Slowing myopia progression with cylindrical annular refractive elements (CARE) – 12-month interim results from a 2-year prospective multi-center trial

Xiaoqin Chen[1], Min Wu[2], Cui Yu[3], Arne Ohlendorf[4], Sankaridurg Padmaja[4,5], Katharina Rifai[4], Christina Boeck-Maier[4], Siegfried Wahl[4,6], Youhua Yang[4], Yi Zhu[4], Lihua Li[1]

[1]Tianjin Eye Hospital Optometric Center, Tianjin, China; [2]Beijing Tongren Vision Care, Beijing Tongren Hospital,, Capital Medical University, Beijing, China; [3]He Eye Specialist Hospital, Shenyang, Liaoning, China; [4]ZEISS Vision Care, Aalen, Germany, Carl Zeiss Vision International GmbH, Aalen, Germany, , Germany; [5]School of Optometry and Vision Science, University of New South Wales, Sydney, New South Wales, Australia; [6]Institute for Ophthalmic Research, Eberhard Karls Universitat Tubingen, Tubingen, Baden-Württemberg, Germany

Purpose
To evaluate the effectiveness of 12 months of spectacle lens (SPL) wear with two SPL incorporating cylindrical annular refractive elements (CARE) introducing simultaneous myopic defocus at the retina in slowing the progression of myopia as compared to a single vision SPL.

Methods
In an ongoing 2-year prospective, double-masked, multi-center clinical trial (NCT05288335), 240 Chinese children aged 6-13 yrs, spherical equivalent refractive error (SE) -0.75D to -5.00D were enrolled and randomly assigned to one of three groups: (1) single vision spectacles SPL (SV, N=80); (2) MyoCare (ZEISS) with CARE mean surface power of +4.6 D and a central clear zone of 7 mm (N=80); and (3) MyoCare S (ZEISS) with CARE mean surface power +3.8 D and 9 mm central clear zone (N=80). Cycloplegic SE and axial length (AL) were measured at six-monthly intervals. Change in SE and AL from baseline was determined at 6 and 12 months and differences between groups assessed. An intent to treat analysis for 12 months with linear mixed models was conducted after adjusting for relevant confounders selected based on the Aikaike information criterion. Statistical significance was maintained at $p<0.05$.

Results
Progression (mean ± SD) in SV wearing eyes after 6 and 12 months of SPL wear was -0.29±0.33D/0.17±0.09mm and -0.65 ± 0.40 D/ 0.32 ± 0.17 mm with SV for SE/AL, respectively. In comparison, progression was significantly reduced both with MyoCare (-0.10±0.32D/0.10±0.10mm and -0.37 ± 0.39 D/ 0.20 ± 0.16 mm, $p<.0001$) and MyoCare S (-0.13±0.27D/0.11±0.11mm and -0.38 ± 0.38 D/ 0.22 ± 0.15 mm, $p<.0001$). Progression did not differ significantly between MyoCare and MyoCare S. Adjusting for site, group, parental myopia, and age, at 12 months, MyoCare showed an absolute change in SE of 0.31D (relative efficacy 48%) and MyoCare S 0.29D (45%) compared to SV. At 12 months, AL reduction was 0.13 mm (41%) with MyoCare and 0.11 mm (34%) with MyoCare S as compared to SV.

Conclusions
In children with myopia, after 12 months of lens wear, both MyoCare and MyoCare S were found to significantly slow myopia progression compared to SV lenses.

Reference until publication in IOVS:

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