Evaluation of the Actalens Silicone Accommodating IOL

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Evaluation of the Actalens Silicone Accommodating IOL: results of initial safety and efficacy study

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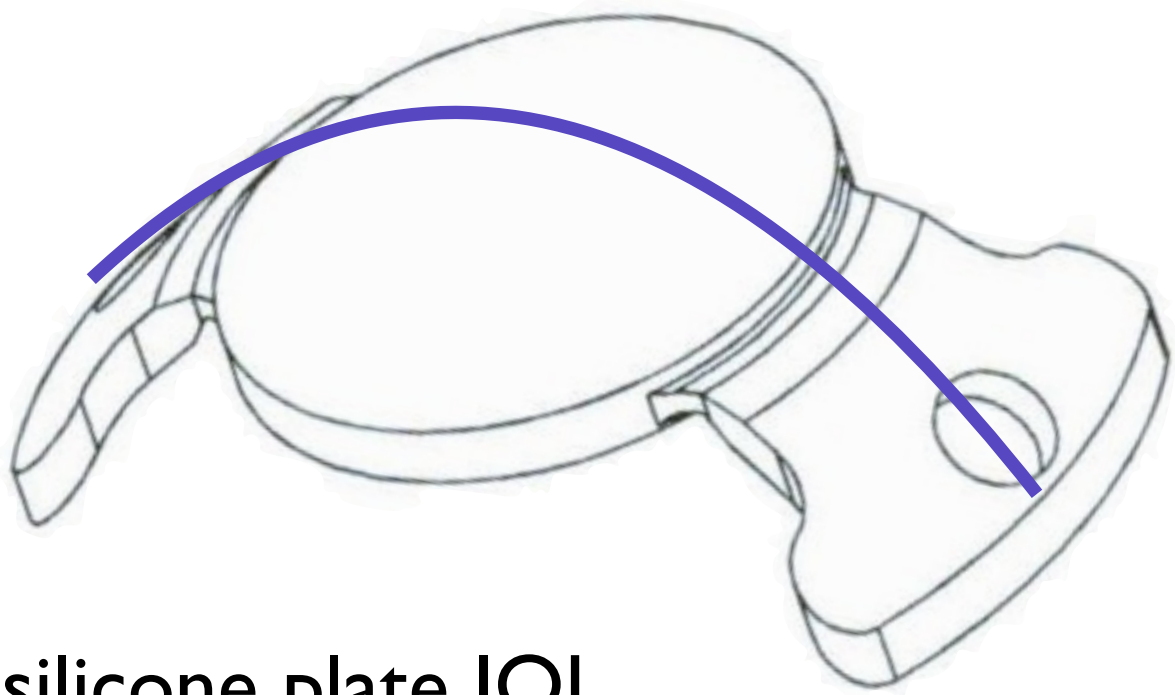
Evaluation of the Actalens Silicone Accommodating IOL

Trial

- To make an initial evaluation of safety and efficacy of the ActaLens™ (Emmetrope, La Canada, CA) accommodating IOL and assess the potential of this new class of restrained IOL
- Eight patients underwent phaco with implant of:
  - 8 ActaLens
  - 4 CrystaLens® AO, 4 Acrysof IQ monofocal in contralateral eye
  - Axial movement: UBM (Reichert) and Scheimpflug imaging (Pentacam HR)
  - Safety: US FDA grid

Restrained Accommodating IOL

- absorbable vicryl 10-0 suture



- single piece silicone plate IOL
- hinge at the optic-haptic junction
- designed with a native forward vault of the optic

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As manufactured

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Restrained

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Implantation

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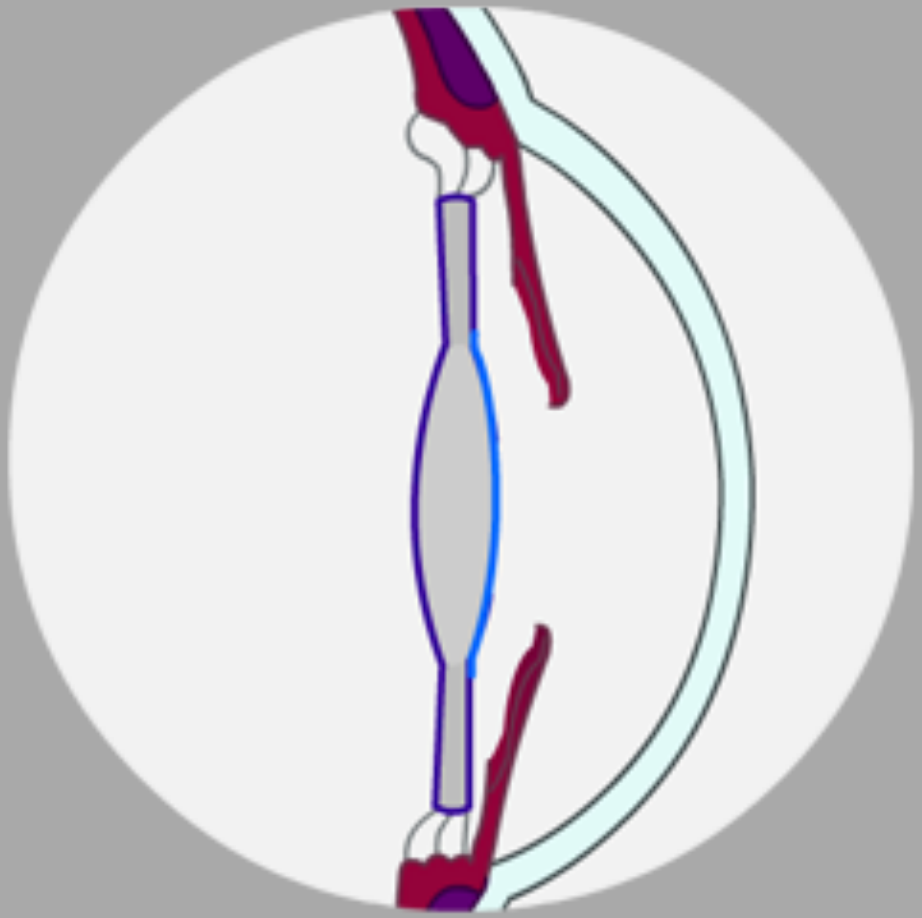
one month of cycloplegia



Restrained during healing

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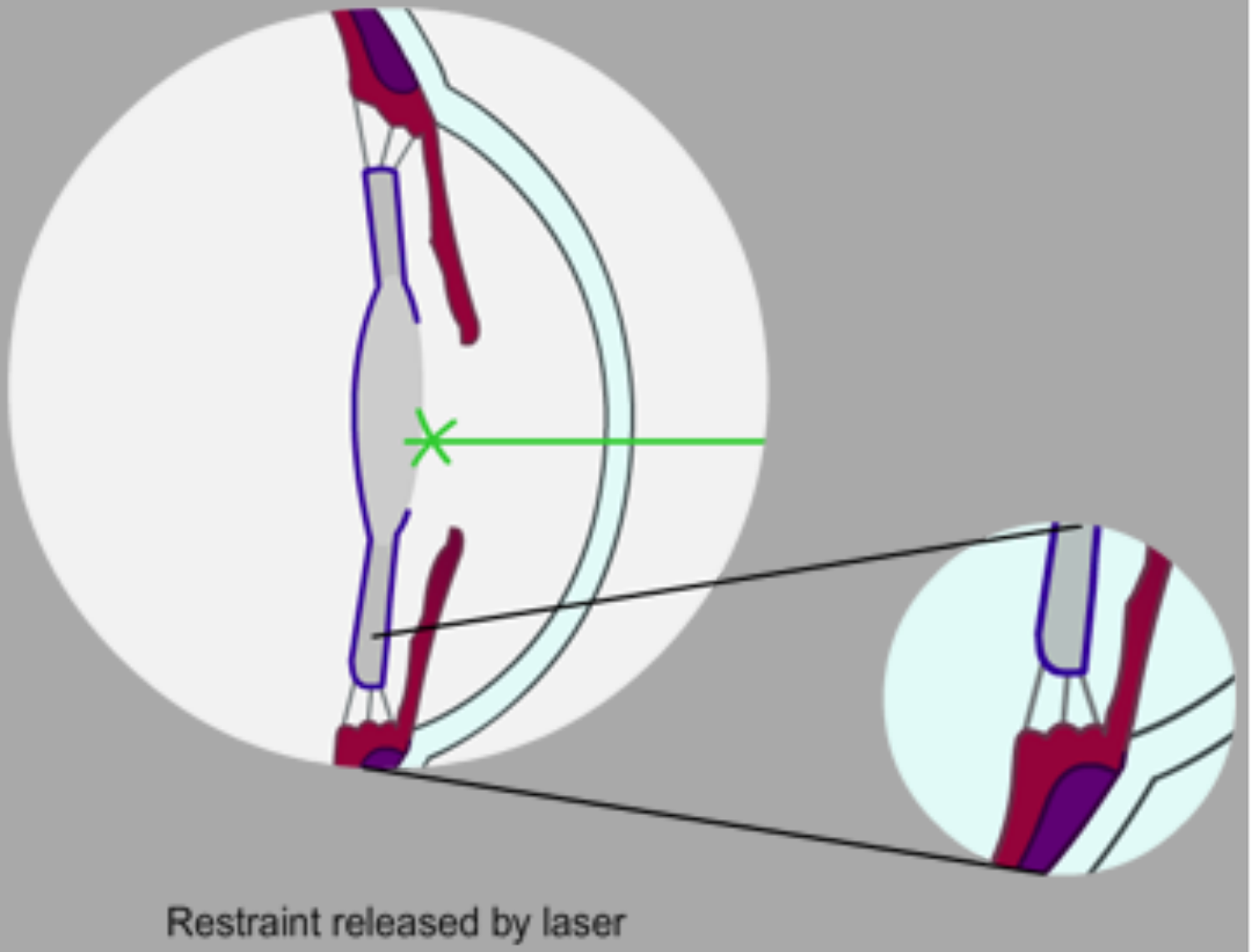
Activated by release of restraint



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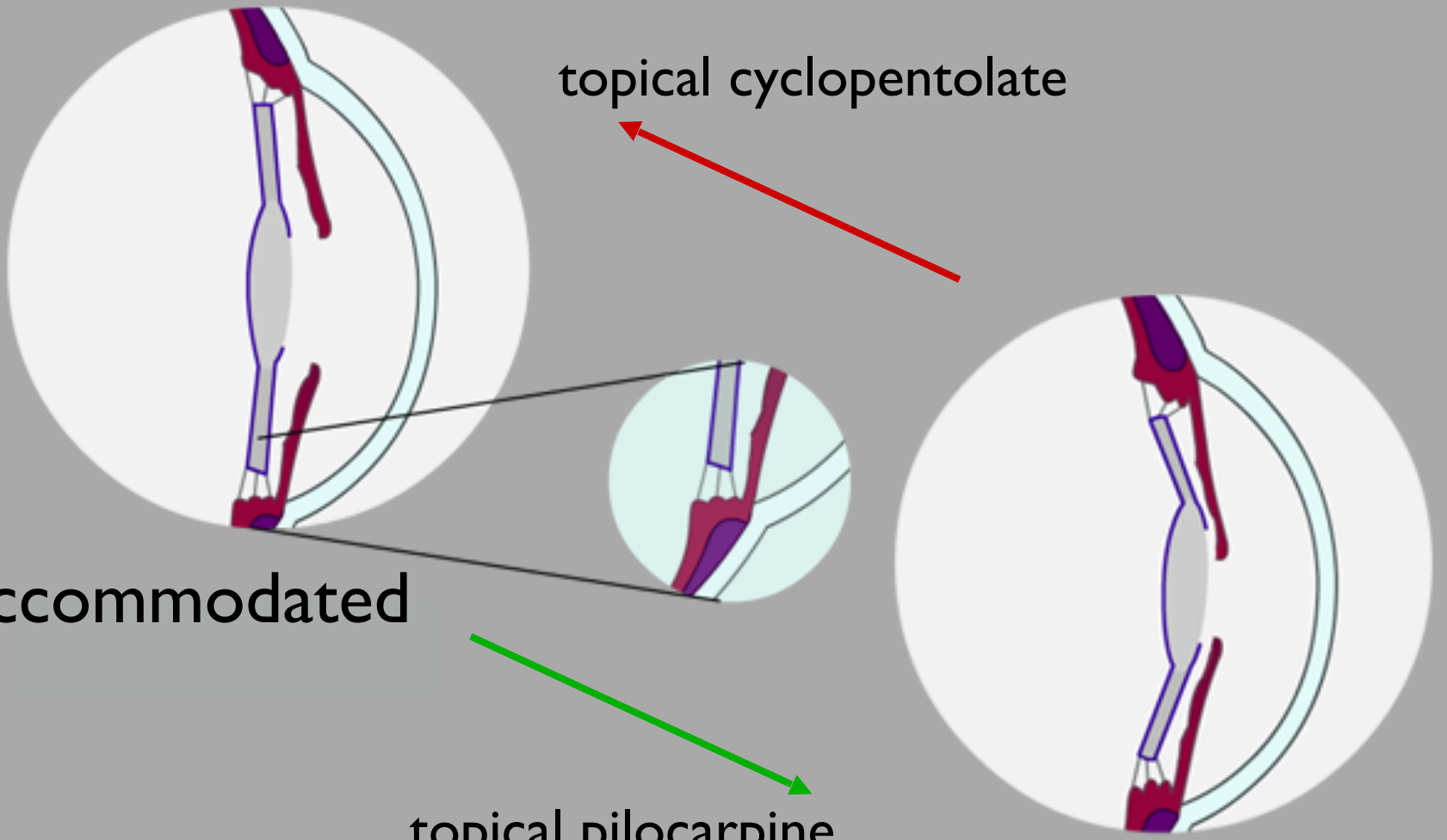
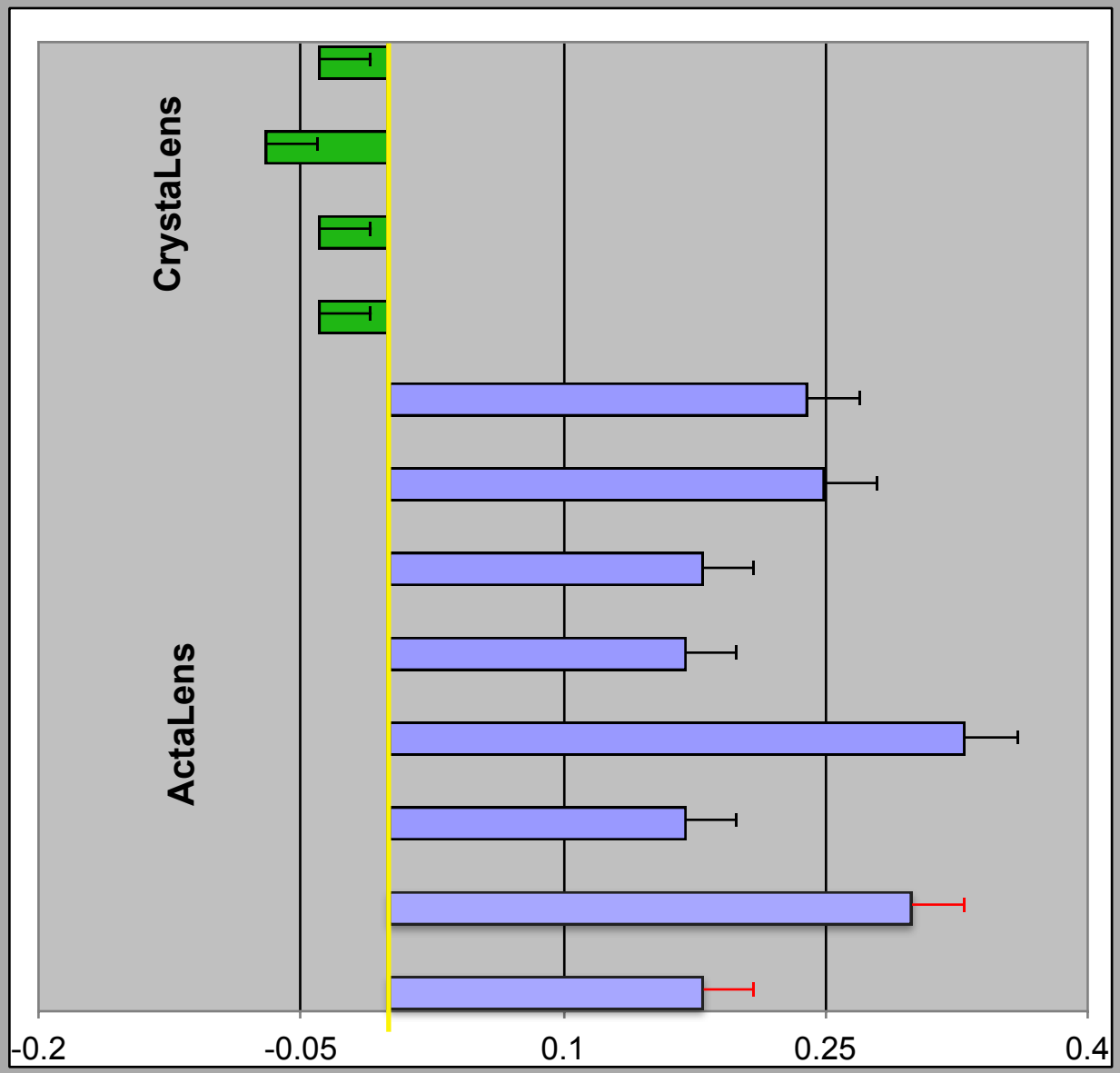


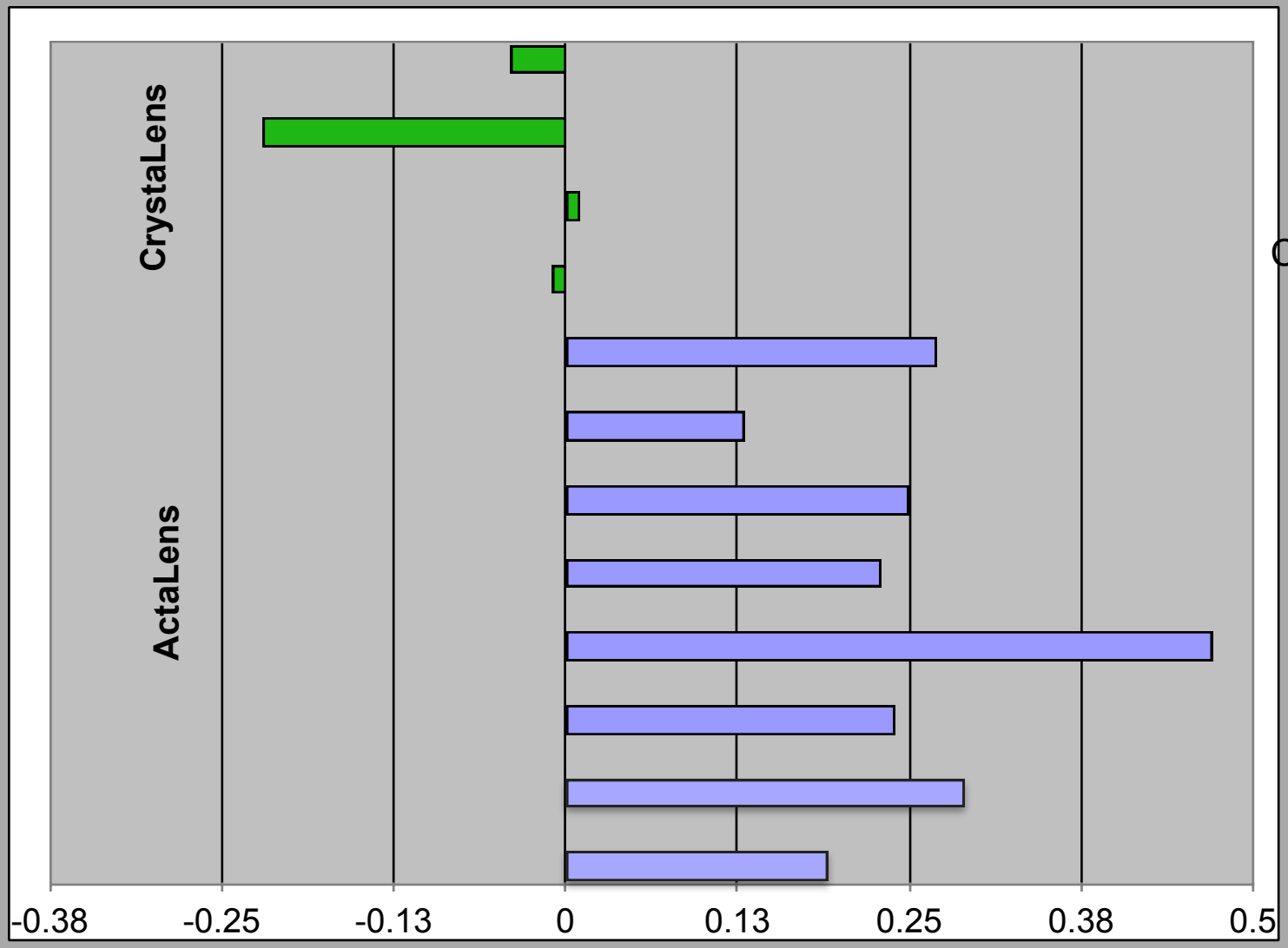
Axial Displacement 6 Weeks Post-Implant
UBM (post-Pilocarpine drops)



CrystaLens® **-0.05 +.02 MM**

ActaLens® **+0.23 +.06 MM**

Axial Displacement 6 Months Post-Implant
Pentacam HR (post-Pilocarpine drops)



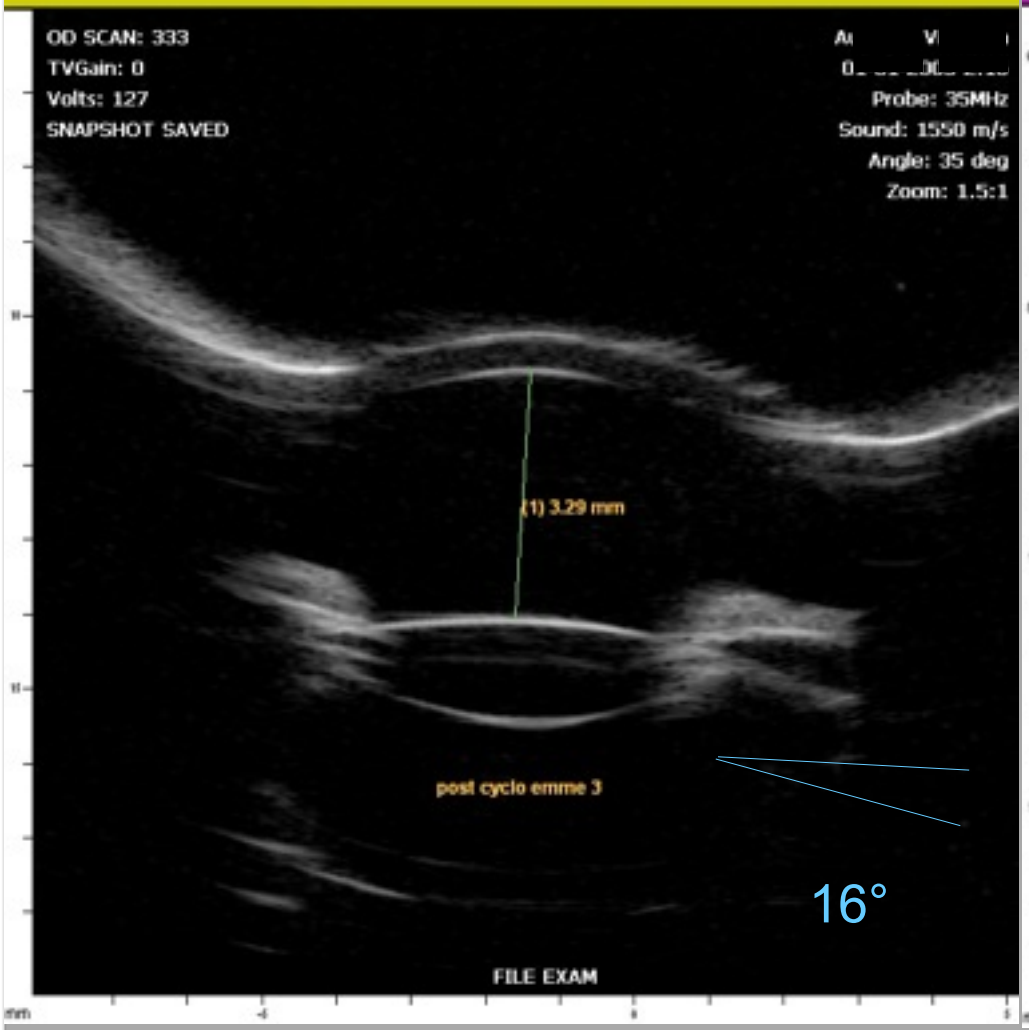
CrystaLens **-0.07 + .11 MM**

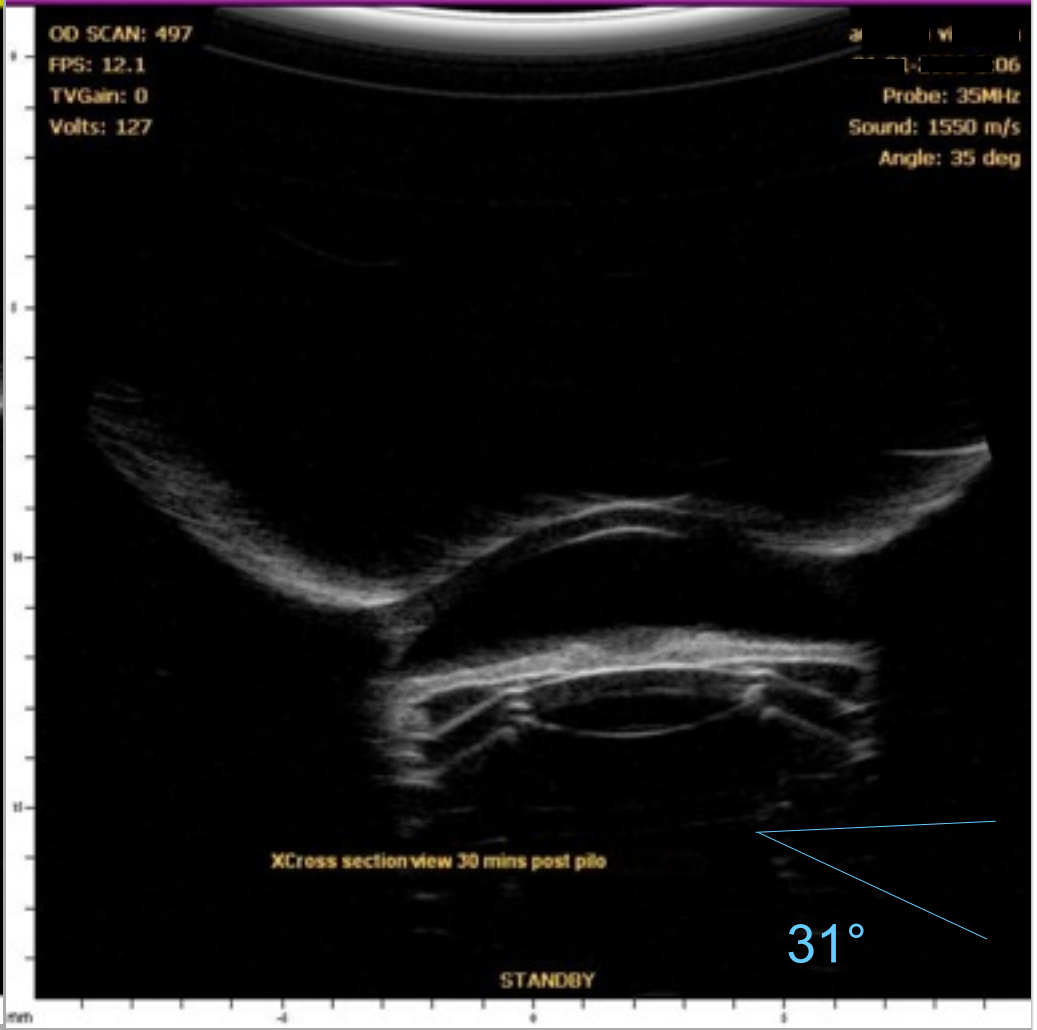
ActaLens **+.26 +.10 MM**

UBM of ActaLens at 10 Months

REICHERT UBM 35MhZ Patient AV, male, 68 y/o, UCVA 20/20-2

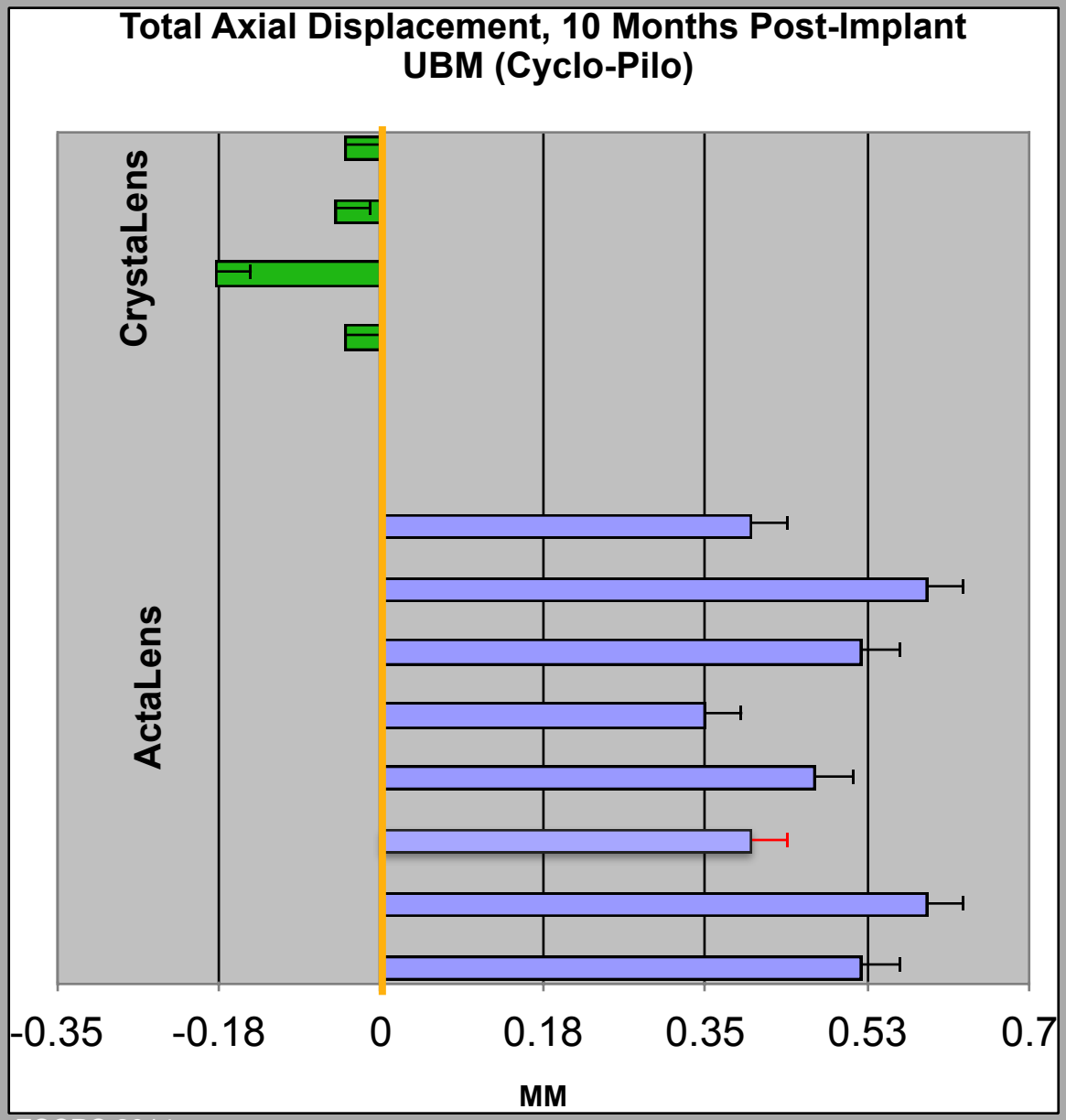
Total axial movement 0.52 MM





Cyclopentalate 1% Pilocarpine 2%

Axial Displacement 10 Months Post-Implant
UBM (from Cylco to Pilocarpine drops)



CrystaLens® **-0.07 ± .07 MM**

ActaLens® **+0.48 ±.09 MM**

Safety Data

Lens	ActaLens	CrystaLens	Acrysof		FDA%
N	8	4	4		
Hyphema	0	0	0		2.2
Cystoid Macular Edema	0	0	0		3.0
Retinal Detachment	0	0	0		0.3
Pupil Block	0	0	0		0.1
Lens Dislocation	0	0	0		0.1
Endophthalmitis	0	0	0		0.1
Hypopyon	0	0	0		0.3
2nd	0	0	0		0.8

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Summary

- At 6 weeks, 6 months, and 10 months, the ActaLens demonstrated consistent movement by both UBM and Scheimpflug imaging.
  - +0.48 MM total movement noted may provide true accommodation that is additive to pseudoaccommodative effects
- The ActaLens was well tolerated in this study.
  - no complications noted
- Novel mechanism validated for single optic ACIOL and should be applicable to:
  - Dual optic IOL
  - Shape-Changing Optic IOL