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

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 change from baseline was approximately 0.25D or less at all annual visits. NVMF SER change data were significantly different from baseline at all points in time ($p < 0.05$). The mean AL total change from baseline was 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) 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 48 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 48 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** or VTI Technical Consultation **1-844-VTI-LENS (1-844-884-5367)**, ext. 102, or **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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