Just Released:
New learnings from the ongoing PROTECT Clinical Trial in addition to how NaturalVue Multifocal manages myopia in children

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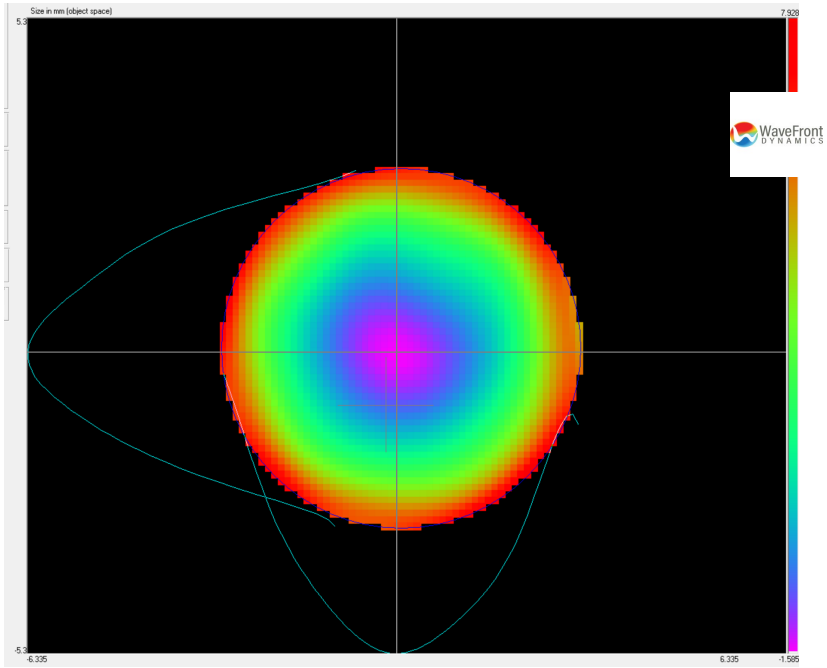
Visioneering Technologies, Inc.

FDA Indication (on-label):

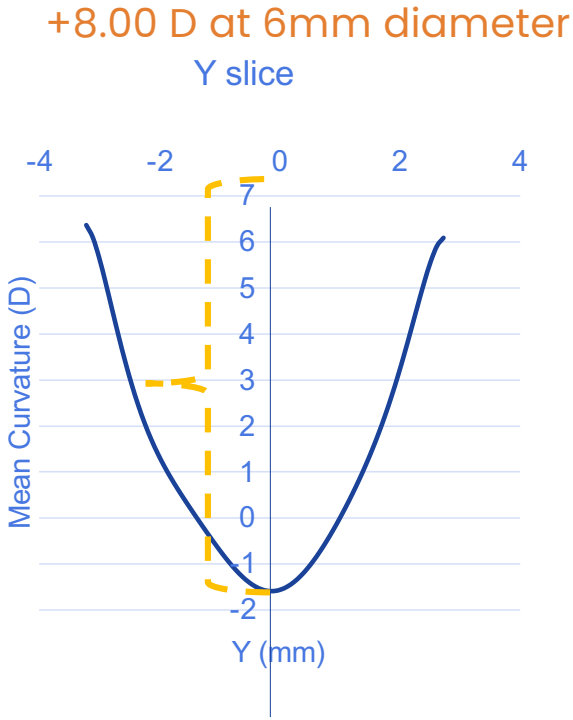
NaturalVue® (etafilcon A) Multifocal 1 Day Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in normal eyes … from -20 D to +20 D …who exhibit astigmatism of 2.00 D or less….

Outside of the US: indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control in normal eyes.

Catenary Power Profile

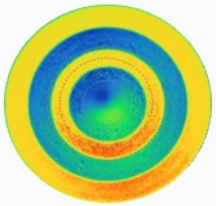


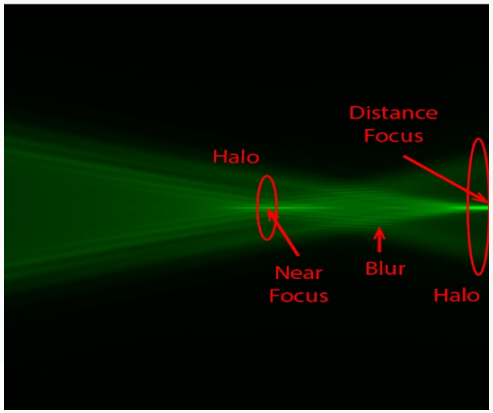
Hartmann-Shack Aberrometer



**US: NaturalVue® (etafilcon A) Multifocal 1 Day™ Disposable Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia in normal eyes. OUS: indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia, and myopia progression control in normal eyes.

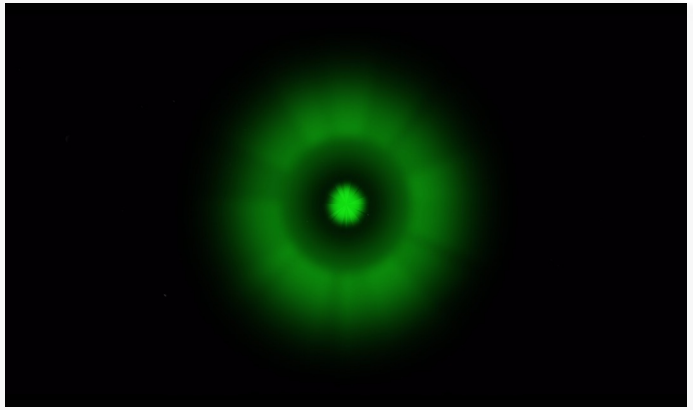
How is this possible? Not all Multifocality is the Same

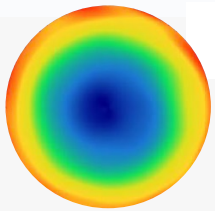


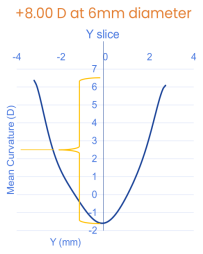


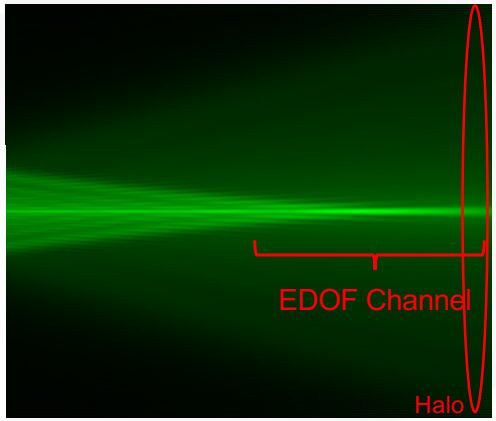
Bifocal/Zonal Refractive optic

- Halo and ghosting could be obvious
- Defocus treatment area is limited



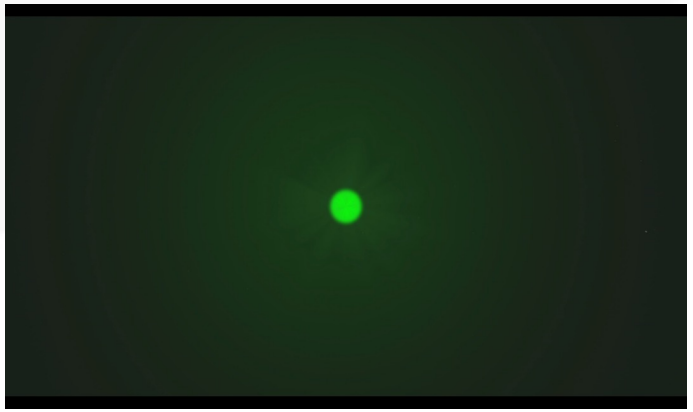






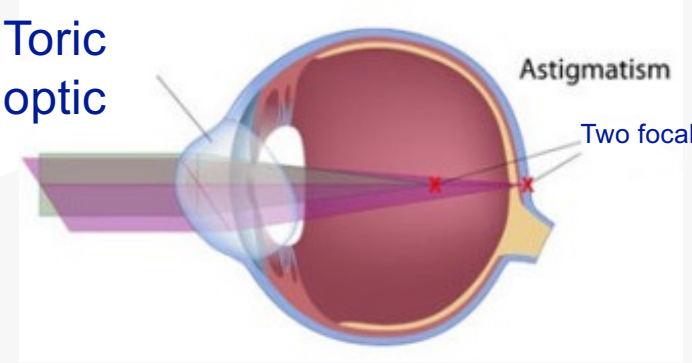
Neurofocus Optics® (Catenary Multifocal)

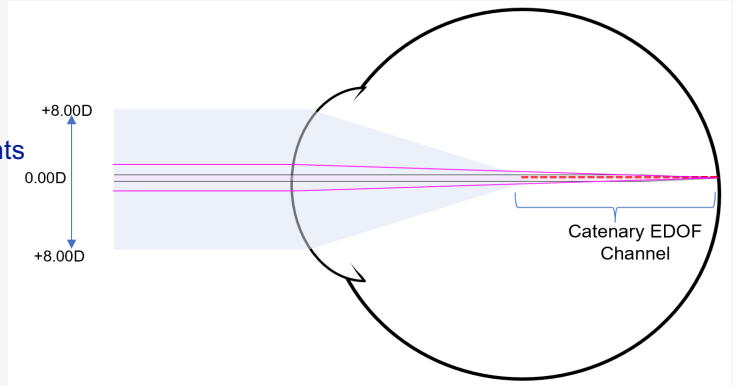
- Halo evenly spread out, reduced intensity
- Defocus treatment area significantly increased >±30°



Catenary Curved Power Profile's EDOF Addresses Astigmatism

Toric optic





- The astigmatic eye has two focal points
- EDOF channel can correct astigmatism (both meridians can be in focus at the same time) [The same way it corrects presbyopia]
- Indicated for up to 2.00 DC

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Pupil Sizes in Children

Average pupil size in children is ~ 5.5-6mm[1,2]

1

Age (y)	No. of Participants	Maximum Pupil Size (mm [SD])	Minimum Pupil Size (mm [SD])
1–2	8	4.82 (1.13)	3.44 (0.71)
2–3	7	4.64 (0.84)	3.10 (0.64)
3–4	6	5.02 (0.83)	3.28 (0.73)
4–5	13	5.27 (0.60)	3.50 (1.09)
5–6	16	4.90 (0.60)	3.34 (0.53)
6–7	14	5.11 (0.73)	3.52 (0.61)
7–8	11	5.31 (0.87)	3.73 (0.65)
8–9	8	4.99 (1.02)	3.42 (0.66)
9–10	14	5.48 (1.17)	3.79 (0.82)
10–11	18	5.56 (0.44)	3.79 (0.44)
11–12	13	5.95 (0.79)	3.81 (0.56)
12–13	20	5.36 (0.83)	3.63 (0.48)
13–14	11	5.82 (0.77)	3.93 (0.51)
14–15	12	5.38 (0.92)	3.64 (0.62)
15–16	12	5.74 (0.64)	3.70 (0.43)
16–17	10	6.01 (1.12)	3.92 (0.66)
17–18	8	5.10 (1.45)	3.42 (0.64)
Total/ average	201	5.36 (0.90)	3.62 (0.65)

SD = standard deviation

- NeurOptics Pupillometer
- Ambient light condition
- N=272

2

Pupil size and anisocoria in children measured by the plusoptiX photoscreener

Jillian Silbert,[a] Noelle Matta, CO, CRC, COT,[a] Jing Tian, MS,[b] Eric Singman, MD, PhD,[c] and David I. Silbert, MD, FAAP[a]

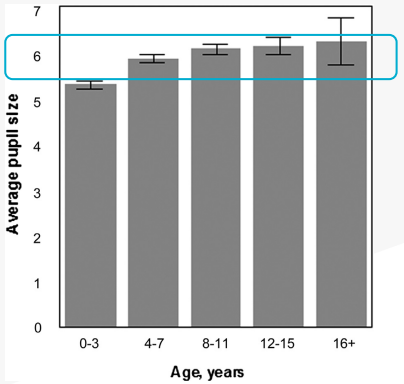
PURPOSE To investigate pupil size and the incidence of anisocoria in children at a single community-based practice using the plusoptiX A04 and A09 photoscreeners (plusoptiX GmbH, Nuremberg, Germany).

METHODS The medical records of consecutive patients <1 to 17 years of age who had received a comprehensive ophthalmological examination that included photoscreening with the plusoptiX were retrospectively reviewed. Data collected included sizes of both pupils, age, sex, laterality, and magnitude of anisocoria.

RESULTS A total of 1,306 patient records were reviewed. Of these, 1,057 (80.9%) had 0-0.4 mm of anisocoria; 219 (16.8%), 0.5-0.9 mm; 20 (1.5%), 1.0-1.4 mm; and 10 (0.8%), ≥1.5 mm. Magnitude of anisocoria appears to increase with age ($P = 0.0073$). Pupil size and age were positively correlated ($P < 0.0001$), that is, older children had larger pupils. Average pupil size of children <1 year of age was 5.0 mm; of children ≥16 years of age, 6.1 mm. When sorted into age buckets of 0-3, 4-7, 8-11, 12-15, and 16-17, this increase becomes apparent. There is no significant relationship between pupil size and sex ($P = 0.14$).

CONCLUSIONS Our study of 1,306 children shows that pupil size increases through childhood, and that 19.1% of children in a clinical population have anisocoria >0.4 mm. (J AAPOS 2013;17:609-611)

- plusoptiX Photoscreener
- Ambient light condition
- N=1,306



1. Connelly M, Neville K. Developmental Changes of Normal Pupil Size and Reactivity in Children. J Ped Ophthal Strab, May 2015. DOI:10.3928/01913913-20150317-11
2. Silbert et al. Pupil size and anisocoria in children measured by the plusoptiX photo screener. JAAPOS 2013;17:609-611

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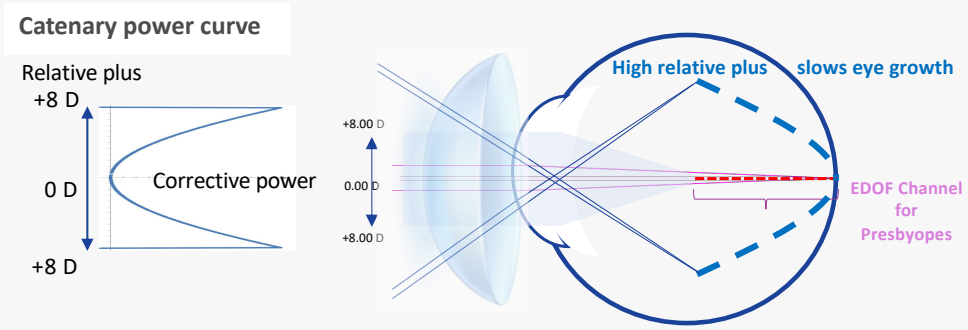
One Optical Design, Two Functions



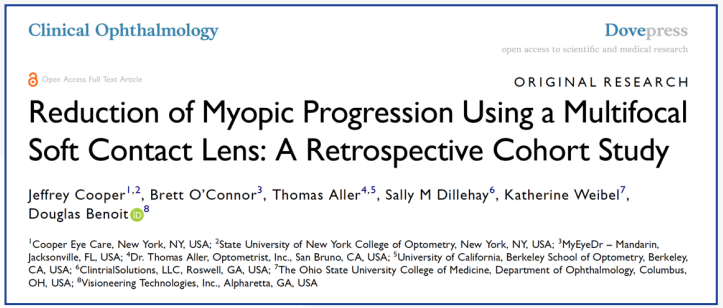
This revolutionary optical design simultaneously provides:

One Universal Add for all ages

Unprecedented magnitude of relative plus (myopic defocus)

Minimal image disturbance results in easy neuroadaptation

- ➔ spectacle level visual quality
- ➔ spectacle level stereopsis



Clinical Ophthalmology

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ORIGINAL RESEARCH

Reduction of Myopic Progression Using a Multifocal Soft Contact Lens: A Retrospective Cohort Study

Jeffrey Cooper[1,2], Brett O'Connor[3], Thomas Aller[4,5], Sally M Dillehay[6], Katherine Weibel[7], Douglas Benoit[8]

[1]Cooper Eye Care, New York, NY, USA; [2]State University of New York College of Optometry, New York, NY, USA; [3]MyEyeDr – Mandarin, Jacksonville, FL, USA; [4]Dr. Thomas Aller, Optometrist, Inc., San Bruno, CA, USA; [5]University of California, Berkeley School of Optometry, Berkeley, CA, USA; [6]ClintrialSolutions, LLC, Roswell, GA, USA; [7]The Ohio State University College of Medicine, Department of Ophthalmology, Columbus, OH, USA; [8]Visioneering Technologies, Inc., Alpharetta, GA, USA

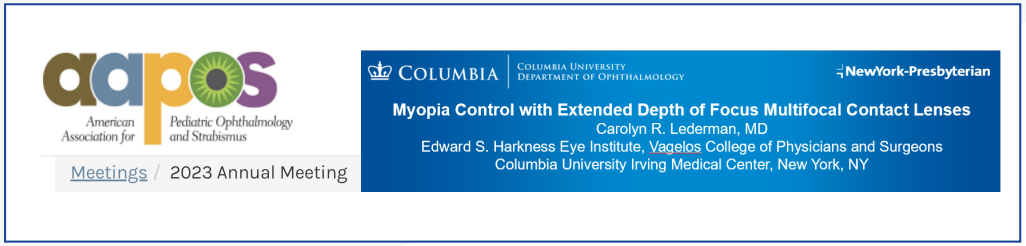
"6 Year Retrospective"
Clinical Ophthalmology
(2022)

ORIGINAL INVESTIGATION

Retrospective Analysis of a Clinical Algorithm for Managing Childhood Myopia Progression

Jeffrey Cooper, OD, MS, FAAO,[1] Thomas Aller, OD,[2] Earl L. Smith, III, OD, PhD, FAAO,[3] Kevin Chan, OD, MS, FAAO,[4] Sally M. Dillehay, OD, EdD, FAAO,[5] and Brett O'Connor, OD, FAAO[6]*

"CAMP Study"
Optometry & Vision Science
(2023)



aapos
American Association for Pediatric Ophthalmology and Strabismus

Meetings / 2023 Annual Meeting

COLUMBIA | COLUMBIA UNIVERSITY DEPARTMENT OF OPHTHALMOLOGY | NewYork-Presbyterian

Myopia Control with Extended Depth of Focus Multifocal Contact Lenses

Carolyn R. Lederman, MD
Edward S. Harkness Eye Institute, Vagelos College of Physicians and Surgeons
Columbia University Irving Medical Center, New York, NY

"Dr. Lederman Cohort"
AAPOS meeting
(2023)

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What You Can Expect with Neurofocus Optics® :

-PROTECT RCT Interim Analyses

PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial (PROTECT)

Randomized Controlled Trial (duration 3 years)

- Sample size: 145 children ages 7 to <13
  - Spherical Equivalent: -0.75 to -5.00D, Astigmatism: ≤ -1.00D, Anisometropia: ≤ 1.00D
  - Treatment naïve (no previous ortho-K, atropine, MPC spectacles or contact lenses)
- Multi-Center: Canada, US, Hong Kong, Singapore
- Double masked: Subject and Outcome measure examiners
  - **NVMF vs Control lens (NV sphere) 2 : 1**
  - Control Group will cross over to treatment after 24M
- Outcomes
  - Change of Cycloplegic SER
  - Change of Axial Length
  - Safety (Adverse Events, Slit Lamp Exam, Visual Acuity)

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PROTECT Interim Data

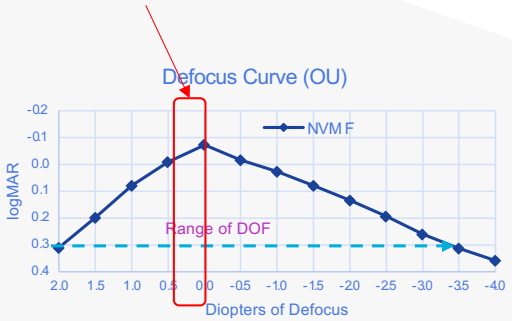
- Planned 1-year interim analysis
- Planned Subgroup analysis on enrolled subjects who met a common myopia control study criteria:

  age 8 to<13, CSER -0.75 to -4.00D
- 10 subjects exited the study (5 voluntary exits; drop-out=3%)
- All available subject data included
- Covariate analysis identified significant variables:

  age, sex, site and **pupil diameter**

Fitting Method

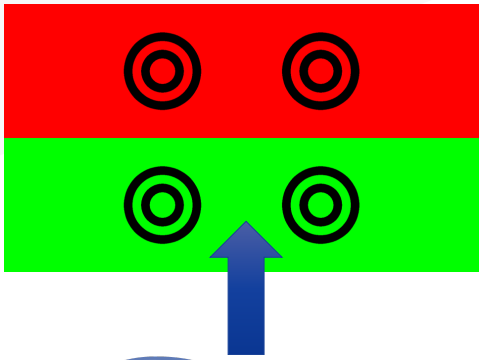
Under-correction = suboptimal vision



Catenary Curve ➔ Great vision

Simple Refraction: Maximize distance vision

- Under-correction will make myopia worse
- **One-click into the Green** after best-sph-cyl-refraction to maximize distance vision



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Spectacle Level Visual Acuity

- All available subjects (ITT)
- Both groups had contact lens HCVA 20/20 or better
- No change in high contrast distance and near visual acuities from the baseline
- One line reduction of low contrast visual acuity

Study Group (Mean±SD)	Dist HCVA OU	Dist LCLLVA OU	Near HCVA OU
BL Spec (n = 41)	-0.04 ± 0.05	0.11 ± 0.14	-0.04 ± 0.06
SVCL (n = 41)	-0.04 ± 0.08	0.11 ± 0.14	-0.03 ± 0.05
p-value (Spec vs CL)	0.946	0.987	0.506
BL Spec (n = 93)	-0.05 ± 0.06	0.09 ± 0.11	-0.03 ± 0.06
NVMF (n = 93)	-0.04 ± 0.07	0.17 ± 0.15	-0.02 ± 0.04
p-value (Spec vs CL)	0.723	<0.001	0.106
p-value (SVCL vs NVMF)	0.883	0.024	0.248

Patient-Reported Outcome (NVMF = SVCL)

Pediatric Refractive Error Profile 2 (PREP2)

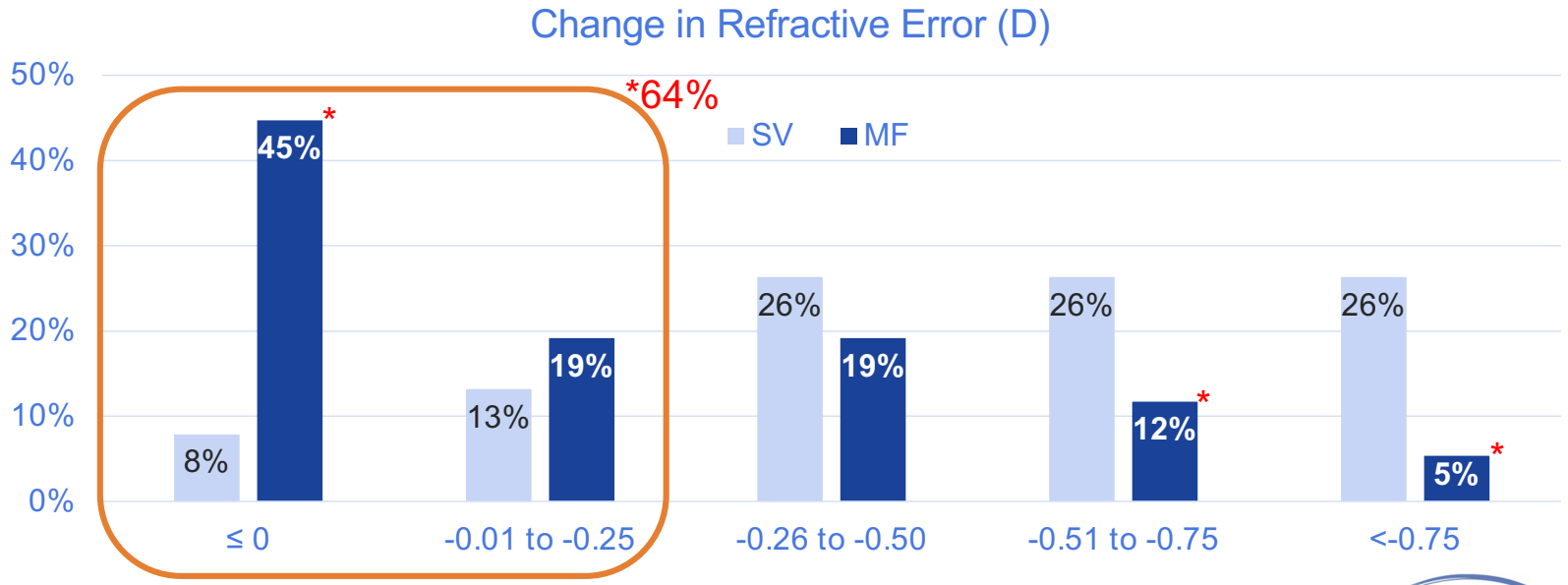
- Validated for the BLINK study, able to separate +2.50D Add from +1.50D Add by 3-4 points
- Both groups improved from the baseline- contact lens wear improves satisfaction
- Both groups reported similar scores of Vision, Symptoms, Activities and Overall satisfaction

Study Group (Mean±SD)	Vision	Symptoms (Comfort)	Activities	Overall
Baseline (n = 41)	42.45 ± 11.82	52.26 ± 15.00	40.32 ± 22.13	44.36 ± 20.18
SVCL (n = 41)	68.06 ± 11.51	57.06 ± 19.50	79.34 ± 14.42	78.36 ± 11.95
Paired p-value	<0.001	0.172	<0.001	<0.001
Baseline (n = 93)	46.27 ± 12.45	51.88 ± 11.95	40.59 ± 20.10	44.79 ± 19.09
NVMF (n = 93)	70.17 ± 12.53	61.79 ± 18.01	77.78 ± 15.86	78.06 ± 14.24
Paired p-value	<0.001	<0.001	<0.001	<0.001
P-value (SVCL vs NVMF)	0.345	0.189	0.577	0.898

Distribution of Myopia Progression

NVMF:

- 64%* study population has ≤0.25D or less myopic progression
- 5% study population may have responded mildly or fast progressors

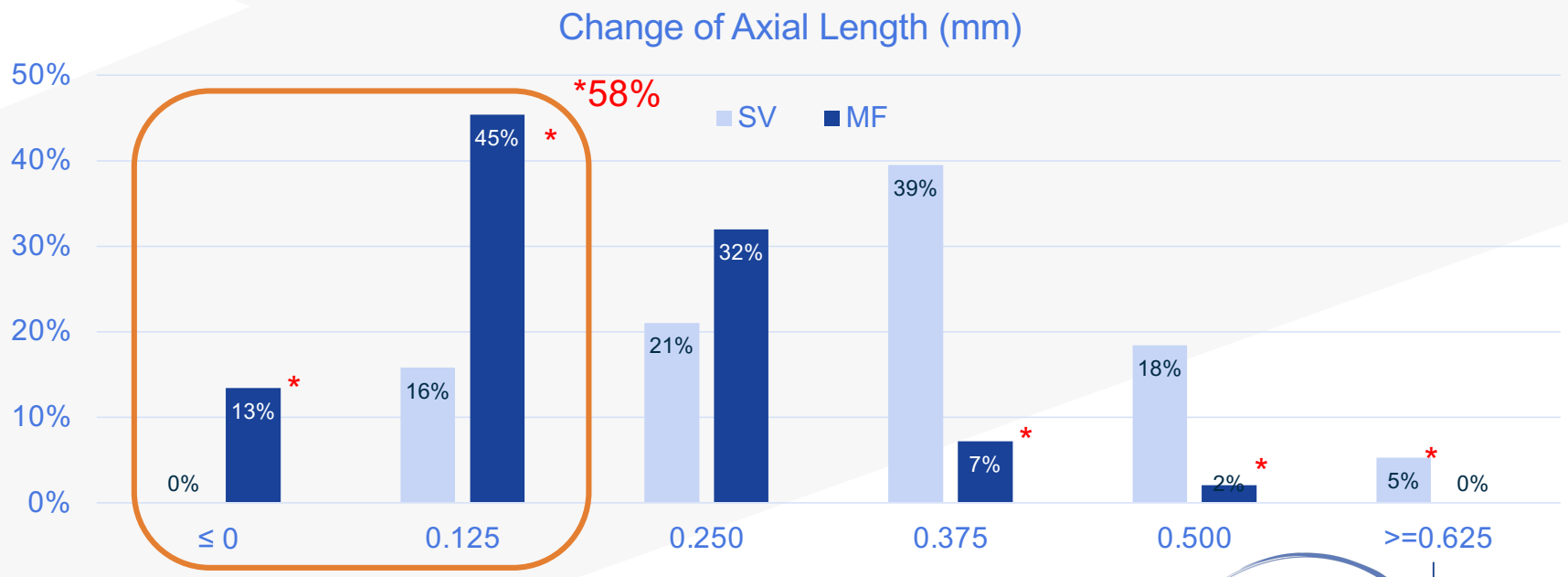


* Proportional analysis showed a significant difference ($p<0.05$) between the two groups

Distribution of Axial Length Elongation

NVMF:

- 58%* of the study population had ≤0.125mm axial elongation ≈ emmetropic growth



* Proportional analysis showed a significant difference (p<0.05) between the two groups

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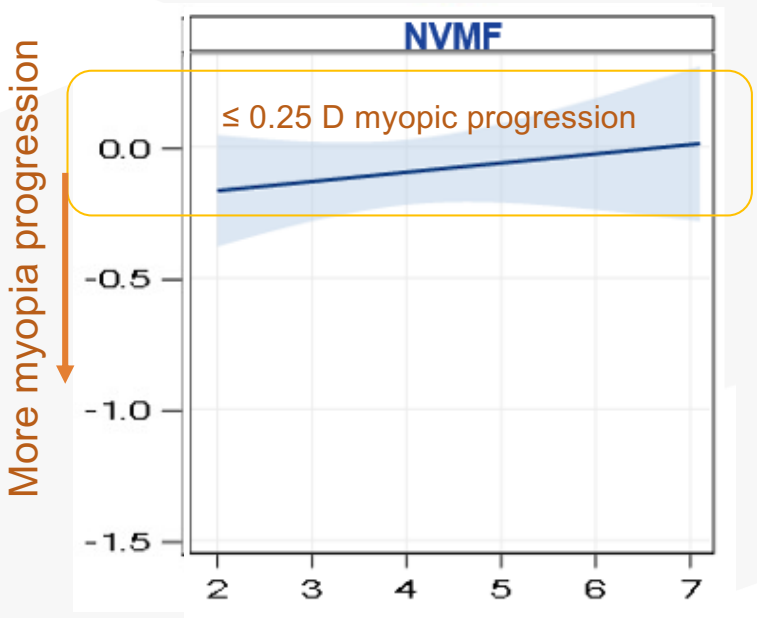
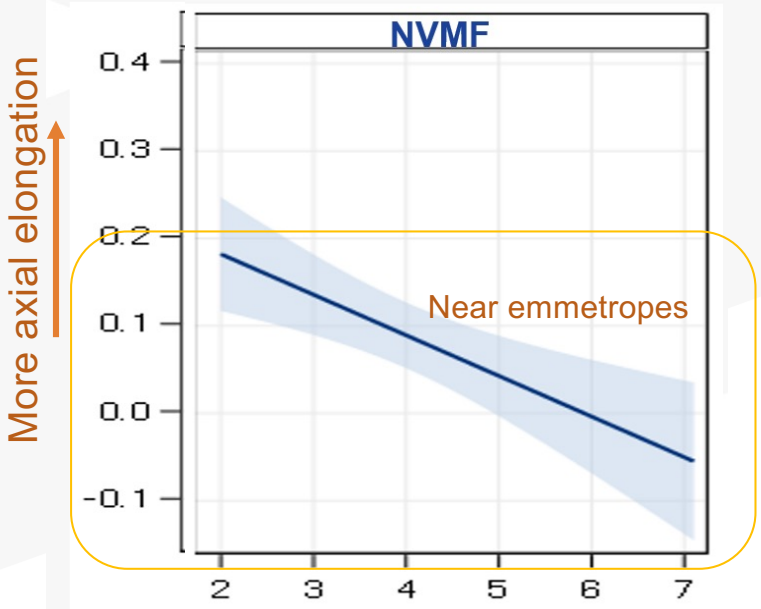
VTI-RCT-CN2

Progression and Pupil Size

CSER change (D)



AXL change (mm)



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12M Unadjusted and Adjusted Treatment Effects -Myopia Progression

CSER (D)	Unadjusted Mean ± SD	p-value*	Adjusted Mean ± SD	p-value*
Planned Subgroup				
SVCL	-0.583 ± 0.064	<0.001	-0.536 ± 0.091	<0.001
NVMF	-0.167 ± 0.041	<0.001	-0.056 ± 0.072	0.4354
SVCL - NVMF	-0.416 ± 0.076 **(71%)**	<0.001	-0.479 ± 0.087 **(89%)**	<0.001

- Adjusted model: age, sex, pupil size, site

* t-statistic comparison between baseline value and 12-month (12M) value, or between the change in SVCL and NVMF.

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12M Unadjusted and Adjusted Treatment Effects -Axial Length Elongation

AXL (mm)	Unadjusted Mean ± SD	p-value*	Adjusted Mean ± SD	p-value*
Planned Subgroup				
SVCL	0.286 ± 0.021	<0.001	0.299 ± 0.028	<0.001
NVMF	0.118 ± 0.013	<0.001	0.126 ± 0.022	<0.001
SVCL - NVMF	0.168 ± 0.025 **(59%)**	<0.001	0.173 ± 0.027 **(58%)**	<0.001

- Adjusted model: age, sex, pupil size, site

* t-statistic comparison between baseline value and 12-month (12M) value, or between the change in SVCL and NVMF.

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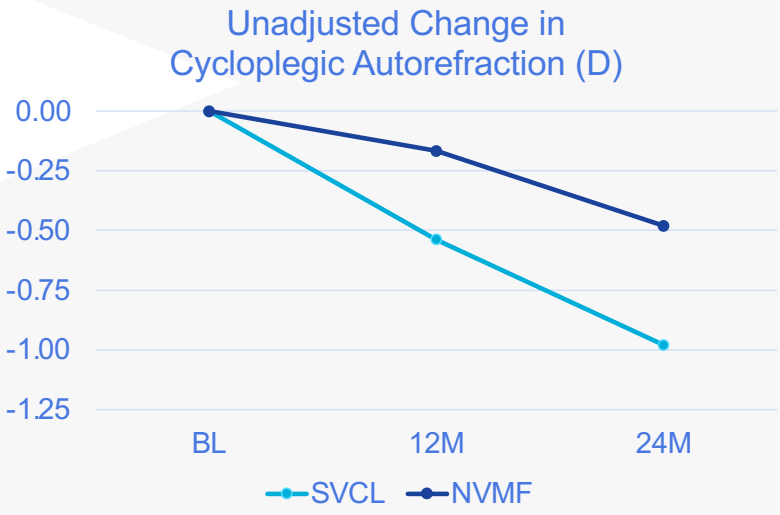
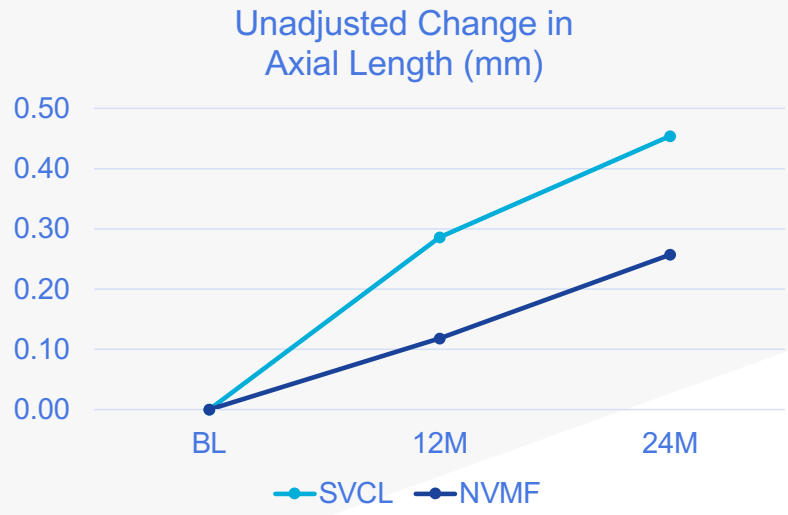
Progression Minimization Continues over 24 months





Adjusted* Tx Effect @ 24M:
0.60 D / 53%

Adjusted* Tx Effect @ 24M:
0.25 mm / 86%

* Full model: reat, Age, Sex, Country (3 levels), baseline AXL/CSER, baseline Pupil Lo, baseline Pupil Hi, study eye (OD or OS)

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VTI-RCT-CN11

Accommodative Accuracy

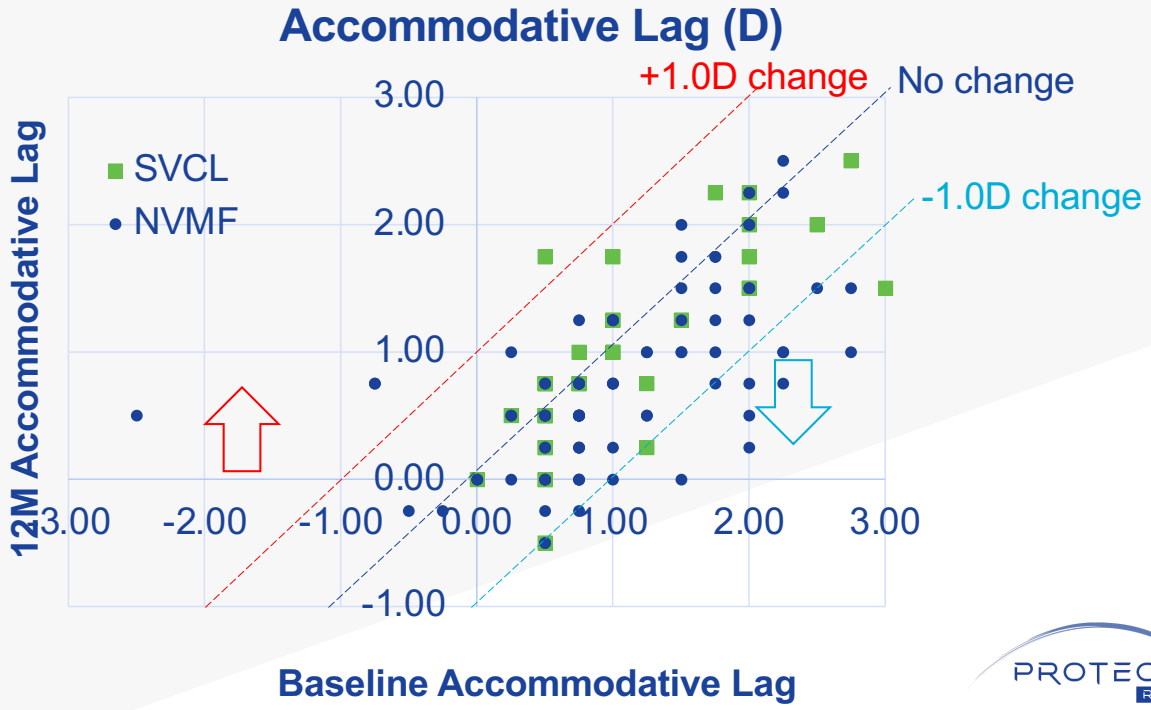
- SVCL: no change in accuracy
- NVMF: less accommodative lag than baseline
- SVCL vs NVMF: almost significantly different
- NVMF wears with **relaxed accommodation did not impact the effect of myopia management**

Study Group	Baseline Mean ± SD	12M CL Mean ± SD	P-value*	Change @12M Mean ± SD
SVCL (38)	1.07 ± 0.75	0.99 ± 0.71	0.286	-0.09 ± 0.49
NVMF (89)	1.04 ± 0.84	0.76 ± 0.67	<.0001	-0.28 ± 0.70
P-value	0.498	0.105		0.082

*Paired t-test

Change from Baseline

- NVMF Lag lowered, more change at higher Baseline accommodative lag
- Baseline accommodative leads moved to lag



Summary and Conclusion

Recent PROTECT* data shows

- NVMF may be safe and effective for **myopia management** in diverse clinical settings, populations, and pupil sizes
- Subject-reported-outcomes reflect the **same level of satisfaction between SVCL and NVMF** wearers
- The catenary multifocal contact lens is **effective for a large range of pupil sizes** but the larger the pupil, the larger the treatment effect
- **2-year preliminary analysis** shows, in the population of 8 to<13-year-olds, baseline CSER between -0.75D to -4.00D, compared with single vision lenses, NVMF had adjusted value of:
  - **0.60 D (53%)** reduction of myopia progression
  - **0.25 mm (86%)** retardation of axial elongation
- NVMF's high relative plus **may have reduced the accommodative stress** for some subjects; in some cases, wearing NVMF appeared to have improved their accuracy to within the typical population range of accommodative lag

*PROTECT is an ongoing clinical trial; NVMF is not approved in the United States for the Myopia Progression Control

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