Randomized Controlled Trial for Myopia Progression Control Using Catenary Power Profile Contact Lenses and Real-World Studies Comparisons

K. Ashley Tuan[1], OD, MS, PhD; Brett O'Connor[2] OD; Sally M. Dillehay[3] OD, EdD; Douglas P. Benoit[1], OD

[1]Visioneering Technologies, Inc., [2] MyEyeDr, Jacksonville FL, [3]ClinTrialSolutions, LLC.

PURPOSE: A commercially available daily disposable soft contact lens* delivering 8D of relative plus power inside the average pupil diameter for children[1,2] has previously demonstrated effectiveness for myopia progression control in multiple real-world studies.[3-5] **PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial (PROTECT)** is a multinational, double-masked, randomized controlled trial (RCT) evaluating the effectiveness and safety of these lenses for myopia progression control in children. A comparison of the trend of effectiveness outcomes between 1-year RCT and Real-World data is presented.

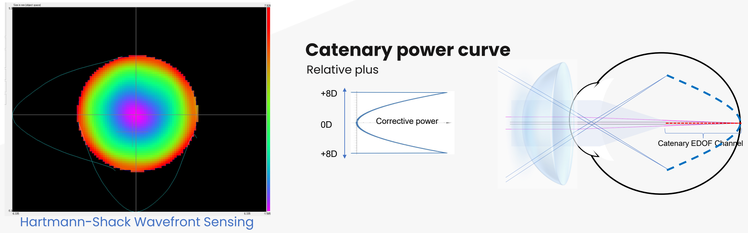

Figure 1. NVMF power profile. a) Wavefront measurement of NVMF and decomposed to power profile; 8D of relative plus at 6mm diameter b) Schematic of the light rays passing through NVMF optic into the eye.

PROTECT Study Design (abridged):

- 3 Year study
- Double Masked
- Control: Single Vision contact lens (NaturalVue Sphere),
- Treatment: Catenary power curve contact lens (NaturalVue Multifocal)
- Control:Treatment 1:2; Control group cross-over after 24-month
- Age 7 to <13 with
- Cycloplegic autorefraction (CSER) between -0.75D and -5D
- Safety: Visual acuity and Adverse Event reporting
- Effectiveness 1° outcome measure: Change of CSER in D
- Effectiveness 2° outcome measure: Change of axial length (AXL) in mm

Reference:

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
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3. Cooper J, O'Connor B, Aller T et al, Reduction of Myopic Progression Using a Multifocal Soft Contact Lens: a Retrospective Cohort Study, Clin Ophthalmol 2022 Jul 4:16:2145-2155. doi: 10.2147/OPTH.S370041
4. Cooper J, Aller T, Smith E et al, Retrospective Analysis of a Clinical Algorithm for Managing Childhood Myopia Progression, Optom Vis Sci 2023 Jan 1;100(1):117-124. doi: 10.1097/OPX.0000000000001978.
5. Lederman C, Myopia Control with Extended Depth of Focus Multifocal Contact Lenses, American Association for Pediatric Ophthalmology and Strabismus conference abstract
6. Nixon A, Brennan N. Managing Myopia: A Clinical Response to the Growing Epidemic. Available at: https:// s3-us-west 2.amazonaws.com/covalentcreative/jjv/media/documents/Managing_Myopia_Clinical_Guide_ Dec_2020.pdf. Accessed September 1, 2021.

*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.

PROECT RESULTS:
145 subjects from Canada, the US, Hong Kong, and Singapore with average age 9.9±1.5 and CSER -2.4±1.3 at enrollment. There was no statistical difference between the two groups for age, gender or race. No Device Related Serious Adverse Events were reported.

logMAR	SV@1M	MF@1M	SV@12M	MF@12M
Dist OU	-0.04±0.07	-0.06±0.06	-0.04±0.06	-0.04±0.08
Near OU	-0.02±0.04	-0.02±0.05	-0.02±0.04	-0.02±0.05

Table 1. High contrast visual acuity in logMAR (0.00=20/20; -0.10=20/16)

Figure 2: Efficacy Results. Unadjusted CSER & AXL Change
Modified Population to match with common myopia control study populations. Ages 8 to <13; CSER -0.75 to -4.00; no Baseline age or CSER difference between 2 groups. Error bar represents Standard Error.

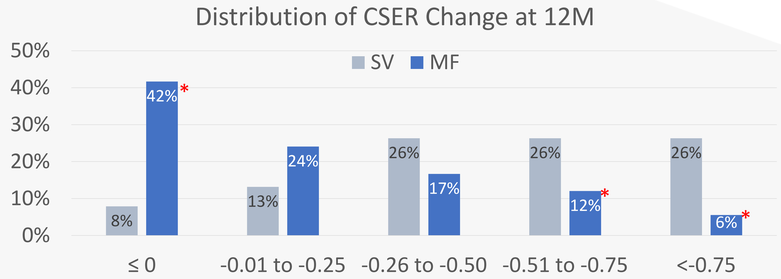

Figure 3. Frequency distribution of change in CSER (D) from Baseline.
* Proportional analysis shown significant difference (p<0.05) between two groups

REAL-WORLD DATA:
The three retrospective analyses included data from 107 US-based subjects between 8 and 16 years old. Two analyses reported AXL.[3,4] Where ethnicity data is available, treatment effects were calculated using an age and ethnicity matched virtual control group.[6]

	Cooper 2022 [3] (n=66)	Cooper 2023 NVMF[4] (n=17)	Lederman data[5] (n=24)	PROTECT (RCT)
Age at BL	10.3 years (8 to <13)	12.6 years (9 to 16)	12.0 years (9 to <13)	9.8 years (8 to <13)
Avg CSER at BL	-3.50 D	-5.63 D	-3.14 D	
12M CSER change: Actual vs Predicted (Difference)	-0.01 vs -0.46 (**0.45 D**)	-0.10 vs -0.33 (**0.23 D**)	-0.10	-0.18 vs -0.58 **(0.40D)**
12M AXL change: Actual vs Predicted (Difference)	0.08 vs 0.25 (**-0.17 mm**)	0.03 vs 0.20 (**-0.17 mm**)	Not Reported	0.12 vs 0.29 **(-0.17mm)**

Table 2. 1-year Real-World data compared with PROTECT data.

For an in-depth analysis of the three Real-World data, please refer to the Poster titled ***Analysis of Real-World Data in Myopic Children Wearing a Highly Aspheric Multifocal Contact Lens***

CONCLUSIONS: While there are differences between retrospective studies and randomized controlled trials, analyzing and correlating their trends provides valuable insight into the consistency in performance of this contact lens under different practice settings. Across all four studies, a majority of children wearing the catenary power profile contact lenses experienced CSER change of ≤0.25D per year and accompany with average axial elongation similar to physiological growth of emmetropes.