

Analysis of Real-World Data in Myopic Children Wearing a Highly Aspheric Multifocal Contact Lens

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PURPOSE

Soft multifocal lenses are an evidenced-based intervention for correcting vision and slowing myopia progression in children.^{1,2} Real-world evidence from children undergoing myopia interventions are a valuable source of data to aid practitioners in gauging the effectiveness of such therapies. Retrospective data from three published cohorts of children wearing a commercially available highly aspheric center-distance multifocal power profile lens³⁻⁵ were compared to published virtual control data⁶ to assess the design's effectiveness for myopia management.

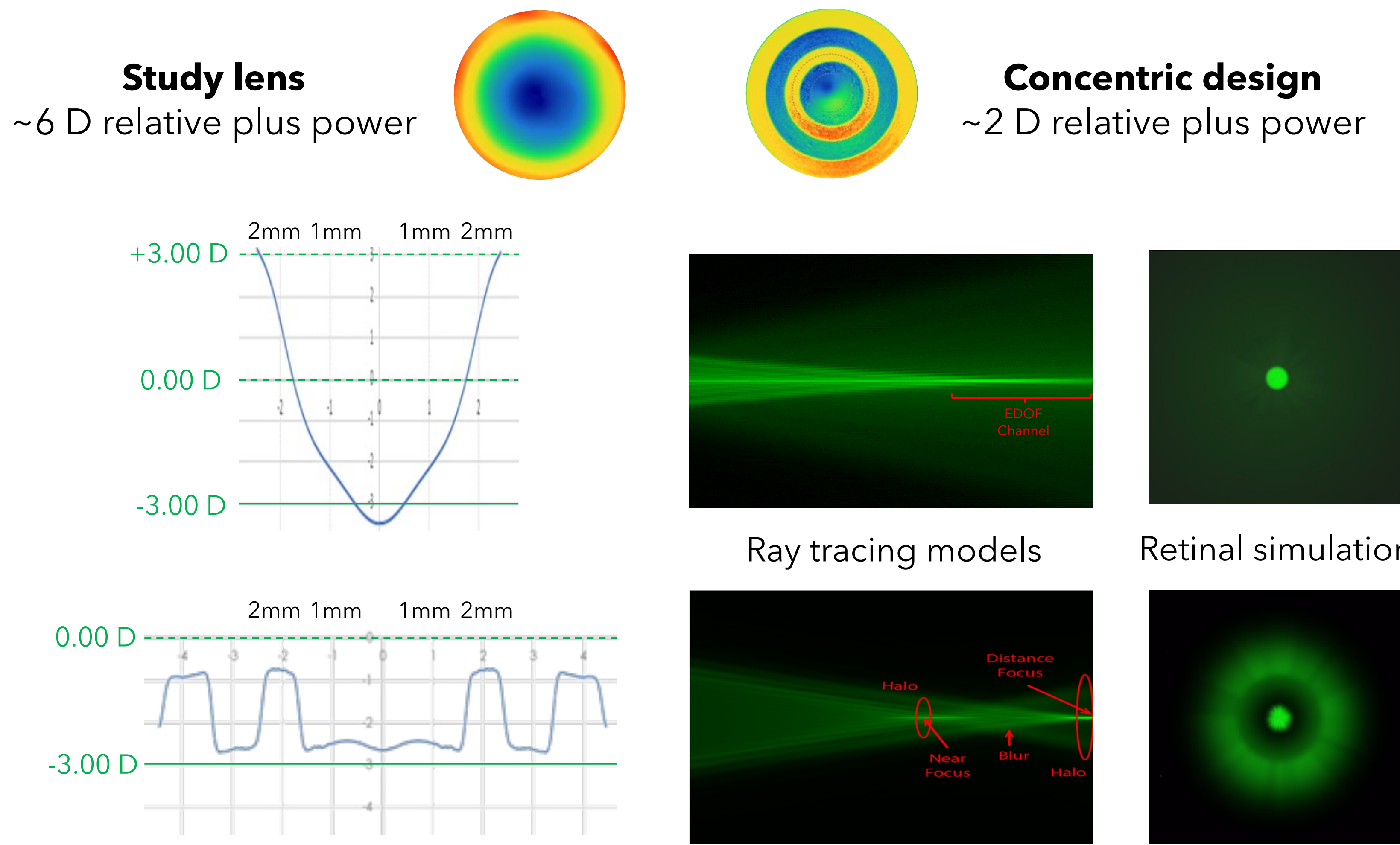


Figure 1. Power profile and ray tracing visualization of the highly aspheric center-distance study lens versus a traditional concentric optic multifocal design (both -3.00 D distance power). The study lens generated a significantly larger area and magnitude of relative plus power across all pupil sizes.

METHODS

Three unique, published real-world cohorts of children wearing the study lens were identified. Change in spherical equivalent refractive error (SER) and axial length (AL) were calculated at 1 and 2 years (right eyes). Two of the cohorts had detailed demographic information available, enabling comparison to values derived from a published model of age- and ethnicity-matched untreated myopic virtual control eyes.⁶ The difference between observed and predicted SER and AL changes were calculated. CARE values (cumulative absolute reduction in axial elongation) from these two cohorts were compared to recently announced interim data (modified per protocol) from randomized controlled trial⁷ evaluating the study lens.

RESULTS

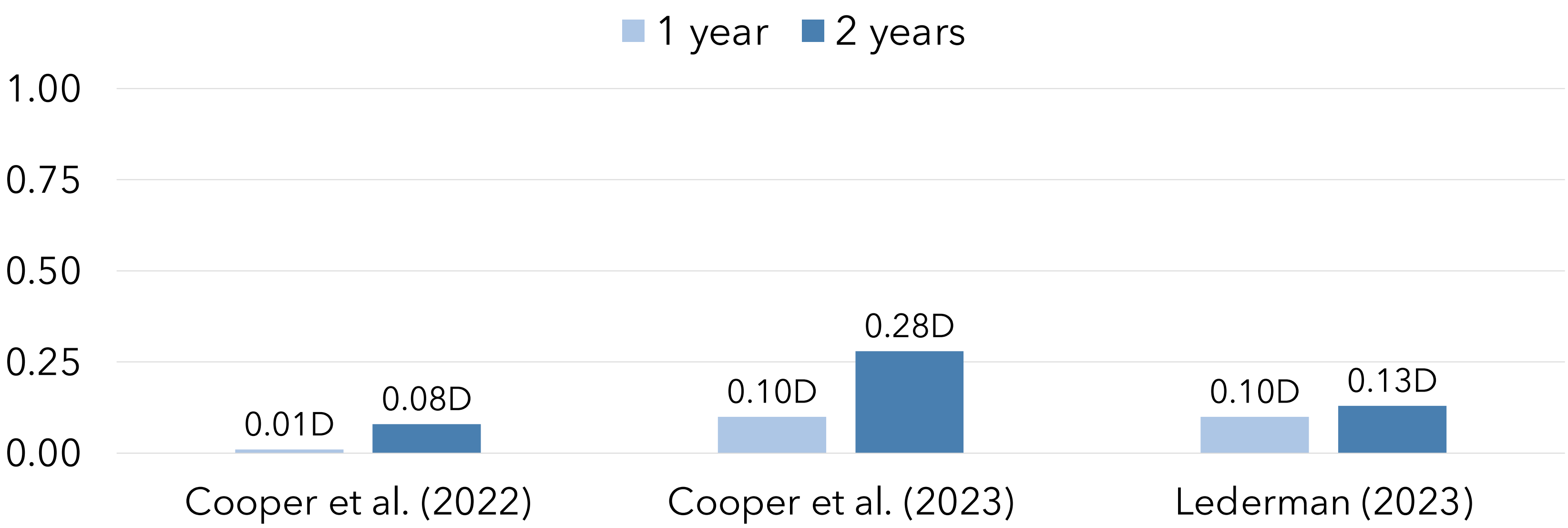


Figure 2a. Average cumulative SER change among subjects wearing the study lens

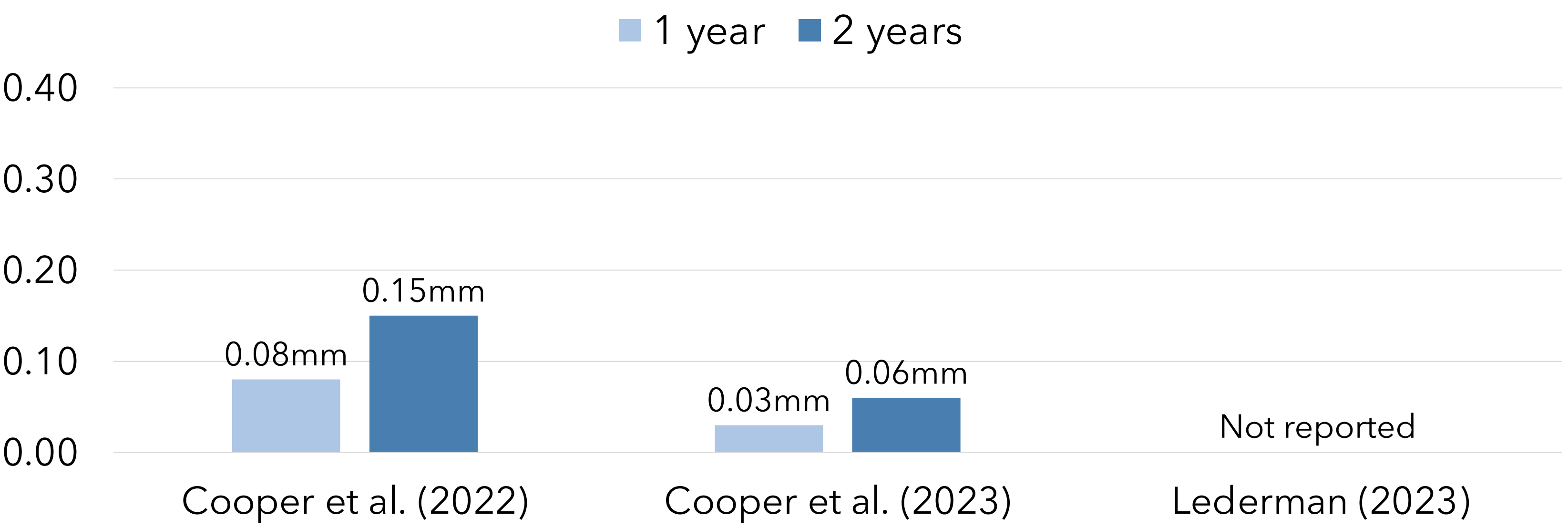


Figure 2b. Average cumulative AL change among subjects wearing the study lens

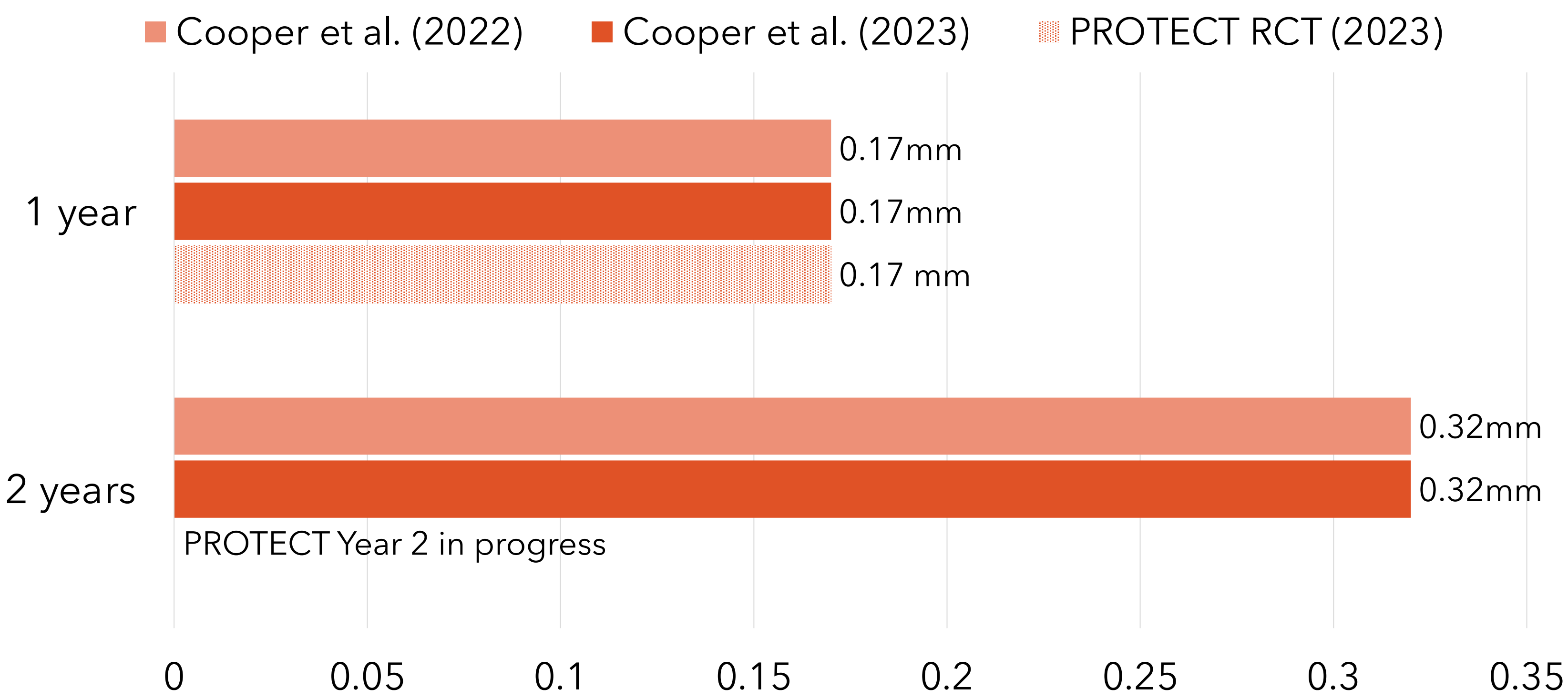


Figure 3. 1-year and 2-year axial elongation treatment effect (CARE value)

	Cooper et al. (2022) ³	Cooper et al. (2023) ⁴	Lederman (2023) ⁵
N (12M)	65	17	24
N (24M)	65	5	14
Avg Age at BL (Years)	10.3	12.6	12.0
Avg CSER at BL (D)	-3.73	-5.63	-3.14
1-Year CSER Change (D): Actual (SD) vs Predicted (SD)	-0.01 (0.27) -0.46 (0.14)	-0.10 (0.43) -0.33 (0.18)	-0.10 (0.15) Not available
2-Year CSER Change (D): Actual (SD) vs Predicted (SD)	-0.08 (0.35) -0.82 (0.13)	-0.28 (0.49) -0.59 (0.26)	-0.13 (0.13) Not available
1-Year AL Change (mm): Actual (SD) vs Predicted (SD)	0.08 (0.06) 0.25 (0.01)	0.03 (0.14) 0.20 (0.05)	Not reported
2-Year AL Change (mm): Actual (SD) vs Predicted (SD)	0.15 (0.13) 0.47 (0.01)	0.06 (0.21) 0.39 (0.08)	Not reported

Figure 4. Demographics and detailed results for each study cohort

CONCLUSIONS

Children in real-world settings fit with a highly aspheric center-distance multifocal power profile lens demonstrated less than or equal to 0.28 D of SER change and less than 0.10 mm of AL change through 2 years of follow up – significantly less than expected in matched untreated myopic children. This data trended closely with interim 1-year results from an ongoing randomized controlled trial using the study lens. These findings demonstrate that this commercially available lens is an effective intervention for slowing the progression of childhood myopia.

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DISCLOSURES

BO, JC, TA, & SD are consultants to Visioneering Technologies, Inc.