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Effects of 0.01% Atropine Eye Drops on Horizontal Meridian Choroidal Thickness Profile in Low to Moderate Myopic Children

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Abstract: *Purpose:* To examine the changes in choroidal thickness (ChT) after 6-month topical treatment of 0.01% atropine eye drops in myopic children. *Methods:* A total of 46 low to moderate myopic children aged 8 to 12 years were recruited and received topical 0.01% atropine once a day for 6 months. Spherical equivalent (SE), axial length (AL), and ChT were measured at baseline, 3 months, and 6 months. *Results:* During the first and second 3-month treatment, there is no significant decrease in progression of SE and AL. Within the range of 3 mm from the temporal side of the fovea to the nasal side, no significant changes in ChT have been observed at any measuring points in low and moderate myopic participants. Changes in ChT were not significantly associated with gender or AL progression. *Conclusion:* A 6-month topical treatment of 0.01% atropine could not cause significant changes in ChT in myopic children.

Keywords: Atropine, Choroidal thickness, Children, Myopia controlling

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1. Introduction

Myopia has been a growing worldwide threat to children and adolescents with its increasing morbidity, irreversible progression, and lasting visual impairment [1–3]. Of all the medical measures to control myopia, atropine is the only drug that has been widely proven to be effective in decreasing the progression of myopia. The efficacy of topical atropine treatment, as well as its adverse reaction ratio, has shown to be proportional to the medical concentration [4, 5]. Thus, 0.01% atropine drops have been widely used for its satisfactory long-term efficacy with mild side effects [5,6].

However, the mechanism of atropine controlling myopia still remains unknown, which leaves controversy about the safety of long-term therapy.

Atropine, as a non-selective M-cholinoceptor blocker, was previously hypothesized to decrease myopic progression by "relaxing accommodation", since it can antagonistically bind the M-cholinoceptors in ciliaris and reduce accommodation induced by near work [7]. But this hypothesis has been disproved, because atropine treatment remained effective in chicks, which have no M-cholinoceptors in ciliaris [8, 9]. M-cholinoceptor also exists in the retina and choroid [10]. As the biggest vascular structure that takes up 90% of ocular blood flow, the choroid plays an important role in regulating the physiological activities of the eye. Changes in choroidal structure and blood flow have been found in various ocular diseases [11, 12]. According to available researches, choroidal thickness (ChT) was significantly decreased in high myopic patients [13, 14], and it is wondered whether atropine can cause choroidal thickening. There have been several studies that have estimated the changes in ChT after atropine treatment, but those results varied with different atropine concentrations, medication durations, and participants [15–17]. In this study, the most widely used concentration (0.01%) of atropine eye drops was chosen and the changes in ChT in low to moderate myopic children was estimated after 6-month treatment.

2. Methods

2.1. Participants

All participants were recruited from patients who visited the Fourth Affiliated Hospital of Zhejiang University School of Medicine during August 2020 to August 2022. After excluding those with other ocular diseases (such as cataract, glaucoma, amblyopia, or anisometropia) or previous use of atropine, a total of 46 children aged 8 to 12 years with myopic refractions less than -6.0D and astigmatism less than −2.0 D in both eyes were finally enrolled in our study. All participants received a 6-month treatment of 0.01% atropine sulphate eye drops (Myopine, Shenyang Xingqi Eye Hospital Co., LTD., Shenyang, China) once per night, and subsequent visits were required every 3 months. During the follow-up period, no other myopia interventions (such as pirenzepine or orthokeratology lens) that might change ChT were used. Depending on the progression of myopic diopter and axial length (AL) at each visit, it would be assessed by ophthalmologists if it's necessary to stop atropine therapy or add other interventions. The study protocol was approved by the Ethics Committee of the Fourth Affiliated Hospital of Zhejiang University School of Medicine, Jinhua, China (Approval number: K2020010), and registered at the Chinese Clinical Trial Registry. Informed consents were signed by both participants and guardians. All procedures were conducted in accordance with the tenets of the Declaration of Helsinki.

2.2. Study procedures

To decrease the influence of diurnal variation of choroid, all measurements were conducted between 9:00 AM to 3:00 PM, and follow-ups were made within 3 hours of the baseline time [18–20]. Outcome measures were made at 3 time points: before atropine, after 3 months and 6 months. At each visit, AL was measured using Lenstar (LS900, Haag-streit AG, Switzerland). After excluding the contradictions of tropicamide, 4 drops of topical tropicamide were administered in both eyes at 5-minute intervals. Further drops were administered if the pupillary light reflex was still present or the pupil size was less than 6.0 mm. After that, refractive diopter was performed using an autorefractor (ARK-1s, NIDEK, Japan).

Optical Coherence Tomography (RTvue XR OCT, optovue, America) was used to scan the ocular fundus

(retina and choroid) before the administration of tropicamide. A 12 mm single line of high-definition mode swept at a -5° default angle, connecting the macular fovea to the central point of the optic disc. Each eye was scanned for 3 consecutive times at every visit to take the average value. The segmentation of each layer was automatically delineated using Matlab (R2021a), and manual calibration was performed by the same researcher where the software misjudged the borderline of each layer. The ChT values were then automatically measured at 0.01 mm intervals by software, taking the fovea as the 0 point and ranging from 3 mm from the temporal side (marked as "-") of the fovea to the nasal side (marked as "+") (**Figure 1**). For statistical analysis, 13 points at 0.5mm intervals were chosen.

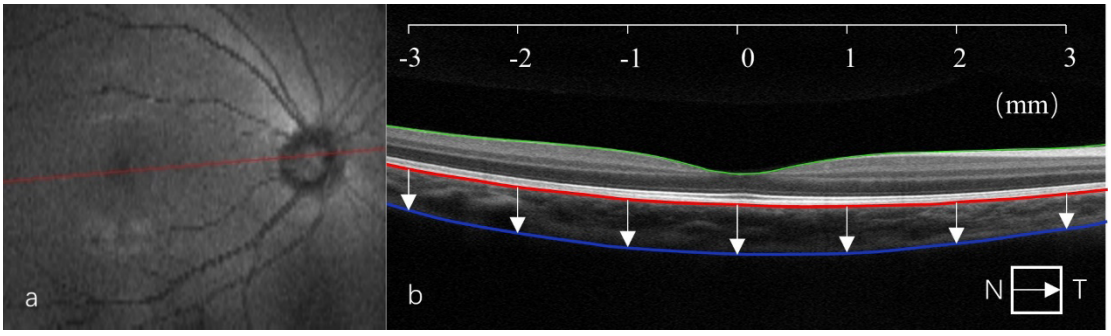

Figure 1. The images of choroid were obtained using OCT; (a) The macular fovea and the central point of optic disc were automatically identified, and the scanning was performed with a single line connecting these two points; (b) The Matlab software automatically lined the segmentation of the inner limiting membrane (green line), the Bruch membrane (red line) and the choroid-sclera interface (blue line). The measuring area is from 3mm from the temporal side (-) of the fovea to the nasal side (+).

2.3. Outcome measures

The primary outcomes were the changes in the average ChT at different points over 6 months. The secondary outcomes were the changes in AL and spherical equivalent (calculated as the spherical power plus one-half of the cylindrical power).

2.4. Statistical analysis

All ocular measurements were described as mean ± standard deviation. Paired t-test was used to test the differences of characteristics before and after atropine treatment. The group differences of ChT in participants of different gender, SE and AL were tested using t-test. Statistical analysis was performed using SPSS software (IBM, Armonk, NY, USA). A P value of less than 0.05 was considered statistically significant.

3. Results

3.1. Baseline characteristics

A total of 46 children aged 8–12 years (9.17 ± 1.21 years) were recruited and finished the 6-month follow-up in our research, including 25 boys and 21 girls. One out of the total 92 eyes was excluded from statistical analysis because of blurred OCT images. The baseline SE of all eyes was -1.83 ± 1.14D, among which there were 69 low myopic eyes (less than -3.0D, average SE -1.37 ± 0.78D) and 22 moderate myopic eyes (-3.0D to -6.0D, average SE -3.59 ± 0.42D). The baseline AL was 24.44 ± 0.88mm (**Table 1**).

Table 1. SE and AL before and after atropine treatment

	SE (D)			AL (mm)		
	baseline	**3 months**	**6 months**	**baseline**	**3 months**	**6 months**
Total	-1.83 ± 1.14	-2.05 ± 1.18	-2.29 ± 1.17	24.41 ± 0.88	24.53 ± 0.87	24.62 ± 0.89
Gender						
Male (*n*=25)	-1.76 ± 1.08	-1.97 ± 1.04	-2.21 ± 1.11	24.71 ± 0.79	24.79 ± 0.77	24.92 ± 0.80
Female (*n*=21)	-1.92 ± 1.20	-2.15 ± 1.31	-2.39 ± 1.23	24.14 ± 0.85	24.25 ± 0.86	24.34 ± 0.86
Baseline refraction						
Low (*n*=69)	-1.37 ± 0.78	-1.57 ± 0.81	-1.81 ± 0.80	24.24 ± 0.81	24.37 ± 0.82	24.44 ± 0.83
Moderate (*n*=22)	-3.58 ± 0.42	-3.85 ± 0.54	-3.97 ± 0.67	25.15 ± 0.65	25.23 ± 0.67	25.31 ± 0.66

Within the measuring area of -3 mm to +3 mm, ChT gradually increased from the nasal to the temporal side, and remained constant from +0.5 mm point to +3.0 mm point (**Figure 2**).

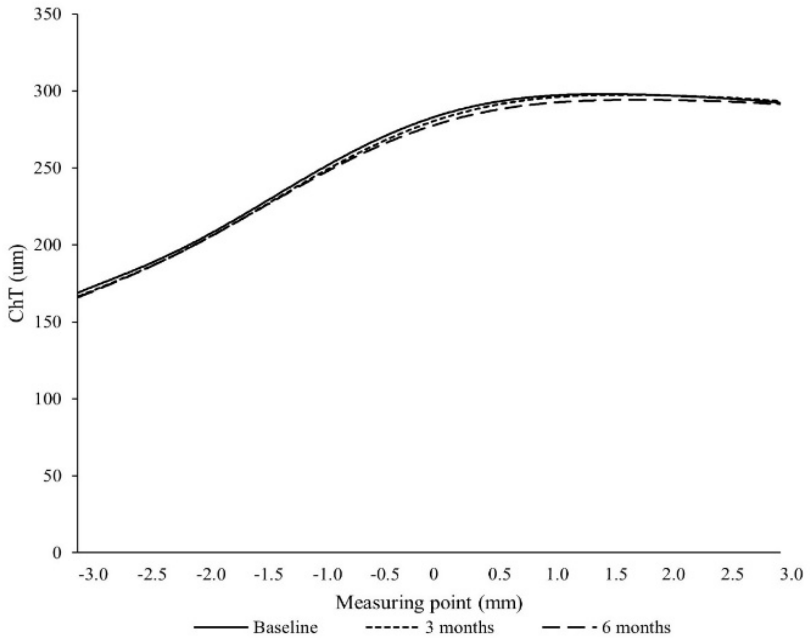

Figure 2. Changes in ChT within -3 mm to +3 mm area during 6-month treatment of 0.01% atropine. At baseline, ChT increased from nasal to temporal side of the fovea and tended to be stable at temporal side. The minimum thickness was 168.93±46.45um at -3mm, and the maximum thickness was 297.96 ± 55.56um at +1.5 mm. The ChTs at the 3-month visit stayed nearly no change from baseline. At the 6-month visit, there was a mild decrease in ChTs within -0.5 mm to +1.5 mm area, but with no statistical significance.

There were no significant differences in ChT between male and female groups, nor between low and moderate myopia groups (**Table 2**).

Table 2. Baseline ChTs at each measuring point

Measuring point (mm)	ChT (um)						
	Total	Gender		*P value	Baseline Refraction		†P value
		Male	Female		Low	Moderate	
-3.0	168.93 ± 46.45	164.01 ± 47.49	174.90 ± 44.47	0.15	170.87 ± 46.16	162.57 ± 46.88	0.48
-2.5	184.40 ± 50.63	179.24 ± 53.59	189.48 ± 46.73	0.23	186.64 ± 50.06	174.70 ± 52.33	0.35
-2.0	202.38 ± 53.85	197.05 ± 58.45	208.76 ± 47.00	0.29	205.12 ± 53.53	193.19 ± 53.90	0.38
-1.5	223.50 ± 56.16	218.18 ± 61.82	229.87 ± 47.84	0.33	226.85 ± 6.242	212.33 ± 54.50	0.30
-1.0	246.21 ± 58.04	240.92 ± 64.27	252.36 ± 48.97	0.35	249.91 ± 58.40	233.39 ± 55.07	0.26
-0.5	266.21 ± 59.26	261.03 ± 65.52	272.24 ± 50.16	0.37	270.13 ± 59.76	252.69 ± 55.53	0.24
0	281.95 ± 59.58	276.80 ± 65.53	287.92 ± 50.97	0.38	285.73 ± 60.18	268.83 ± 55.60	0.26

Note: * Comparison between male and female participants in this study using the Student t-test; † Comparison between low and moderate myopic participants in the study using the Student t-test

3.2. Changes in SE and AL during 6-month atropine treatment

The progression of SE after 6 months was -0.46 ± 0.42D, with -0.22 ± 0.34D and -0.24 ± 0.24D in the first and second 3 months respectively. The progression of AL after 6 months was 0.22 ± 0.13 mm, with 0.12 ± 0.10 mm and 0.10 ± 0.07 mm in the first and second 3 months respectively. The progressions of myopia and eye elongation did not slow down during the therapy. In subgroups, changes in SE and AL had no significant differences between male (-0.46 ± 0.43D, 0.22 ± 0.14mm) and female (-0.47 ± 0.41D, 0.20 ± 0.13mm), neither between low (-0.43 ± 0.39D, 0.21 ± 0.14mm) and moderate (-0.43 ± 0.43D, 0.16 ± 0.13mm) myopic participants, indicating that the progressions of myopia and eye elongation do not correlate with gender and myopic degree (**Table 1**).

3.3. Changes in ChT during 6-month atropine treatment

Figures of ChT within the -3.0 mm to +3.0 mm area were plotted from datums automatically measured at 0.01mm intervals (**Figure 2**), and statistical analysis was conducted using datums of 13 points at 0.5 mm intervals (**Table 3**). At the 3-month visit, the ChTs barely changed compared with the baseline values. At the 6-month visit, a mild decrease in ChT were noticed in the macular area, but still with no statistical significance ($p > 0.05$). There were also no significant differences in ChTs between subgroups of low and moderate myopic children ($p > 0.05$). According to available researches, the elongation of axis in untreated myopic children and adolescents is 0.2-0.4 mm per year. Thus, 0.15 mm was considered the cut point between slow and fast AL progression [21, 22]. Still, no significant differences in ChT were found between these two subgroups (24 in slow group and 67 in fast group, $p > 0.05$).

Table 3. ChTs at each measuring point during 6-month 0.01% atropine treatment

Measuring point (mm)	ChT (um)								
	Treatment time		*P value	AL progression		†P value	Baseline Refraction		‡P value
	3 months	6 months		ΔAL ≤ 0.15 mm	ΔAL > 0.15mm		Low	Moderate	
-3.0	166.51 ± 45.07	166.00 ± 47.12	0.14	164.64 ± 55.56	166.24 ± 40.48	0.88	168.18± 47.37	158.76 ± 45.55	0.69
-2.5	182.26 ± 48.64	181.97 ± 50.87	0.27	180.52 ± 61.74	182.09 ± 42.10	0.89	184.34 ± 50.83	174.26 ± 50.27	0.78
-2.0	200.54 ± 51.32	200.47 ± 53.84	0.50	199.54 ± 66.45	200.04 ± 43.48	0.97	203.29 ± 53.65	191.28 ± 53.39	0.81
-1.5	221.43 ± 53.39	221.12 ± 56.19	0.42	220.61 ± 69.52	220.29 ± 45.22	0.98	224.53 ± 56.01	210.57 ± 55.54	0.89
-1.0	243.71 ± 55.17	242.74 ± 58.02	0.23	242.31 ± 71.43	241.67 ± 47.00	0.96	246.23 ± 57.93	231.56 ± 56.92	0.91
-0.5	263.45 ± 56.58	261.65 ± 59.16	0.12	261.02 ± 72.29	260.38 ± 48.26	0.96	264.95 ± 59.31	251.31 ± 57.41	0.65
0	279.33 ± 57.53	276.73 ± 59.50	0.08	275.85 ± 72.11	275.15 ± 48.71	0.96	279.31 ± 60.02	268.37 ± 56.84	0.41
+0.5	289.88 ± 57.82	286.73 ± 58.91	0.09	285.79 ± 70.83	284.67 ± 48.22	0.93	288.42 ± 59.97	281.00 ± 54.80	0.27
+1.0	295.38 ± 57.31	291.98 ± 57.38	0.15	291.36 ± 68.57	289.37 ± 46.95	0.87	292.89 ± 59.06	288.80 ± 51.27	0.32
+1.5	297.34 ± 55.73	294.02 ± 54.95	0.25	294.10 ± 65.31	290.81 ± 45.21	0.78	294.33 ± 57.23	292.76 ± 46.57	0.23
+2.0	297.13 ± 53.21	294.13 ± 52.18	0.40	295.20 ± 61.43	290.32 ± 43.73	0.67	294.11 ± 54.86	294.03 ± 42.04	0.27
+2.5	295.81 ± 50.15	293.25 ± 49.67	0.59	295.54 ± 57.13	288.83 ± 43.28	0.54	293.07 ± 52.41	293.97 ± 39.16	0.30
+3.0	293.37 ± 47.43	291.30 ± 47.92	0.82	295.03 ± 52.85	286.17 ± 44.18	0.40	290.92 ± 50.23	292.89 ± 39.29	0.27

Note: * Comparison between ChT at baseline at the 6-month visit using paired t-test; † Comparison between slow and rapid elongation eyes at the 6-month visit using the Student t-test; ‡ Comparison between low and moderate myopic children in the study using the Student t-test

4. Discussion

In this study, we observed the changes in SE, AL, and ChT in low to moderate myopic children during a 6-month topical use of 0.01% atropine. Both SE and AL increased almost the same rate in the first and second 3 months, indicating that 0.01% atropine did not significantly decrease the progression of myopia in the first 6-month treatment. This corresponded to the findings from the ATOM study and the LAMP study [23, 24], that comparing with moderate concentrations of atropine, longer treatment time (more than 6 months) is required for low concentration atropine to show its effects [5].

In review of all the available studies about the changes in ChT during atropine treatment for myopia, it is found that only the ChT under fovea was measured in almost all the previous studies, and an all-sided knowledge of the changes in ChT of the whole choroid could not be achieved. In this study, a 6mm diameter area around the macular fovea was used and measured the ChT at tiny intervals of 0.01mm. On this account, a profile of choroidal thickness within a relatively large area, covering the shortage of the previous studies to some extent, was achieved.

In the profiles of ChT taken, the choroid showed a constant thickening from nasal to temporal side and tending to be stable from +0.5 mm to +3.0 mm. After the 6-month use of 0.01% atropine, no significant changes in ChT were observed, even when the variables of gender, myopic degree and AL were taken into consideration. In the most measuring area, a mild decrease of ChT was noticed, which contradicts our initial hypothesis that 0.01% atropine may cause choroidal thickening. Similar results have also been found in several other studies, where the ChT significantly decreased after 0.01% atropine treatment, even when prolonging the treatment to 2 years [15, 17]. Meanwhile, higher concentrations of atropine (0.025%, 0.05% and 0.3%) could cause significant choroidal

thickening [15, 16]. These findings indicated that the effects of atropine on ChT may be correlated with the drug concentration. However, there are also opposite results found in several studies, showing a significant increase in ChT during 2-month treatment of 0.01% atropine [25, 26]. Until now, no definite conclusion about the impact on ChT by 0.01% atropine can been reached yet. The discrepancy may be derived from different measuring method of ChT. An inopportune timing for choroid scanning or manually tracing the choroidal boundary could both lead to significant inaccuracies. In this study, by severely controlling the time quantum for measurement and automatically plotting the choroidal boundary by software, measuring errors could be greatly reduced.

Considering that 0.01% atropine remained equally effective in controlling myopia despite of the various ChT changes in different studies, there is possibility that the changes in ChT might be an incidental or indirect effect of atropine, instead of being the essential pathway to controlling myopia.

There were several limitations in this research. First, a placebo group for comparing the changes in ChT after atropine treatment with that in untreated myopic children was not made during this study. Meanwhile, a 6-month treatment might be too short to induce significant changes in ChT, and further follow-ups are needed.

5. Conclusion

This research suggested that in low to moderate myopic children, topical use of 0.01% atropine for 6 months could not cause significant changes in ChT in an area of 3 mm from the temporal side of the fovea to the nasal side.

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Disclosure statement

The authors declare no conflict of interest.

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