PROTECT RCT DATA UPDATE:
Year 1 Summary of Results
(of the 3 year Clinical Trial)
As of January 2025

Protect AND Correct: Manage myopia AND reduce compromised vision.

Early results suggest that NaturalVue® Multifocal 1 Day contact lenses may be the only myopia management soft contact lens that can reduce vision challenges in children.[1,2]

Year 1 findings from the 3-year trial demonstrate clear vision, safety, and comfort, leading to high compliance and effective outcomes. These lenses empower kids to enjoy life while managing myopia risks - Win **AND** Win!

Scan for full details of PROTECT Year 1 Summary.

PROTECT RCT

Year One Results of 3 year Clinical Study:

Myopia Management, Visual Performance and Predictable Data[1, 2]

Happy kids. High compliance.

Uncompromised vision and comfort thus far.

- Distance and near high-contrast VA (20/20 or better) preserved, comparable to spectacles
- Minimal reduction in low-contrast VA (one line), clinically imperceptible
- Results from the validated Patient-Reported Outcome PREP2* showed that children reported the same high level of satisfaction as those wearing single vision contact lenses, with no perceived trade-offs in vision or comfort
- Preserved stereoacuity

12 *hrs/day*

7 *days/week*

*Pediatric Refractive Error Profile 2

Astigmatic compatibility.

- Indicated to correct up to 2.00 D of astigmatism.
- Now proven to clinically correct 100% astigmatism at 2.00 D and 83% correct at 3.00 D

Normalized accommodative accuracy seen in data.

- Children achieved relief from accommodative stress and improved performance for near tasks and digital device usage

High compliance noted Year 1. (a significant component of efficacy)

- Children achieved wearing time of 11-12 hours per day (during waking hours), exceeding study protocol minimums (10 hrs/day, 6 days/wk)
- Low dropout rate thus far (4%) highlights exceptional comfort, comparable to single-vision wearers

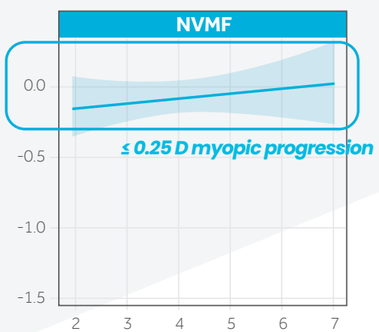
Continuous treatment across all pupil sizes.

Proven efficacy through year 1 across pupil sizes (2–7 mm), ideal for children active outdoors or on digital devices.

- Larger pupils enhance treatment effects, strengthening myopia management
- Nearly 2/3 of children achieved near-emmetropic change

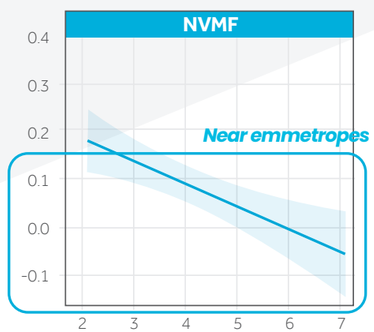
Note: The average indoor pupil size is 5.5 to 6.0 mm[3,4]

CSER change (D)



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

AXL change (mm)



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

The future looks bright – Predictive Data.

Predictable, impactful myopia management. The year one treatment outcomes showed a significant reduction in myopic progression**(year 1 out of a 3 year study).

	Adjusted Treatment Effects **		Unadjusted Treatment Effects	
	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 59%	0.12 mm

**Adjusted data, equalized for key variables such as age, sex, and pupil size.

*** not statistically different from 12 months ago

Distribution of Change in Refractive Error (D) in Patients -Year 1

- **45%** 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)

Distribution of Change in Axial Length (mm) in Patients - Year 1

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

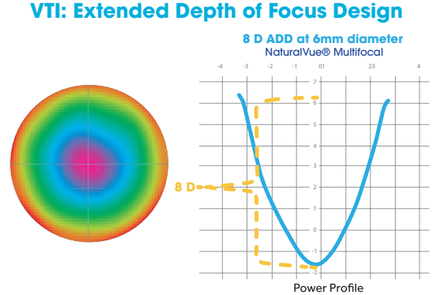
Innovative design. Positive results.

NaturalVue® Multifocal (NVMF) lenses perform well in clinical studies and real-world practice due to the patented design.

As the first and only center-distance EDOF aspheric lens, NaturalVue® Multifocal feature a rapid, smooth, uninterrupted rise in relative plus power (+6.00 D to +8.00 D) beginning after the central 5 um of the optic zone and increasing across the therapeutic zone, proving a full range of pupil coverage.

The Neurofocus Optics® Technology redirects this high amount of relative plus power to counteract hyperopic defocus, for myopia management while the smooth transitions preserve vision. The broad EDOF channel provides a large range of astigmatism correction and accommodative stress relief.

VTI: Extended Depth of Focus Design



The first and only center-distance, extended depth of focus design with a rapid, smooth and uninterrupted rise in relative peripheral plus power of +6.00 D to +8.00 D across the entire therapeutic area.

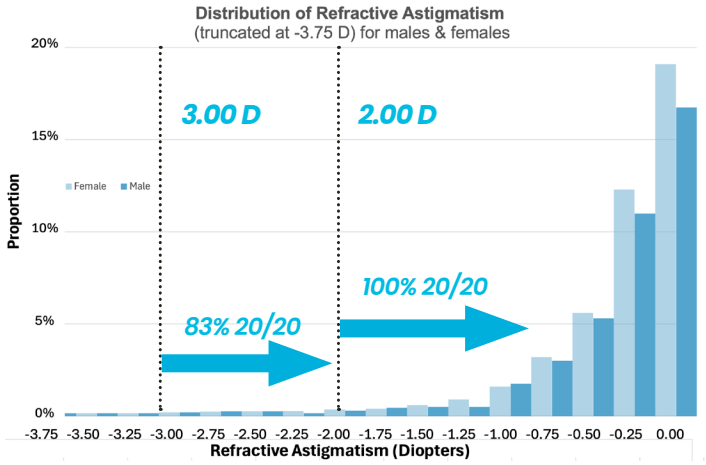
Mechanism for Myopia: **Peripheral Defocus**

Clinically Proven to Correct Astigmatism up to 2.00 D

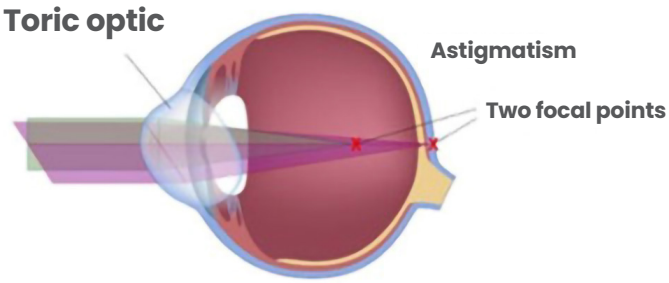
A recent clinical study[2] demonstrated that NaturalVue® Multifocal effectively corrected astigmatism (with 20/20 or better vision):

- 100% of astigmatism up to 2.00 diopters (D)
- 83% of astigmatism up to 3.00 diopters (D)
- 77% rated their Overall Visual Quality as satisfactory or very satisfactory
- 83% rated their Overall Comfort as satisfactory or very satisfactory
- Stereopsis preserved
- Works well with all pupil sizes

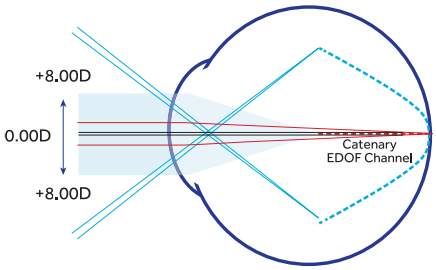
Scan for full details from Astigmatism presentation



Traditional Toric Optic



Extended Depth of Focus Optics by VTI



The study found that, unlike traditional toric optics, NaturalVue® Multifocal corrects an extensive range of astigmatism by enabling both meridians to focus simultaneously. This clinical trial validated the NaturalVue® Multifocal lens's astigmatism correction indication.

Visit global.vtivision.com/protect-study/ for more details.

References:

1. Tuan, KM (Ashley). Learnings of Managing Myopic Children Using Catenary Power Profile Multifocal Soft Contact Lenses from the PROTECT Randomized Clinical Trial. Poster presented at Global Specialty Lens Symposium; January 17, 2025; Las Vegas, NV, USA. https://global.vtivision.com/protect-study/ **2.** Carracedo, G.. Evaluation of Visual Acuity with Multifocal Catenary Curve-Based Contact Lens Design in Different Degrees of Astigmatism. Podium presentation from Global Specialty Lens Symposium; January 16, 2025; Las Vegas, NV, USA. https://qrco.de/bffoEt **3.** 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. **4.** Silbert et al. Pupil size and anisocoria in children measured by the plusoptiX photo screener. JAAPOS 2013;17:609-611

Data is based on a modified PP (Per Protocol) analysis including children between ages 8 and <13 with refractive error between -0.75 and -4.00 D versus age-matched controls wearing spherical lenses. SD = standard deviation.

This information 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. It is intended for educational purposes only.
NaturalVue® Multifocal is part of an ongoing randomized clinical trial (RCT) studying its effectiveness for myopia progression control.

VTI-RCT-FS1 r7.1

PROTECT RCT