Clinical, Familial, and Social Risk Factors for Myopia Progression: Learnings from the PROTECT 2-Year Data

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PURPOSE:

Identifying risk factors for myopia progression helps determine which children are most susceptible to rapid progression, enabling targeted interventions and preventive strategies.

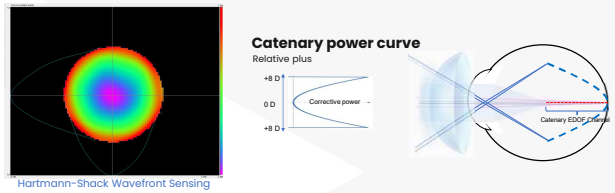

Figure 1. NVMF power profile. Left: Wavefront measurement of NVMF and decomposed to power profile; 8 D of relative plus at 6mm diameter Right: Schematic of the light rays passing through NVMF optic into the eye.

METHODS:

- A prospective, multi-center, double-blind, placebo-control clinical trial (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial, NCT05159765) on pediatric myopes.
- 145 subjects enrolled in the United States, Canada, Hong Kong, and Singapore. 129 completed 24-month visit.
- Intervention arm: The NVMF contact lens is a daily disposable soft contact lens featuring a distance-center aspheric multifocal optic (Figure 1).
- Control arm: The control lens (SVCL) was a single vision daily disposable lens in the same material, etafilcon A.
- Baseline age: 7 to 12 years old
- Baseline cycloplegic autorefraction: -0.75 D to -5.00 D
- Primary and Secondary Outcomes: Change of cycloplegic autorefraction [CSER] from baseline to 24 months, and change of axial length [AXL] from baseline to 24 months.
- Risk factors evaluated in this study: Baseline CSER, AXL, age and pupil size, age of onset, family history, and lifestyle factors were obtained and evaluated
- Statistical method: Machine Learning methods were used to identify unique trajectories of change over the baseline, 12 month and 24 month outcomes in the Control and Intervention arms, with gradient boosting methods employed to identify and rank the most powerful factors, and the degree to which the contact lens intervention could reduce the impact of these underlying risk factors.

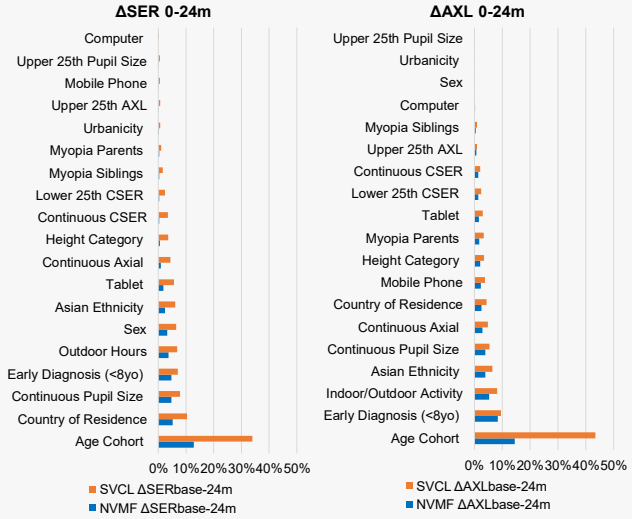

Figure 2. GLMM for heterogeneous treatment effects risk factors

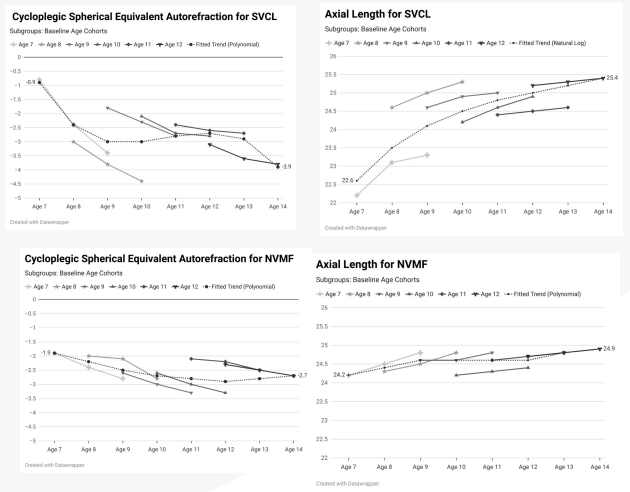

Figure 3. Refractive error (CSER) and axial length (AXL) by age at observation, stratified by baseline age cohort

RESULTS:

- For baseline age 8–12 and CSER -0.75 to -4.00D, average CSER progression was -1.06±0.11D (SVCL) vs -0.47±0.06D (NVMF), a difference of 0.59D; AXL progression was 0.47±0.04 mm (SVCL) vs 0.25±0.026 mm (NVMF), a difference of 0.22 mm.
- CSER progression risk factors (Figure 2):
  - -Control (= natural history), the top risk factor was age
  - -NVMF: minimized the total impacts by 58%
- AXL progression risk factors (Figure 2):
  - -Control (= natural history), top risk factors was age
  - -NVMF: minimized the total impacts of the above by 45%
- Wearing NVMF showed a slower progression of CSER and AXL, and the magnitude was similar across age (Figure 3), suggesting that age of initiation did not alter treatment effect.
- Under natural progression (SVCL), being female tends to have faster progression rate than being male; wearing NVMF minimized this risk factor by reducing the average progression rate of female (Figure 4).

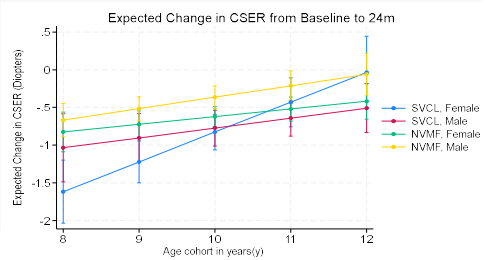

Figure 4. Change in CSER from baseline to 24m by baseline age, sex and treatment assignment

CONCLUSIONS:

- Myopia progression occurs most rapidly in children with early age of onset, parental/genetic risk, and life style.
- NVMF significantly reduced CSER and AXL progression, and buffered the influence of both modifiable and immutable risk factors known to portend myopia progression.

**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.