

Original Article

Homemade Chinese herbal fumigation eye patch prevents myopia in children and adolescents

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Abstract: Objective: To demonstrate the clinical efficacy of a homemade Chinese herbal fumigation eye patch in the prevention and treatment of myopia in children and adolescents. Methods: In this retrospective study, participants were grouped according to different intervention methods. A primary school was selected, wherein 50 myopic students in each grade and a total of 300 from the 6 grades were selected as the observation group. According to the 1:1 matching principle, another 300 myopic students matched with the uncorrected visual acuity (UCVA), gender, and class were selected as the control group. The observation group was treated with the Chinese herbal fumigation patch, once daily between 12:00 and 13:00, 10-15 min/time, for 30 consecutive days. The control group did not get any intervention measures. The UCVA, diopter (D), and axial length (AXL) of both groups were recorded on the 1st, 15th, and 30th day after enrollment. Results: Six hundred children and adolescents, including 324 males and 276 females with an average age of (8.8±2.3) years and UCVA of (4.51±0.37), were included, with none lost to follow up. No statistical significance was determined in pre-interventional TCM syndrome distribution, D and AXL between groups (all $P > 0.05$). Univariate analysis identified that the UCVA of the observation group changed with time ($P < 0.05$), presenting a linear trend ($P < 0.05$). In the control group, the changes in UCVA, D, and AXL over time were also statistically significant (all $P < 0.05$), and the reverse changes showed a linear trend with statistical significance (all $P < 0.05$). Multivariate analysis determined the presence of statistical inter-group differences in UCVA, D, and AXL (all $P < 0.05$), as well as an interaction between grouping and time. Conclusions: The homemade Chinese herbal fumigation eye patch can improve UCVA, delaying D deterioration and preventing eye axial lengthening among myopic children and adolescents, with clinical popularization value.

Keywords: Myopia, children and adolescents, Chinese herbal fumigation eye patch, prevention and treatment

Introduction

Myopia is a common eye disease manifested primarily as blurred long-distance vision, which can cause certain obstacles to the life, study, and future work of children and adolescents [1]. The modernization of society has led to an increasing incidence of juvenile myopia, which may be related to an increase in the time spent on learning and viewing electronic screen devices and a decrease in outdoor activities in children or adolescents [2, 3]. According to a cross-sectional analysis [4], the detection rate of myopia was 76.0% in primary school students (7-12 years old) in China, 80.0% in junior high school students, and 90.0% in senior high school students, so it is prevalent in children

and adolescents [5]. Therefore, it is urgent to continue to explore effective treatment strategies for the prevention and treatment of myopia among children and adolescents.

From the perspective of modern medicine, there is currently no effective medication for myopia [6]. In 2018, eight ministries and commissions jointly issued the "Implementation Plan for Comprehensive Prevention and Control of Myopia in Children and Adolescents" [7], and in 2019, the National Health Commission issued a "Notice on the Appropriate Technical Guidelines for the Prevention and Control of Myopia in Children and Adolescents" [8], both requiring the full play of the role of traditional Chinese medicine (TCM) in the prevention and

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control of myopia in children and adolescents. Chinese herbal fumigation is an effective TCM method for preventing and treating myopia among children and adolescents [9]. However, fumigation is usually carried out in medical institutions and takes a long time, resulting in poor patient compliance. Therefore, our hospital has cooperated with high-tech enterprises to develop simple and convenient traditional Chinese herbal fumigation patches according to the addition and subtraction of classical prescriptions under the guidance of TCM dialectics, which are reported below.

Of note, the innovation of this study is the homemade Chinese herbal fumigation eye patch, which provides a new treatment option for the prevention and treatment of myopia in children and adolescents. Second, from the perspectives of uncorrected visual acuity (UCVA), diopter (D), and axial length (AXL), we conducted a quantitative analysis on the prevention and therapeutic efficacy of the Chinese herbal fumigation eye patch in children and adolescents with myopia and verified the effectiveness of this therapy and its therapeutic effect over time, providing novel clinical references for the treatment of myopia in children and adolescents.

Participants and methods

Research participants

This is a retrospective study. From March 2021 to April 2022, a primary school was selected, and the participants were grouped according to different intervention methods. The observation group consisted of 300 myopic students selected from all 6 grades, with 50 cases per grade. Additionally, based on the 1:1 matching principle, another 300 myopic students with the same UCVA (rather than D due to the difficulty of obtaining the same D in a large sample size), gender, and class were selected as the control group (the class can be appropriately changed if that grade has no UCVA- and gender-matching students). All eyes with poor UCVA were taken as research subjects.

Inclusion criteria: children or teenagers aged 6-18 with left eye or right eye visual acuity < 1.0 and < 300 degrees by optometry, and no contraindications to treatment or previous treatment for myopia were included.

Exclusion criteria: 1) organic diseases; 2) family history of strabismus and glaucoma; 3) severe skin allergy; 4) other eye diseases.

The research protocol were approved by the Ethics Committee of Linping Hospital of Integrated Traditional Chinese and Western Medicine, Hangzhou (Approval Number: 2019-LLKY007), and strictly followed the relevant principles laid down in the *Declaration of Helsinki*. Because the analysis uses anonymous clinical data approved by the Ethics Committee of Hangzhou Linping District Hospital of Integrated Traditional Chinese and Western Medicine, subjects or guardians did not need to give informed consent to the study.

Inspection methods

An inspection team consisting of professional ophthalmologists, doctors of TCM, and school doctors was set up. The UCVA was checked by using the standard visual acuity chart, and the eyes with poor visual acuity were recorded. In addition, D and AXL were measured for eyes with poor UCVA. The spherical equivalent (SEQ) was determined using an automatic image measuring instrument. According to the international D classification standard [10], mild, moderate, and severe myopia were determined at an SEQ of -0.75--3.00 D, -3.25 D--6.00 D, and \leq -6.25 D, respectively. The AXL was measured with an IOL Master optical biometer. All of the above values were repeatedly measured 3 times to collect the means, and the data were checked and input by special personnel.

Preparation method of Chinese herbal fumigation eye patches

Modern physicians [11] have summarized the basic syndromes of myopia into three types: heart-yang deficiency, qi and blood deficiency, and deficiency of both liver and kidney. On this basis, we put forward the medicinal mechanism of "warming the heart and blood to replenish qi, and strengthening liver and kidney to produce essence", and carried out the external treatment by TCM fumigation [12]. The selection of medications mainly referred to the following classical prescriptions [13]: Zhujing Pill, Dingzhi Pill, and Tangkuei Blood-supplementing Decoction. The TCMs (portions) used were as follows: climbing groundsel herb (1 copy), Cortex Dictamni Radicis (1 copy), Radix Sophorae

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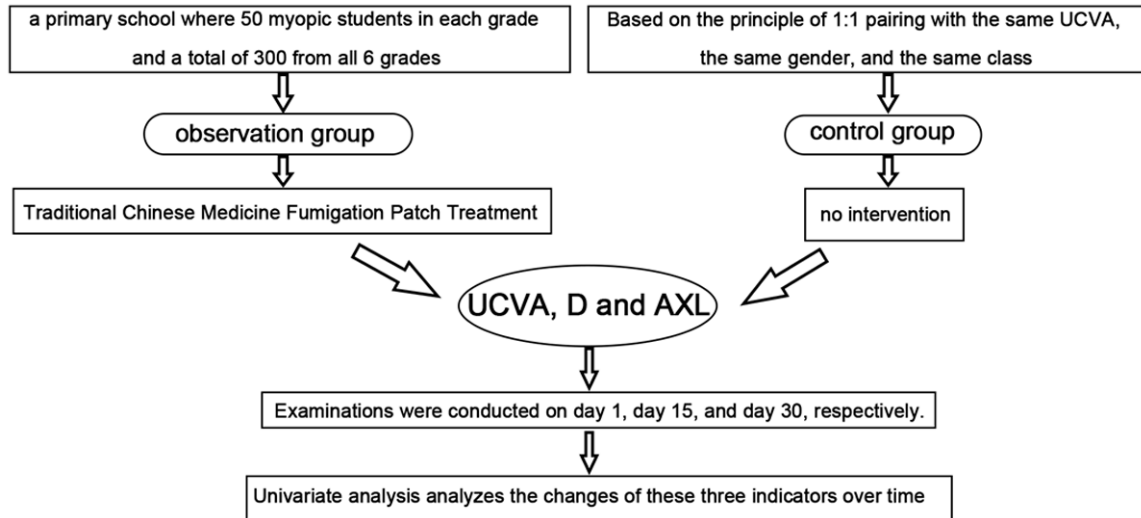


Figure 1. Flow chart. UCVA, uncorrected visual acuity; D, diopter; AXL, axial length.

Flavescentis (3 copies), Flos Chrysanthemi Indici (1 copy), Folium Mori (1 copy), Herba Taraxaci (1 copy), Radix Angelicae Sinensis (1 copy), Rhizoma Ligustici Chuanxiong (1 copy), Semen Cuscutae (2 copies), and Fructus Lycii (3 copies). Among them, Chrysanthemi Indici, Radix Angelicae Sinensis, and Rhizoma Ligustici Chuanxiong, all fat-soluble medicines, were extracted by steam distillation and preserved as the first liquid. The residue was soaked with other medicines, purified and concentrated by the heating decocting method, and used as the second liquid medicine. The first and the second liquid medicines were then thoroughly stirred and left standing, after which the supernatant was centrifuged. The resulting supernatant was then canned and sterilized. Finally, using modern technology, it is made into a Chinese herbal fumigation patch that can be used directly after unpacking. This product has been licensed as a national invention patent (ZL 202011043254.3).

Intervention methods

In the observation group, the above-mentioned Chinese herbal fumigation eye patch was used, which was directly unpacked and attached to the eyes for drug fumigation. The treatment was given once daily from 12:00 to 13:00 pm, 10-15 minutes/time, for 30 consecutive days. Students were supervised by their head teachers at school and parents at home to ensure that they were fumigated as required. The control group did not use any intervention.

Examinations were conducted on day 1, day 15, and day 30, respectively. The specific research process can be seen in **Figure 1**.

Statistical analysis

Data analysis and mapping were performed by SPSS 26.0 and Graphpad, respectively. Counted data (%) were compared by the Chi-square test between groups. The between-group and intra-group comparisons of measurement data, denoted by $(\bar{x} \pm s)$, were performed by independent t-test and paired t-test, respectively. Data comparisons between multiple time points were performed using the repeated measures analysis of variance (ANOVA). The significance level was $P < 0.05$.

Results

General data were comparable between the two groups

A total of 600 subjects were enrolled, including 324 males and 276 females with an average age of 8.8 ± 2.3 years old and an UCVA of 4.51 ± 0.37 . The observation group ($n=300$) and the control group ($n=300$) were non-significantly different in the number of cases with TCM syndromes of myopia ($P > 0.05$), with the number of cases presenting with “deficiency of heart-yang, deficiency of qi and blood, and deficiency of both liver and kidney” accounting for 95.33% of the total. D and AXL also differed insignificantly between the two cohorts (all

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Table 1. General information

Group	Male (%)	Female (%)	Deficiency of heart-yang (%)	Deficiency of qi and blood (%)	Deficiency of both liver and kidney (%)	Others (%)	Uncorrected visual acuity	Diopter (D)	Axial length (mm)
Observation group	162 (54%)	138 (46%)	53 (17.67)	71 (23.67)	164 (54.67)	12 (3.99)	4.51±0.37	-4.122±1.297	25.119±1.118
Control group	162 (54%)	138 (46%)	49 (16.33)	64 (21.34)	171 (57.00)	16 (5.33)	4.51±0.37	-4.083±1.322	25.011±0.976
t value	/		X ² =1.238			/		t=0.365	t=1.260
P value				0.744			0.715		0.208

Table 2. Results of repeated measures analysis of variance

Variable	Day 1	Day 15	Day 30	Time		Between-group		Grouping × time	
				F value	P value	F value	p value	F value	P value
Uncorrected visual acuity						8.957	0.003	7.531	< 0.001
Observation group ^a	4.51±0.37	4.54±0.35	4.59±0.41	3.842	0.023				
Control group ^a	4.51±0.37	4.48±0.34	4.44±0.29	3.054	0.041				
Diopter (D)						5.127	0.017	2.564	0.021
Observation group	4.122±1.297	4.127±1.159	4.136±1.266	1.715	0.237				
Control group ^a	4.121±1.322	4.135±1.258	4.159±1.317	3.112	0.034				
Axial length (mm)						4.889	0.024	2.381	0.034
Observation group	25.119±1.118	25.122±1.127	25.129±1.136	1.248	0.421				
Control group ^a	25.120±0.976	25.143±1.014	25.167±1.028	3.089	0.038				

Note: ^alinear fitting test, ^aP < 0.05.

$P > 0.05$), as shown in **Table 1**. Moreover, no adverse reactions were observed in the observation group during the 30-day application of Chinese herbal fumigation eye patches.

UCVA in both groups

In the repeated measures ANOVA, the change in each index over time in both cohorts was first evaluated by the univariate analysis, followed by multivariate analysis to investigate the grouping effect and the interaction between grouping and time. Univariate analysis revealed that in the observation group, only the UCVA changed statistically with time ($P < 0.05$), and the linear fitting of the variation trend was significant ($P < 0.05$). In the control group, the changes of UCVA over time were significant ($P < 0.05$), showing a linear trend and developing in a worse direction ($P < 0.05$). Multivariate analysis identified a significant difference between the two cohorts in UCVA ($P < 0.05$), as well as the interaction between grouping and time. In addition, UCVA improved significantly in the observation group and deteriorated in the control group. See **Table 2** and **Figure 2** for details.

D in both groups

In the control group, the change of D over time was statistically significant ($P < 0.05$), showing

a linear trend and developing towards deterioration ($P < 0.05$). Observation group showed a D that changed little over time ($P > 0.05$). The results of multivariate analysis showed a significant in D between the two cohorts, as well as an interaction between grouping and time. See **Table 2** and **Figure 3** for details.

AXL in both groups

In the control group, AXL changes over time were significant ($P < 0.05$), showing a linear trend and a worsening tendency ($P < 0.05$). In the observation group, AXL had no significant change over time ($P > 0.05$). The results of multivariate analysis showed significant AXL between the two cohorts ($P < 0.05$), as well as the interaction between grouping and time. See **Table 2** and **Figure 4** for details.

Discussion

While the pathogenesis of myopia in children and adolescents remains to be clarified from a TCM perspective, starting from the dialectics of TCM and combining TCM techniques with modern techniques provides novel insights into the prevention and management of myopia in such a patient population. Through extensive reviewing of research literature on myopia treatment by TCM and literature inquiry, the authors con-

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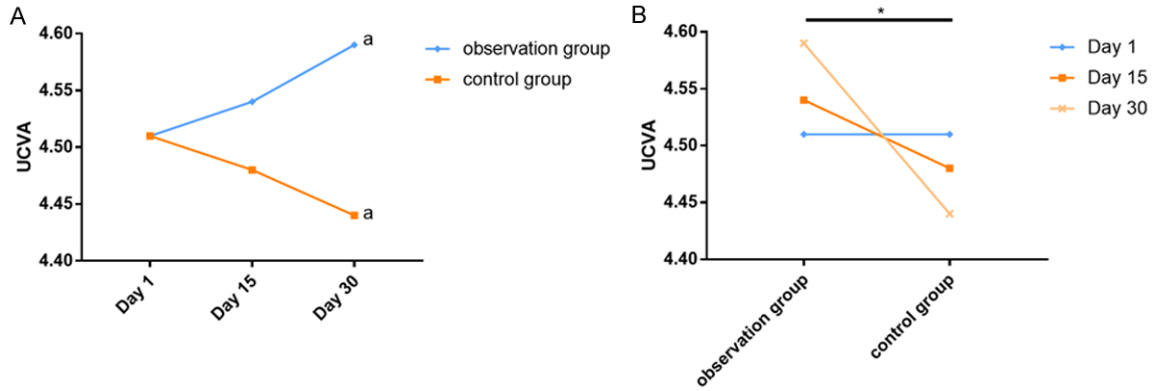


Figure 2. Estimated marginal means of uncorrected visual acuity (UCVA). A: Variation trend in UCVA in the two groups over time; B: Comparison of UCVA between two groups at different time points. ^alinear fitting test, ^a $P < 0.05$; * $P < 0.05$ between groups.

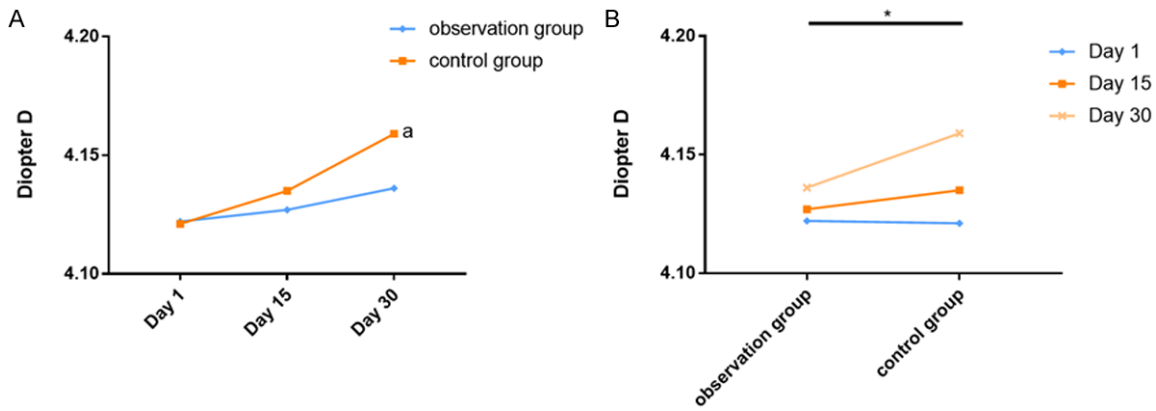


Figure 3. Estimated marginal means of diopters (D). A: The variation trend of D in two groups over time; B: Comparison of D between two groups at different time points. ^alinear fitting test, ^a $P < 0.05$; * $P < 0.05$ between groups.

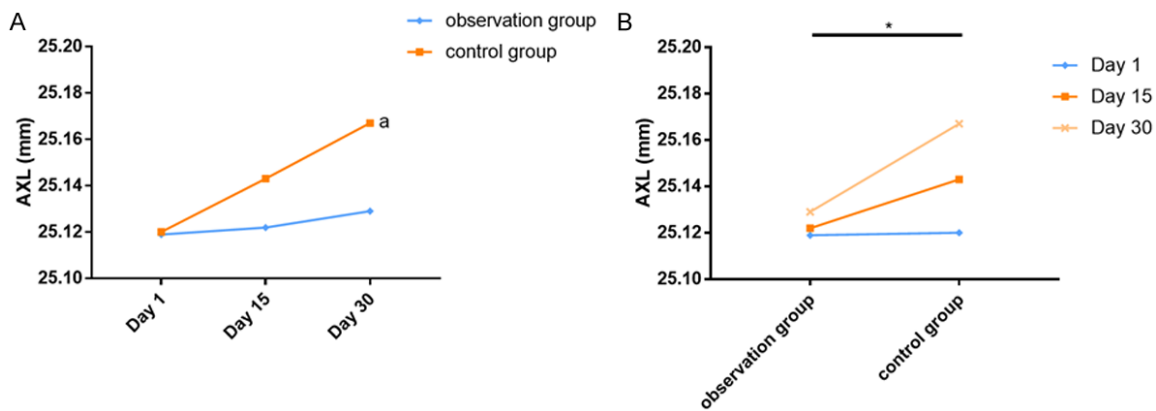


Figure 4. Estimated marginal means of axial length (AXL). A: The variation trend in AXL in two groups over time; B: Comparison of AXL between two groups at different time points. ^alinear fitting test, ^a $P < 0.05$; * $P < 0.05$ between groups.

cluded “deficiency of heart-yang, deficiency of qi and blood, and deficiency of both liver and

kidney” as the main TCM syndromes [14, 15], with 95.33% of the 600 myopic children and

adolescents included in this research falling into the above three types of TCM syndromes, similar to the findings of Li et al. [9]. This could be related to the clinical experience of TCM practitioners. On the other hand, it suggests that TCM syndromes in children and adolescents with myopia are still dominated by these three types. According to the dialectical principle of “deficiency of heart-yang, deficiency of qi and blood, and deficiency of both liver and kidney”, the treatment principle of “warming heart and blood to replenish qi, strengthening liver and kidney to produce essence” is put forward, which is similar to many domestic theories of myopia in TCM [16, 17].

Many researchers have proposed TCM-based treatments for the prevention and treatment of eye diseases and conducted clinical application analyses [18, 19]. For example, Zhang et al. [18] pointed out that Osthole played an anti-angiogenic role in corneal neoangiogenesis associated with alkali burn by inhibiting the growth migration and angiogenesis of endothelial cells associated with vascular endothelial growth factor (VEGF). In addition, Yang et al. [19] proposed that curcumin can be used in the treatment of diabetic retinopathy, which is related to the improvement of glycolipid metabolism, oxidative stress and inflammation, and the inhibition of insulin resistance. Furthermore, electroacupuncture has been shown to reduce inflammation in dry eye diseases by regulating the $\alpha 7$ -nicotinic acetylcholine receptor ($\alpha 7$ -nAChR)/nuclear factor- κ B (NF- κ B) axis [20]. This study found that compared to the control group, the Chinese herbal fumigation eye patch improved UCVA, D, and AXL over time and delayed myopia progression in children and adolescents in the observation group, indicating an antagonistic interaction between time and grouping. It further suggests that the herbal fumigation eye patch has an advantage over non-intervention, improving UCVA and further delaying the growth of D and AXL. Tang et al. [21] demonstrated significantly improved visual fatigue symptoms, D, and curative efficacy by TCM hot pressing plus health education in adolescents with visual fatigue, which is consistent with our findings. The mechanism may be that the local heat generated by the eye patch can dilate the surrounding blood vessels, accelerate blood circulation, and promote the absorption of drugs by tissues, so that drugs

can reach the lesion site [22]. Also, it may be attributed to the effects of the medicinal formula to warm the heart and invigorate the qi, to nourish the liver and kidneys, to relieve the nebula to improve vision, to nourish yin to moisten dryness, to promote blood circulation to remove meridian obstructions, and to induce resuscitation to improve eyesight. Besides, this study demonstrated that without any intervention measures, myopia of children and adolescents would deteriorate to varying degrees over time, which is consistent with many domestic studies that the degree of myopia becomes more serious with the increase of time and age [23, 24]. Therefore, we should start from the idea of “treat before getting illness” of the preponderant thinking of TCM, and pay more attention to prevention when the current treatment effect is not particularly clear.

Furthermore, it was found that this Chinese herbal fumigation patch had a curative effect on some myopic children and adolescents who had dry and sore eyes, consistent with other studies [25, 26]. The reason behind this may be that the heat produced by such eye patches can moisten eyelids and eyeballs, thus alleviating the symptoms of dry and sore eyes. Moreover, we found no adverse reactions during treatment during the application of the Chinese herbal fumigation eye patch, suggesting a high safety profile of this eye patch.

This study still has room for improvement. Due to the small sample size and skewness distribution, the inter-group difference at each time point cannot be reflected by the median and interquartile range, so the data are presented in the form of the mean and standard deviation. In addition, the observation time of the intervention is short, while the short-term change in myopia, a chronic disease, is not obvious. Later, the sample size and trial scope should be expanded, focusing on all children and adolescents and on a quarterly or annual basis, to further demonstrate the prevention and control effects of the Chinese herbal fumigation eye patch, so as to provide more convincing results. Moreover, due to the retrospective nature and limited data, there was no in-depth analysis of the underlying mechanism of action related to the homemade Chinese herbal fumigation eye patch to enrich the results. Basic research in this area will be supplemented to further enrich the results.

To sum up, starting from the main TCM dialectics of myopia in children and adolescents, and guided by the principle of medication by mechanism, the Chinese herbal fumigation eye patch made by external fumigation combined with high-efficiency modern techniques is effective in preventing and treating myopia in children and adolescents. Not only does this address the low efficiency and poor compliance of traditional fumigation, but it can be mass-produced and is cheap and convenient to use.

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Disclosure of conflict of interest

None.

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