

New Clinical Evidence Through 6 years: NaturalVue Multifocal for Myopia Management

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Introduction

Myopia is increasing around the world. Myopia is certainly recognized globally as a major public health issue. The World Health Organization has prioritized it as the second largest cause of blindness and the leading cause of moderate and severe vision impairment.¹ It is estimated that by the year 2050, 5 billion people on the planet will be myopic.² A whopping 1 billion will be highly myopic.² Myopia is caused by increases in axial length, and this axial elongation carries with it risks for ocular diseases such as cataracts, glaucoma, retinal detachment, and myopic maculopathy.³ With traditional correction of myopia, the foveal image is in focus, but the peripheral light rays may fall behind the retina, creating peripheral hyperopic defocus, which is thought to stimulate a growth signal and lead to the lengthening of the eye.⁴

Objective

To evaluate the rate of progression of myopic refractive error and axial length in children fit with a commercially available, center-distance, aspheric, extended depth of focus, multifocal soft contact lens with attributes theoretically expected to slow the progression of myopia.

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 they were currently using a myopic progression control treatment, leaving 196 children (392 eyes). Average age at baseline was 12.3 ± 2.8 years (range 5-20 years) Initial spherical equivalent refraction (SER) was (Mean ± SD) -3.60 ± 2.00D, and Axial Length (AL) 25.05 ± 1.50mm. 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 from initial fit through 72 M.

Results

The study encompassed a review of 1260 patient visits. The cohort was 62% female; reported ethnicities were 50% Caucasian, 30% Asian, 10% Other. The average age at first fitting was 12.6 ± 3.0 years. The mean SER total cumulative change from baseline was approximately 0.25D or less at all annual visits: Y1: -0.16, Y2: -0.27, Y3: -0.24, Y4: -0.10, Y5: -0.05, Y6: -0.11. NVMF SER change data were significantly different from baseline at all points in time (p < 0.05). The mean AL total cumulative change from baseline was: Y1: 0.07, Y2: 0.15, Y3: 0.18, Y4: 0.40, or approximately ≤ 0.10 mm/year through 48 M. NVMF AL change data were significantly different from baseline at all points in time (p < 0.05).

A subset of the data (N=188 RE) was age and ethnicity matched to published control group data for children ages 8 to < 13,⁵⁻⁹ 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 -0.57D per year and -1.09D over 3 years. Both SER and AL change for NVMF were significantly less (p < 0.05) as compared to published age and ethnicity matched virtual control group data.⁵⁻⁹ Using the age and ethnicity matched virtual control group data, a Cumulative Absolute Reduction in axial Elongation (CARE) value of 0.44mm less axial elongation over 3 years as compared to the age and ethnicity matched virtual control group was determined for NVMF.⁵⁻¹⁰

Age and Ethnicity Matched Virtual Control Group Refractive Error Change (D)⁵⁻⁹

Baseline	Y1	Y2	Y3	3 Yr Cumulative
-0.57	-0.46	-0.36	-0.27	-1.09

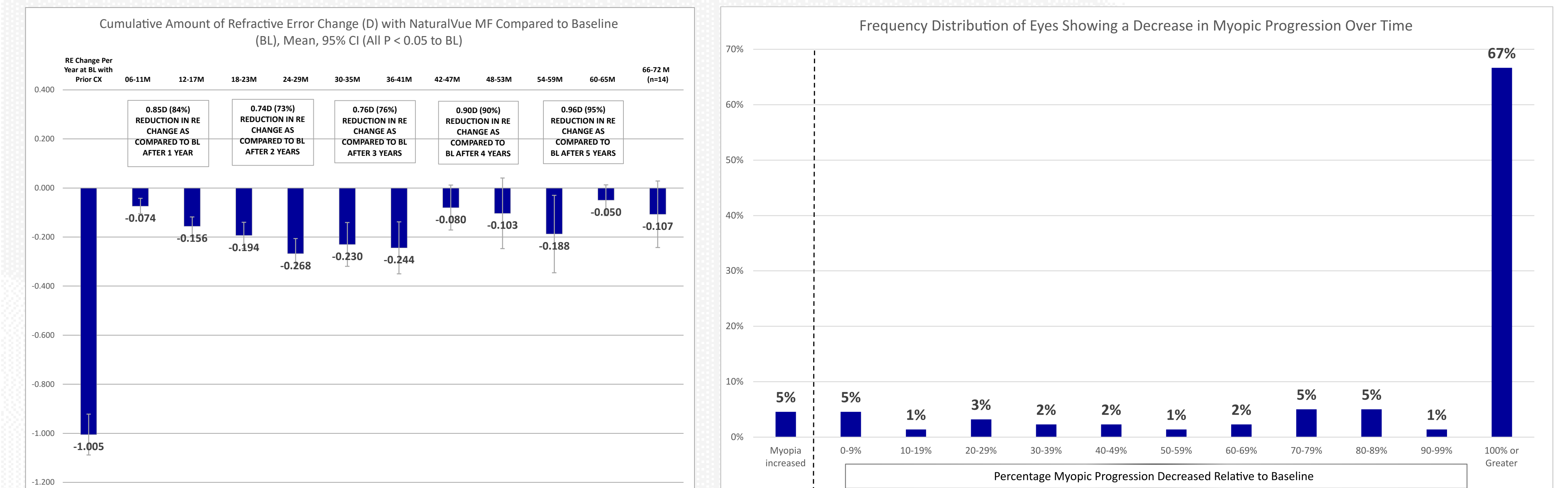
Actual Observed Refractive Error Change with NaturalVue Multifocal (D)				
Baseline	Y1	Y2	Y3	3 Yr Cumulative
-0.98	-0.012	-0.071	+0.021	-0.062
				-1.03D Diff to Control

Age and Ethnicity Matched Virtual Control Group Axial Elongation (mm)⁵⁻⁹

Baseline	Y1	Y2	Y3	3 Yr Cumulative
0.20	0.25	0.22	0.20	0.67

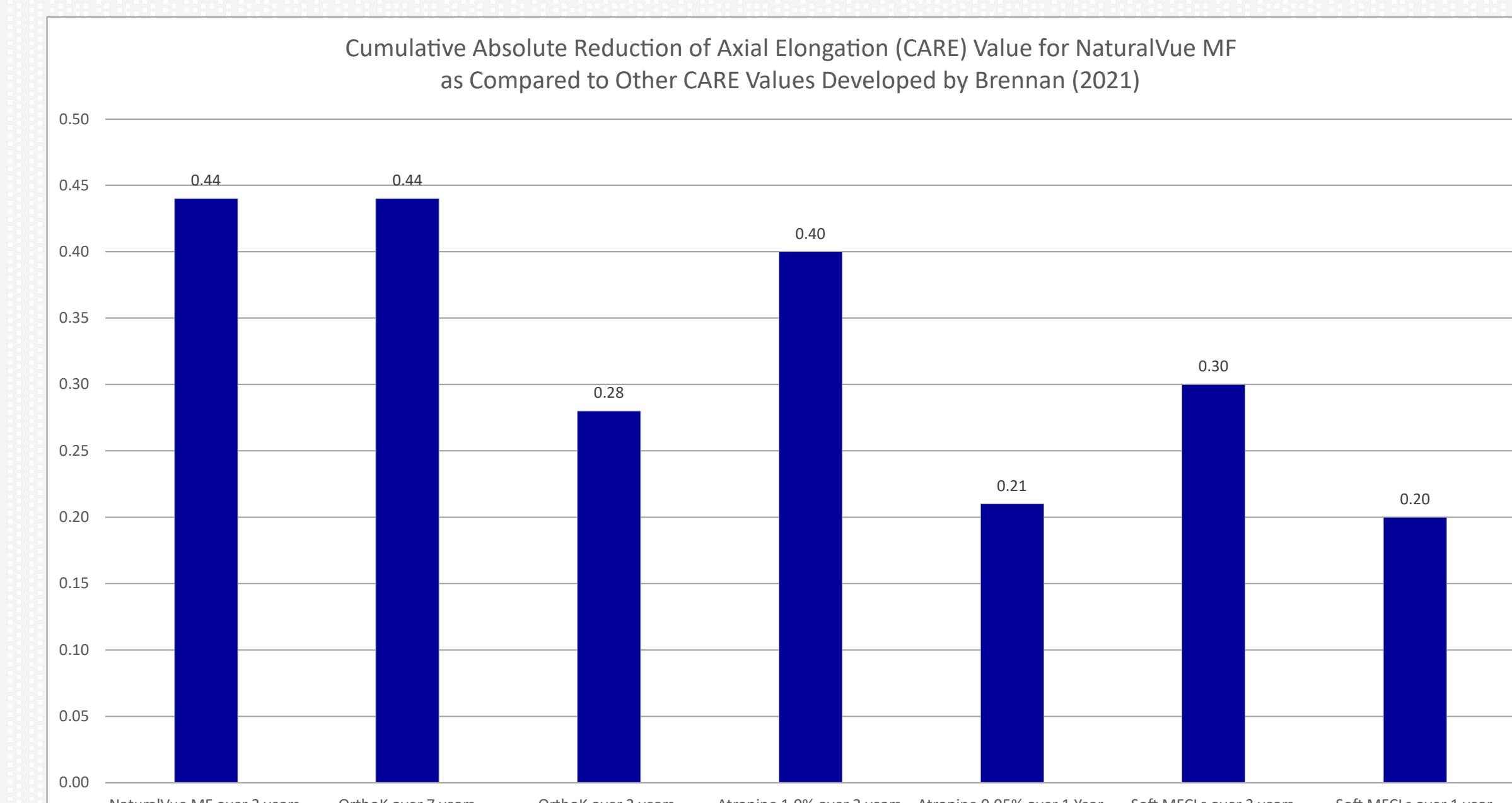
Actual Observed Axial Elongation with NaturalVue Multifocal (mm)				
Baseline	Y1	Y2	Y3	3 Yr Cumulative
0.33	0.08	0.07	0.08	0.23
				0.44 mm Diff to Control (CARE value)

Results (Continued)



Cumulative NVMF Refractive Error Change from Baseline through 72M

Distribution Graph – Cumulative NVMF Refractive Error Change through 72M



NVMF CARE value determined from age and ethnicity matched virtual control group data⁵⁻⁹ compared to CARE values determined by Brennan¹⁰

An analysis using age and ethnicity matched Virtual Control Group data from a meta-analysis by Brennan et al,⁵⁻¹⁰ predicts a CARE value (cumulative difference in axial elongation to the control group) for NaturalVue MF of 0.44 over 3 years. An estimate of the predicted dioptric effect can be made by multiplying CARE by 2.1;¹⁰ therefore, a RE difference for NVMF to the age and ethnicity matched virtual control group of 0.92D over 3 years is predicted by these data, even greater than that observed in the retrospective analysis after 3 years.

Conclusions

- NVMF demonstrated a 0.85 D reduction in refractive error change, or 85% (calculated average OU) from baseline (p < 0.05)
- 95% of the children showed a reduction in myopic progression; 78% showed a decrease of 70% or greater
- 67% of children had no increase in myopic progression through the entire NVMF wearing period of up to 72M
- Through a 4-year time frame, the average AL change with NVMF was approximately 0.10mm/year, similar to emmetropic children
- A CARE value of 0.44 over 3 years (or approximately 0.92D) for NVMF is predicted based on age and ethnicity matched virtual control group data.⁵⁻¹⁰

The unique, center-distance, aspheric, extended depth of focus design of NaturalVue Multifocal 1 Day contact lenses continues to be proven effective in reducing myopic progression, even through 6 years for the vast majority of children. These findings add to the growing evidence that the NVMF center-distance, multifocal soft contact lenses may slow the progression of myopia.

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