

# 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.<sup>1</sup> It is estimated that by the year 2050, 5 billion people on the planet will be myopic.<sup>2</sup> A whopping 1 billion will be highly myopic.<sup>3</sup> 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.<sup>3</sup> 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.<sup>4</sup>

## 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  $12.3 \pm 2.8$  years (range 5-20 years) Initial spherical equivalent refraction (SER) was (Mean  $\pm$  SD) -3.60  $\pm$  2.00D, and Axial Length (AL) 25.05  $\pm$  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  $12.6 \pm 3.0$  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  $\leq 0.10$  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,<sup>5-9</sup> with an average age of  $10.5 \pm 1.3$ ; 47% were Caucasian, 30% Asian, 23% Other. At baseline, SER averaged  $-3.60 \pm 2.00D$ , AL  $24.97 \pm 0.58$ mm, 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.<sup>5-9</sup> 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.<sup>5-10</sup>

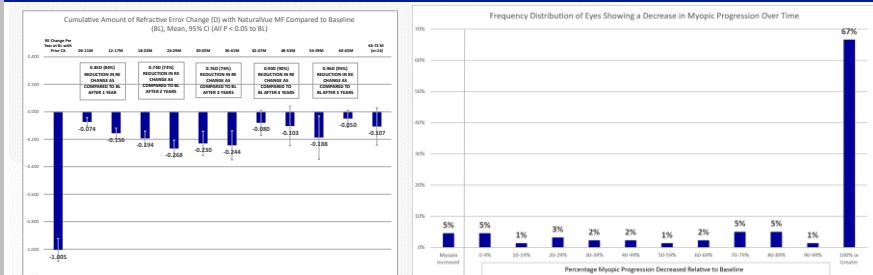
### Age and Ethnicity Matched Virtual Control Group Refractive Error Change (D)<sup>5-9</sup>

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)<sup>5-9</sup>

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 data<sup>5-9</sup> compared to CARE values determined by Brennan<sup>10</sup>

An analysis using age and ethnicity matched Virtual Control Group data from a meta-analysis by Brennan et al,<sup>5-10</sup> 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;<sup>10</sup> 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.<sup>5-10</sup>

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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**Commercial Relationship Disclosures:** DPB: Executive Director of Professional Services, VTI SMD: Consultant to, and former CMO for VTI

