

Evaluation of Pupil Size and Visual Acuity in a Myopic Pediatric Population Wearing a Soft Contact Lens with Non-Coaxial Focus

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Purpose

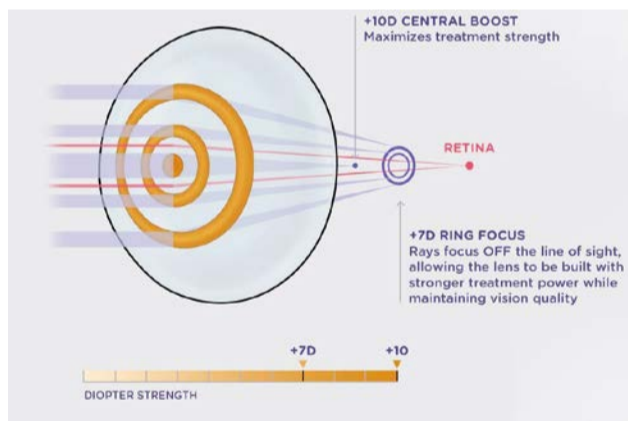
All soft contact lenses for myopia control are expected to impact vision to some extent. The effect on vision is design dependent, but the extent of the effect may also be influenced by interaction with the pupil diameter.

Dolce et al reported that the effect of pupil diameter (3 mm vs 6 mm) on **high contrast** visual acuity (VA) for a center distance multifocal (comfilcon A, +2.50 D ADD) was negligible, but resulted in a nearly two-line reduction in VA in the same lens for **low contrast** VA.¹

A soft contact lens with non-coaxial focus (EE) was designed to enhance myopia control efficacy while providing good visual performance. Data from Cheng et al supported that the design intent was met regarding myopia control efficacy and vision performance.² A series of assessments of VA³ and patient-reported outcome assessments^{4,5} have shown EE provides good visual performance. An illustration of EE is provided in Figure 1, below.

The purpose of this analysis was to explore the impact of pupil size on low contrast logMAR visual acuity (VA) in pediatric patients wearing the EE lens.

Figure 1: EE Lens with RingBoost™ Technology Illustration



Methods

Study Design: multi-center, randomized, controlled, two arm parallel, double masked study in previously untreated, 7-12 year old myopic children

Duration: 3 months following lens dispensing, with monitoring at 1 week, 1 month, and 3 months

Study Lenses: Two senofilcon A based lenses, with one for enhancing efficacy [Test, EE] of myopia control and a single vision lens (Control, SV)

VA System: M&S Clinical Trial Suite (CTS) 1500 (M&S Technologies, Niles, IL) at 4 m. VA scored letter-by-letter, with test stopping when subject missed 3 or more letters on a single row.

VA Conditions: Room lighting conditions were 0-10 lux and the screen (chart) luminance was 85 cd/m² with an allowable range of $\pm 5\%$.

Pupil Size: Assessed OD only with Neuroptics VIP-300 pupillometer while subject viewed the VA display at 4 m

Analyses were conducted using mixed models with repeated measures (MMRM) for the intention-to-treat (ITT) population.

Results

99 subjects were randomized, with 95 completing the study. Reasons for discontinuation were unable to apply lenses in-office (1), lens handling difficulty (2), and disallowed medication (1). Figure 2 shows the subjects who completed each visit by group and Table 1 describes characteristics of the study population.

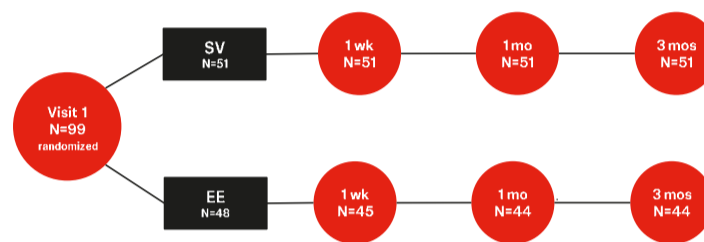


Figure 2: Subjects completed by group and study visit

	EE (n=48)	SV (n=51)	Overall (n=99)
Age, mean (SD)	10.3 (1.65)	10.1 (1.58)	10.2 (1.61)
Female subjects, n (%)	24 (50.0%)	31 (60.8%)	55 (55.6%)
White subjects, n (%)	24 (50.0%)	31 (60.8%)	55 (55.6%)
Habitual CL Wearers,* n (%)	10 (20.8%)	13 (25.5%)	23 (23.2%)
Pupil diameter, mm (mean \pm SD)	5.8 \pm 0.95	6.4 \pm 0.99	6.1 \pm 1.01
Refractive Error, D (mean \pm SD)	-2.3 \pm 1.09	-2.2 \pm 0.98	-2.2 \pm 1.03

Table 1: Summary of the intention-to-treat study population

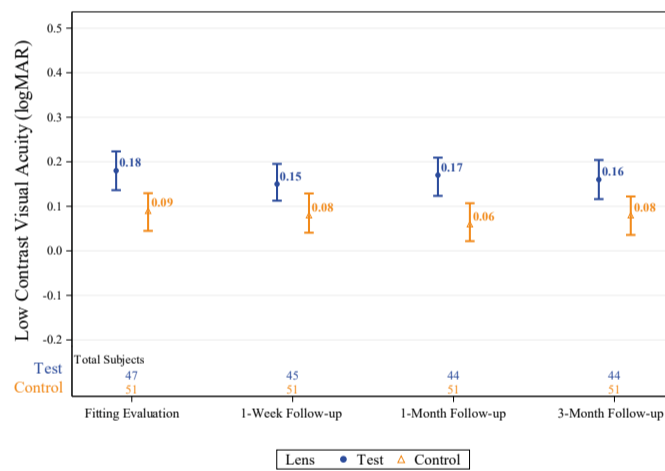


Figure 3: Least squares means and 95% confidence intervals for binocular low contrast distance VA, by lens group and timepoint

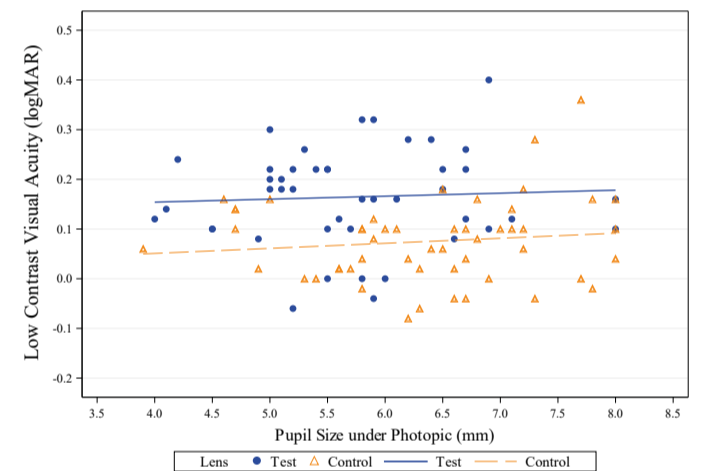


Figure 4: Scatterplot of low contrast VA and pupil diameter for 3-month follow-up

Discussion and Conclusion

The mean difference in binocular low contrast VA between EE and SV ranged from 0.07-0.11 logMAR, similar to other soft CLs tested for myopia control⁶

There was a significant fixed effect of pupil diameter ($p=0.0427$) on binocular low contrast logMAR VA. Larger pupil diameters corresponded to slightly worse logMAR VA (about $\frac{1}{2}$ line).

No significant interaction of pupil size and lens group was found ($p=0.2075$), and the regression lines for the EE and SV groups appeared nearly parallel over the range of pupil diameters (see Figure 4).

References

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Disclosures:

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