

# Clinical Evaluation of Myopia Control Results through 6 Years



The study reviewed clinical data from 309 children in 15 practices for all patients fit with NaturalVue Multifocal® (NVMF) from Dec 2014-Dec 2020

## Purpose

To quantify the effectiveness of a unique extended depth of focus daily disposable contact lens in slowing myopic progression, through a retrospective data review conducted in real-world clinical practices.

## Methods

The study reviewed clinical data from 309 children in 15 practices for all patients fit with NaturalVue Multifocal (NVMF) from Dec 2014-Dec 2020, with at least 6 months (M) of follow-up data. Participants were not included if currently using a myopic progression control treatment. Initial spherical equivalent refraction (SER) was (Mean + SD)  $-3.60 + 2.00D$ , and Axial Length (AL)  $25.05 + 1.50$ . Baseline SER progression reported averaged  $-1.01D/yr$ . SER was captured at baseline and annual visits. AL was captured at baseline and annual visits for a sub-set of practices. Participants were followed for initial fit through 72 M.

## Results

- Retrospective case series analysis - 196 subjects, 6 years, 15 real-world practices.
- 95% of subjects showed a decrease in refractive error change, with 78% showing a decrease of 70% or more.
- At all points in time, the average amount of myopia progression observed was  $\leq 0.25D$  from baseline.
- The average refractive error change slowed by 0.85D (or 85%) as compared to baseline from 6-72 months.

A subset of the data (N=188) was age-matched to published control data for children ages 8 to < 13, with an average age of  $10.5 + 1.3$ ; 47% were Caucasian, 30% Asian, 23% Other. At baseline, SER averaged  $-3.60 + 2.00D$ , AL  $24.97 + 0.58mm$ , with average baseline progression of  $-1.03D/yr$ . Using all available eyes analysis as was done for the control data, SER total change from baseline in this younger group again was approximately  $< 0.25D$  at all annual visits. AL total change from baseline was approximately  $< 0.10 mm/year$  through 47 months, even in the younger cohort. Both SER and AL change for NVMF were significantly less ( $p < 0.05$ ) as compared to published age-matched control group data.

## Conclusion

These data indicate NVMF significantly decreased the myopic progression rate compared to the SER and AL progression experienced by the children prior to being fitted. In an age-matched cohort to published control data of myopic children, the SER and AL changes observed with NVMF continued to be  $< 0.25D$  of total change in SER through 72 M, and less than  $0.10mm/yr$  of AL change through 47 M, indicating that NVMF was significantly effective at decreasing myopic progression as compared to published age-match control group data for both SER and AL change.



For additional information, please contact Dr. Doug Benoit at [dbenoit@vtivision.com](mailto:dbenoit@vtivision.com) or VTI Technical Consultation **1-844-VTI-LENS (1-844-884-5367)**, ext. 102, or [TechnicalConsultation@vtivision.com](mailto:TechnicalConsultation@vtivision.com)

This information may describe uses for multifocal contact lenses that have not been approved or cleared by the FDA for use in the US.

NaturalVue® (etafilcon A) Multifocal Daily Disposable Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), and/or presbyopia in normal eyes.

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