

Developing a non-human primate model for the objective assessment of presbyopia treatment

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I have no relevant financial relationships.

Presbyopia treatment is a clinically unmet need

10% of presbyopes were willing to trade 5% of their lives for spectacle freedom¹

826 M

Visual Impairment from
presbyopia²

US\$25.4 B

Productivity Loss³

US\$150 M

Market size by 2034⁴



1. Am J Ophthalmol. 2008;145(4):618-622.

2. Am J Ophthalmol. 2017;174:134-144.

3. Clin Ophthalmol. 2020;14:3439-3450.

4. Nyxol [Internet]. Ocuhire Pharma, Inc. 2022.

Emerging pharmacotherapies for presbyopia



However, the *modular effects* of these treatments have not been evaluated.

Name (components)	Company	Development
Liquid Vision PRX-100 (aceclidine + tropicamide)	Presbyopia Therapies	Phase I/2
Brimochol (VTI-001, Carbachol 3% + Brimonidine 0.2%)	Visus Therapeutics	Phase 2
Presbidrops (CSF-I) (parasympathomimetic + NSAID)	Oasis Pharmaceuticals	Phase 3
Presbycarrod Drops SL (pilocarpine + bromfenac)	Presbycarrod	Phase Not Applicable
Vuity™ (AGN-190584, pilocarpine HCl 1.25%)	Allergan	FDA approved
ACN-24IC22 (alpha-2 adrenergic receptor agonist)	AbbVie	Phase I/2
Nyxol (phenotolamine + pilocarpine)	Ocuphire Pharma Inc.	Phase 2
CLX-DPH-361	Gellix Bio	Pre-clinical
Aquaporin 0 (AQPO) with TRPV1/4	NA	Discovery
Glutathione	NA	Discovery
UNR844-Cl / EV06 (1.5% lipoic acid choline ester)	Novartis	Phase I/2

1. Curr Opin Ophthalmol. 2021;32:319-323

Aims

Aim 1

To develop an NHP model for presbyopia studies



Aim 2

To evaluate the effect of Vuity® (1.25% pilocarpine)



Study Protocol

A prospective animal study on 12 non-human primates (NHPs)



Macaca mulatta (Rhesus)



Macaca fascicularis (Cynomolgus)

Study Protocol

A prospective animal study on 12 non-human primates (NHPs)

Protocol 1

Baseline



2% homatropine



15 minutes later



≥ 7 days
washout

Protocol 2

Vuity®



15 minutes later



10% phenylephrine



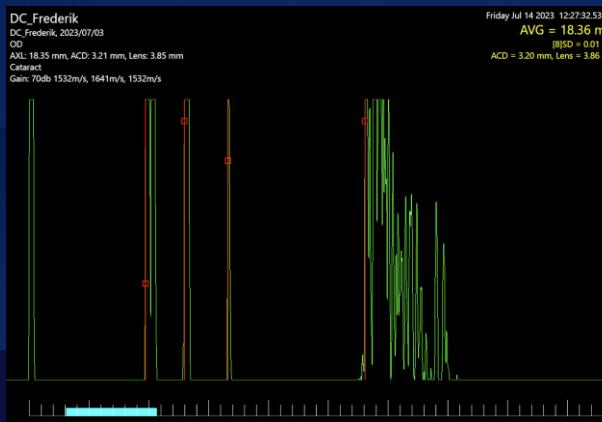
15 minutes later



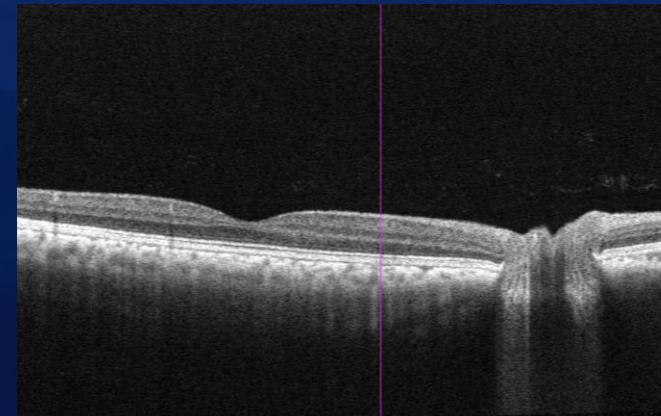
Ophthalmic investigations

Each investigation was performed twice in each protocol

Immersion A-scan



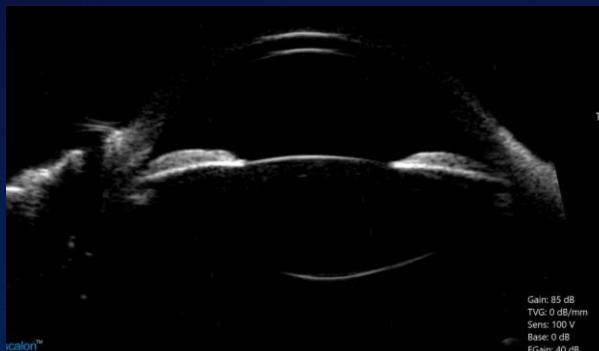
Posterior segment OCT



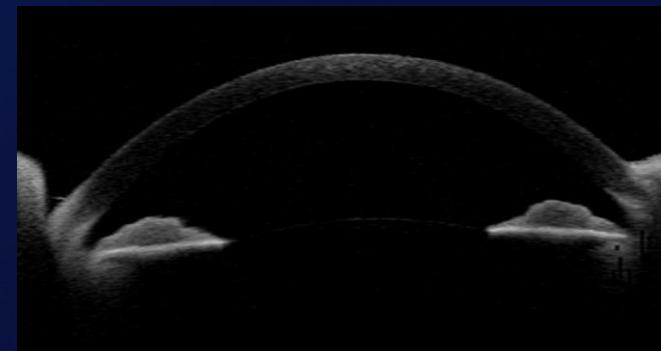
Autorefraction



Ultrasound biomicroscopy



Anterior segment OCT



Intraocular pressure

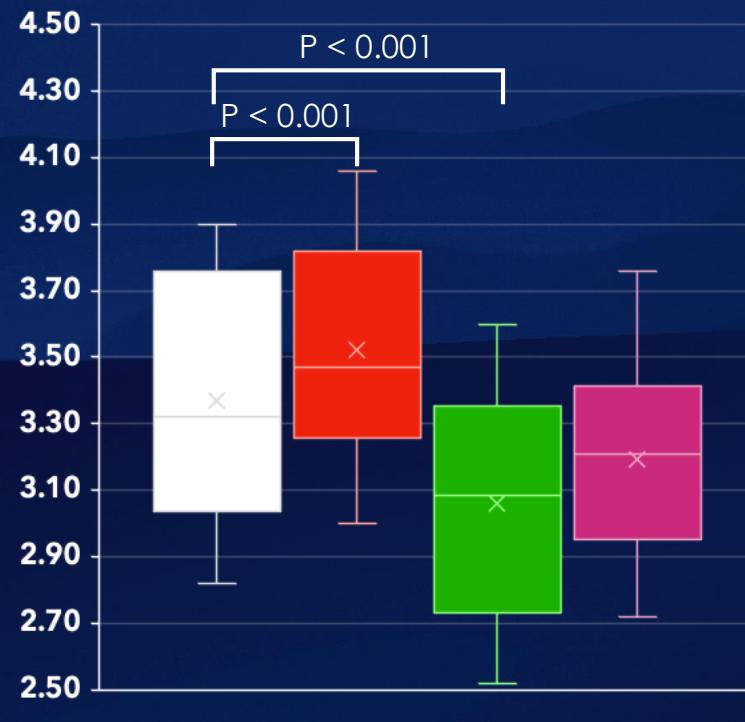


Study Outcomes

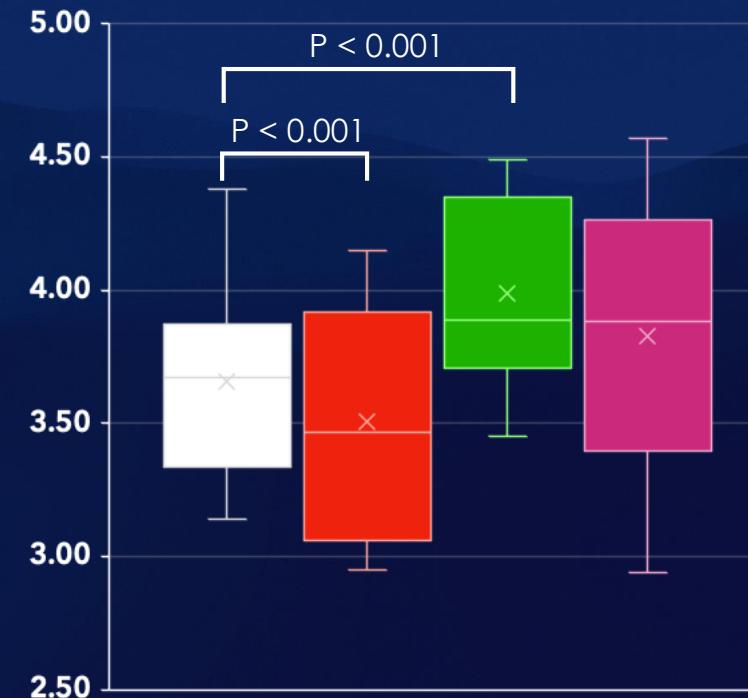
- ❖ To quantify the effect of Vuity® on anterior segment structures in NHPs
 - ❖ Anterior chamber depth (ACD)
 - ❖ Lens thickness (LT)
 - ❖ Spherical equivalent refraction (SER)
- ❖ To determine the age- and species-dependent differences

Quantitative changes after medications

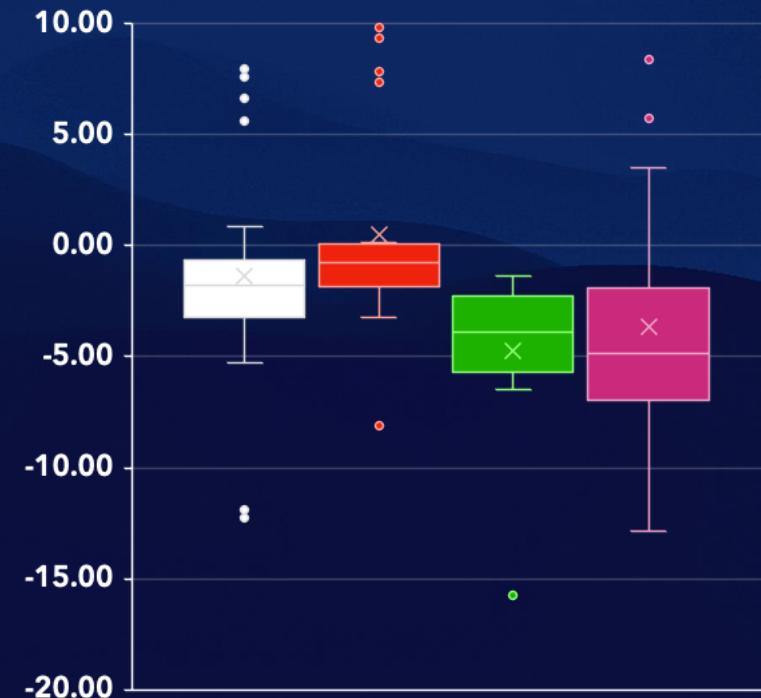
Anterior Chamber Depth



Lens Thickness



Spherical Equivalent Refraction



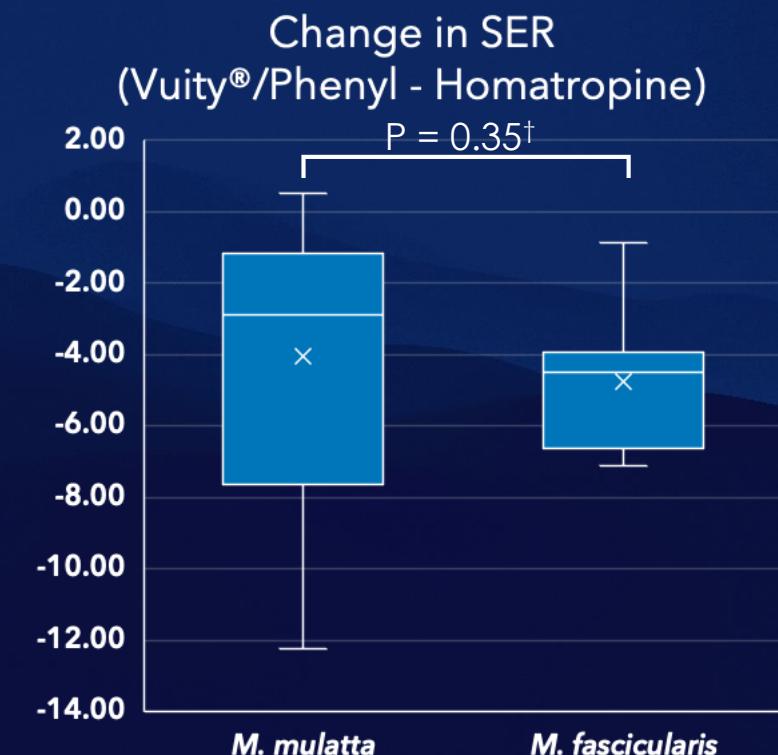
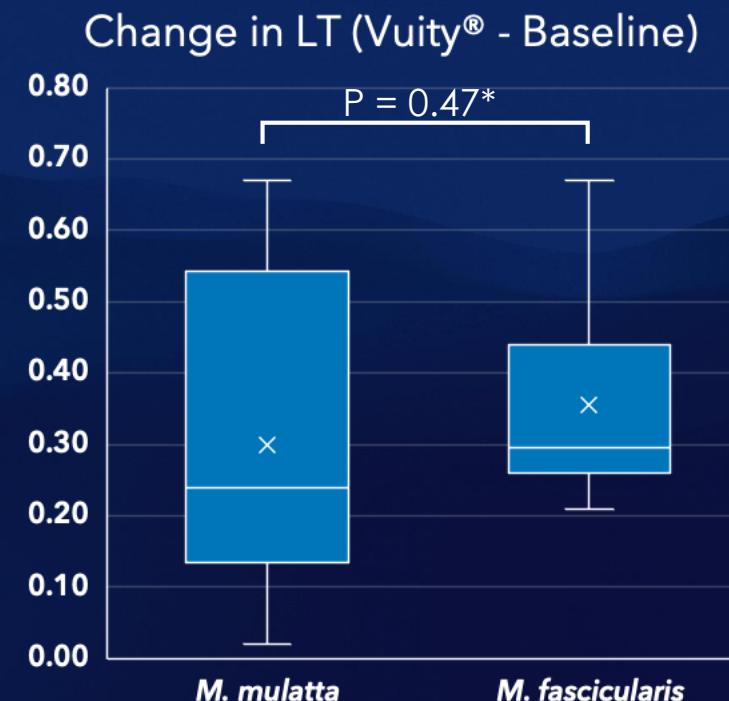
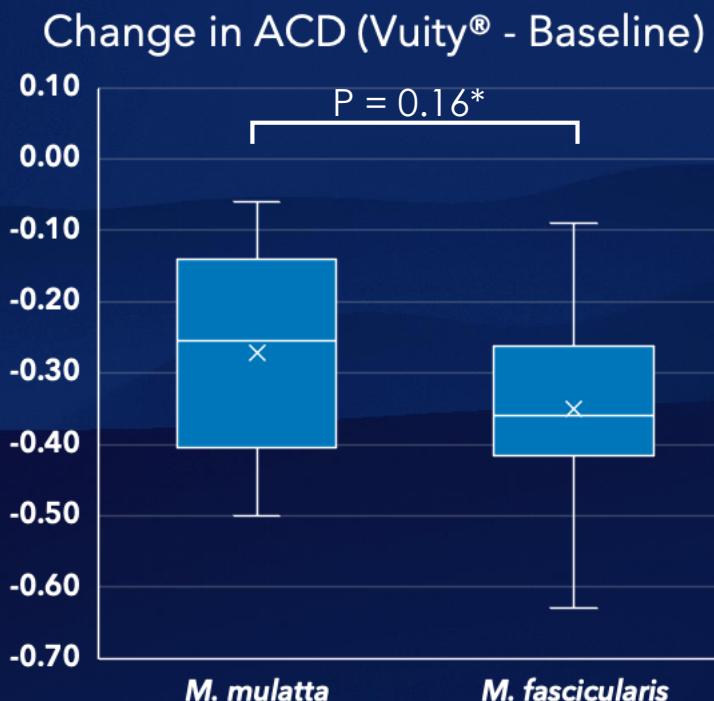
Baseline

5% homatropine

Vuity®

Vuity® + 10% phenylephrine

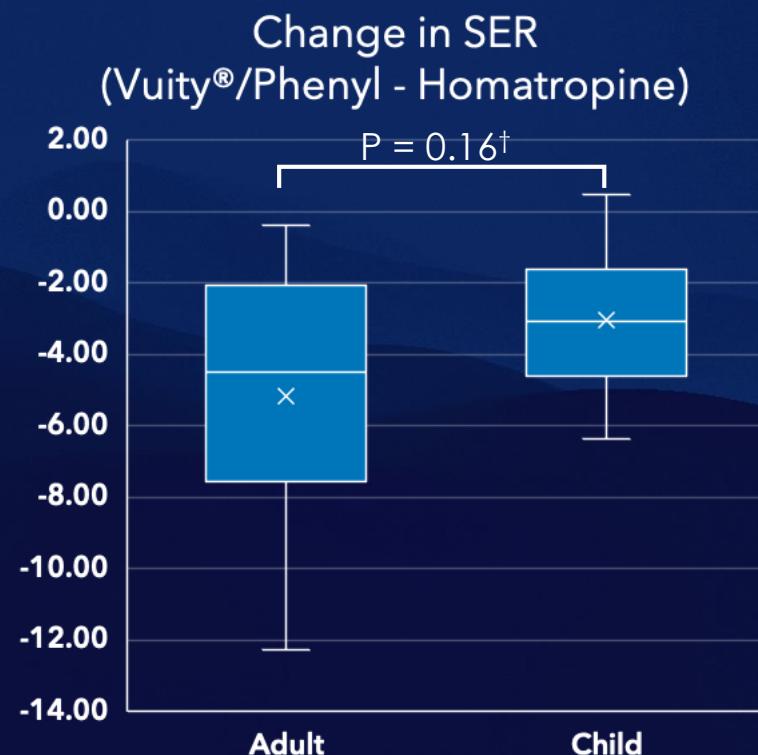
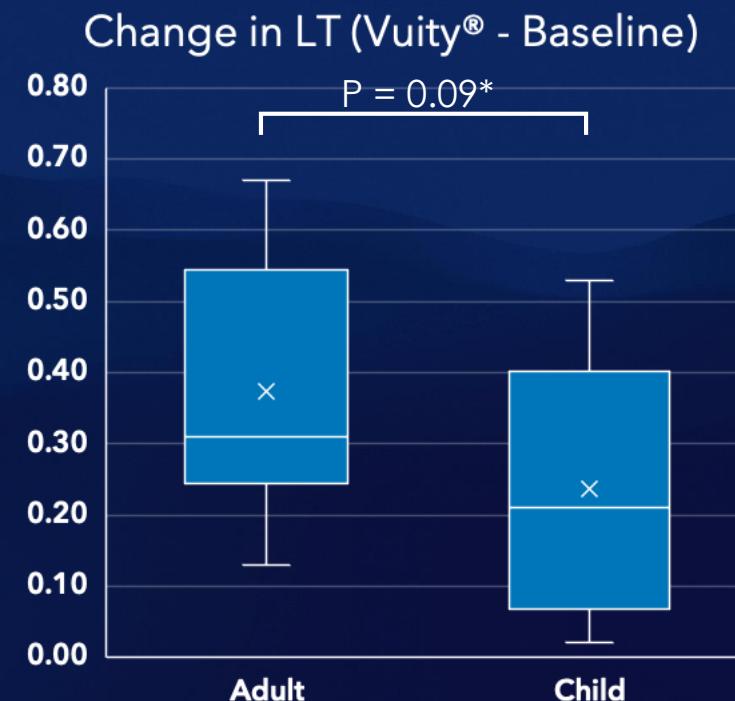
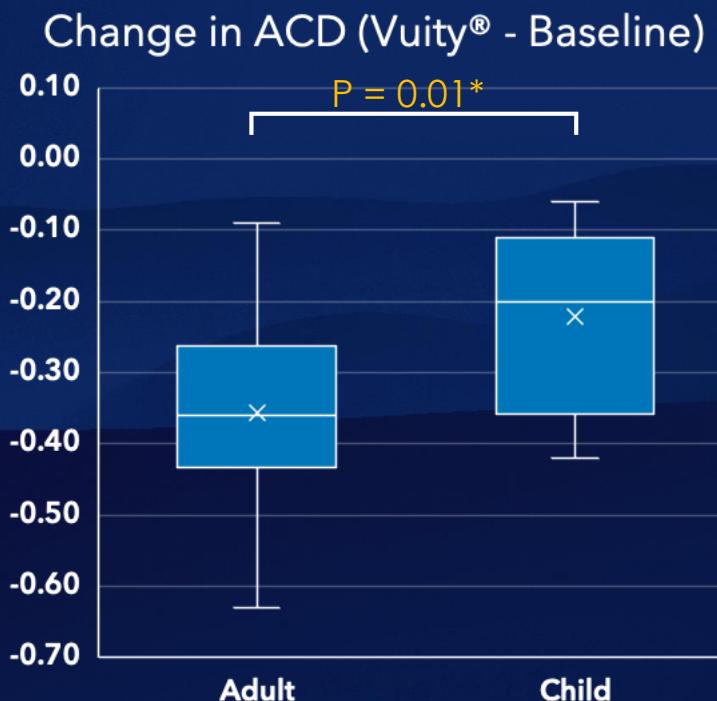
Comparison between *M. mulatta* and *M. fascicularis*



* Independent T-test
† Mann-Whitney U test

No inter-species differences

Comparison between *M. mulatta* and *M. fascicularis*



* Independent T-test
† Mann-Whitney U test

Adults had greater decrease in ACD

Conclusion

An NHP model for objective evaluation of presbyopia treatment

- ❖ Vuity® resulted in greater LT, lower ACD, and a more negative SER
- ❖ Vuity® resulted in a greater ACD decrease in adult NHPs
- ❖ These results may be useful as a reference for future treatments for presbyopia