PROTECT RCT DATA UPDATE

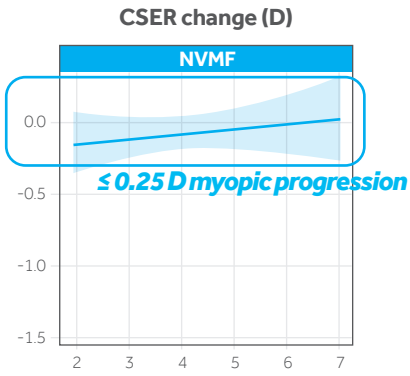
Results from the 1-Year Data Set (out of a 3-Year Trial)
As of September 2024

The NaturalVue PROTECT Randomized Clinical Trial Delivers Positive Results from 1-Year Data Set

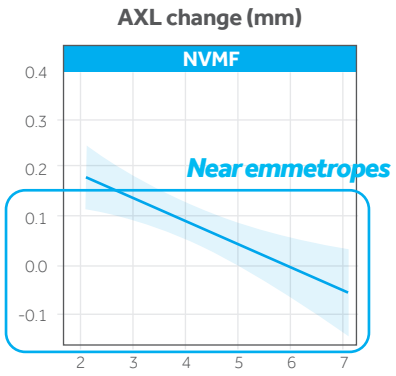
New Results:

Treatment Effect and Pupil Size

- New data suggests that regardless of children's pupil size, most patients received a treatment effect with NaturalVue Multifocal.
- The larger the pupil size, the greater the treatment effect
- When the pupil is smaller (such as when patients spend time outdoors playing sports, etc.), nearly all patients should receive continuous treatment with NaturalVue.



Significant co-variate ($p<0.01$) with the change of Cycloplegic Spherical Equivalent autorefraction (CSER) and Treatment, with 95% CI



Significant co-variate ($p<0.01$) with change of axial length (AXL) and Treatment, with 95% CI

Adjusted Data

(compared to same subset of patients as previously released unadjusted data)

- 89% (or 0.48 D) reduction in refractive error progression vs. control, and, found on average, no myopic change from 12 months ago and compared to unadjusted data = 71% or (0.41 D)
- 0.17 mm (or 58%) reduction in axial elongation vs. control and compared to unadjusted data = 0.17 mm (or 61%)

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The Results
(1-Year Data Set)

Both analyses showed positive results for refractive error and axial length change.

	Adjusted Treatment Effects (new data)		Unadjusted Treatment Effects (reported Jan 2024)	
	Average Reduction vs. Control Group	Average Change	Average Reduction vs. Control Group	Average Change
Refractive Error	89% or 0.48 D	-0.06 D*	71% or 0.41 D	-0.17 D
Axial Length	0.17 mm or 58%	0.13 mm	0.17 mm or 61%	0.11 mm

* not statistically different from 12 months ago

Why do we show both?

Unadjusted treatment effects are calculated by averaging the outcome measures from the study population.

Adjusted treatment effects equalize other factors (such as age, sex, pupil size, site) that may influence myopic progression. Removing these factors may make Adjusted results a better statistical representation of the actual effect of the intervention being studied, thus required by the FDA.[1]

Distribution of Change

58% ***Axial Length***
of patients wearing NaturalVue had axial growth similiar to age-matched emmetropic children

45% ***Refractive Error***
of patients had no progression (change ≤ 0 D)

≈**2/3** of patients or **64%** experienced no meaningful progression of myopia (defined as -0.25 D or less of progression)

Wearing Time/Compliance

12 *hrs/day*
7 *days/week*

- Similiar to the control group (single vision lenses) and greater than study protocol (10 hours/day, 6 days/week)
- These longer wearing times indicate that vision and comfort were acceptable to children and strongly supported compliance.

- Published real-world data indicates Year 2 myopia progression data **likely to trend closely** with Year 1 values.
- Combined with the 6-year data previously published in Clinical Ophthalmology in 2022, and the analysis from 3 independent studies released in September, the one-year data suggests NaturalVue Multifocal may be **safe and effective in slowing myopia progression in diverse clinical settings, populations, and pupil sizes**

Note: This reflects the 1-Year data set. The PROTECT study is ongoing and the data will continue to be reviewed and analyzed with additional details to be shared as available.

This information may describe uses for this product, i.e., Myopia Progression Control, which have not been approved by the FDA for use in the United States and is intended for educational purposes only. NaturalVue® Multifocal is part of an ongoing clinical trial (RCT) that is studying its effectiveness for myopia progression control.

1. Akerman D., Editor's Perspective. Review of Myopia Management, September 2024.

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