PROTECT RCT | naturalVue®

COMPLETED 3-YEAR PROTECT RANDOMIZED CONTROLLED TRIAL CLINICAL UPDATE, *October 2026*



PROTECT 3-Year Results: NaturalVue® (etafilcon A) Multifocal 1 Day Reduces Myopia Progression by 1.06 D and Axial Elongation by 0.58 mm.[1,2]

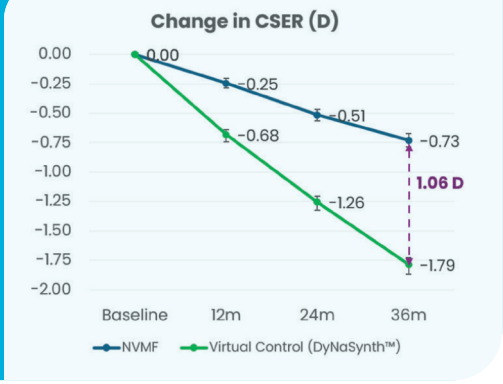
Key Findings at 36 Months.[1,2]

Over three years, children wearing NaturalVue Multifocal 1 Day demonstrated the following versus a virtual control group:

1.06 D

less myopic refractive progression (cSER)

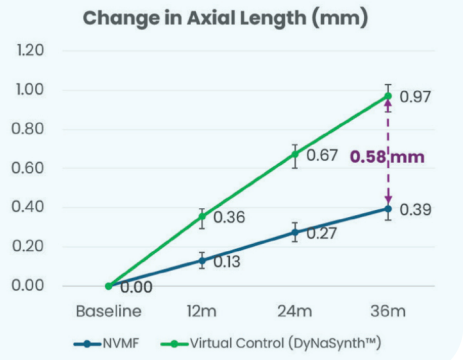
(95% CI 0.86 to 1.25), p < 0.001) Per Protocol Cohort, baseline age 7-12, -0.75 to -5.00, n= 102. (p < 0.001). Data were adjusted for age, sex, ethnicity, country, study site and baseline refractive value.



0.58 mm

less axial elongation (AXL)

(95% CI -0.66 to -0.49), p < 0.001 Per Protocol Cohort, baseline age 7-12, -0.75 to -5.00, n= 102. (p < 0.001). Data were adjusted for age, sex, ethnicity, country, study site and baseline refractive value.



Why One Diopter Matters

Published research confirms each additional 1.00 D of myopia is associated with higher risks.[3,4]

Ocular Complication		Each additional 1.00 D of Myopia	Each 1.00 D less Myopia
Myopic Maculopathy		**67% increase** in the prevalence of myopic maculopathy.	**≈40% lower risk** likelihood of developing myopic maculopathy.
Retinal Detachment		**30% increase** in the risk of retinal detachment.	**≈23% lower risk** of retinal detachment.

Less myopia may mean better long-term eye health and quality of life.

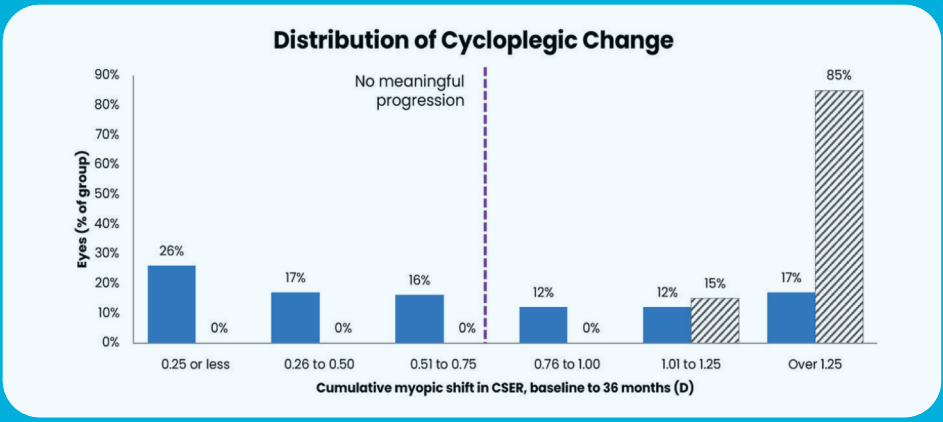
Note: Data shown here from published papers – See Bullimore, et al 2019 and Bullimore, et al 2021. PROTECT did not evaluate these outcomes.

Minimal Progression for the Majority of Children[1,2]

Additional Findings: Most Children Had Little to No Progression[1,2]

In the PROTECT clinical trial, children wearing NaturalVue Multifocal 1 Day showed eye growth similar to non-myopic children over 36 months:[1,2]

59% progressed **≤0.25 D**/year, consistent with the threshold commonly used to define non-progressive myopia.[5]

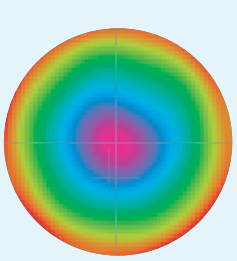


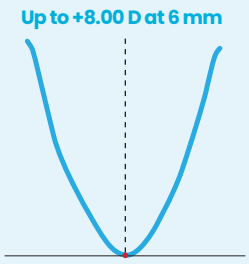
Comparisons at 36 months are to a projected control model. Individual and real-world results may vary.

- Children in NaturalVue Multifocal had refractive myopic change of ≤0.75 D myopic change at 36 months.
- The study showed that without NaturalVue, 100% of participants would have increased myopic progression by **at least 1.00 D.**

The Design Behind the Result, The Patented Catenary Curve

The Treatment Signal is delivered by the curve design. The mechanism for myopia management is Myopic Defocus, which is associated with slowing eye growth.





Aspheric catenary curve shape that creates a smooth, uninterrupted ramp in relative plus power that builds from the center.

Evidence that the Design is at Work

Axial Length

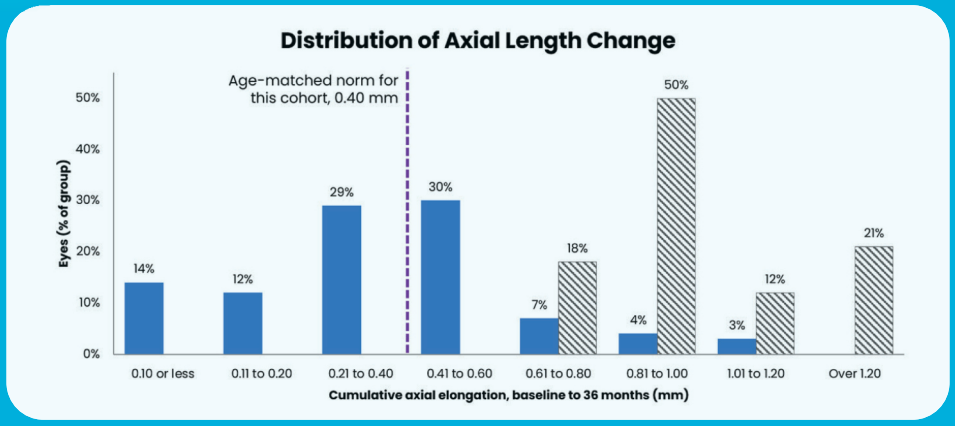
The design targets eye growth, so axial length is the most direct measure of its effect: 0.58 mm less elongation.[1,2] Refraction (1.06 D less progression) reflects the change in uncorrected vision and may be seen as an indicator of excessive axial length growth. Both matter.

Risk Factors

PROTECT findings suggest NaturalVue helps offset common risk factors associated with myopia progression such as age, ethnicity and lifestyle.[1,2]

55%

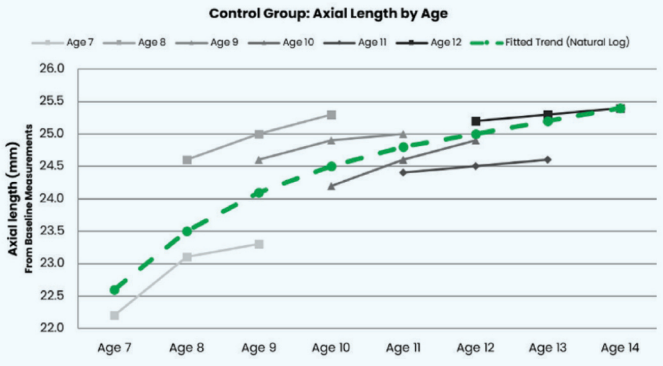
had axial growth within the age-matched emmetropic benchmark of the study.[1,2]

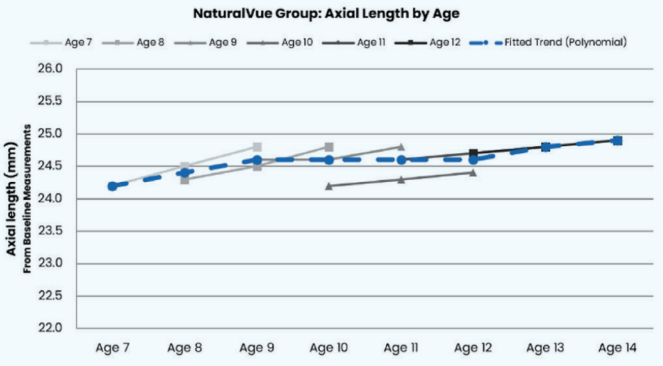


Comparisons at 36 months are to a projected control model. Individual and real-world results may vary.

- Children in NaturalVue Multifocal had axial elongation within the age-matched normal range for non-myopic children (≤0.40 mm over three years).
- The study showed that without NaturalVue, the majority of the patients' myopia would have increased by over 1.00 mm or more over three years.

Across all age groups studied, average axial growth trends stayed within published emmetropic growth ranges.[6,7]





Without NaturalVue (single-vision lenses)
On average, axial length trends rose more steeply with age, meaning more eye growth and more myopia progression over time.

With NaturalVue,
On average, axial growth trends were flatter across the ages studied, closer to how eyes grow in children without myopia.

With NaturalVue, average axial growth trends were flatter and closer to those of non-myopic eyes.

Based on average growth trends across baseline age cohorts. Control group: actual through 24 months; 25–36 months modeled. NaturalVue group: observed through 36 months. Note: The Y-axis shows the participants' actual axial length measurements through 24 months. Individual cohorts and children varied. Projected results are estimates; real-world results may differ.

Manage Myopia and Astigmatism

Many myopic children are also astigmatic.

- **28% had ≥1.00 D** of astigmatism in a U.S. multiethnic study.[8]
- Myopic children are **more likely to develop astigmatism and may experience greater astigmatic change during childhood.**[9,10]

NaturalVue® Multifocal 1 Day: Clinically proven to correct astigmatism up to 3.00 DC[11]

20/20

- **100%** of patients reached 20/20 binocular visual acuity
- **100%** of patients achieved astigmatic correction through 3.00 DC
- **Stereopsis was maintained** across the astigmatic range studied; **NaturalVue adapted to all pupil sizes**

Astigmatism data shown here was not evaluated in the PROTECT study.

For more details, visit www.positiveimpact.co.uk/our-portfolio/contact-lenses/naturalvue or contact 01424 851375 or sales@positiveimpact.co.uk

About PROTECT (PROgressive Myopia Treatment Evaluation for NaturalVue Multifocal Contact Lens Trial; NCT05159765) is a three-year, prospective, multicenter, double-masked, randomized controlled trial conducted in the United States, Canada, Hong Kong, and Singapore. A total of 145 children aged 7 up to 13 years, with cycloplegic spherical equivalent refraction (CSER) of -0.75 D to -5.00 D and astigmatism of ≤1.00 D, were randomized 2:1 to NaturalVue Multifocal 1 Day (NVMF) or single-vision contact lenses (SVCL). As planned, the SVCL group crossed over to NVMF at 24 months, so 36-month NVMF outcomes were compared with modeled control data.† Of the children enrolled, 126 completed the 36-month study. Outcomes were adjusted for age, sex, ethnicity, country, study site, and baseline value.*

The three-year PROTECT results provide clinical evidence on both key measures of myopia progression: cycloplegic spherical equivalent (CSER), measured by autorefraction, and axial length, measured by optical biometry (e.g., IOL-Master, Carl Zeiss Meditec).

Results are from a single randomized trial and may not apply to patients outside the studied population. Individual results may vary. See the full PROTECT study report for study limitations, and the package insert for indications, contraindications, warnings and precautions.

*Values based on per-protocol cohort: baseline ages 7 to <13, baseline refraction -0.75 D to -5.00 D, n = 102 ($p < 0.001$).

†36-month control values were derived from several complementary analyses, including SVCL projections (24-month SVCL patient data projected to 36 months) and a DyNaSynth™ Synthetic control matched to the SVCL group's baseline characteristics. The modeled control trajectories showed a high degree of concordance with published virtual control models. Projected results are calculated estimates, and real-world results may differ.

In the United States, NaturalVue® (etafilcon A) Multifocal 1 Day Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in normal eyes. Outside the United States, they are also indicated for myopia progression control in normal eyes. This information may describe uses for this product, including myopia progression control, that the FDA has not approved for use in the United States. It is intended for educational purposes only. Refer to the package insert for complete indications, contraindications, warnings and precautions.

References: **1.** Data on file. PROTECT 3-Year Results, 2026. Data adjusted for key variables, including age, sex, ethnicity, country, study site, and baseline value. Per-protocol cohort, baseline age 7–12 years, -0.75 D to -5.00 D, n = 102 ($p < 0.001$). All data vs. virtual control group. 36-month single-vision contact lens control values were derived from several complementary analyses, including SVCL projections (24-month SVCL patient data projected to 36 months) and a DyNaSynth™ virtual control matched to the SVCL group's baseline characteristics. The modeled control trajectories showed a high degree of concordance with published virtual control models. **2.** Tuan KA, Novak S, Chan J, Dillehay SM; PROTECT Study Group. PROTECT Completed 3-Year Study Results: A Catenary-Curve Multifocal Contact Lens Reduces Pediatric Myopia Progression and Mitigates Common Risk Factors. Poster presented at: American Academy of Optometry Annual Meeting; September 30–October 3, 2026; Anaheim, California. **3.** Bullimore MA, Brennan NA. Myopia Control: Why Each Diopter Matters. Optom Vis Sci. 2019;96(6):463–465. doi:10.1097/OPX.0000000000001367. **4.** Bullimore MA, Ritchey ER, Shah S, et al. The Risks and Benefits of Myopia Control. Ophthalmology. 2021;128(11):1561–1579. doi:10.1016/j.ophtha.2021.04.032. 23% number is a derived number. The paper reports that each 1 D of myopia increases retinal detachment incidence by 30%. The 23% reduction is the inverse (1 - 1/1.30). **5.** Chen J, Liu S, Zhu Z, et al. Axial length changes in progressive and non-progressive myopic children in China. Graefes Arch Clin Exp Ophthalmol. 2023;261(5):1493–1501. doi:10.1007/s00417-022-05901-5. **6.** Naduvilath T, He X, Saunders K, et al. Age, gender and regional/ethnic variations in emmetropic axial growth rate. Ophthalmic Physiol Opt. 2025;45(6):1485–1495. doi:10.1111/opo.13545. **7.** Zadnik K, Mutti DO, Mitchell GL, Jones LA, Burr D, Moeschberger ML. Normal eye growth in emmetropic schoolchildren. Optom Vis Sci. 2004;81(11):819–828. doi:10.1097/01.opx.0000145028.53923.67. **8.** Kleinstein RN, et al. Refractive error and ethnicity in children. Arch Ophthalmol. 2003;121(8):1141–1147. doi:10.1001/archopht.121.8.1141. **9.** Tong L, et al. Incidence and progression of astigmatism in Singaporean children. Invest Ophthalmol Vis Sci. 2004;45(11):3914–3918. doi:10.1167/iovs.04-0492. **10.** Kim YS, Lee SY, Park SH. Longitudinal changes in refractive error in a pediatric referral population in Korea. J Pediatr Ophthalmol Strabismus. 2017;54(1):43–51. doi:10.392 **11.** Data on file. 2025. Clinical study "Evaluation of Visual Acuity with Multifocal Catenary Curve-Based Contact Lens Design in Different Degrees of Astigmatism," conducted by Carracedo G; Complutense University of Madrid, Spain.

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