Communication

Short-Term Axial Length Changes in Myopic Eyes Induced by Defocus Spectacles for Myopia Control

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Abstract: Background. This study tested short-term axial length changes with Lenstar using a simple peripheral plus-add spectacle design. Methods. The subjects for this study were current users of monofocal glasses or contact lenses, aged 18–25 years, with myopic spherical refractions ranging from $-1.00$ to $-5.00$ diopters in both eyes. This study tested subjects while using a pair of special defocus spectacles that possess a central zone with the distance myopic correction and a peripheral zone with +3.50 added diopters. The procedure consisted of reading an online book with black letters on white background on a desktop computer, in two periods—one with the usual spectacles and the second with special defocus spectacles. Before and after these periods, 10 axial length measurements of the right eye were made with Lenstar and averaged up to three decimal points.

Results. Seventeen subjects (thirteen female and four male; mean age 22.3 ± 5.5 years) participated in this study. The mean spherical equivalent of their right eye was $-2.31 ± 1.06$ diopters. There was a significant difference of +8.1 microns which increased the axial length from baseline when reading the usual prescription levels during the first 40 min period. When subjects read in the same situation with the defocus spectacles, the axial length significantly returned to baseline measurements, which were shortened by $-10.6$ microns. Conclusions. The decrease in axial length with these spectacles might indicate an effect on axial elongation signals from the choroid. These spectacles could be tested for myopia control purposes.

Keywords: defocus spectacles; myopia control; axial length

1. Introduction

During the last decade, diluted atropine 0.01% and outdoor exposure became a more popular treatment option for reducing myopia development in schoolchildren [1,2]. While this was happening, researchers in the optical field were testing spectacle and contact lens designs based on multifocality to provide clear foveal distance vision while simultaneously imposing hyperopic defocus at the surrounding perifoveal posterior pole of the eye [3]. Research in the latter area has developed in such manner that today there are many options pertaining to contact lenses and spectacles that are claimed to reduce myopia progression in children [2]. Of note, randomized clinical trials in the last five years have shown that peripheral hyperopic defocus spectacles or contact lenses have 50–70% effectiveness in reducing myopia progression in Chinese schoolchildren [4–6]. This is the case, for example, for the spectacles that derive from “defocus incorporated multiple segments” (DIMs) designed by Lam et al. some years ago, which have been proven to have good compliance and have arrested myopia progression in a long-lasting clinical trial [7,8].
With so many options, the counselling and treatment indication for a myopic school-age child has become very complex, including, for example, an expensive apparatus for keratometric and biometric follow-up in addition to the usual cycloplegic autorefractometry [9]. Moreover, treatment options include a variety of lifestyle changes, such as education and reading habits, or outdoor exposure [10], in addition to medical or optical options such as diluted atropine drops or defocusing spectacles and contact lenses [11]. The multiplicity of options poses burdens for the patient and the patient’s family, eye care practitioners, and the health system as a whole [12]. In this sense, there is interest in developing affordable options that can be used in underdeveloped societies. The prevalence of myopia is lower in such societies, but even a historical population prevalence of high myopia [13] around 1–2% can produce a heavy burden of visual disability after age 40. This has been shown in the city of Buenos Aires, which has a low prevalence of high myopia [14]; however, in the city, myopic maculopathy is the principal cause of visual disability in the working-age population [15].

The main ocular refractive component explaining the development of school myopia is an abnormal axial elongation. Between ages 5 and 15, eyes that remain emmetropic grow for a mean of 100 microns per year, while the loss of lens power compensates optically for this growth to keep the refraction stable [16,17]. However, eyes that develop myopia at the same ages undergo more than double that rate of elongation, at 240 microns per year, with no possible compensation by lens power loss [18]. The mean axial length for adults is 23.74 mm [19], but it exceeds 25.00 mm in most cases of myopia and can reach 30.00 mm in high myopia [20]. As said, these later cases with myopic maculopathy have arisen as the first cause of visual disability in working-age populations [15]. Furthermore, early-onset myopia (beginning at ages 6–12) predisposes adults to high myopia [2,21,22]. To some extent, there is interest in myopia control spectacles, since children of those ages seldom use contact lenses [23], and a multifocal defocus spectacles would not only correct distance vision, but could have a benefit on reducing progression more than the usual monofocal aspheric spectacles.

Simple peripheral plus-add spectacle designs can be carved in any conventional or digital optical laboratory, taking many years of animal and human research on myopia control into account. Before testing the effectiveness of reducing progression in a randomized study over several years, spectacles of this design can be tested for their short-term effect on axial elongation, as it is well known that contrast and defocus experimental paradigms produce a change of about 10–20 microns in choroidal thickness in humans after as little as 30 min of exposure [24]. Choroidal thickness is difficult to measure because the outer limit of the choroid is not well defined by current imaging methods such as OCT, but the choroidal changes produce concurrent changes in axial length that can be captured much more easily and accurately with optical biometry [25,26]. The finding of a short-term decrease in axial length after treatment to arrest myopia progression suggests the good efficacy of such a treatment, which then could be the starting point for a pilot study before a clinical trial is performed.

In this sense, the purpose of the present study was to test whether short-term axial length changes might be induced by such a special digitally designed spectacles with peripheral plus-add power [27]. Our hypothesis was that this spectacle design would decrease axial length, based on the fact that increased choroidal thickness and decreased axial length have been reported previously with the use of peripheral plus-add spectacles [28]. We also tested eye and head movements, tolerance of lens wear, and visual fields under the use of spectacles with this novel design [27].

2. Materials and Methods

Subjects for this study were current users of monofocal glasses or contact lenses, aged 18–25 years, with myopic spherical refractions ranging from $-1.00$ to $-5.00$ diopters in both eyes and astigmatism levels less than $-1.00$ diopters. They gave verbal informed consent to participate in the study (that lasted approximately two hours) using a pair of special
Subjects for this study were current users of monofocal glasses or contact lenses, aged 18–25 years, with myopic spherical refractions ranging from −1.00 diopters to −5.00 diopters in both eyes and astigmatism levels less than 1 mm and high astigmatic values similar to those of the transition zones in bifocal spectacle lenses. The optical pupil centering was digitally measured in a photograph of the subject’s face with frames in place, taken with the aid of a specially designed centering device (IPD, Novar, Buenos Aires, Argentina). Fifteen days later, after the spectacle lenses had been manufactured, the experiments were conducted at 9 o’clock in the morning. Subjects were advised to rest and sleep for about 8 h the night before and to have a light breakfast that could consist of tea or coffee with something light to eat in the day of the experiment. The subjects were also advised to wear their habitual monofocal spectacle correction. During the whole procedure, subjects did not drink or eat anything else except for a sip of water, and they were sat down or walked briefly in the room where the experiment was performed.

Next, the subject continued reading the book on the computer for 40 min with the same monofocal glasses. After this, during a short pause, a new axial length measurement of the right eye was made with Lenstar, deleting the outlier ones as the machine pointed at them. These measurements were averaged up to three decimal points.

Figure 1. AutoCAD design of the defocus spectacles to the left, and image formation of a −2.00 D for a distance of +/+3.50 added diopters in the periphery to the right.

The experiment involved reading an online book with black letters on white background on a desktop computer. The text font was Times New Roman, and the letters subtended a visual angle of 1 degree at a 50 cm viewing distance (20/200 near visual acuity) [29]. In the first step of the experiment, the subjects were instructed to read for 20 min with their monofocal lenses in order to adapt to the artificial illumination of the room. Then, without any interval, 10 axial length measurements of the right eye were made with Lenstar, deleting the outlier ones as the machine pointed at them. These measurements were averaged up to three decimal points.

In the second step of the experiment, the subjects were instructed to read for 40 min more;
this time, special defocus spectacles were used for the research study, and a third axial length measurement was taken at the end of that period. After approximately two hours of work, the experimental procedure was finished and the subjects carried home the special spectacles to test their tolerance for 4 weeks, after which they completed a short questionnaire about its use.

Using sample size calculations for a difference of 0.003 mm between pre- and post-test measurements, with a variance of 0.002 mm, a significance (p) value less than 0.05, and statistical power of 95%, it was estimated that 15 participants would be sufficient [25,26]. Statistical analysis was performed with SPSS 25 software. The mean values for baseline and for first and second periods in each subject’s right eyes were recorded, and the differences up to 1 micron between pre- and post-spectacle use were calculated. As the axial length distributions were normal, according to the Kolmogorov–Smirnov test, and had similar variances, paired Student’s t-tests were performed to compare axial length means for baseline, usual spectacles, and defocus spectacles. A p value < 0.05 was considered significant.

3. Results

For the present study, 17 subjects of both genders (13 female and 4 male) were studied with the same protocol; their mean age was 22.3 ± 5.5 years. Their mean spherical equivalent of the right eye was −2.31 ± 1.06 diopters. The mean axial lengths—at baseline (after 20 min adaptation), after usual spectacles (40 min more), and after special defocus spectacles (other 40 min more)—are given in Table 1. There was a significant increase of +8.1 microns in axial length from baseline when reading with the usual prescription. When subjects read in the same situation with defocus spectacles, axial length compared to baseline measurement was decreased by 10.6 microns (Table 2). Figure 2 shows the actual measured values for each subject.

Table 1. Lenstar axial lengths at baseline, monofocal, and defocus lenses.

<table>
<thead>
<tr>
<th></th>
<th>20 min.</th>
<th>60 min.</th>
<th>100 min.</th>
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<tbody>
<tr>
<td>Mean axial length (mm)</td>
<td>24.317</td>
<td>24.325</td>
<td>24.314</td>
</tr>
<tr>
<td>Standard deviation (SD) (mm)</td>
<td>0.637</td>
<td>0.641</td>
<td>0.641</td>
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Table 2. The effect of monofocal and custom defocus spectacles on axial length.

<table>
<thead>
<tr>
<th></th>
<th>Monofocal</th>
<th>Defocus</th>
</tr>
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<tbody>
<tr>
<td>Mean change in axial length (microns) (±SD)</td>
<td>+8.1 ± 10.4</td>
<td>−10.6 ± 8.9</td>
</tr>
<tr>
<td>Paired Student’s t-test</td>
<td>p = 0.0108</td>
<td>p = 0.0028</td>
</tr>
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After 1 month, tolerance for wearing the specially designed spectacles was assessed via a new interview with all the subjects. They reported that these spectacles were uncomfortable for walking around the streets in. The volunteers could use them easily to work or read at the computer at the usual desktop working distance, but had some trouble when reading text in a book or with a cellphone in their hands, as they had to tilt their chin and head downwards. They also reported that they had to move their head from side to side to read comfortably at the computer. In spite of these minor discomforts and inconveniences, however, they were happy with the idea of using some device for myopia control purposes.

Visual fields were tested in one subject with monofocal and defocus spectacles. The visual field was normal for the monofocal spectacles. Testing with defocus spectacles showed normal visual fields in the central 20° diameter (macula). In addition, it also showed a 5% reduction in sensitivity in the central area up to 60° in diameter (Figure 3). This volunteer was also filmed while reading on the computer (only from behind, to maintain anonymity), so as to record his subtle lateral head movements; the movements were similar to the lateral head movements observed in older subjects while reading with multifocal spectacles.
Figure 2. Actual values of axial length change in each individual with usual spectacles (black columns) and defocus spectacles (grey columns). The black bars denote the change from baseline to 40 min with usual spectacles. The gray bars denote the change from 40 min after reading with usual spectacles to 40 min more reading with defocus spectacles. It can be seen that few subjects had shortened eyes with both paradigms, but most of them showed elongation with usual spectacles but returned to baseline with defocus spectacles.

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Figure 3. Visual field of the right eye of one subject fitted with defocus spectacles.
4. Discussion

This paper presents evidence on axial length changes after 40 min of reading with special defocus spectacles with peripheral plus +3.50 added diopters. These changes in axial length have been shown with similar methods in human subjects under hyperopic or myopic defocus [30], under super-diluted atropine drops [24], while also reading with letters in positive or negative contrast [25] or with especial spectacles or contact lenses for myopia control [31]. It is generally believed that these changes in axial length are due to corresponding changes in choroidal thickness [29]. Choroidal thickening, as has thus been shown indirectly in this study with defocus spectacles, is in line with a possible application of these spectacles for myopia control. This novel approach of indirectly estimating choroidal change by measuring axial length change is becoming the gold standard in myopia research, as it is far more accurate (up to ±1 micron) than the direct measurement of choroidal thickness using OCT because the presence of lacunae in the outer part of the choroid makes the estimation of the outer choroidal limit inaccurate.

When we designed the study protocol, we thought of randomly testing the defocus spectacles first or in second place. However, pilot testing showed that the use of defocus at first while reading did not shorten the eye in three patients, while reading with usual spectacles made the eye longer, as was previously described by Schaeffel’s team a few years ago [25]. We then realized that defocus spectacles returned the axial length to normal when the usual spectacles were used in the first place. While testing reading with usual spectacles during the two consecutive periods, we made the eye even longer, as expected [25], and we also tested this in three subjects. So, by bearing these facts in mind, we designed the protocol to show that the tested defocus spectacles neutralized the eye elongation produced by reading with usual spectacles in bigger samples.

The studies carried out by Frank Schaeffel on letter size and contrast polarity [25,26,29] are difficult to test in a clinical trial, as this can be easily attempted by any subject in computers and cellphones with “dark mode” and no pending patent. Indeed, this research on contrast and letter size shows promising results because choroidal changes are the first indication of what will happen in time with ocular growth [32]. Argentinian specialists are now recommending dark mode for myopia control purposes in clinics [23]. The same could also apply to myopia control spectacles.

The fact that this special spectacle design can be used relatively well for reading, but is not effectively tolerated for walking, suggests that a clinical trial of tolerance and effectiveness on myopia control would be of relevance. Given that it would be unacceptable today to leave a control group under the natural history of myopia without any treatment, these special spectacles could be tested in a non-inferiority trial against super-diluted atropine or already-tested spectacle designs from the industry. Myopic defocus signals in the retina have been shown to be more robust in animals than hyperopic defocus signals [32,33], and the presentation or myopic defocus is more effective in the afternoon than in the morning [34]. Thus, the possible trial could test this new design in children on a part-time daily basis, for only 3–4 h at home after school and before going to bed, whereas, during the rest of the day, they would use their usual monofocal prescription for school and outdoor activities.

We also observed that, in the design of these glasses with peripheral defocus and only 9 mm diameter central zone for distance vision, the centering in the frames must be optimized because, in our experience, tolerance and adaptation to these spectacles strongly depend on the correct centering of the central zone. The effectiveness of different designs and clinical regimens for applying spectacles with peripheral defocus treatments is still being studied. The precision of methods and power analysis showed that, even with a small number of subjects, it is possible to obtain robust results in older children and teenagers who cooperate better than small children for measurements and experimental design purposes. In this sense, it is very interesting that choroidal changes preceding axial changes are still very active in these young adults, and not only in younger schoolchildren.
Further research in this area is promising in order to find an easy and affordable treatment option for myopia control.

In conclusion, the results of this study of young myopic subjects showed that axial elongation was decreased by wearing specially designed spectacles with peripheral defocus plus-add refraction surrounding the central zone for clear distance vision. This decrease in axial elongation is probably produced by choroidal thickening, which in turn indicates the potential for these spectacles to control myopia progression. A long-lasting trial showing the tolerance and effectiveness of this kind of new spectacles is included in our agenda.

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References


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