

Myopia control efficacy of MyoCare explained by an absolute rather than proportional effect

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Purpose

Myopia management (MM) approaches using optical, behavioral, light-based, or pharmaceutical methods aim to reduce progression of myopia (determined using change in spherical equivalent or axial length (AL) or both). To determine if the 12-month efficacy of spectacle (SPL) lenses incorporating cylindrical annular refractive elements (C.A.R.E, MyoCare, ZEISS Vision Care) is better explained by an absolute effect or a proportional (relative) effect.

Methods

- In an ongoing, prospective clinical trial (NCT05919654), 300 children with myopia, aged 6 to 13 years randomized to either single vision (SV) SPL or C.A.R.E SPL (ZEISS Vision Care)¹.
- 12-month AL change was determined in 107 and 118 children with C.A.R.E vs SV SPL respectively. Absolute changes in AL binned into groups of 0.1mm for both groups and plotted as relative frequency distribution curves.
- To determine if efficacy is explained by absolute or relative effect, a) mean difference in progression in mm between groups subtracted from SVL SPL and b) relative percent difference between groups added to the SVL SPL group to create two new distribution curves (SVL SPL by mean difference; SVL SPL by relative efficacy)².

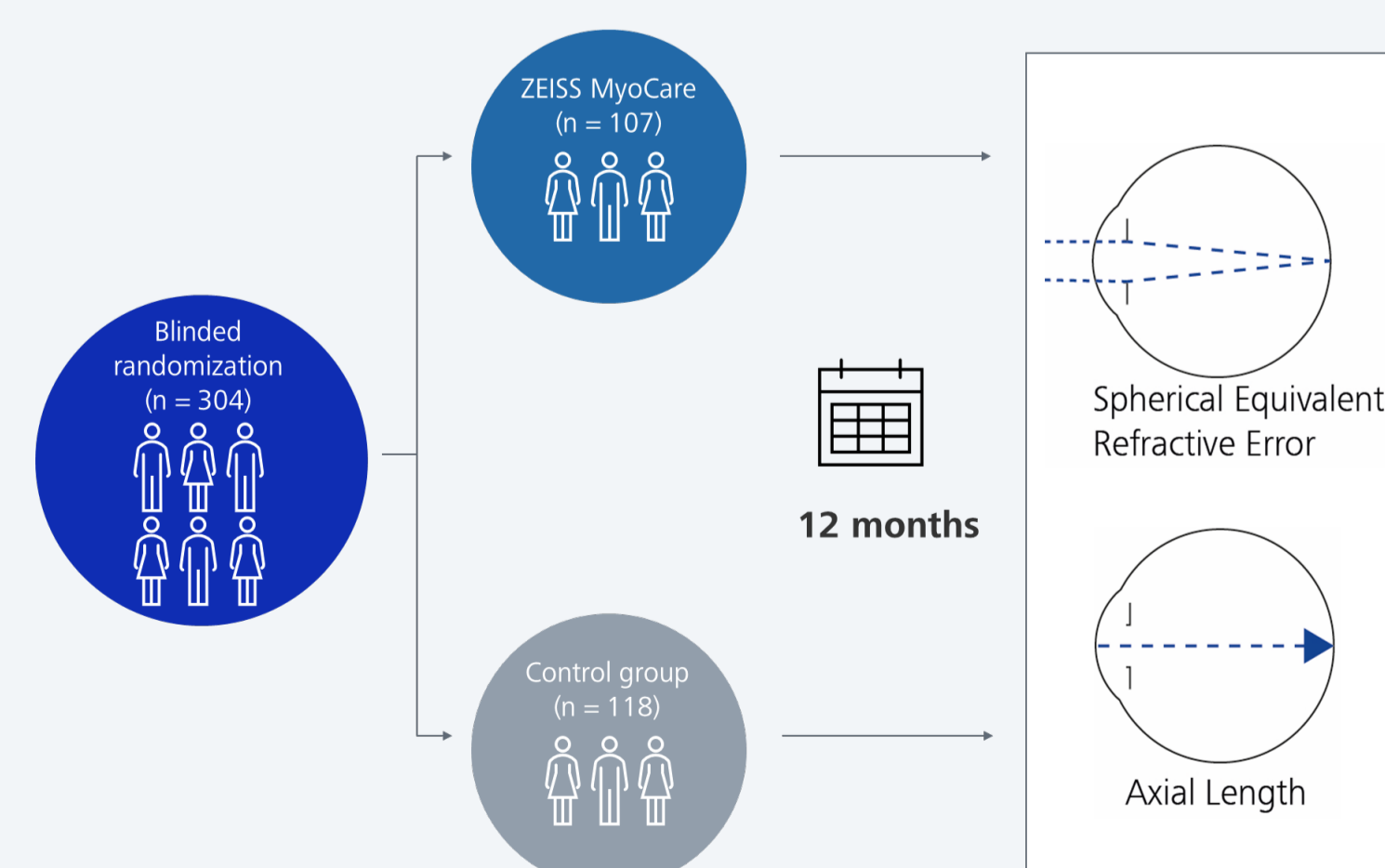


Figure 1. Overview of the randomized controlled clinical trial.

Results

- After 12 months of wear, absolute difference in AL between CARE and SV SPL was 0.11mm (relative efficacy - 49%), relative frequency distribution curves for C.A.R.E (blue curve) and SVL (red curve) are similar in width (SD \pm 0.14mm) and height (Figure 2).

Absolute effect?

- Subtracting the mean difference of 0.11mm from the SVL distribution curve resulted in a new SVL curve (Figure 2, orange dotted line) that overlapped the distribution curve of C.A.R.E group.

Relative effect?

- Applying the relative efficacy of 49% to the SVL distribution curve resulted in a new SVL curve (Figure 2, Orange line) that was narrow with a peak at 0.1mm (S.D \pm 0.07mm).

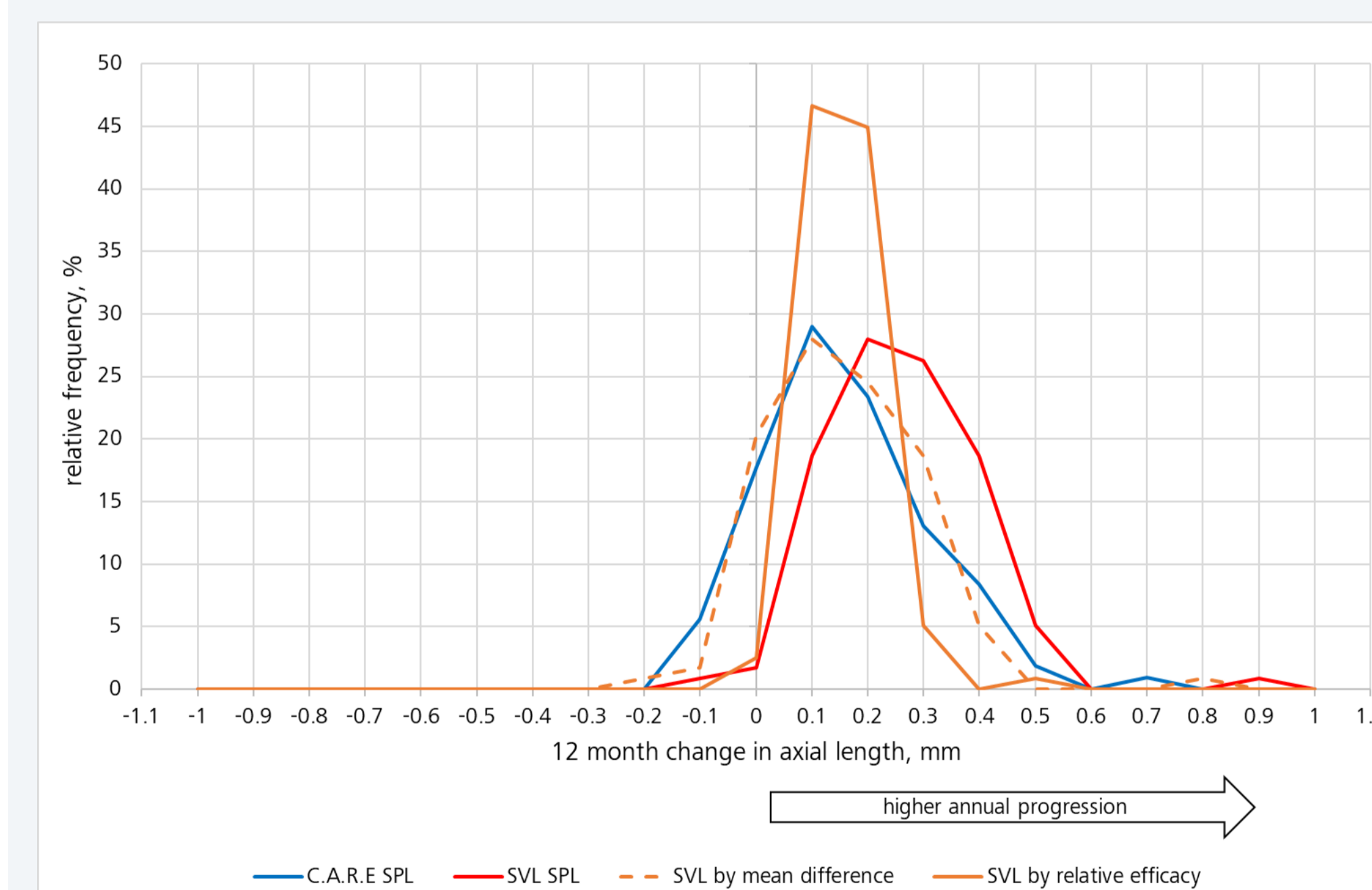


Figure 2. Relative frequency of axial length progression over 12-month as a function of its value for C.A.R.E SPL (blue) and SVL SPL (red) groups. Additionally, progression of SVL SPL by shifting 12-month data along the x-axis by the mean difference (0.11mm, orange dotted line) and 12-month progression of SVL SPL by shifting distribution by relative efficacy (49%, orange line).

- Additionally, relative effect overestimated the number of kids that showed medium elongation of axial length within 12-months (0.1 to 0.2mm) progressors by 39%, while underestimating slow (0 to 0.1mm per year) by 21% and fast progressors (>0.2mm per year) by 18%³.

Discussion

Our results indicate that efficacy of C.A.R.E is better explained using the absolute treatment effect rather than relative efficacy. When the AL progression of eyes wearing SV SPL were shifted by an amount that equaled the mean difference in progression between C.A.R.E and SV (0.11mm in one year), the new distribution coincided with the CARE distribution (with similar standard deviation). Thus, it appears that myopia management SPL reduce progression across the entire wearer group, rather than having a greater effect on eyes with higher rates of axial length progression. Comparison to other clinical data from ongoing studies in East Asia will confirm if the results are consistent.

Conclusion

The use of percent (relative or proportional effect) results in overestimation of efficacy for average progressors but underestimates slow as well as fast progressors. It is preferred that absolute reduction values are used to report the efficacy of myopia control strategies.

References

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