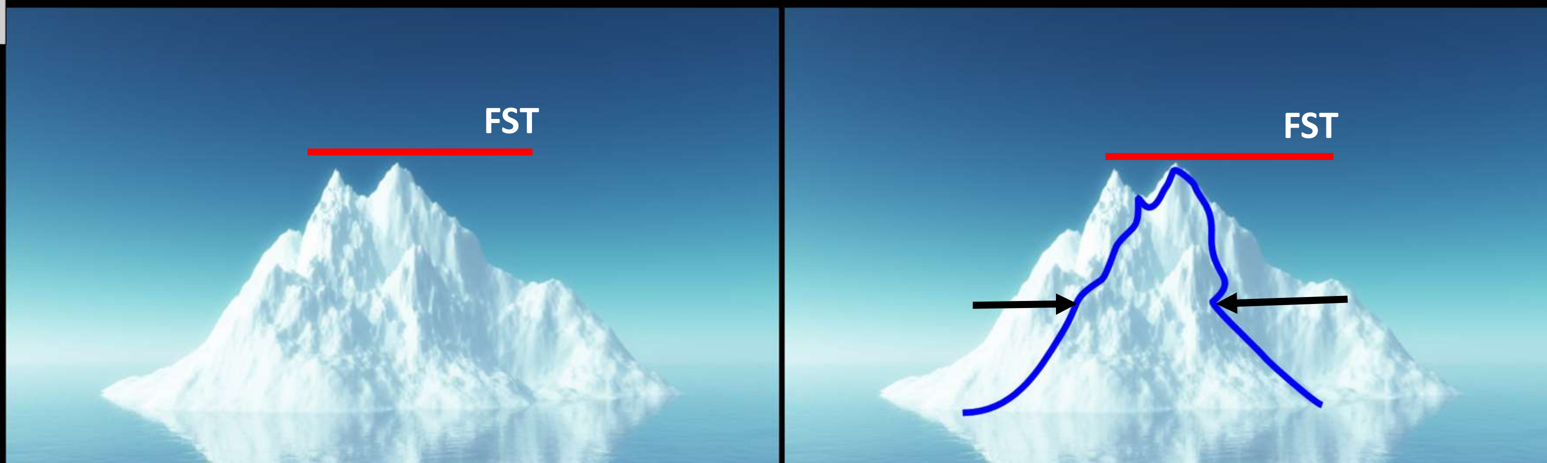
Full-field stimulus testing: Role in the clinic and as an outcome measure in clinical trials of severe childhood retinal disease

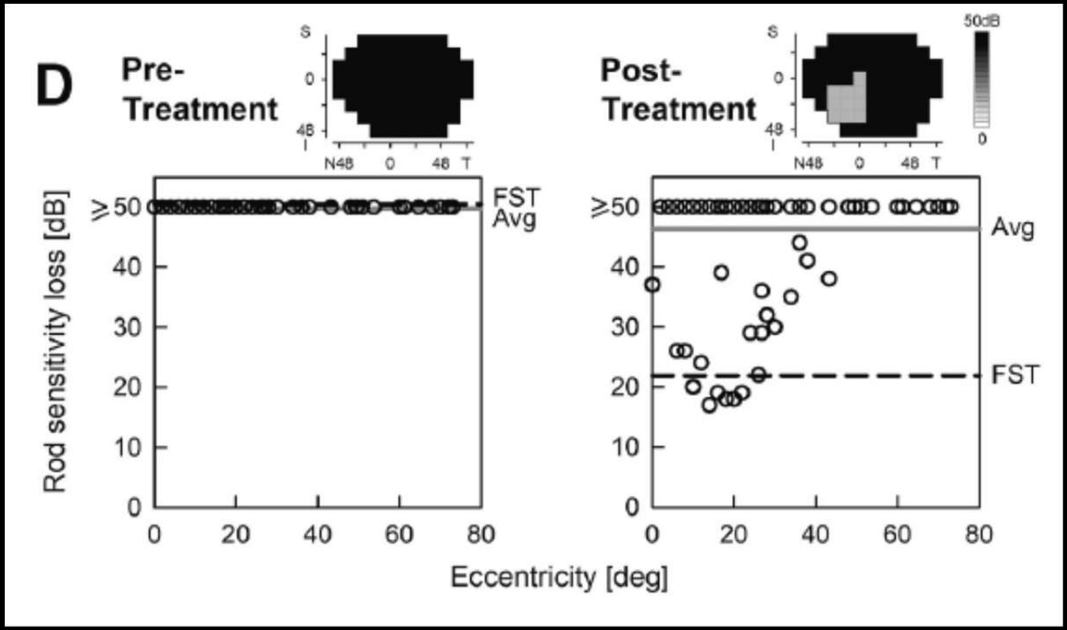
Alejandro J. Roman, Artur V. Cideciyan, Vivian Wu, Alexandra V. Garafalo, Samuel G. Jacobson *

FST: virtues and limitations



- In theory, limited use in this scenario (minimal change in maximal sensitivity, contraction of the field).
- Although, usually both occur simultaneously (general depression and constriction).

Relates well with perimetry after treatments



➢ Can monitor local improvement too

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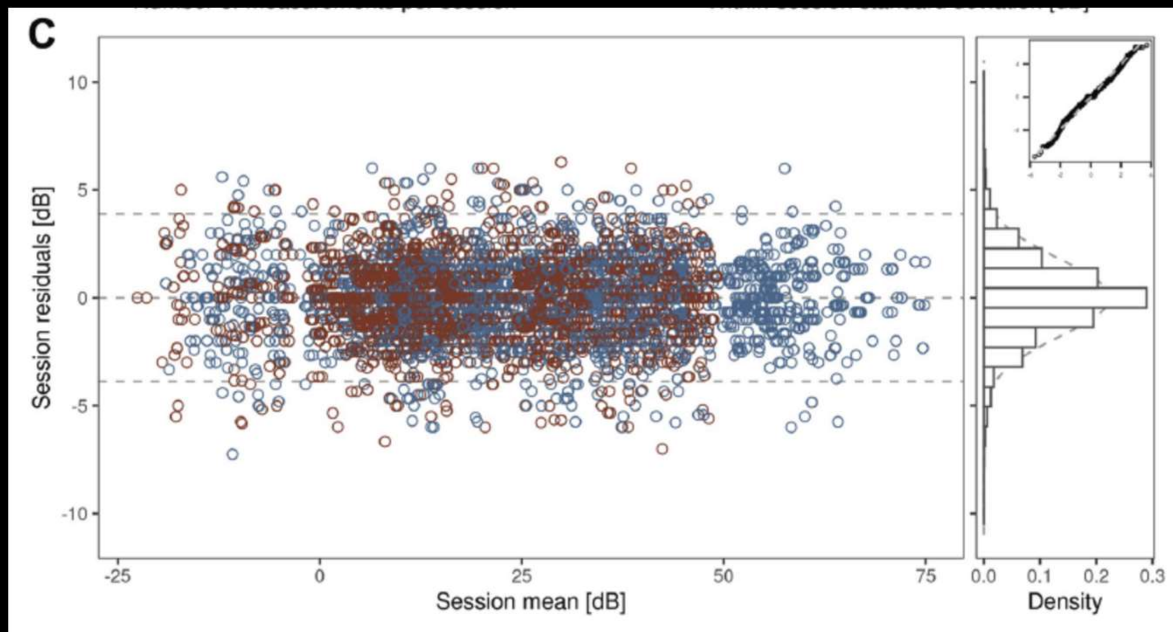
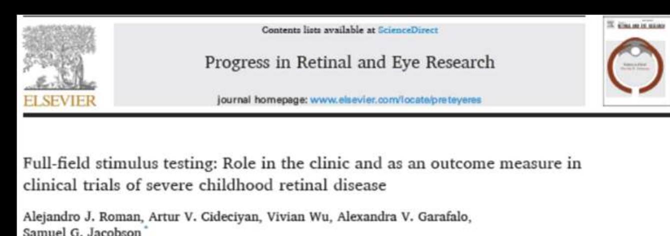
FST Performance
Within session variability



- 273 consecutive subjects with FST
- between 2004 and 2021
- SD estimated as the
- residual SE = 1.98 dB



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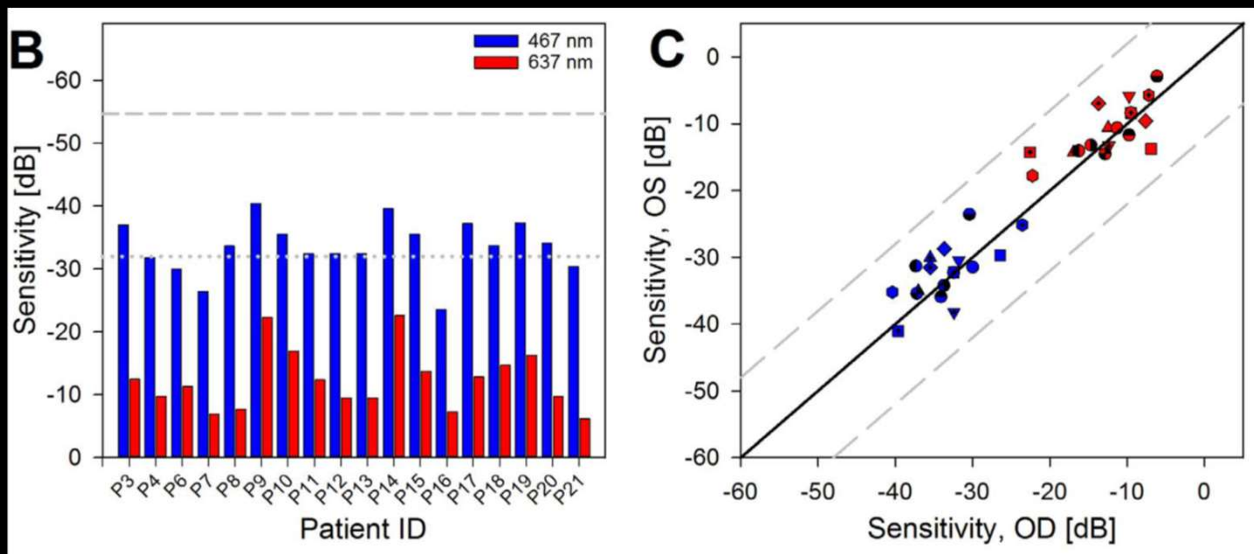
Alejandro J. Roman, Artur V. Cideciyan, Vivian Wu, Alexandra V. Garafalo, Samuel G. Jacobson *

FST ease of delivery = use in children

At least ages 6 and older

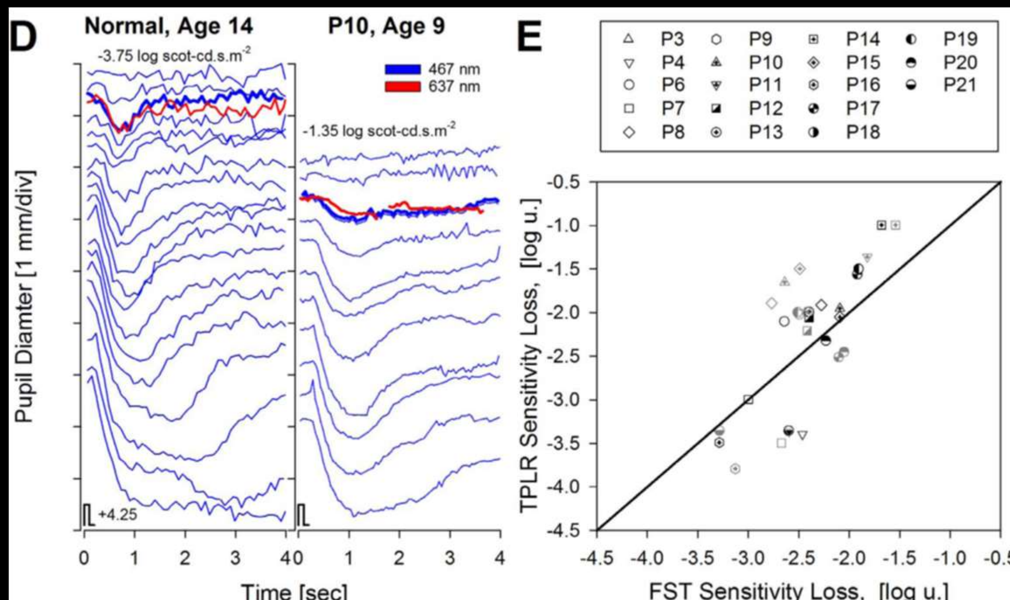


RDH12 Mutations Cause a Severe Retinal Degeneration With Relatively Spared Rod Function

Tomas S. Aleman,[1,2] Katherine E. Uyhazi,[1] Leona W. Serrano,[1] Vidyullatha Vasireddy,[2] Scott J. Bowman,[1] Michael J. Ammar,[1] Denise J. Pearson,[1] Albert M. Maguire,[1,2] and Jean Bennett[1,2]

Invest Ophthalmol Vis Sci. 2018;59:5225–5236. https://doi.org/10.1167/iovs.18-24708

FST relates to objective measures (Pupillometry)



- When in doubt (i.e. in children) –> relates with objectives measures of sensitivity

***RDH12* Mutations Cause a Severe Retinal Degeneration With Relatively Spared Rod Function**

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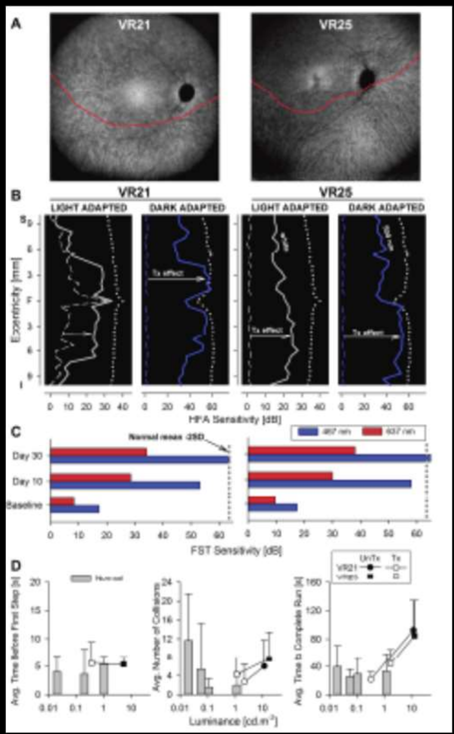
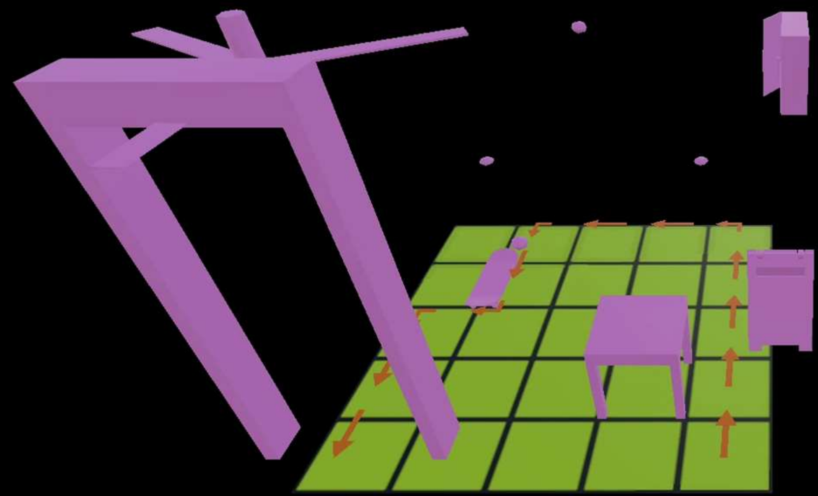
FST relates to changes in other readouts

Local Measures and Functional Vision (Orientation & Mobility)



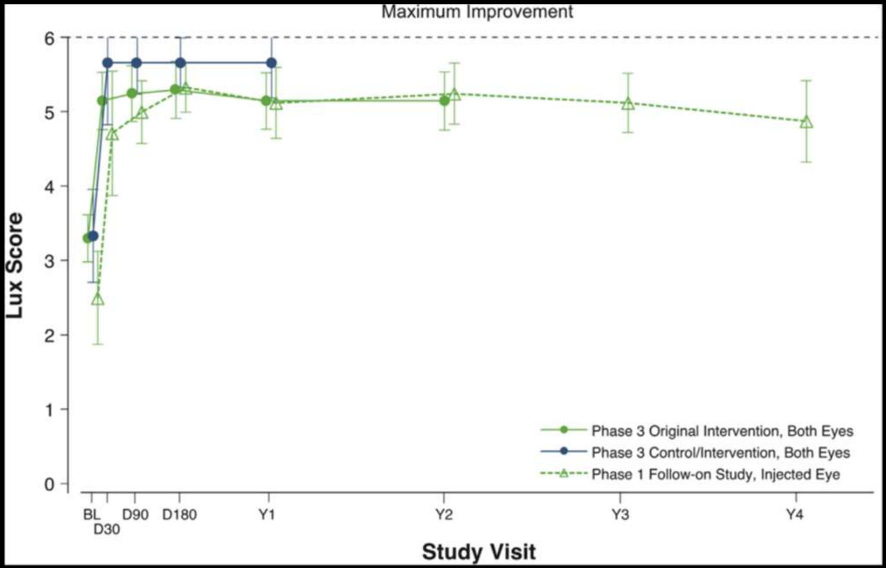


A Virtual Reality Orientation and Mobility Test for Inherited Retinal Degenerations: Testing a Proof-of-Concept After Gene Therapy

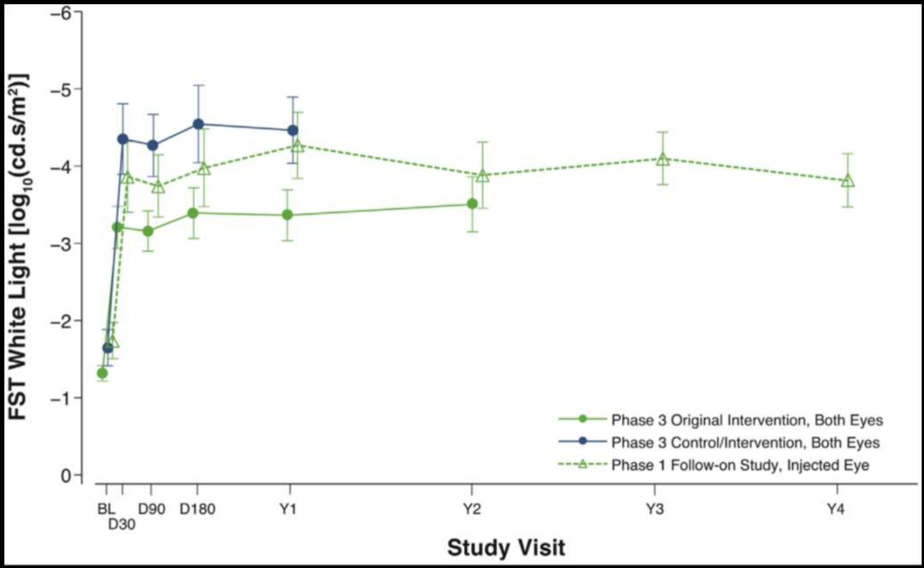
Tomas S Aleman[1–3]
Alexander J Miller[4]
Katherine H Maguire[1,2]
Elena M Aleman[2]
Leona W Serrano[1,2]
Kali B O'Connor[1,2]
Emma C Bedoukian[5]
Bart P Leroy[3,6–8]
Albert M Maguire[1–3]
Jean Bennett[1,2]

Relationship with Functional Vision
(Orientation & Mobility)

MMLT



FST



Efficacy, Safety, and Durability of Voretigene Neparvovec-rzyl in *RPE65* Mutation–Associated Inherited Retinal Dystrophy

Results of Phase 1 and 3 Trials

Albert M. Maguire, MD,[1,2] Stephen Russell, MD,[3] Jennifer A. Wellman, MS,[2,4] Daniel C. Chung, DO, MA,[2,4] Zi-Fan Yu, ScD,[5] Amy Tillman, MS,[5] Janet Wittes, PhD,[5] Julie Pappas, BA,[5] Okan Elci, PhD,[6] Kathleen A. Marshall, COT,[7] Sarah McCague, MS,[7] Hannah Reichert, BS,[7] Maria Davis, BA,[7] Francesca Simonelli, MD,[8] Bart P. Leroy, MD, PhD,[9,10] J. Fraser Wright, PhD,[2,4] Katherine A. High, MD,[2,4] Jean Bennett, MD, PhD[2,7]

Ophthalmology 2019;126:1273-

Treating the RPE in *RPE65*-LCA

Improvement in rod photoreceptor-mediated vision

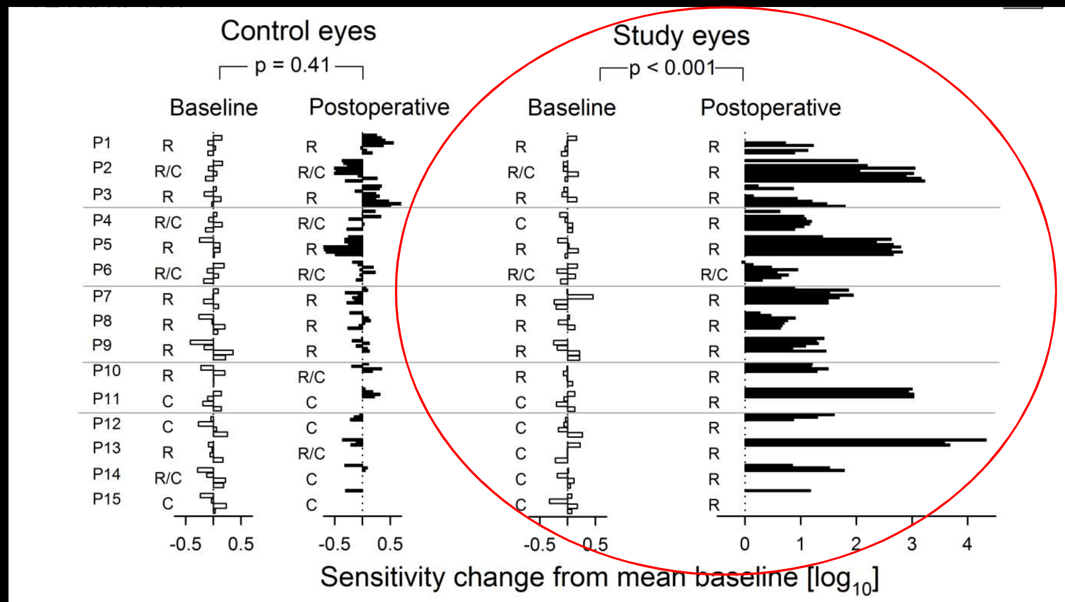


Table 3. Measures of Ocular Function at Baseline and After Surgery

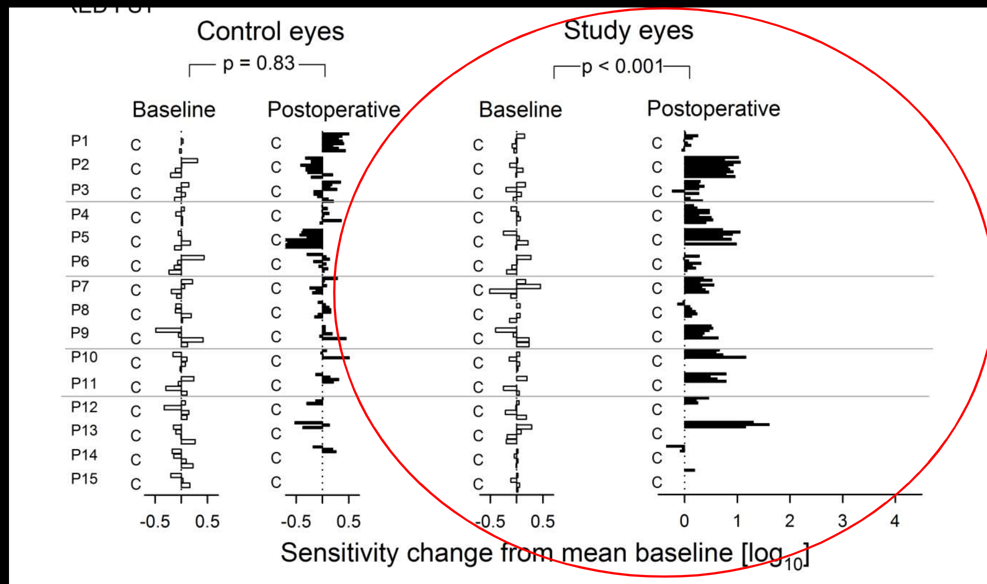
Measure	Control Eyes, Mean (SE) Baseline	Control Eyes, Mean (SE) After Surgery	Control Eyes, Mean (SE) Difference[a]	*P* Value[b]	Study Eyes, Mean (SE) Baseline	Study Eyes, Mean (SE) After Surgery	Study Eyes, Mean (SE) Difference[a]	*P* Value[b]
FST sensitivity, blue[c], $\log_{10}$	1.22 (0.10)	1.17 (0.11)	−0.05 (0.06)	.41	1.12 (0.099)	2.72 (0.21)	1.59 (0.25)	<.001
FST sensitivity, red[d], $\log_{10}$	0.75 (0.10)	0.74 (0.12)	−0.02 (0.06)	.83	0.70 (0.12)	1.14 (0.12)	0.45 (0.10)	<.001
TPLR sensitivity[e], $\log_{10}$	−0.90 (0.20)	−0.91 (0.18)	−0.01 (0.05)	.87	−0.89 (0.14)	0.28 (0.27)	1.17 (0.20)	<.001
VA[f], logMAR	0.96 (0.13)	0.91 (0.13)	−0.05 (0.02)	.02	1.09 (0.11)	0.97 (0.11)	−0.12 (0.05)	.02

Arch Ophthalmol. 2012;130(1):9-24.

Gene Therapy for Leber Congenital Amaurosis Caused by *RPE65* Mutations

Safety and Efficacy in 15 Children and Adults Followed Up to 3 Years

Treating the RPE in *RPE65*-LCA
Improvement in cone (C) vision; modest changes in VA.



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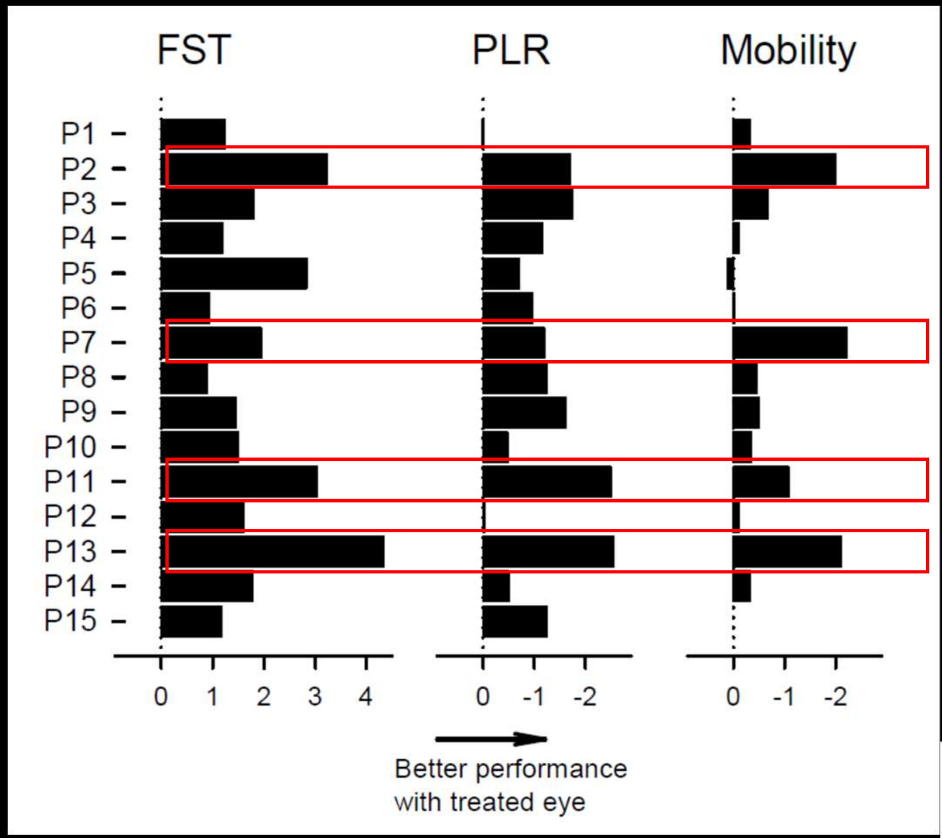
Safety and Efficacy in 15 Children and Adults Followed Up to 3 Years

Treating the RPE in *RPE65*-LCA

FST supports changes in other readouts



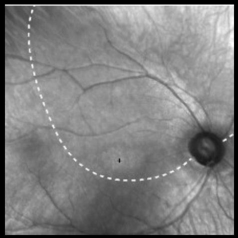
Gene Therapy for Leber Congenital Amaurosis Caused by *RPE65* Mutations

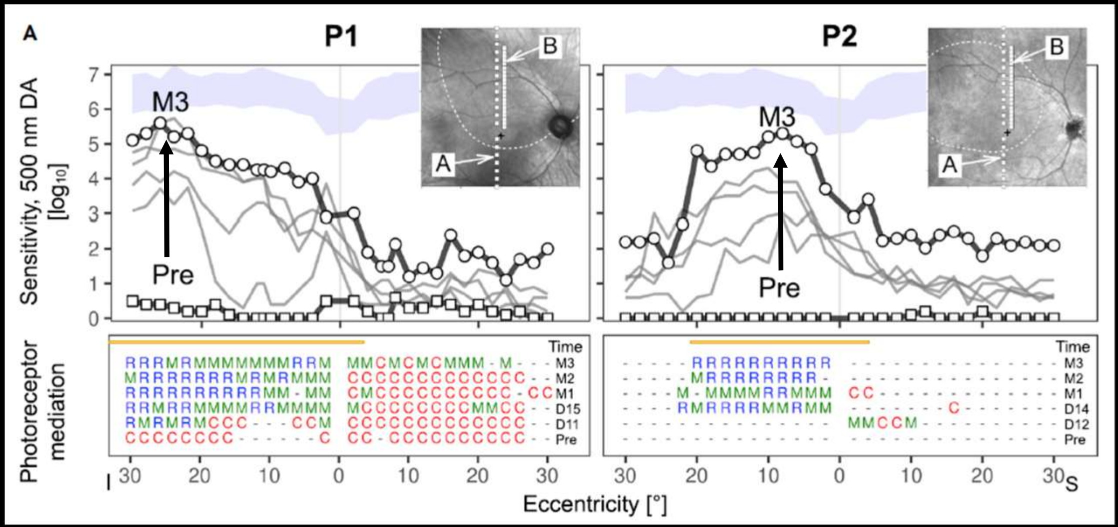
Safety and Efficacy in 15 Children and Adults Followed Up to 3 Years

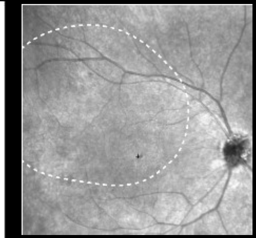
Samuel G. Jacobson, MD, PhD; Artur V. Cideciyan, PhD; Ramakrishna Ratnakaram, MD; Elise Heon, MD; Sharon B. Schwartz, MS, CGC; Alejandro J. Roman, MS; Marc C. Peden, MD; Tomas S. Aleman, MD; Sanford L. Boye, MS; Alexander Sumaroka, PhD; Thomas J. Conlon, PhD; Roberto Calcedo, PhD; Ji-Jing Pang, MD, PhD; Kirsten E. Erger, BS; Melani B. Olivares, BA; Cristina L. Mullins, BA; Malgorzata Swider, PhD; Shalesh Kaushal, MD, PhD; William J. Feuer, MS; Alessandro Iannaccone, MD, MS; Gerald A. Fishman, MD; Edwin M. Stone, MD, PhD; Barry J. Byrne, MD, PhD; William W. Hauswirth, PhD

Arch Ophthalmol. 2012;130(1):9-24.

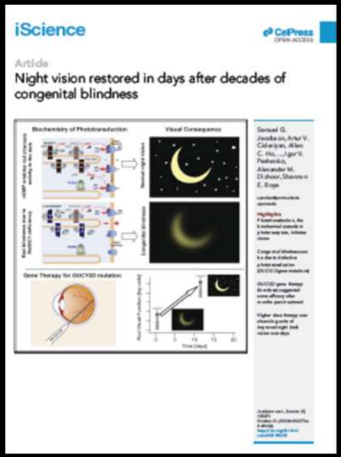
Localizing improvements by specialized perimetry







- Robust local improvements in rod- and cone-mediated vision
- Modest change in VA (0.12 logMAR)



Jacobson SG, Cideciyan AV, Ho AC, Roman AJ, Wu V, Garafalo AV, Sumaroka A, Krishnan AK, Swider M, Mascio AA, Kay CN, Yoon D, Fujita KP, Boye SL, Peshenko IV, Dizhoor AM, Boye SE. Night vision restored in days after decades of congenital blindness. iScience. 2022 Oct 4;25(10):105274.

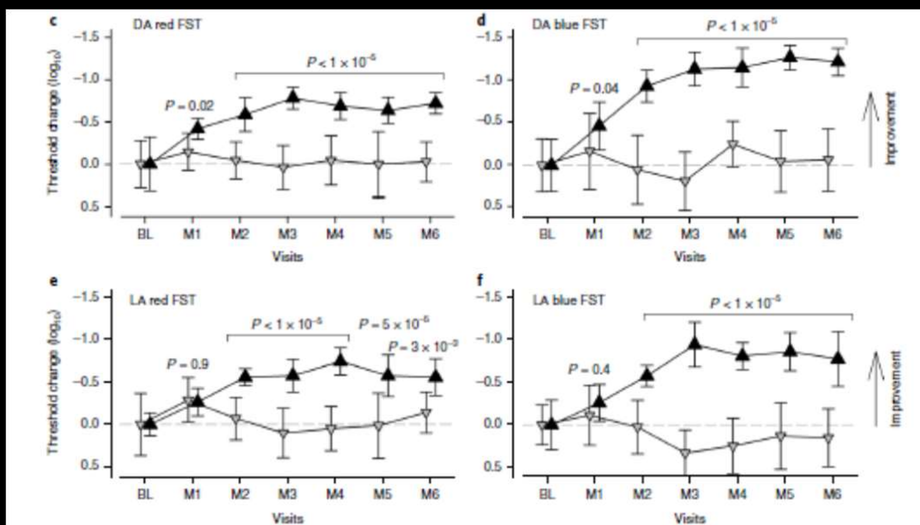
FST detects photoreceptor-specific improvements

Dark adapted vs Light Adapted FST

Sepofarsen for *CEP290*-LCA
Improvements in rod and cone vision

Dark-adapted

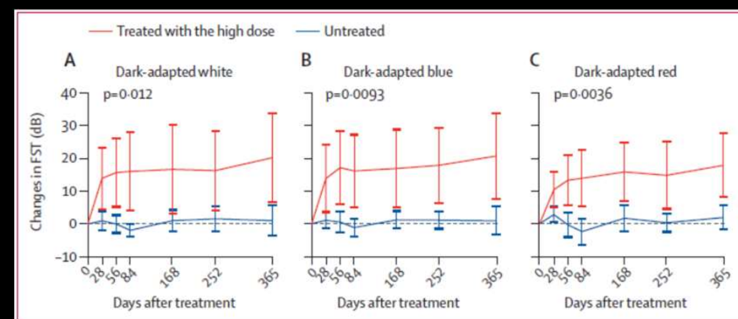
Light-adapted

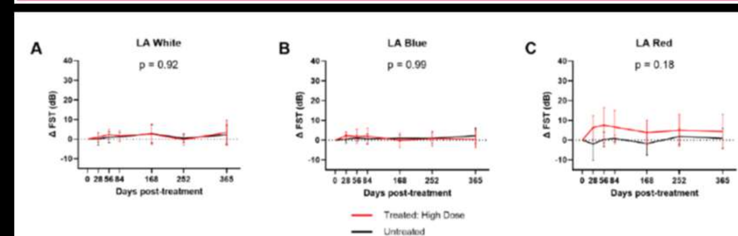


Effect of an intravitreal antisense oligonucleotide on vision in Leber congenital amaurosis due to a photoreceptor cilium defect

Artur V. Cideciyan, Samuel G. Jacobson, Arlene V. Drack, Allen C. Ho, Jason Charng, Alexandra V. Garafalo, Alejandro J. Roman, Alexander Sumaroka, Ian C. Han, Maria D. Hochstedler, Wanda L. Pfeifer, Elliott H. Sohn, Magali Taiel, Michael R. Schwartz, Patricia Biasutto, Wilma de Wit, Michael E. Cheetham, Peter Adamson, David M. Rodman, Gerard Platenburg, Maria D. Tome, Irina Balikova, Fanny Nerinckx, Julie De Zaeytijd, Caroline Van Cauwenbergh, Bart P. Leroy and Stephen R. Russell

GUCY2D-LCA Gene Augmentation
Improvements rod but not cone vision



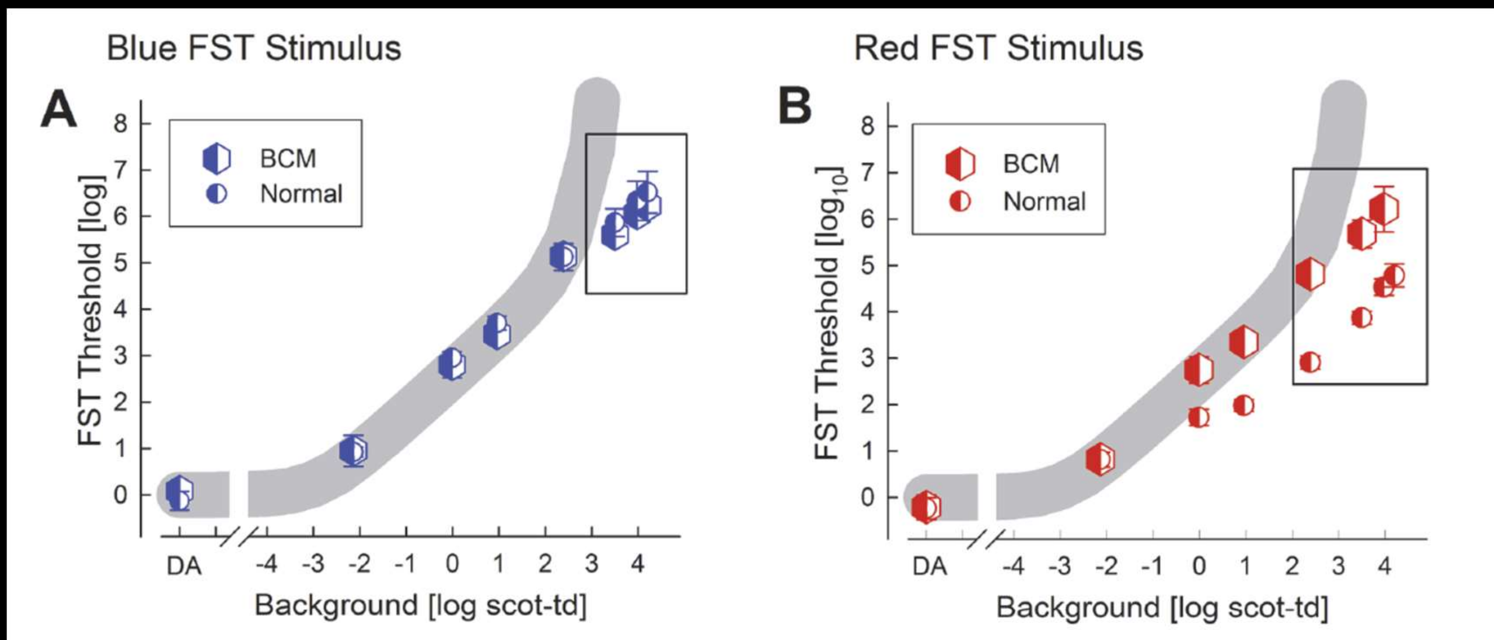


Safety and efficacy of ATSN-101 in patients with Leber congenital amaurosis caused by biallelic mutations in *GUCY2D*: a phase 1/2, multicentre, open-label, unilateral dose escalation study

Paul Yang, Laura P Pardon, Allen C Ho, Andreas K Lauer, Dan Yoon, Shannon E Boye, Sanford L Boye, Alejandro J Roman, Vivian Wu, Alexandra V Garafalo, Alexander Sumaroka, Malgorzata Swider, Iryna Viarbitskaya, Tomas S Aleman, Mark E Pennesi, Christine N Kay, Kenji P Fujita, Artur V Cideciyan

FST detects photoreceptor-specific improvements

Dark adapted vs Light Adapted FST
Blue Cone Monochromacy

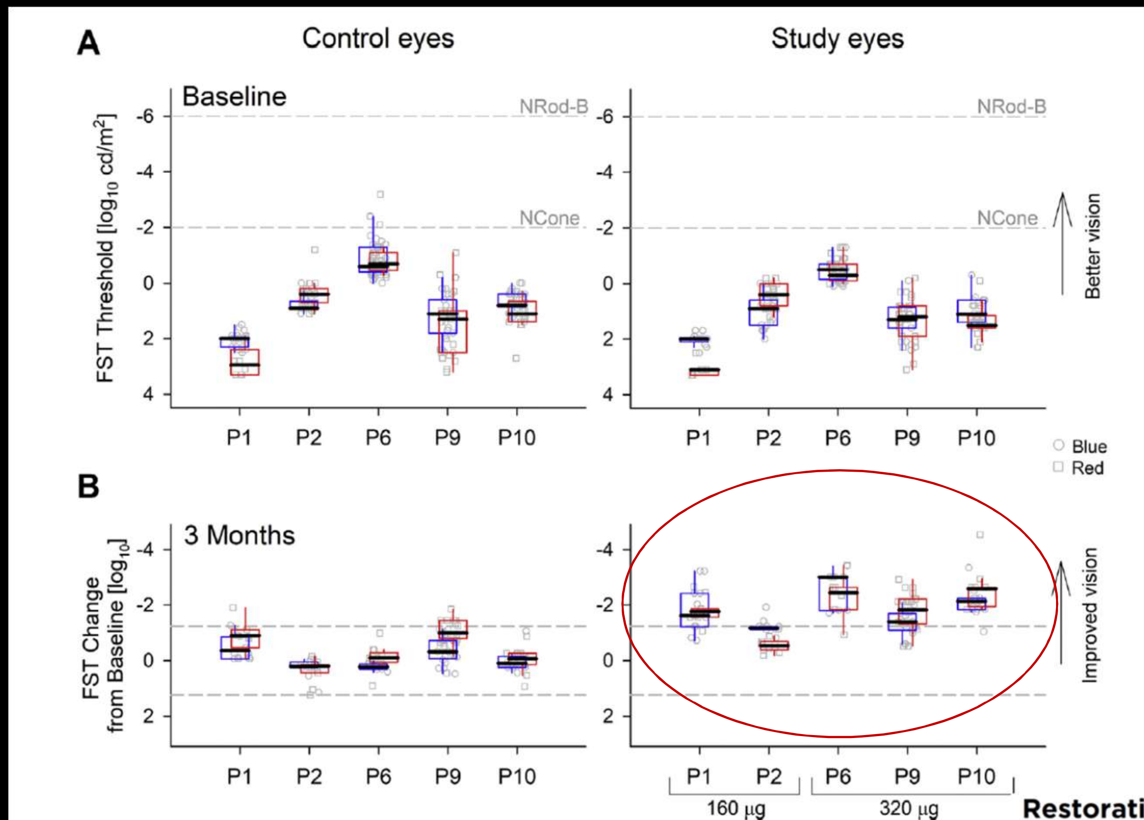


Blue Cone Monochromacy: Visual Function and Efficacy Outcome Measures for Clinical Trials

Xunda Luo[1¶], Artur V. Cideciyan[1¶]*, Alessandro Iannaccone[2], Alejandro J. Roman[1], Lauren C. Ditta[2], Barbara J. Jennings[2], Svetlana A. Yatsenko[3], Rebecca Sheplock[1], Alexander Sumaroka[1], Malgorzata Swider[1], Sharon B. Schwartz[1], Bernd Wissinger[4], Susanne Kohl[4], Samuel G. Jacobson[1]*

PLOS ONE | DOI:10.1371/journal.pone.0125700 April 24, 2015

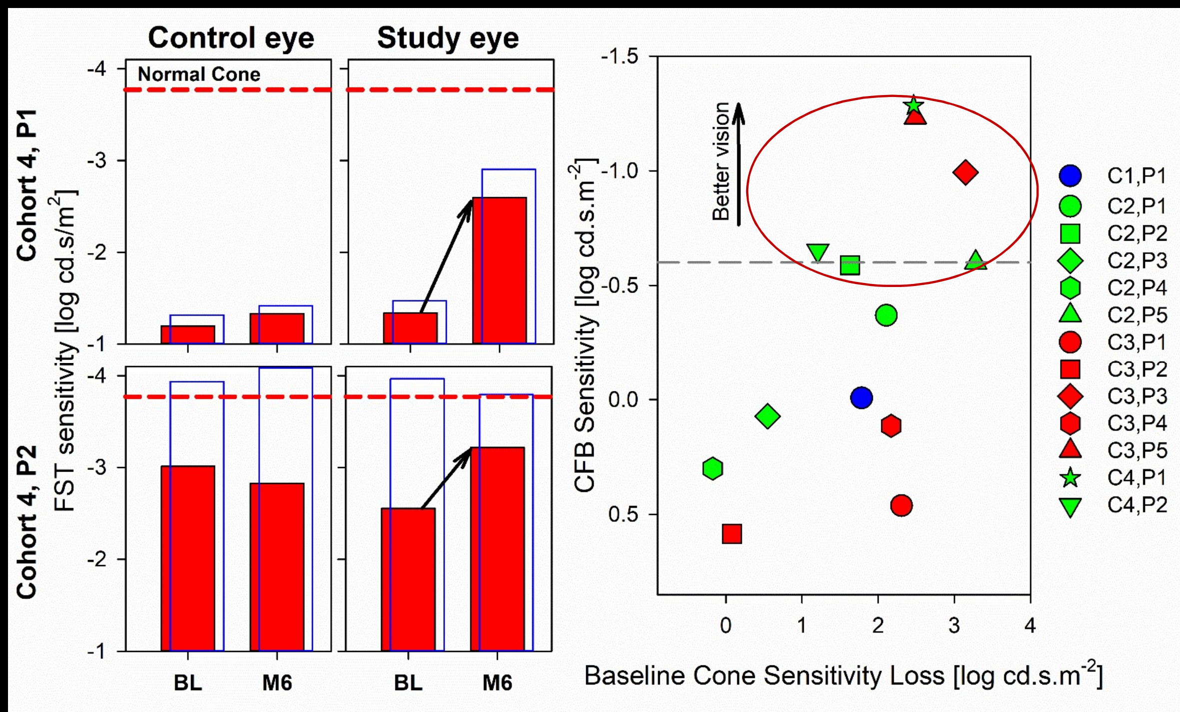
CEP290-LCA treated with Sepofarsen



Restoration of Cone Sensitivity to Individuals with Congenital Photoreceptor Blindness within the Phase 1/2 Sepofarsen Trial

Artur V. Cideciyan, PhD,[1] Samuel G. Jacobson, MD, PhD,[1] Allen C. Ho, MD,[2] Arun K. Krishnan, OD, PhD,[1] Alejandro J. Roman, MS,[1] Alexandra V. Garafalo, MS,[1] Vivian Wu, MS,[1] Malgorzata Swider, PhD,[1] Alexander Sumaroka, PhD,[1] Caroline Van Cauwenbergh, PhD,[3] Stephen R. Russell, MD,[4] Arlene V. Drack, MD,[4] Bart P. Leroy, MD, PhD,[3,5,6] Michael R. Schwartz, MS,[7] Aniz Girach, MD[7]

Gene Editing Successfully Treats *CEP290*-LCA



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Gene Editing for *CEP290*-Associated Retinal Degeneration

E.A. Pierce, T.S. Aleman, K.T. Jayasundera, B.S. Ashimatey, K. Kim, A. Rashid, M.C. Jaskolka, R.L. Myers, B.L. Lam, S.T. Bailey, J.I. Comander, A.K. Lauer, A.M. Maguire, and M.E. Pennesi

- Large changes from baseline (CFB) in cone vision in nearly half of the patients
- Latest example of efficacy that relates to baseline sensitivity losses in structurally spared photoreceptors

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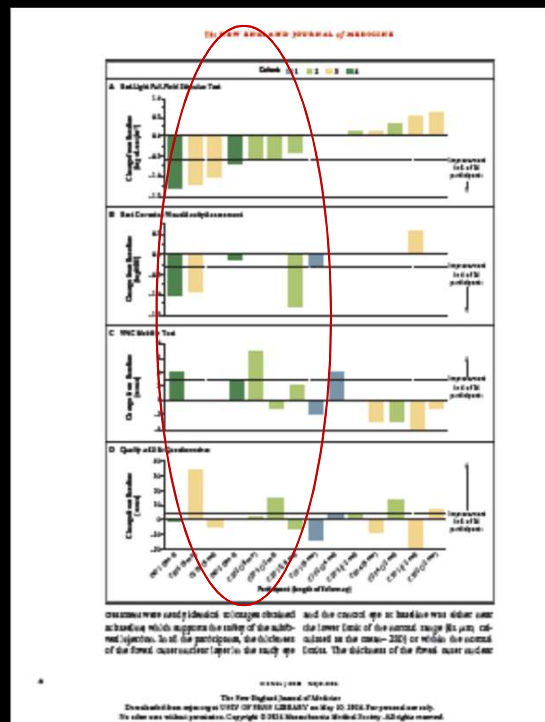


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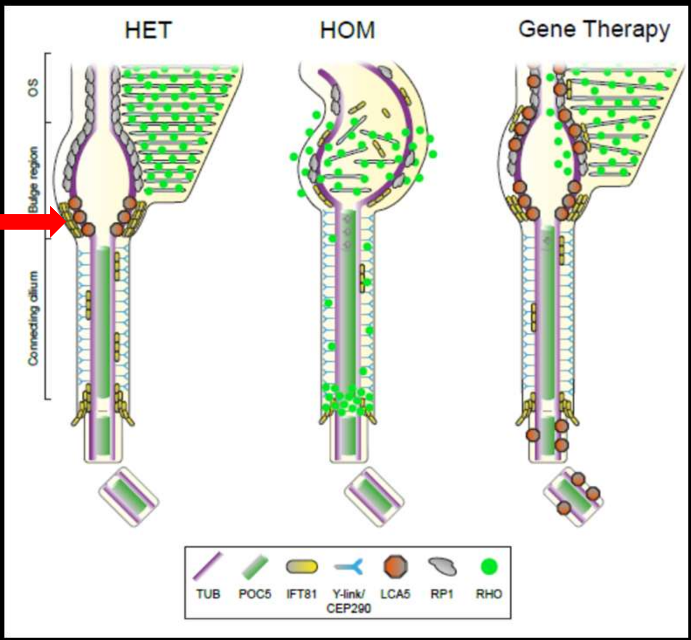
- **Large changes from baseline (CFB) in cone vision in nearly half of the patients**
- **Latest example of efficacy that relates to baseline sensitivity losses in structurally spared photoreceptors**

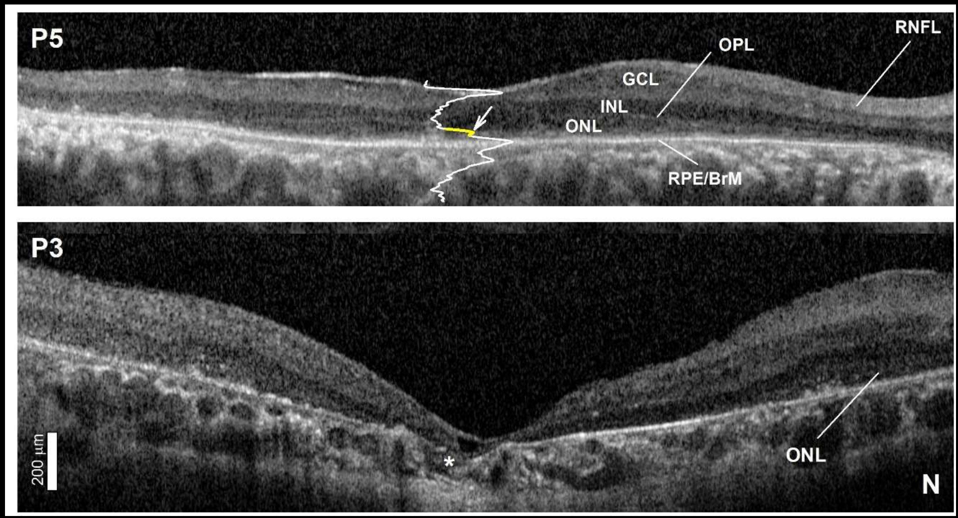
A Unique Challenge

Treatment of Severe Among Severe (*LCA5*-LCA)

Endpoints to the test



Faber et al. JCI Insight. 2023;8:e169162.

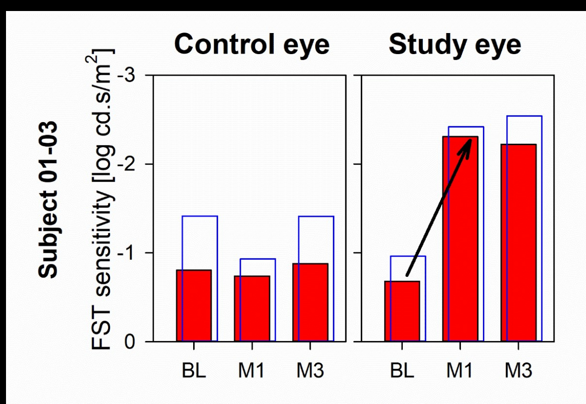


Uyhazi et al. Invest Ophthalmol Vis Sci. 2020 ;11;61:30

- ***Lebercilin*** **localizes to the bulge region of the photoreceptor outer segment**
- **Detectable but severely abnormal photoreceptors**

Full-fields Stimulus Testing

01-03



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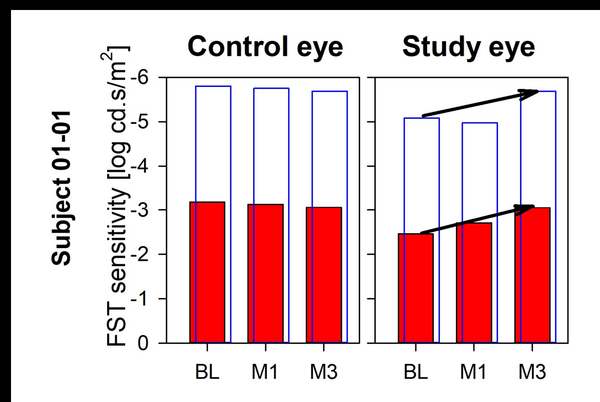

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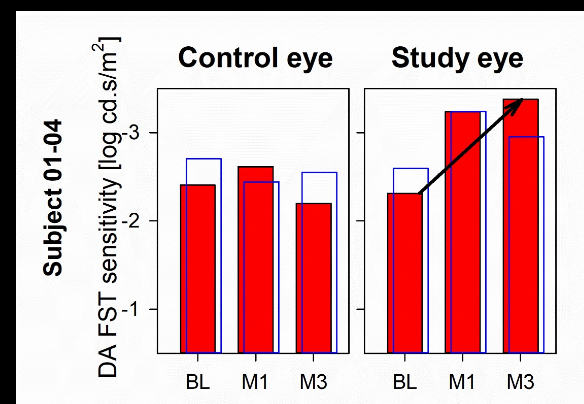
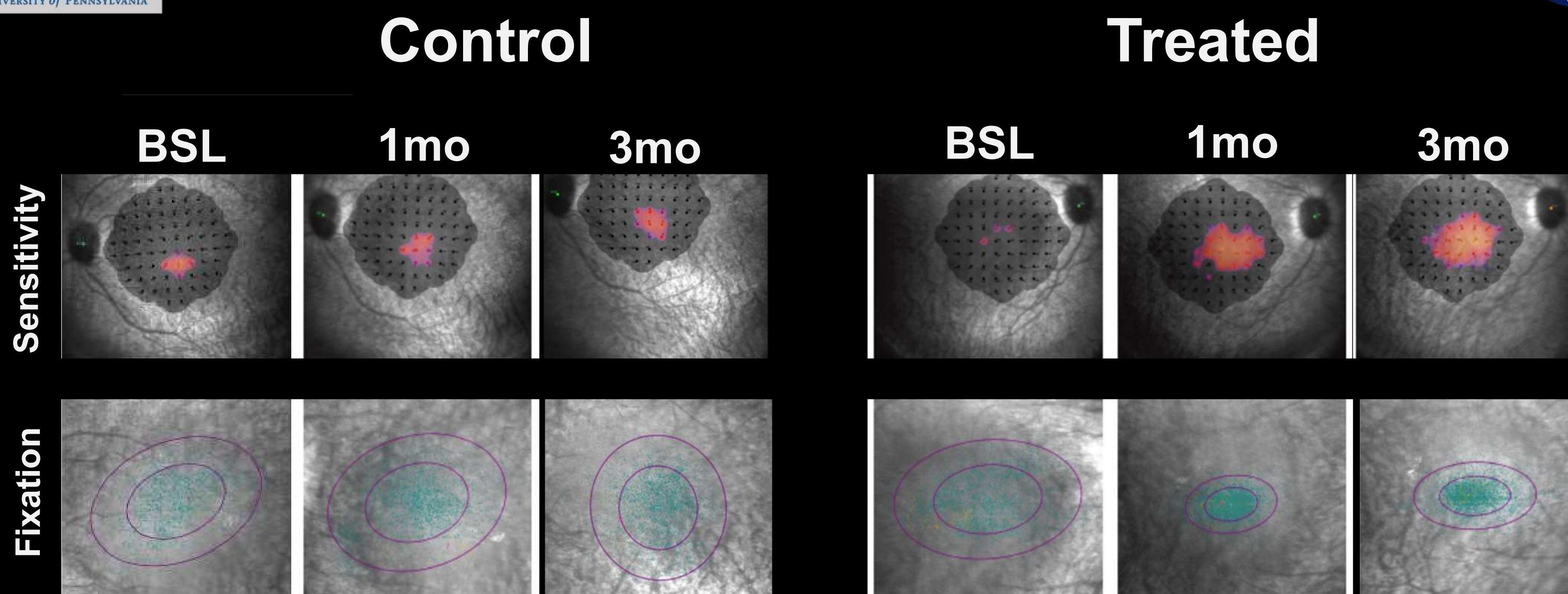


LARGE GAINS IN CONE-MEDIATED SENSITIVITIES

- Significant gain (>1.5 log u.) in cone-mediated sensitivity compared to contralateral control eye and to baseline (BL) values.
- Results are similar for both red (red bars) and blue (blue outlined bars) stimuli = no change in photoreceptor mediation.

Microperimetry [0104]

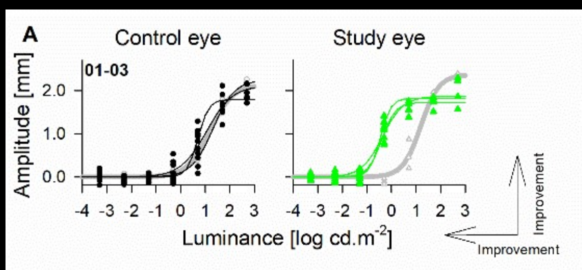


MICROPERIMETRY CONFIRMS FOVEAL IMPROVEMENT

- Microperimetry, possible in one patient, demonstrates sensitivity gain and,
- Movement of a more stable fixation to the foveal center

Pupillometry

01-03



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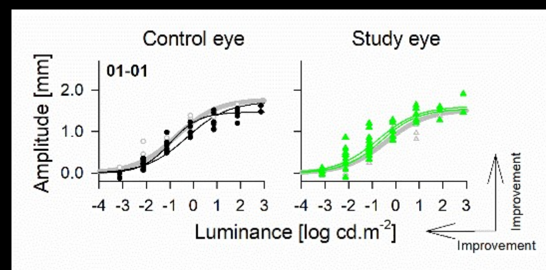

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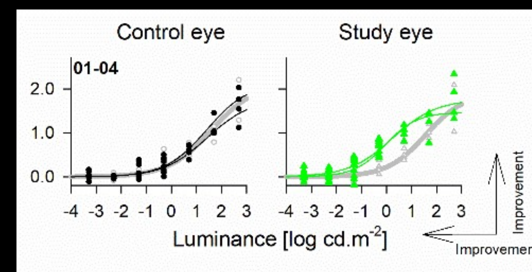

PUPILLOMETRY OBJECTIVELY CONFIRMS EFFICACY/BIOLOGIC ACTIVITY

- Pupil responses are larger in the study eye (green) compared to the contralateral control eye and to baseline values (gray curves).

Conclusions:

- <u>The past and future are bright but our field is stuck…</u>

With a plethora of successful proof-of-concept pre-clinical treatments

With robust safety and efficacy signals in clinical trials

But not being able the move forward to later clinical trial phases and thus treat relevant critical stages and move to clinical applications.

Conclusions:

- <u>We have the readouts/endpoints!</u>

Selection and proper interpretation of readouts is critical.

Expectations are disease and disease stage specific -> this needs to be understood and accepted.

Extrapolations from the use of common end points in other conditions (AMD, DM, Glaucoma) are useful but not straight forward

Conclusions:

- FST, a promising endpoint

Sensitive, reproducible and relatable to other tests.

Easy, fast, applicable over a wide age range.

Proven performance in natural history studies and clinical trials.

Main method in use in clinics worldwide to measure treatment outcomes after Luxturna® administration in clinic as treatment for *RPE65*-IRDs.

Useful over a range of functional phenotypes and severity.

Permits an insight into mechanisms of disease and thus validate/understand othe refficacy signals.

With potential to serve as vision endpoint in cellular replacement therapies (stem cell) as solution for severe vision loss in retinal and optic nerve diseases.

Perelman School of Medicine
University *of* Pennsylvania

Scheie Eye Institute · 50 Years · 1972-2022
Department of Ophthalmology · 150 Years · 1874-2024

Thanks to my closest collaborators!

Jean Bennett &
Albert M. Maguire

Artur V. Cideciyan

Clinical Team

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Emily Kraus
Katherine Maguire
Albert Maguire
Erin O'Neil
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Sarah MacCague
Sarah Galal

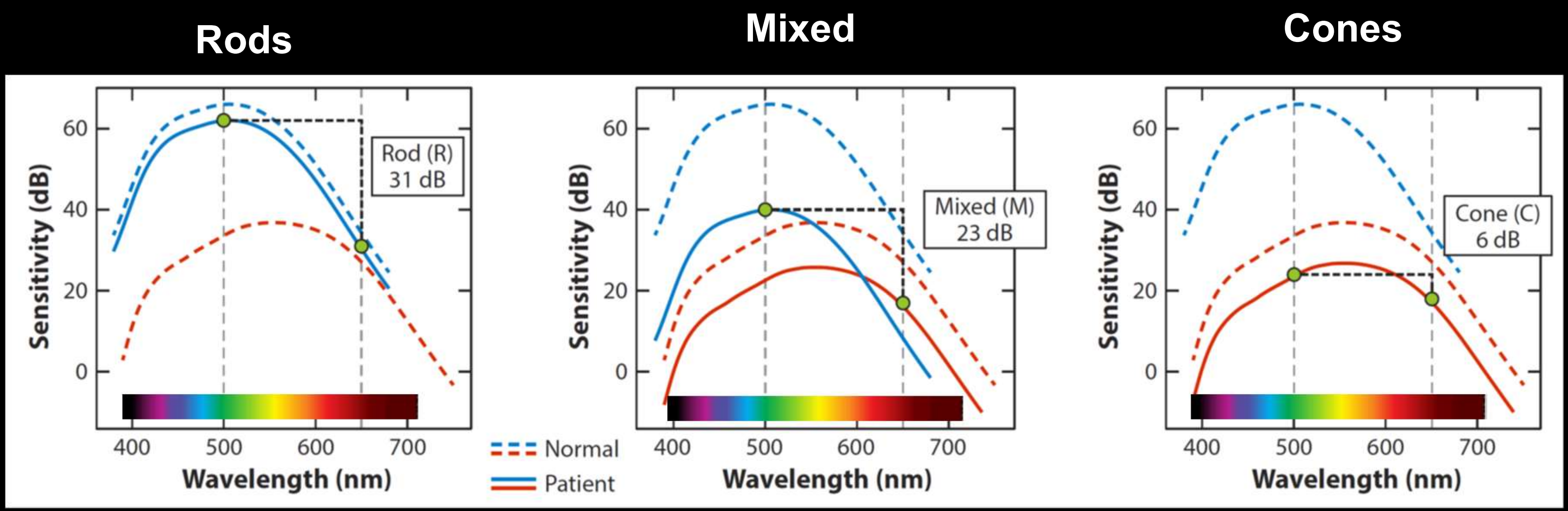
FFB:

David Brint
Rusty Kelley
Peter Ginsberg
Jason Menzo

Opus:

Ash Jayagopal
Sarah Tuller
Ben Yerxa

We can use spectral sensitivity changes during degeneration



Use of two colors to determine the dominant photoreceptor type mediating the response