MYOPIA CONTROL

Six months results with defocus spectacles for myopia control in Argentina (MyoFix trial)

Rafael Iribarren,[1-2] Abel Szeps, [2] Martín de Tomás,[2] Gabriel Martín. [2]

1 Drs. Iribarren Eye Consultants, Buenos Aires, Argentina.
2 Opulens (Novar), Buenos Aires, Argentina

PURPOSE

Two spectacle designs first published for myopia control have an array of small lenslets with positive add surrounding a central distance area for clear vision. These designs were based on the fact that positive lenses in animal models arrested experimental myopia. Our group designed a digital laboratory prototype for myopia control presented at the IMC 2022, which showed positive results concerning choroidal thickening after the use of such device for 40 minutes while reading.(1) This work reports on a clinical trial with these spectacles.

OBJECTIVES

To present baseline data from a clinical trial with special digitally carved defocus spectacles tested in Argentina (*Myofix, Novar). Additionally, 6 months compliance and effectiveness
are reported.

METHODS

After ethical approval was searched during 2022 via the Ethics Committee of the Argentine Society of Ophthalmology, in June 2023 we began a clinical trial enrolling myopic subjects age 8 to 14 that would use for one year their habitual cycloplegic correction carved with a central 9mm zone for the distance correction and a plus 3.50 D add in the rest of the peripheral spectacle lens. As most children in Argentina opt for myopia control treatments, a virtual control group from an atropine study in USA (Repka) was considered for comparison.(2)

Cycloplegic exams and biometry are being performed at baseline and repeated at 6 months visits. Laser biometry was used in all cases for the axial length measurement. Six month progression are compared by Student t test to six month progression in the virtual control group for subjects who have completed 6 months follow up.

RESULTS

A total of 53 patients were enrolled from June 2023 to March 2024 with the Novar Myofix spectacle lens. Their mean age was 10.72 +/- 2.48 years old and 23 of them were girls. Their mean spherical equivalent was -2.61 +/- 1.12 dioptres in the right eye and -2.37 +/- 1.12 dioptres in the left eye. The mean keratometry was 43.52 +/- 1.32 dioptres in the right eye and there wasn´t any significant difference with the left eye. The average axial length was 24.38 +/- 0.79 mm for the right eye and 24.34 +/- 0.79 mm for the left eye.

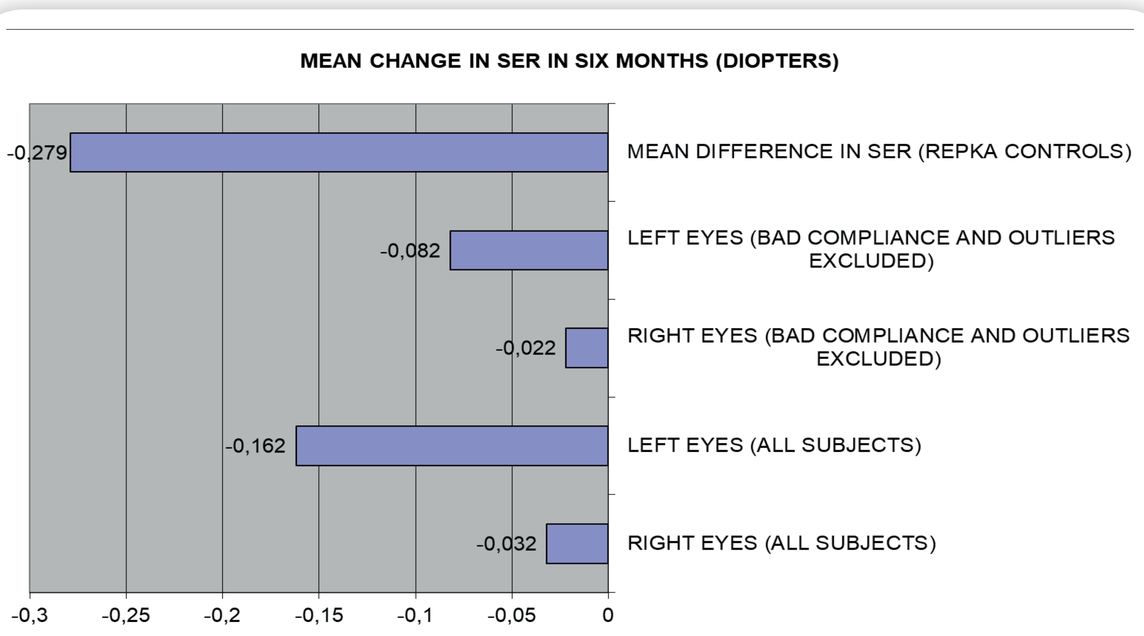
There were 8/48 cases of high myopic mother and 4/48 cases of father with high myopia. In all, 28/48 children went to school only 4 hours a day, and 24/48 children lived in houses with gardens and 10/48 lived in an apartment. The mean age of the first prescription of spectacles was 7.66 +/- 1.5 years old. In all, 10/48 took tutorial extracurricular classes.

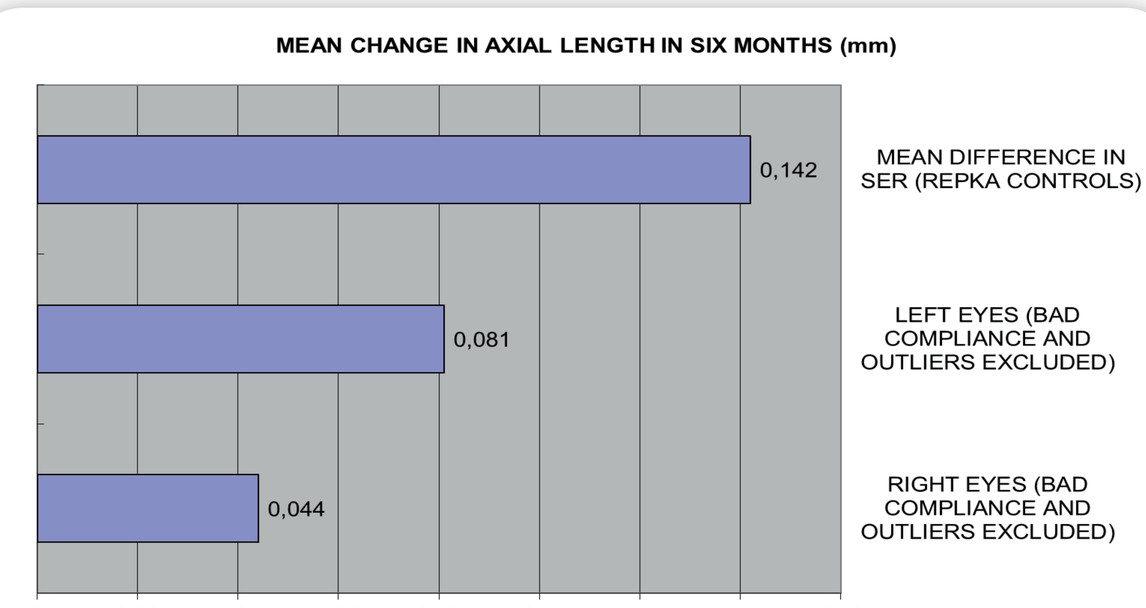
Children spent about an hour and a half doing homework on weekdays or weekends and an hour and a half outdoors on weekdays and three and a half hours outdoors on the weekends. Finally, the children spent two and a half hours with the tablet or mobile phone on weekdays and three and a half hours on weekend days.

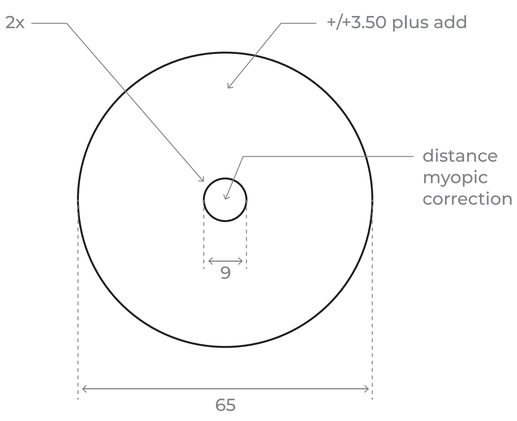
Considering follow up, up to August 2024, 27 out of 53 enrolled subjects had returned to the six months follow up visit. Their mean change in spherical equivalent and mean change in axial length can be seen in the table compared to Repka published data in the virtual control group. Four out of 27 who had returned had bad compliance, not having used the myopia control spectacles because they were low myopes with less than -1.00 D spherical equivalent.

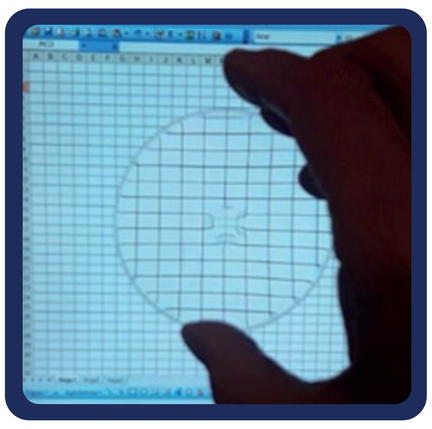
SIX MONTHS PROGRESSION	SER (D)	AL (mm)
MEAN DIFFERENCE RIGHT EYES (ALL SUBJECTS)	-0,032*	0,099
MEAN DIFFERENCE LEFT EYES (ALL SUBJECTS)	-0,162*	0,169
MEAN DIFFERENCE RIGHT EYES (BAD COMPLIANCE AND OUTLIERS EXCLUDED)	-0,022*	0,044*
MEAN DIFFERENCE LEFT EYS (BAD COMPLIANCE AND OUTLIERS EXCLUDED)	-0,082*	0,081°
MEAN DIFFERENCE IN SER REPKA (RIGHT EYES)	-0,279	0,142

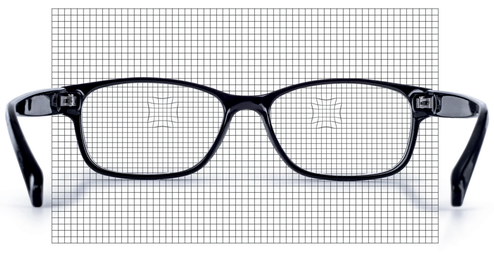
*p<0.01
°p<0.05











These bad compliance subjects who had -0.50 D progression in six months were drawn out of the study and changed to diluted atropine drops treatment to avoid progression, as was suggested by the ethics committee. The mean six years progression of the rest of the subjects is shown in the table. Four in 27 represents 14.8% of bad compliance to Myofix prescription, and was related to spectacle non-dependence due to low prescriptions.

Discussion. The results of this study show good promise for the Myofix spectacle in arresting myopia progression. Myofix design is based on myopic defocus and represents the lens with the greatest defocussed area produced by the industry. This trial shows good adaptation to this type of spectacle use.

1.Iribarren R, Szeps A, Kotlik C, Laurencio L, De Tomas M, Impagliazzo R, Martin G. Short-Term Axial Length Changes in Myopic Eyes Induced by Defocus Spectacles for Myopia Control. Photonics. 2023; 10(6):668. https://-doi.org/10.3390/photonics10060668 2. Repka MX, W eise KK, Chandler DL, Wu R, Melia BM, Manny RE, Kehler LAF, Jordan CO, Raghuram A, Summers AI, Lee KA, Petersen DB, Erzurum SA, Pang Y, Lenhart PD, Ticho BH, Beck RW, Kraker RT, Holmes JM, Cotter SA. Low-Dose 0.01% Atropine Eye Drops vs Placebo for Myopia Control: A Randomized Clinical Trial. JAMA ophthalmology 2023; 141: 756-65.