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Will the new anti-myopia spectacles be the standard of care in future?

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Reports of myopia increases across the world show an expanding growing public health problem. Myopia prevalence is exceptionally high in some continents, especially in Asia particularly east Asian countries, but was also reported to have increased in other continents, such as North America and Europe, although there is considerable variation between geographic areas and racial groups in the myopia burden.[1–3] The presence of myopia, especially high myopia increases the risk of development of pathological myopia and visual impairment. The peak incidence of myopia occurs in childhood, but the associated blinding ocular complications develop

later during adulthood. Children with increased risk of visual impairment due to pathologic myopia often have longer duration of the disease, longer axial length (AL), and thinner choroid. Thus, myopia control therapies should be implemented early to avoid the development of high myopia as early-age of myopia onset plays a fundamental role in myopia progression with about 50% of children with myopia onset at 7 or 8 years of age developing high myopia in adulthood, if left untreated.[4] Increased prevalence of high myopia related to AL elongation is likely to result in higher rates of myopic macular degeneration (MMD). At present we do not know if treating myopic progression will avoid the development of MMD. However, it seems logical to slow AL elongation to prevent severe disease and complications associated with pathologic myopia. Consequently, controlling myopia progression has become one of the highest priorities for eye care professionals all over the world.

The search for effective, adverse events free and widely accessible treatment options has increased tremendously and exponentially in the last 10 years. In the last thirty years, several Randomized Clinical Trials (RCTs) with orthokeratology, low-dose atropine eyedrops and multifocal contact lenses were conducted and have shown promising results in myopia control, although there are side-effects and risk of adverse events. More recently, new methods such as red light-based therapy and anti-myopia lenses have emerged as new methods for myopia control. Spectacles are an appealing option with less side-effects compared with pharmacologic treatments and contact lenses. The new generation of spectacle lenses for myopia control have new designs such as Defocus Incorporated Multiple Segments (DIMS), Highly Aspherical Lenslet Target (HALT) technology, Diffusion Optics Technology (DOT), Cylindrical Annular Refractive Element (CARE) spectacle lenses and Shamir Myopia Control (SMC)

lenses.[5–9] All designs have a clear single vision zone located in the lens center and additional peripheral areas with simultaneous defocus (DIMS), volume of myopic defocus (HALT), modulation of retinal contrast (DOT), high-order aberrations (CARE) and peripheral defocus (SMC).

The authors of the recent study published in the American Journal of Ophthalmology report the results of an RCT designed to evaluate whether SMC lenses can arrest myopia progression.[9] Children from Israel aged 6 to 13 years-old with spherical equivalent refraction (SER) of -0.5 to -6.25 diopters (D) were randomized into intervention (n=65) and control groups (n=61). After 1 year of follow-up the authors found that SMC lenses were an effective anti-myopic progression strategy controlling both SER and AL, in particular for children with parental myopia. By comparing the results of SMC lenses with single vision lenses (SVL) the authors found that AL was slowed by 0.11 mm and SER by 0.16 D. In younger children (6-10 years-old) progression was slowed by 0.17 mm and 0.31 D and in children with 2 myopic parents' progression was slowed by 0.15 mm and 0.36 D. The study offers some noteworthy results, and the analysis of younger children and parental myopia is helpful for clinical practice. One of the limitations of the study is related with significant differences at baseline in parental myopia. The SVL group had significantly higher percentage of parents with myopia, which may influence progression in this group and biased the results towards more efficacy in the intervention group. Additionally, there was a drop-out rate of about 30% in the control group, with 5% having rapid myopia progression. The drop-out rate was less in the intervention group (14%) and 8 % of dropouts were related with visual symptoms (6%) and rapid myopia progression (2%).

Table 1 summarizes the results of 1-year RTCs using new generation eye-glasses technologies for myopia control. SMC are represented in the table to help us to understand how the results of this study compare with other published studies. The control groups of HAL and CARE studies showed higher SER progression, followed by the SMC, DIMS and DOT studies. However, the intervention groups from DOT, DIMS and HAL studies progressed less than the SMC and CARE studies. AL progression results followed a similar pattern.

Based on previous studies[10,11], it seems that emmetropic children growth about 0.1 mm per year, while myopic children between 6 to 10 years old may exhibit axial elongation of 0.3 mm per year, if left untreated. Thus, slowing axial elongation to levels below 0.3 mm and closer to normal growth in non-myopes seem to represent an effective result of current therapies to control myopia progression. Figure 1 shows the mean AL progression over 1 year (mm) of RCTs using new generation of spectacle lenses for myopia control. All the control groups progressed at least 0.30 mm or more, although the study populations differ ethnically. Regarding the interventions groups all studies achieved a reduction in AL growth relative to the control groups. However, the levels of effectiveness where different. The intervention groups of SMC and CARE lenses showed AL growth between 0.21 mm and 0.26 mm. While the intervention groups of DIMS, HAL and DOT achieved levels of AL growth below 0.20 mm.

Most importantly, none of the RTCs on anti-myopia spectacles reported treatment-related adverse events or significant symptoms. Further studies are necessary to compare the data from SMC over two years and longer follow-ups to ascertain long-term efficacy. However, it is important to highlight that treatment results seem to be most effective in the first year of therapy due to children growth with age and natural

decline in progression.[12] The latest study on DIMS shows the long-term efficacy results for 6 years.[13] Children from the intervention group (DIMS lenses over 6 years) had −0.15 D/year of myopia progression and 0.10 mm/year of axial elongation. As expected, the authors found that older children at enrolment showed less myopia progression with DIMS lenses compared to younger children, as myopia progression slows with age. Additionally, the authors found no rebound effect after 2.5 years of ceasing the therapy.

Will the new anti-myopia spectacles be the standard of care in future? The new generation of spectacles might represent a promising intervention for myopia control in childhood to reduce the risk of development of pathological myopia. However, it is known that most of the treatment effect for all therapies currently available appears to occur in the first year. Although it seems that optical treatments are less affected by rebound effect, more studies are crucial to determine if different types of optical treatments and ethnical diverse populations will lead to similar and consistent results. Thus, further studies on treatment effects over two years and longer periods will be necessary to ascertain long-term treatment efficacy of SMC and other anti-myopia spectacles.

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Figures

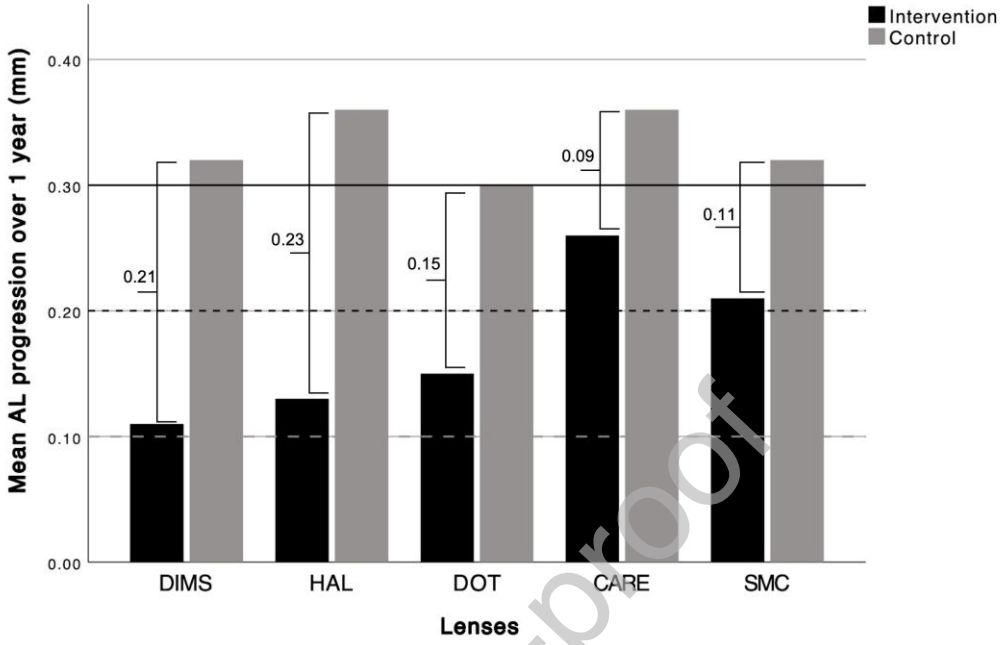

Figure 1. Mean axial length progression over 1 year (mm) of Randomized Clinical Trials using new generation of spectacle lenses for myopia control. Defocus Incorporated Multiple Segments (DIMS); Highly Aspherical Lenslet Target (HALT) technology; Diffusion Optics Technology (DOT); Cylindrical Annular Refractive Element (CARE) spectacle lenses; Shamir Myopia Control (SMC) lenses; Single Vision (SV) lenses; Spherical Equivalent Refraction (SER); Axial Length (AL); Horizontal lines represent 3 levels of AL growth (0.30 mm black line, 0.20 mm black dotted line and 0.10 mm grey dotted line). Left braces represent the difference between intervention and control groups.

Table 1. One-year results of Randomized Clinical Trials using new generation of spectacle lenses for myopia control.

Lenses	Country	Age (years)	Sample size	SER progression ± SD or 95% CI (D)			AL progression ± SD or 95% CI (mm)		
				Intervention	Control	Difference	Intervention	Control	Difference
DIMS[5]	China	8-13	DIMS=79 SV=81	-0.17±0.05	-0.55±0.04	0.38	0.11±0.02	0.32±0.02	0.21
HAL[6]	China	8-13	HAL=54 SV=52	-0.27±0.06	-0.81±0.06	0.53	0.13±0.02	0.36±0.02	0.23
DOT[7]	14 sites in North America	6-10	DOT=83 SV=93	-0.14±0.05	-0.54±0.05	0.40	0.15±0.02	0.30±0.02	0.15
CARE[8]	China	8-12	CARE=61 SV=57	-0.56±0.46	-0.71±0.39	0.14	0.26±0.18	0.36±0.16	0.09
SMC[9]	Israel	6-13	SMC=65 SV=61	-0.48 (-0.35; -0.62)	-0.64 (-0.47; -0.82)	0.16	0.21 (0.17; 0.25)	0.32 (0.27; 0.38)	0.11

Defocus Incorporated Multiple Segments (DIMS); Highly Aspherical Lenslet Target (HALT) technology; Diffusion Optics Technology (DOT); Cylindrical Annular Refractive Element (CARE) spectacle lenses; Shamir Myopia Control (SMC) lenses; Single Vision (SV) lenses; Spherical Equivalent Refraction (SER); Axial Length (AL); Standard Deviation (SD); Confidence Intervals (CI).

Table of Contents Statement

Reports of myopia increases across the world show an expanding growing public health problem. Spectacles are an appealing option with less side-effects compared with pharmacologic treatments and contact lenses, but further studies on treatment effects over two years and longer periods will be necessary to ascertain their long-term treatment efficacy.

Biographic sketch

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