Shared Vision

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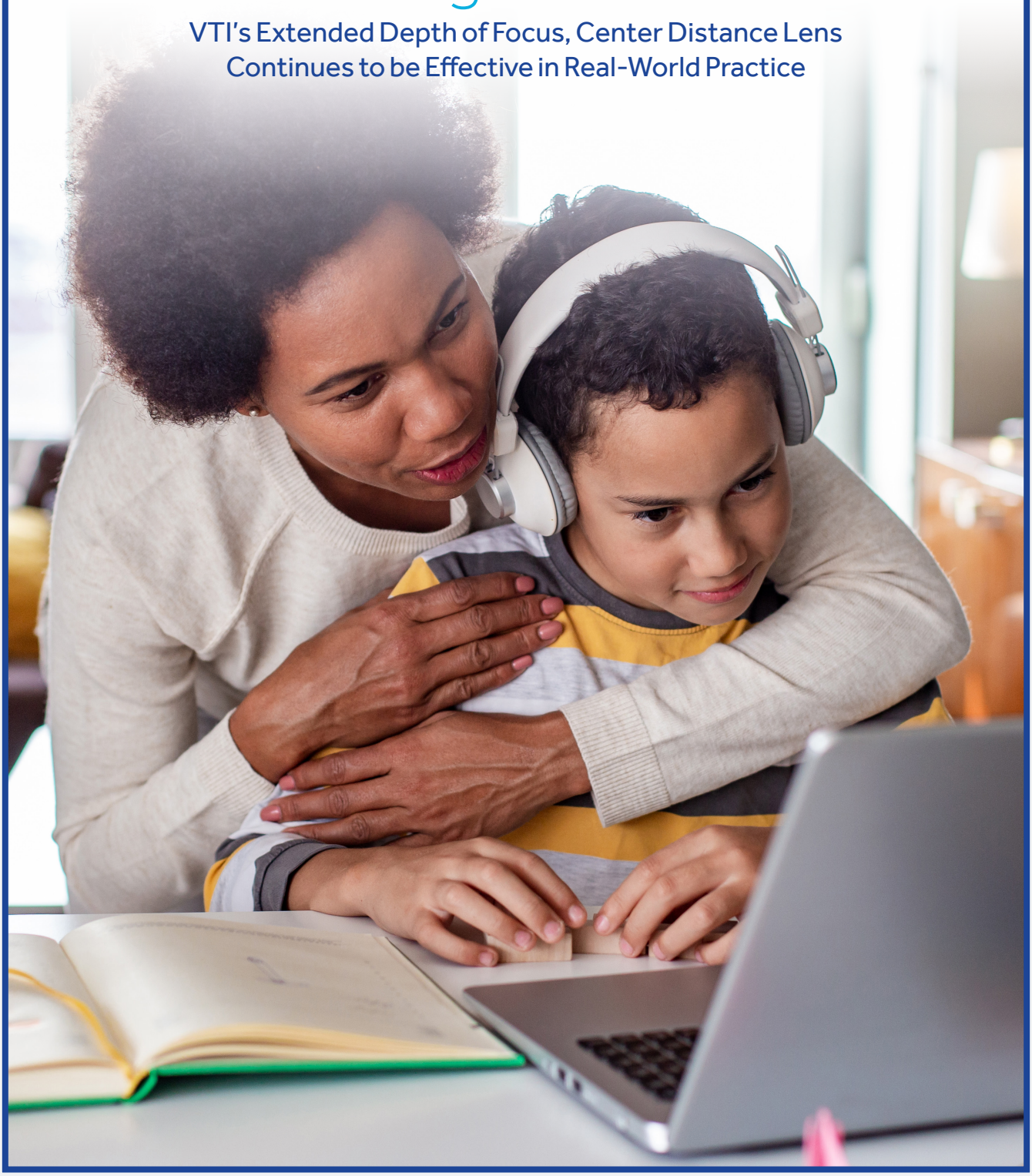
New Clinical Evidence through 6 Years:

VTI's Extended Depth of Focus, Center Distance Lens Continues to be Effective in Real-World Practice



New Clinical Evidence through 6 Years:

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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 ≤ 0.25D from baseline.
- The average refractive error change slowed by 0.85D (or 85%) as compared to baseline from 6-72 months.

Background

A 2018 retrospective case series analysis of 32 myopic children, in a real-world evidence retrospective cohort analysis (mean age: 10.98 ± 2.95 years) from 10 practice locations in the United States wearing daily disposable soft multifocal lenses (NaturalVue® Multifocal 1 Day, Visioneering Technologies, Inc., Alpharetta, GA) exhibited significant reductions in myopic progression.[1] In the initial retrospective cohort analysis, the duration of wear for the 32 patients was just under 1 year (Mean 10.94 ± 4.76 months; Range 6 to 25 months). The study authors subsequently endeavored to report on the NaturalVue Multifocal efficacy over an expanded wear time/follow up of about six years (72 months) and with a larger cohort of 196 patients who had not previously used other interventions for myopic progression such as soft multifocal contact lenses, orthokeratology, or atropine.

Recently, new 6-year data was presented with the VTI extended depth of focus, center distance, daily disposable multifocal contact lenses*. A summary of the results is outlined here:

Methodology

A retrospective case series analysis of data from 196 patients fit with the multifocal lens between December 2014 and December 2020 (72 months), from 15 practices in the United States was conducted. The patients showed at least -0.50D of myopic progression in at least one eye prior and had not previously used other interventions for myopic progression (soft multifocal contact lenses, orthokeratology, or atropine).

Results Detail

- 95% of wearers showed a decrease in myopia progression.
    - Additionally, 78% of wearers showed a decrease in myopia progression of 70% or greater. *Figure 1*
- The average myopia progression slowed by approximately 0.85D or 85% compared to baseline, statistically significant at all points in time (P<0.05). *Figure 2*
    - The average myopia progression while wearing the lens never exceeded more than about 0.25D from baseline.
- Axial length change was measured for a subset of the population**. The average change was approximately 0.10 mm per year through 47 months of follow up. *Figure 3*

Figure 1

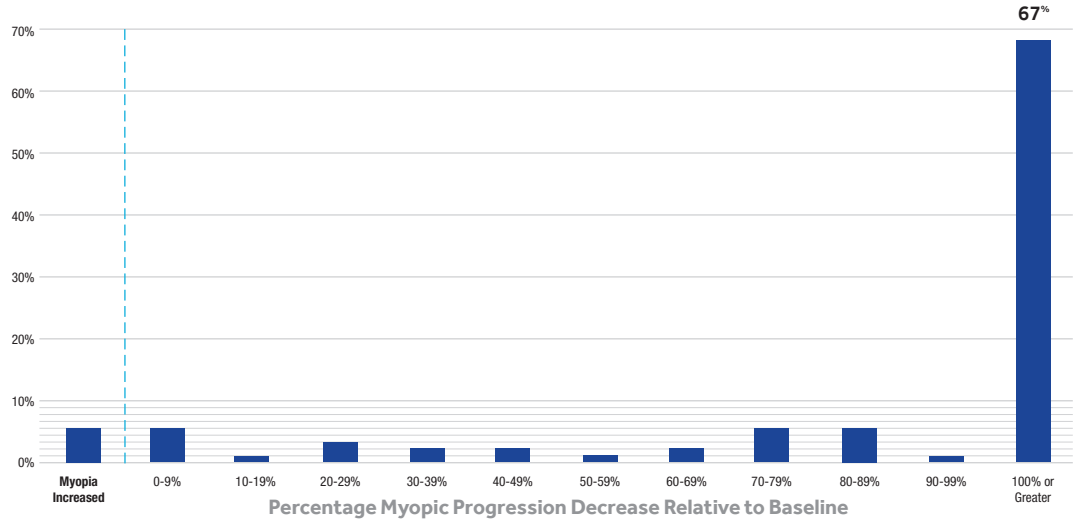


Figure 2 Cumulative Amount of Refractive Error Change (D) with NaturalVue MF Compared to Baseline (BL) Mean, 95% CI (All P < 0.05 to BL)

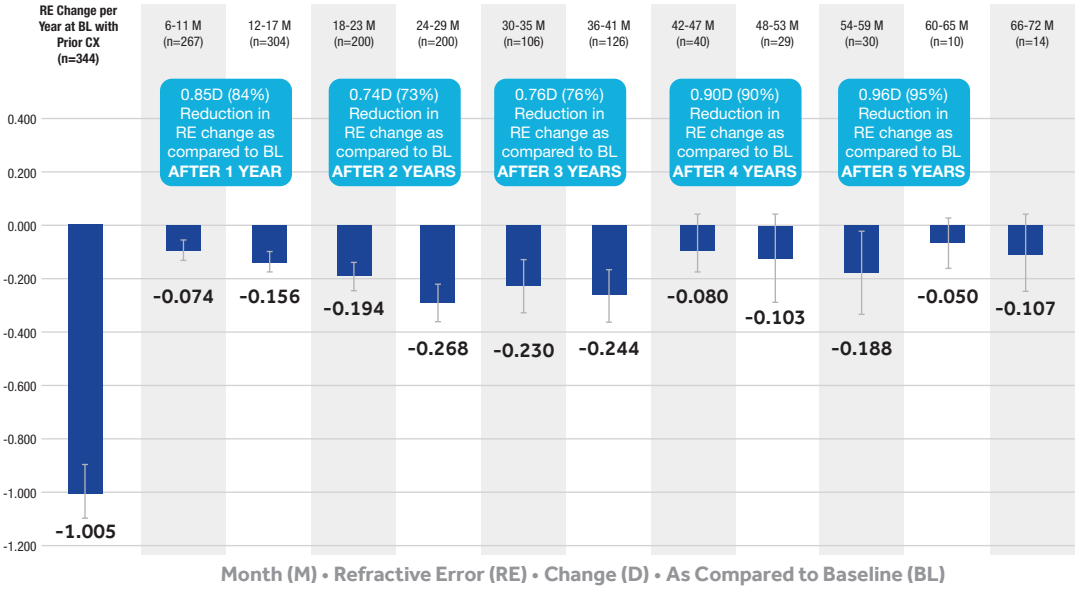
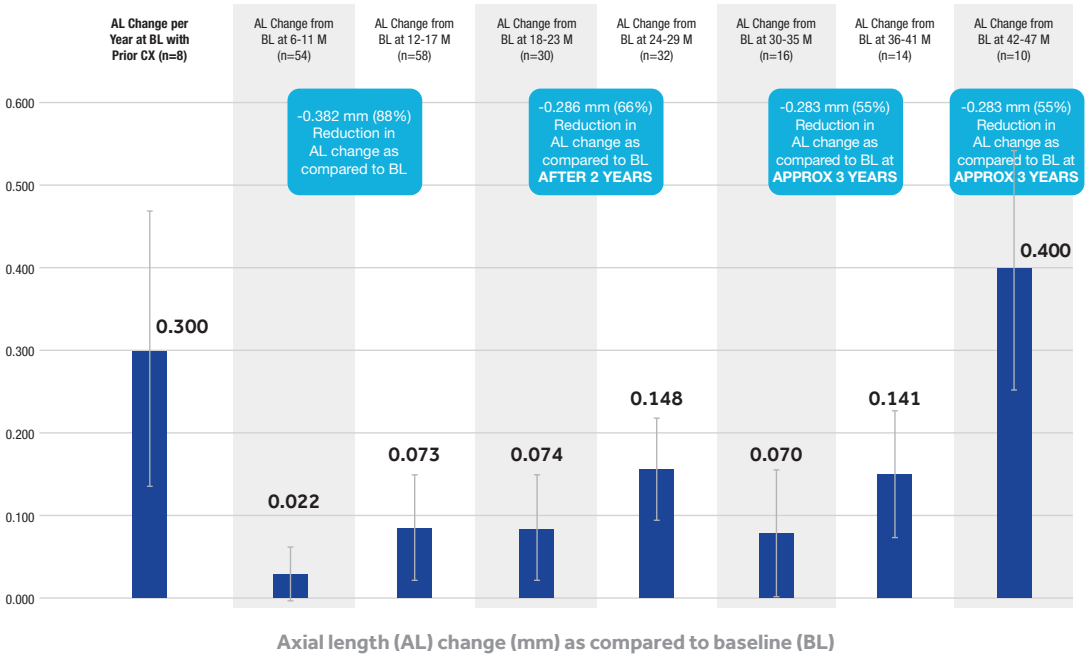


Figure 3

Cumulative Amount of Axial Length (mm) Change as Compared to Baseline (BL) Mean, 95% CI



Conclusions of the study

The VTI lens continues to be proven effective in reducing myopic progression, even after 6 years for some children. Further research is needed to understand the clinical importance of the observed differences as well as long-term outcomes.

Limitations of the analysis

- The analysis included results from a retrospective case series (196 children). Patients were not randomized to a treatment group, and there was no control group. All patients were not followed for the same amount of time.
- Each child was used as his/her historical control.
- Children who did not do well with the lenses may have dropped out and this could create bias in the long-term results.
- An important limitation is the small sample size for which axial length data are available.

Each practitioner needs to come to their own conclusions about how to interpret research and how it may impact or influence his/her decisions with patients. Further research is needed to understand the clinical importance of the observed differences as well as long-term outcomes.

Implications

The higher amounts of peripheral plus power found in this lens may be contributing to a stimulus which inhibits AL growth and therefore myopia progression.

The importance of this data is that it comes from real-world practice with clinicians treating patients that they see every day.

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REDEFINING VISION VTI

*NaturalVue Multifocal is a commercially available daily disposable, center-distance, soft multifocal contact lens with an aspheric extended depth of focus design.

**Data was less for axial length measurements due to lack of measurement instrumentation available in some practices at the time the study began. Data calculated through 3 years (35 months) in a smaller sample.

Reference 1. Cooper J, O'Connor B, Watanabe R, et al. Case Series Analysis of Myopic Progression Control With a Unique Extended Depth of Focus Multifocal Contact Lens. *Eye Contact Lens.* 2018;44(5):e16-e24.