

# Evaluating the Effect of a Myopia Control Spectacle Lens Among Children in Israel: 12-Month Results



COHEN YUVAL\*, CHASSID OTZEM\*, BENHAIM-SITBON LAURA, RATZON SHIREL, GOTTHILF-NEZRI DANA, WEISS ATALIA, BARAN NOAM, ERDINEST NIR, AND MORAD YAIR

- **PURPOSE:** To investigate the effectiveness of a novel spectacle lens designed to slow the progression of myopia in children.
- **DESIGN:** A prospective, randomized, double blind clinical trial.
- **METHODS:** One hundred twenty-six Israeli children aged 6-13 years with spherical equivalent (SER) refractive errors of  $-0.5$  to  $-6.25$  diopters (D) were randomized into either the Shamir Myopia Control (SMC) lens design group or the conventional single-vision spectacle lenses (SVL), the control group. Outcomes measured were changes in axial length and cycloplegic refraction as well as subjective rating of visual experience over a period of 12 months.
- **RESULTS:** At 12 months, AL and SER progression were slowed by  $0.11$  mm (35%,  $P < .05$ ) and  $0.16$  D (25%,  $P = .122$ ), respectively. In the subgroup of 6-10-year-olds, AL and SER progression were slowed by  $0.17$  mm (41%,  $P < .05$ ) and  $0.31$  D (43%,  $P < .05$ ), respectively. Similarly, for the subgroup of children with 2 myopic parents AL and SER progression were slowed by  $0.15$  mm (45%  $P < .05$ ) and  $0.36$  D (42%,  $P < .05$ ), respectively. Subjective visual experience reported in the 12-month questionnaire revealed no difference between the SMC and SVL groups, and average daily wearing hours were also not different between the groups:  $14 (\pm 1.4)$  and  $13.8 (\pm 2.3)$  hours, respectively. The study continues to its second year.
- **CONCLUSIONS:** SMC lenses were effective in slowing the progression of SER and AL, especially for younger children and those having 2 myopic parents. The subjective rating of visual experience and the daily duration of use reported by the SMC group at 12 months

were similar to the control group, indicating good lens tolerability. (Am J Ophthalmol 2024;257: 103–112. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>))

**D**URING THE LAST FEW DECADES, THERE HAS BEEN A significant global increase in the prevalence of myopia.<sup>1</sup> This has been accompanied by a decrease in the age of onset, resulting in longer periods of myopia progression and consequently higher rates of high myopia. Because high myopia is associated with sight-threatening ocular complications, and the quality of life of myopic people is adversely affected by financial, cosmetic, and psychological factors, it is crucial to slow myopia progression.<sup>2</sup>

One method to achieve that goal is by inducing myopic defocus in the peripheral retina using multifocal lenses.<sup>3</sup> This approach has shown success in animal studies<sup>4,5</sup> and has been implemented in humans through techniques such as orthokeratology,<sup>6</sup> multifocal soft contact lenses,<sup>7</sup> or specially designed spectacle lenses.<sup>8,9</sup>

Spectacle lenses are an ideal solution for myopia control as they are easier to use for children. Commercial designs using peripheral myopic defocus (MD) have been found to be effective in reducing the rate of myopia progression and axial elongation compared with single-vision spectacle lenses (SVLs). In the MD lenses, the MD is implemented using tiny optical elements, shaped concentrically on the front lens surface. Concerns have been raised in the literature about the possible effect of these patterns on the visual comfort of the wearer.<sup>10,11</sup>

Shamir Myopia Control (SMC) is a newly designed MD lens that implements the defocus in a unique back surface design, manufactured using Shamir Free Form technology. The lens has a smooth and clear design without any visible patterns on the lens surface. The defocus, rather than a concentric design, is in a U-shape creating a clear central vertical canal and a continuous defocus toward the periphery (Fig. 1), so as to achieve minimal disturbance to the visual experience in the vertical plane. The goal of our study is to evaluate these newly designed spectacle lenses produced by Shamir and compare their effect with SVL in slowing down the progression of myopia and axial elonga-

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From the Department of Ophthalmology, Ziv Medical Center (C.Y., C.O.), Safed; Azrieli Faculty of Medicine, Bar-Ilan University (C.Y., C.O.), Safed; Department of Ophthalmology, Shamir Medical Center (M.Y.), Be'er-Ya'akov; Sackler Faculty of Medicine, Tel-Aviv University (M.Y.), Tel-Aviv; School of Optometry and Vision Sciences, Faculty of Life Sciences, Bar-Ilan University (B.-S.L.), Ramat-Gan; Myopia Center (R.S.), Petach Tikva; Shamir Optical Industry, Research and Clinical Department (G.-N.D., W.A., B.N.); Department of Ophthalmology, Hadassah-Hebrew University Medical Center (E.N.), Jerusalem, Israel.

Inquiries to Yair Morad, Department of Ophthalmology, Shamir Medical Center, Beer Yaakov, Israel; e-mail: [yair.morad@gmail.com](mailto:yair.morad@gmail.com)

\* Cohen Yuval and Chassid Otzem have contributed equally.

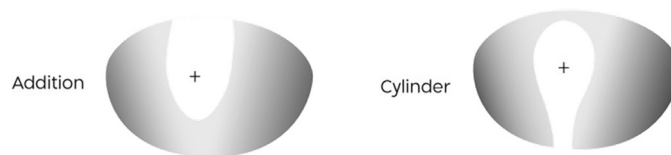


FIGURE 1. SMC lens design scheme. Central vertical canal: addition and cylinder maps.

tion, as well as in visual comfort and compliance in children. The following are the results of the first year of a 2-year study.

## METHODS

- **STUDY DESIGN:** A controlled randomized, double-masked trial was conducted to evaluate the effectiveness of the myopia control spectacle (SMC) lens. The SMC group wore the myopia control spectacle lens, whereas the control group wore a standard single-vision lens (SVL).

- **OUTCOME MEASUREMENTS:** The following outcome measurements were taken:

1. Mean change from baseline in axial length (AL).
2. Mean change from baseline in objective cycloplegic spherical equivalent refraction (SER).
3. Subjective visual experience related to children's adaptation to SMC lenses and comfort of lens usage.

- **SMC SPECTACLE LENS DESIGN:** The SMC lens design consisted of a central vertical aperture called the Central Vertical Canal corrected for distance refractive error. The periphery of the lens incorporated a power profile with relatively more positive power compared to the central aperture, creating peripheral defocus. The vertical canal is symmetrically located around the center point in the horizontal meridian, with a width of 10 mm. In the vertical meridian, the canal extended up to the lens periphery, while inferiorly, it measured 10 mm. The relative positive power gradually increased from approximately 0.5 diopters (D) at the edge of the canal to 3.00 D at 17.5 mm from the center horizontally and 1.50 D at 16 mm from the center in the inferior meridian. Depending on the frame size, the relative positive power at the inferior rim ranged from 1.00 to 1.50D. The lens design aimed to provide good-quality vision for far, intermediate, and near distances, while ensuring comfortable and healthy posture for the wearer.

- **ENROLLMENT AND SAMPLE SIZE CALCULATION:** A total of 126 participants were enrolled, accounting for an estimated dropout rate of approximately 5%. Random allocation assigned half of the participants to the SMC group and the other half to the control group. The sample size

calculation was based on an estimated annual myopia progression rate of 0.6 D in children in Israel. The SMC group was expected to have a 30% lower progression rate compared to the control group (0.18-D difference). With a standard deviation of 0.35 D, the sample size for each group was determined to be 60 children. Accounting for an expected dropout rate of 5%, the overall sample size was calculated as 126 children. The trial included 2 age groups: younger children aged 6-10 and older children aged 10-13, with each group consisting of 63 children. Randomization was applied separately to each age group to ensure an equal distribution of SMC and control lens wearers.

- **RECRUITMENT:** The study participants were recruited from the databases of multiple optical shops. We initiated contact with the parents via telephone and extended an invitation for their children to participate in the study, providing them with the opportunity to receive the spectacles at no cost.

### *Inclusion criteria*

Participants were included in the trial if they met the following criteria:

- the parent or legal representative comprehended and signed the informed consent form.
- were aged between 6 and 13 years,
- had cycloplegic objective spherical equivalent refractive error ranging from  $-0.50$  D to  $-6.00$  D in at least 1 eye,
- had astigmatism not exceeding  $-1.50$  D,
- had corrected visual acuity of 20/25 or better, and
- expressed willingness to wear the trial spectacles according to the protocol plan.

### *Exclusion criteria*

Participants were excluded from the trial if they had

- any general health or ocular health pathology that could affect the treatment,
- strabismus,
- amblyopia,
- allergy or intolerance to cycloplegic eye drops,
- history of ocular injury or ocular surgery, or
- previous treatment with any myopia control treatments (ie, orthokeratology, myopia control spectacle/contact lenses, multifocal lenses, bifocal lenses, and atropine).

• **TRIAL:** The trial included a screening visit and follow-up visits every 6 months. Both test and control group children were asked to wear the spectacles throughout the day, every day.

#### Screening visit (visit 1)

Screening visits included the following steps.

- Signing of informed consent
- Baseline documentation of medical history, parents' and siblings' myopia, indoor and outdoor activities profile, and socioeconomic profile
- Lensmeter measurements of patients' spectacles
- Performing baseline measurements including best-corrected visual acuity, objective and subjective refraction under cycloplegia (objective refraction made using Nidek AR-330A autorefractometer), peripheral refraction under cycloplegia, slitlamp examination, functional tests: cover test, Titmus test, Worth Four Dot test, AL and pupil size measurements (using TOMMY optical biometer OA-2000 [partial coherence interferometry])
- Frame selection and frame measurements

#### Delivery visit (visit 2)

Delivery visits were performed approximately 10 days after the screening visit and included the following procedures.

- Delivery of trial spectacles
- Completion of a subjective questionnaire while wearing the trial spectacles
- Best-corrected far and near visual acuity (with the trial spectacles)
- Confrontation visual field test with the trial spectacles
- Instructions on how to wear the trial spectacles
- Documentation of any relevant adverse events

#### Follow-up visits

The follow-up visits were performed 6 months ( $\pm 1$  week) after the previous visit (visits 3 and 4) and included the following.

- Documentation of any changes in medical history since the last visit
- Completion of a subjective questionnaire regarding the wearing period with the trial spectacles and feedback (Figure 2)
- Performance of follow-up measurements, including best-corrected far and near visual acuity, objective and subjective refraction under cycloplegia, peripheral refraction under cycloplegia, slitlamp examination, functional tests (cover test, Titmus test, Worth Four Dot test), AL, and pupil size measurements
- If the subjective refraction showed a spherical equivalent (SE) change from the last refraction of at least  $-0.50$  D, a new lens order was placed for new lenses, and a delivery visit was scheduled to deliver the new test spectacles; the procedures mentioned above in the delivery visit (visit 2) were then performed

- Documentation of any relevant adverse events

This trial was conducted according to the applicable Good Clinical Practice and local regulations. All essential documents were reviewed and approved by the "Ziv" ethics committee prior to the beginning of the trial. Any amendments of these documents were reviewed and approved by the ethics committee prior to implantation in the trial. The trial was registered at the NIH (ClinicalTrials.gov Identifier: NCT05477329).

• **TERMINATING PARTICIPATION IN THE TRIAL:** These were the cases in which an early termination of participation in the trial might have occurred:

1. Myopia progression of the patient greater than 1.00 D after 1 year or other significant refractive changes (such as more than 0.5[D] cylinder)—the investigator recommended the patient to discontinue the participation in the trial and to consider using other myopia control treatments such as low-dose atropine drops. This was defined because of ethical considerations.
2. If the far/near visual acuity with the trial spectacles was less than the best-corrected visual acuity of the patient, the investigator recommended the patient to discontinue the participation in the trial.

The effect of the lens in terms of progression in those outcome measures was analyzed using *t* test (data normality exist) and also by using linear mixed models that adjusted for age, gender, baseline objective refraction (spherical equivalent) / baseline axial length, parental myopia, daily time wearing spectacles (hours), and treatment period (days).

The expected effect in the SMC group is a decrease in 1 or more of those parameters' mean change from the baseline (decrease in progression from baseline) compared with the control group.

A *P* value  $<.05$  was defined as statistically significant. This analysis was performed for all the sample as a whole and also for subgroups defined by age (younger and older children as mentioned above) and by parental myopia.

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## RESULTS

One hundred twenty-six children with a mean age of  $9.92 \pm 1.7$  years, ranging from 5.7 to 12.8 years, were recruited and randomized into SMC ( $n = 65$ ) and control ( $n = 61$ ) groups. The demographic and ocular characteristics of each group at baseline are shown in Table 1. Parental myopia rate was significantly greater in the control group. Age of myopia diagnosis was  $7.18 \pm 1.72$  years for the SMC group and  $6.87 \pm 2.06$  years for the control group ( $P = 0.37$ ). As seen in Table 2, there was no difference between groups in time spent indoors or outdoors, or in daily activities.

## Compliance Questionnaire

1. How long did it take you to adjust to the glasses?  
*To be implemented only on CRF\_visit 3*
  - Immediately
  - within 3-4 days
  - More than 4 days
  
2. How many days a week do you wear the glasses?
  - 1 day
  - 2 days
  - 3 days
  - 4 days
  - 5 days
  - 6 days
  - 7 days
  
3. How many hours a day (in average) do you wear the glasses during weekdays?  
 \_\_\_\_\_
  
4. How many hours a day (in average) do you wear the glasses during weekends?  
 \_\_\_\_\_
  
5. Please rate your satisfaction with each of the following issues relating to your experience with the glasses:

	1-very low	2	3	4	5	6	7	8	9	10- very high
General comfort with the glasses										
General comfort with the glasses compared to your previous glasses										
Appearance of the lenses										
Appearance of the lenses compared to the lenses in your previous glasses										
Comfort with the glasses while walking/exercising										

**FIGURE 2.** Compliance questionnaire.

Seventy percent of the control group and 86% of the SMC group completed the 1-year study. Despite this higher than expected dropout rate, a power of 0.88 was achieved, meaning that this sample size is enough to detect the difference between the groups. As seen in [Figure 3](#), the reasons for terminating the participation in the control group were mainly due to failure to wear the spectacles regularly (8%), lack of interest from parents in continuing (8%), and loss to follow-up (5%). Another 5% were excluded or withdrew because of rapid myopia progression. Reasons for terminating the participation in the SMC group were different: 6% withdrew because of visual symptoms that made wearing the spectacles uncomfortable, only 2% were excluded or withdrew because of rapid progression, and 5% were lost to follow-up.

When comparing the baseline characteristics between the children who completed the 12 months' treatment

and those who dropped out, no statistically significant difference was detected in terms of axial length, age, gender, and parental myopia. Children who dropped out of the study exhibited a statistically significant lower baseline refraction compared to those who completed the 12-month period (0.88 D,  $P = .014$ ). Nevertheless, this disparity is unlikely to yield any clinical implications for the trial. Our analysis, using a linear mixed model and accounting for various covariates, including baseline Rx, revealed that the interaction between baseline Rx and the treatment group was not statistically significant ( $P > .05$ ).

At 6 months, the adjusted mean progression in AL and SER were 0.25 mm and 0.57 D in the control group and 0.16 mm and 0.35 D in the SMC group respectively. A statistically significant ( $P < .05$ ) effect was found in AL-adjusted mean progression and SER-adjusted mean progression. In

**TABLE 1. Demographic and Ocular Characteristics of Each Group at Baseline.**

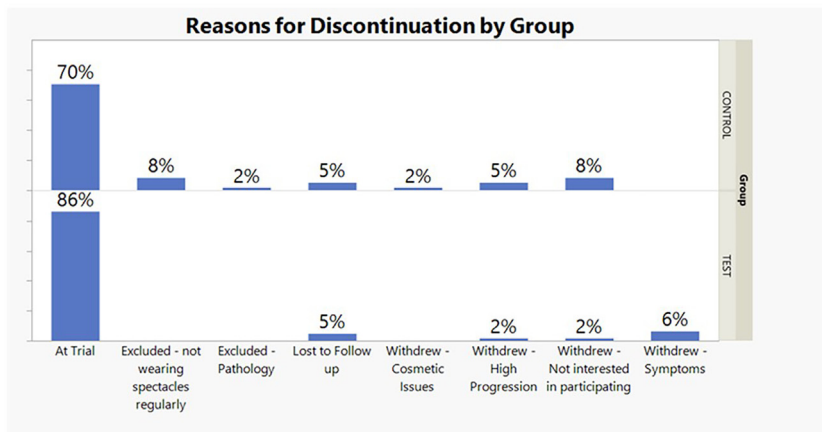
	SMC Group (n = 65)	SVL Group (n = 61)	P Value
Age, y, mean±SD	9.87±1.71	9.97±1.72	.74
Gender: male/female, %	41.5/58.5	54.1/45.9	0.16
Age at myopia diagnosis, mean±SD	7.18±1.72	6.87±2.06	0.37
Parental myopia, %			
None	20	1.64	.0046
One parent	38.46	42.62	
Two parents	38.46	50.82	
Unknown	3.08	4.92	
Baseline objective Rx SE, D			
No. of eyes	130	122	
Mean±SD	-2.53±1.20	-2.74±1.37	.34
Baseline axial length, mm			
No. of eyes	130	120	
Mean±SD	24.27±0.90	24.39±0.78	.42

SE = spherical equivalent, SMC = Shamir Myopia Control, SVL = single-vision spectacle lens.

**TABLE 2. Daily Indoor and Outdoor Activities.**

	SMC Group, Mean±SD (n = 64)	SVL Group, Mean±SD (n = 60)	P Value
Daily hours at school	6.11±1.08	5.91±0.95	.27
Daily hours of watching TV	1.44±1.33	1.49±1.42	.83
Daily hours of using a computer	1.07±1.42	1.25±1.83	.54
Daily hours of using tablet/smartphone	3.22±2.36	3.02±2.20	.62
Daily hours of reading books	0.55±0.73	0.65±0.77	.48
Daily hours of reading and writing (homework)	0.69±0.97	0.50±0.63	.19
Daily outdoor time	1.68±1.40	1.39±0.94	.18

SMC = Shamir Myopia Control, SVL = single-vision spectacle lens.

**FIGURE 3. Reason for discontinuation of the study by group.**

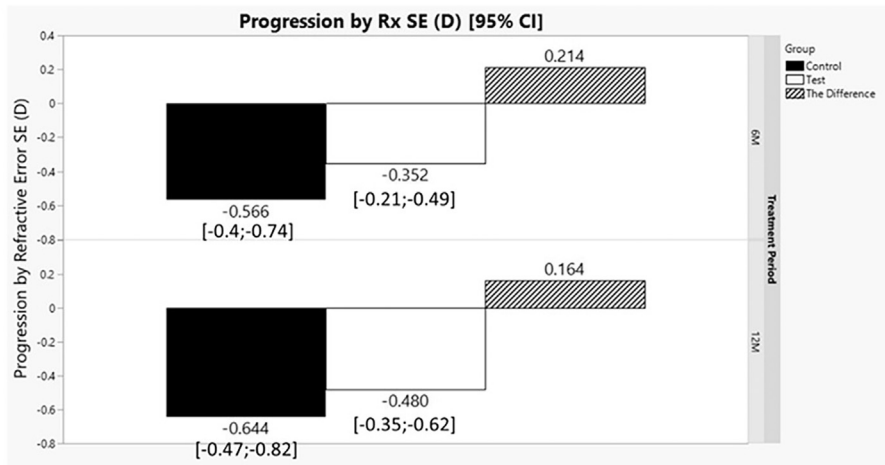


FIGURE 4. Adjusted changes in spherical equivalent over 6 and 12 months in the full sample.

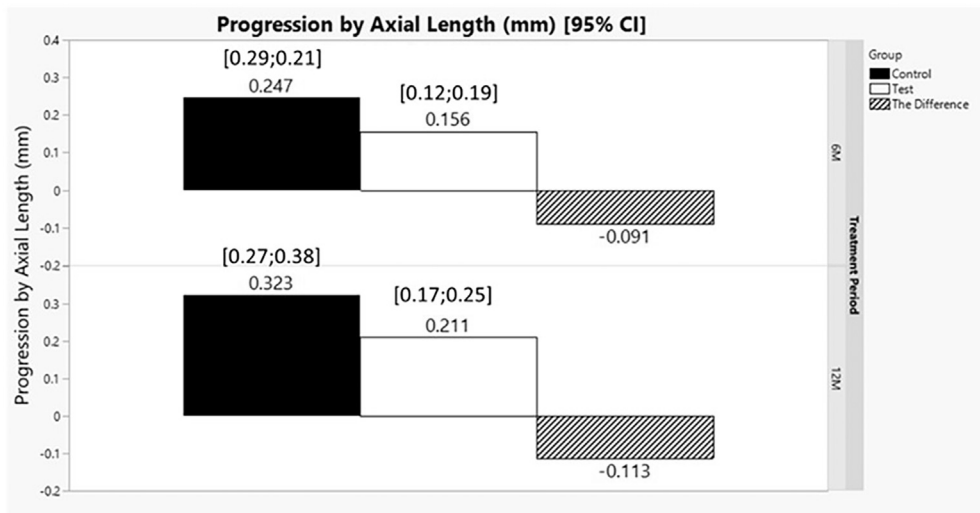


FIGURE 5. Adjusted changes in axial length over 6 and 12 months in the full sample.

the SMC group, AL progression was slowed by 0.09 mm (37%) and SER progression was slowed by 0.21 D (38%) compared to the control group. At 12 months, the adjusted mean progression in AL and SER were 0.32 mm and 0.64 D in the control group and 0.21 mm and 0.48 D in the SMC group, respectively. A statistically significant ( $P < .05$ ) effect was found in AL-adjusted mean progression but not in SER-adjusted mean progression. In the SMC group, AL progression was slowed by 0.11 mm (35%) and SER progression was slowed by 0.16 D (25%) compared to the control group (Figures 4 and 5).

Analyzing the data by age groups showed a different effect of SMC lens: for children aged 6-10 years, a statistically significant ( $P < .05$ ) effect was found in AL-adjusted mean progression and SER-adjusted mean progression. AL progression was slowed by 0.14 mm (45%) and SER was slowed

by 0.28 D (50%) at 6 months and by 0.17 mm (43%) and 0.31 D (41%) at 12 months (Figures 6 and 7). In the older age group (10-13 years), AL-adjusted mean progression was slowed by 0.05 mm (28%) and SER-adjusted mean progression was slowed by 0.14 D (24%) at 6 months and by 0.06 mm (24%) and 0.04 D (7%) by 12 months. This difference between the progression of the SMC and control group was not statistically significant.

Another interesting difference was found between children with two myopic parents and the rest of the SMC group. A statistically significant ( $P < .05$ ) effect was found in children with two myopic parents in both SER and AL at 12 months progression. AL progression was slowed by 0.15mm (42%) and SER progression was slowed by 0.36D (45%). No statistically significant effect was found in children with one myopic parent or no myopic parents.

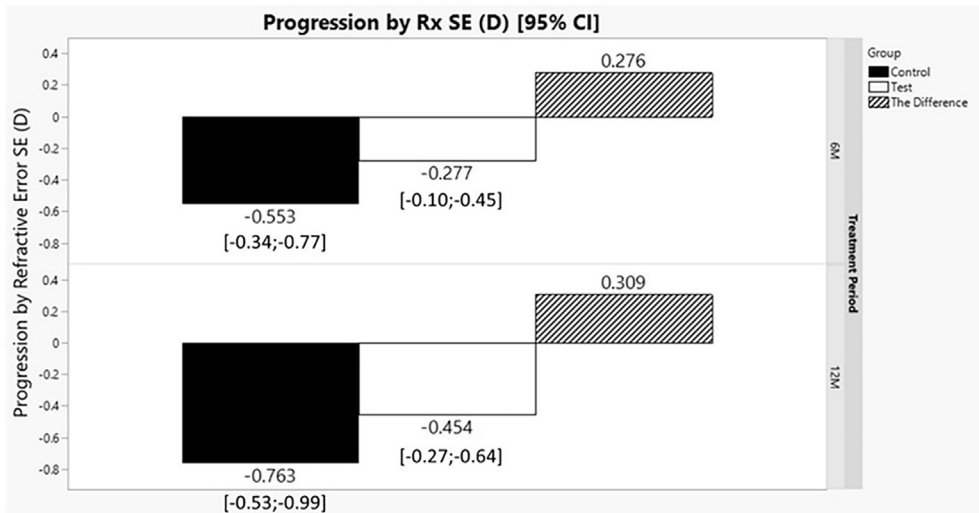


FIGURE 6. Adjusted changes in spherical equivalent over 6 and 12 months in the 6-10-year-old subgroup.

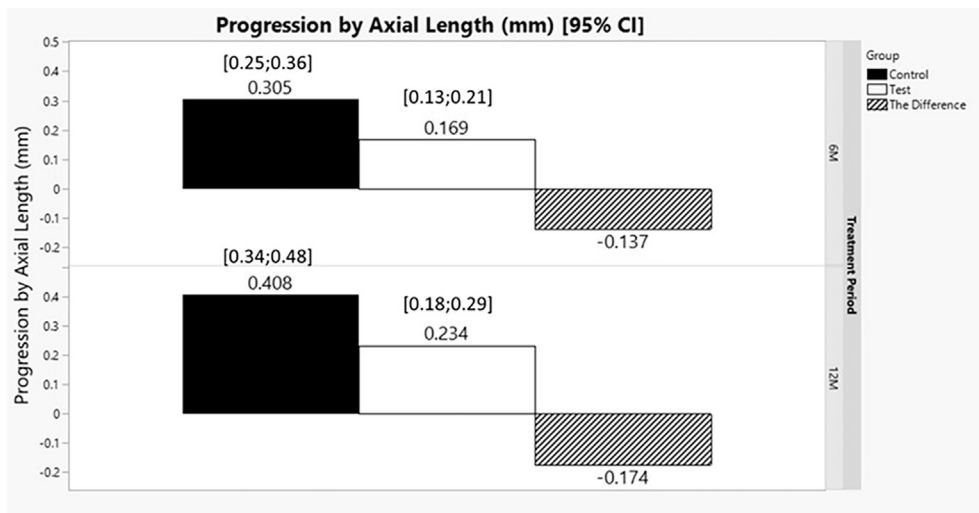


FIGURE 7. Adjusted changes in axial length over 6 and 12 months in the 6-10-year-old subgroup.

As for subjective rating of visual experience, there were no statistically significant differences between the SMC and control groups in various aspects of visual comfort and lens appearance (Table 3) or in the total time the spectacles were used every day ( $14 \pm 1.4$  hours and  $13.8 \pm 2.3$  hours in the SMC and control groups, respectively).

## DISCUSSION

These 12-month results of a randomized clinical trial present an interim analysis of the SMC lens effect on myopia progression. When analyzing the entire cohort of children from both age groups within the SMC group, a positive myopia control effect was found in both AL and SER pro-

gression. In AL progression, which was slowed by 0.11 mm (35%), the effect was statistically significant.

It is known that the AL measurement is of high importance in myopia control trials for 2 reasons: axial elongation is the leading cause of myopic complications and it is a more objective measure, not influenced by the level of cycloplegia. Refraction changes on the other hand, could be due to the lens's own internal dynamics, as described by Iribarren,<sup>12</sup> and therefore not always relevant to future complications of myopia.

In children aged 6-10 years, the effect of SMC lenses was statistically significant both in SER and AL: SMC lenses slowed AL progression by 43% and slowed SER progression by 41% compared to SVL. Children younger than 10 years of age are reported in other epidemiologic studies to have more rapid myopia progression than older children.

**TABLE 3. Subjective Rating of Visual Experience.**

Subjective Rating of Visual Experience Group	6 mo, Mean±SD		12 mo, Mean±SD	
	SMC	SVL	SMC	SVL
Overall comfort with glasses	8.95 (±1.1)	9.18 (±1.0)	9.07 (±1.6)	9.38 (±1.1)
Comfort with glasses while walking /dynamic activities	8.68 (±1.9)	8.48 (±2.3)	8.95 (±1.8)	9.26 (±1.2)
Subjective visual comfort with glasses				
Far	8.98 (±1.1)	8.78 (±1.3)	9.3 (±1.4)	9.36 (±1.0)
Intermediate	9.31(±1.2)	9.08 (±1.6)	9.46 (±1.5)	9.52 (±0.8)
Near	9.2 (±1.6)	9.1 (±1.9)	9.34 (±2.0)	9.4 (±1.1)
Satisfaction from the look of the lens	9.44 (±1.1)	9.58 (±0.7)		

SMC = Shamir Myopia Control, SVL = single-vision spectacle lens.

**TABLE 4. Progression Rates of Our "High Progressor" Control Groups and Asian Control Groups.**

	HAL Study, Control Group	LAMP Study, Control Group	SMC Study	
			Below 10-Y-Old, Control Group	Two Myopic Parents, Control Group
AL progression, mm	0.36	0.41	0.41	0.38
SER progression, D	0.81	0.81	0.76	0.80

AL = axial length, D = diopter, HAL = Highly Aspherical Lenslet, LAMP = Low-Concentration Atropine for Myopia Progression, SER, spherical equivalent refraction, SMC = Shamir Myopia Control.

Verkicharla and associates, in a study of 6984 myopic individuals (age range: 1-30 years), showed that the maximum change in refractive error was noted in children aged 6-10 years.<sup>13</sup> Moreover, in the LAMP study, younger children required an increased dose of atropine treatment to achieve a similar retardation of myopia progression compared with older children.<sup>14</sup>

In our study, control group children younger than 10 years progressed more rapidly than children older than 10 years (0.41 mm and 0.76 D compared to 0.25 mm and 0.54 D in 12 months, respectively). In the SMC group, wearing SMC lenses caused a statistically significant myopia control effect in the younger children.

Children having 2 myopic parents are also known to have an increased rate of myopia and myopia progression as reported in other studies.<sup>13,15</sup> In our study, children in the control group with 2 myopic parents progressed rapidly compared to children having 1 myopic parent or no myopic parents (0.38 mm and 0.80 D compared to 0.29 mm and 0.34 D, respectively). In the SMC group, wearing SMC lenses caused a statistically significant myopia control effect on children having 2 myopic parents. In addition, 45% and 42% were found to have AL and SER progression, respectively, compared to SVL.

These 2 subgroups ("younger than 10" and/or "have 2 myopic parents") represent the expected "fast progressors" among myopic children, and it is therefore important to

treat these children as early as possible to limit the growth and avoid high myopia.

In recent years, several studies have examined the use of lens spectacles that utilize peripheral myopic defocus created on the periphery of the retina to slow down myopia progression.<sup>8,9,16,17</sup> Most of these studies were conducted in East Asia on children of Chinese origin. The prevalence of myopia among adolescents in East Asia is estimated to be between 80% and 90%.<sup>18</sup> The annual progression rate reported in the control groups in these studies is also high: 0.81 D in the HAL Study<sup>17</sup> and 0.81 D in the LAMP Study.<sup>14</sup> The defocus incorporated multiple segments control values were exceptionally lower in the Hong Kong study, but higher in a later retrospective study in China, 0.85 D.<sup>20</sup> The difference presented in AL shows the same trend: 0.41 mm and 0.36 mm in the HAL and LAMP studies.

Our study was conducted in Israel on children of either Jewish Ashkenazi or Middle Eastern origin. The prevalence of myopia in Israel, as examined at the Israel Defense Forces recruitment center at age 16, is 31%.<sup>19</sup> This large difference from the East Asian population also exists in the progression rate of our control group, which was 0.64 D and 0.32 mm. In contrast, the fast-progressing groups ("younger than 10 years" and "having 2 myopic parents") in the control groups of our study had similar rates of progression as the Asian control groups in the HAL and LAMP studies (Table 4). Interestingly these 2 groups were the ones that



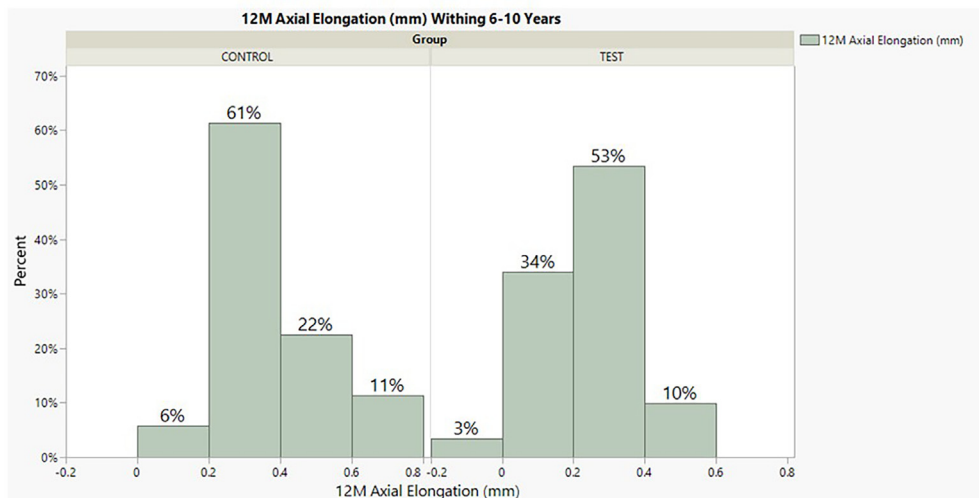


FIGURE 8. Twelve-month axial elongation within a subgroup of 6-10-year-olds.

were most positively affected by SMC lenses in terms of SER and AL progression.

The large-scale Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) study found that children aged 6-14 years who remained emmetropic showed an average of 0.1 mm/y axial growth. Growth rate was faster for age 6-9 years (0.16 mm/y) and later slowed to 0.08 mm/y for age 9-12 years and to 0.02 mm/y for age group 11-14 years.<sup>20</sup> In our study, when comparing the AL progression of SMC and control group within the subgroup of children aged 6-10 years (Figure 8), we found that there was a significantly greater percentage of a slow progression rate of up to 0.2 mm in the SMC group compared with the control group (37% and 6%, respectively). This difference was statistically significant ( $P < .05$ ). This high percentage in the SMC group means that approximately 1 of 3 children wearing SMC lenses experienced a low progression rate of AL, similar to the rate reported in emmetropic children.

The visual experience while wearing the glasses is of crucial importance, because treatment efficacy depends on wearing time. In the HAL Study for example, clear dependency between wearing time and myopia control effect was shown.<sup>9</sup>

In our study, the wearing time was  $14 \pm 1.4$  hours a day (including weekends) in the SMC group vs  $13.8 \pm 2.3$  hours in the control group. SMC group children wore the SMC lens throughout all waking hours in a similar number of hours as the control group. As far as we know, this is the longest wearing time of myopia control spectacle lenses reported in clinical trials as of this writing. This may relate

to the more natural appearance and ergonomic advantages of the lens, as a result of the nonconcentric MD design, aiming flexible vertical eye movement to any distance and eliminating the need for head and neck repositioning. This is especially helpful for today's digital lifestyles, with children spending many hours focused at close distances such as while writing, reading, using smartphones, computers, etc. This was intended to minimize stress on the child's head, neck, and upper body muscles.<sup>21-24</sup>

The withdrawal rate due to visual symptoms in the SMC group was very low, and the overall comfort score reported at 1 year was  $9.07 \pm 1.6$  in the SMC group compared to  $9.38 \pm 1.1$  in the control group. The remarkable similarity in comfort ratings, despite the peripheral defocus area in the SMC lens, indicates a positive visual experience for children wearing SMC spectacles.

In conclusion, this study examined a novel spectacle lens design aimed at reducing the rate of myopia progression in Israeli children while maintaining a good visual experience. Although this report is limited to only the first year of a 2-year study, we have found that the use of the SMC lens caused a statistically significant reduction in AL progression in the entire SMC group. Additionally, there was a statistically significant reduction in AL and SER progression among children younger than 10 years and those with 2 myopic parents. The SMC group adapted to the spectacles easily and reported high satisfaction. Participants had an average wearing time of 14 hours, similar to the control group, and a low dropout rate. These are positive indications that the SMC spectacle lenses provide a good visual experience.

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