Calculated age-independent myopic axial length growth in the CYPRESS clinical trial

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Purpose

Axial length is a robust primary outcome measure for longitudinal clinical trials evaluating the efficacy of myopia control therapies. However, axial length growth, in coordination with increases in body stature, is evident even in persistent emmetropic eyes and is most rapid before preadolescence. The purpose of this research was to evaluate treatment efficacy of DOT spectacle lenses in respect to physiological emmetropic and pathological myopic eye growth to derive an age-independent estimate of axial length growth.

Methods

Myopic children aged 6 to 10 years were enrolled in CYPRESS (NCT03623074): a 3-year double-masked, randomized, controlled clinical trial across 14 North American sites. 181 children were randomised to wear either DOT lenses (T1, n=88) or standard single-vision Control lenses (n=93). Children were advised to wear the study spectacles all waking hours, apart from when participating in high-impact sports or swimming. Children were classified as full-time wearers if they wore their study spectacles for near vision activities, as reported by parental questionnaires. Axial Length (AL) and Spherical Equivalent Refraction (SER) were measured at baseline, 12, 24 and 36 months. Physiological AL growth was calculated based on age-matched emmetropic eye growth data from the Orinda Longitudinal Study of Myopia and compared to AL growth observed in the CYPRESS study.

Results

A total of 154 children completed the 3-year study, of which 64% were classified as full-time wearers (T1 42/71, Control 57/83). After 3 years, the LS mean AL and SER (± SE) of the Control group increased by 0.72 ± 0.05 mm and -1.22 ± 0.12 D, respectively, in full-time wearers. Compared to Control, T1 progressed significantly less in AL (0.48 ± 0.06 mm, difference -0.24 mm, p=0.010) and SER (-0.65 ± 0.14 D, difference 0.57 D, p=0.012) in full-time wearers after 3 years. The calculated pathological AL change after 3 years was 0.08 ± 0.06 mm for T1 and 0.31 ± 0.05 mm for Control (difference -0.23 mm, p=0.003). The percentage reduction in pathological AL growth for T1 full-time wearers was 83% after 2 years and 73% after 3 years.

Conclusion

After 3 years, children who wore DOT spectacle lenses full-time had significantly less myopia progression than control group participants. Considering expected physiological AL change is important to understand and compare AL change in an age-independent manner.