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Clinical trial of press needle therapy with low-dose atropine for mild myopia in children

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Abstract: **Background**: The rising prevalence of mild myopia among kids needs very effective methods for preventing its progression. Recent research suggests that a combination of acupuncture and a small dose of atropine eye drops might be more effectively combined for myopia control. The trial will evaluate myopia control among kids aged 6-14 years old using buried needle acupuncture with low-dose atropine 0.01%. **Objectives**: To evaluate if there is a synergistic effect from periocular acupuncture and low doses of atropine on mild myopia in children 6-14 years old. **Methods**: A total of 80 children with mild myopia and 160 eyes were included in the randomized controlled trial from March 2020 to June 2021. All participants were then randomly assigned equally into both the treatment group, which included acupuncture and low doses of atropine and routine eye care, and the control group, which included sham acupuncture and routine eye care. The main outcomes were uncorrected visual acuity, best-corrected visual acuity, spherical equivalent refraction, amplitude and facility of accommodation, and axial length. All these were measured at 0, 2, 6, and 12 months. Treatment compliance and attendance were monitored. **Results**: The treatment group showed marked improvement in UCVA and BCVA, accommodation function, and rate of SER and axial length progression compared with the control group ($P < 0.05$). There were no serious side effects; two patients complained of mild transient pain. The combination regimen was generally tolerated without serious ocular or systemic side effects. **Conclusion**: Periocular acupuncture with low dose atropine solution (.01%) seems to be a safe and more effective method as compared with conventional treatment alone for controlling mild myopia in children. Large scale trials should be conducted for validating these findings.

Keywords: Axial length; Accommodation; Child myopia; Low-dose atropine; Periocular acupuncture; Visual acuity

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INTRODUCTION

Myopia is the global most common refractive visual condition and is no longer unique to adults. It has increased exponentially in children and adolescents to become a global public health concern (Alvarez-Peregrina *et al.,* 2022). In children, myopia not only deteriorates vision at distance but also exposes the patients to severe eye disorders such as retinal detachment, macular degeneration and retinal holes, leading to the loss of vision and quality of life on a permanent basis (Bullimore and Brennan, 2023). Therefore, early treatment and the right measures to slow the progression of myopia are prime areas of focus in modern ophthalmology (George *et al.,* 2023).

Myopia is induced by parallel beams of light converging in front of the retina due to an excess of axial length or refractive power, resulting in blurred distance vision. Individuals with myopia frequently experience visual fatigue, night vision blur and focusing problems, issues that significantly impede school performance, daily functioning and quality of life (Sun *et al.,* 2025; Talebnejad *et al.,* 2022).

Current epidemiological accounts reveal concerning trends. As there is increased application of digital technology, decreased outdoor time and greater academic pressure, myopia in childhood is increasing sharply (Shah *et al*., 2024). The myopia prevalence in China is 13.7% in primary school, 42.9% in middle school and 69.7% in high school and in the world, 1.406 billion individuals (22.9%) were myopic in 2020 and are likely to grow up to 4.756 billion (49.8%) by 2050 (Singh *et al*., 2022). Progressive myopia is fraught with a high risk of vision-loss complications such as macular hemorrhage and retinal detachment (Maulvi *et al.,* 2025; Ebadi, 2025a).

Traditional treatments like optical correction with glasses or contact lenses are reversible and do not have impacts on disease progression or axial elongation (Ng *et al.,* 2022). Pharmacological intervention with low-dose atropine (0.01%) eye drops has been shown to be safe and effective and this reduces myopia progression and axial elongation in children (Russo *et al.,* 2022).

Low-dose atropine acts via muscarinic receptor blockage within the sclera and retina to inhibit overactive ocular and scleral remodeling, without higher doses' side effects such as photophobia and impaired near vision (Li *et al.,* 2024). The adjunctive treatments such as Traditional Chinese Medicine (TCM) periocular buried needle acupuncture act towards enhancing visual function and correcting axial length by needling specific periocular acupoints (Wang *et*

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al., 2024). Still, clinical evidence for acupuncture alone remains limited and inconclusive, with most research poorly conducted. This highlights the need to explore integrative therapies that incorporate modern pharmacology and traditional methods (Zou *et al.,* 2024; Kong *et al.,* 2023; Niu *et al.,* 2022). The present study evaluates the synergistic action of low-dose atropine and periocular buried needle acupuncture, where atropine is primarily focused on structural development by modulating axial elongation and acupuncture targets functional outcomes like accommodative amplitude, reduction in visual fatigue and improved uncorrected visual acuity (Zhang *et al.,* 2025). This dual strategy aims at providing a safe, minimally invasive and patient-focused approach to the control of childhood myopia, specifically for parents who are seeking options other than surgery or prolonged single drug monotherapy (Surico *et al.,* 2024; Saxena *et al.,* 2023).

We hypothesized that the addition of low-dose atropine with periocular acupuncture would yield structural as well as functional benefits over that of usual care by itself. To confirm this, we conducted a prospective randomized trial in 6-14-year-old children with comparison of outcome at 12 months using stringent inclusion/exclusion criteria and standardized protocols. This study will provide preliminary evidence to guide multicenter trials and integrative clinical practice for pediatric myopia treatment.

MATERIALS AND METHODS

Study subjects

From March 1, 2020, to June 31, 2021, 80 children (160 eyes) between 6 and 14 years of age with diagnosed mild myopia were included in this prospective randomized controlled trial. A priori sample size estimation was done for primary outcome of axial length change, with a difference in means of 0.20 mm assumed, a standard deviation of 0.30 mm, two-tailed alpha of 0.05 and 80% power and anticipated 15% loss to follow-up, providing minimum number of 40 patients per group required.

The children were assigned randomly to the treatment group (n = 40), receiving periocular buried needle acupuncture and nightly 0.01% atropine along with regular eye care, or the control group (n = 40), receiving sham acupuncture and regular eye care only. The baseline values of age, gender distribution, spherical equivalent refraction (SER), best-corrected visual acuity (BCVA) and daily screen use were not significantly different, indicating adequate group homogeneity (Table 1).

Inclusion and exclusion criteria

Inclusion Criteria

Children were enrolled if they m*et al*l the following criteria. Post-cycloplegia spherical equivalent refraction (SER) was between -0.50D and -3.00D in both eyes, so only mild cases of myopia were recruited. Best-corrected visual acuity (BCVA) had to be ≥1.0 for both near and distance vision to create a baseline visual integrity. Participants must have ≤2 hours of daily screen time and ≥8 hours of daily sleep because lifestyle aspects could influence study results. Children must also have the capacity to demonstrate capacity to complete all follow-up visits scheduled and to strictly follow the study protocol. Informed consent by writing from parents or guardians prior to joining was obtained, with ethical regulation and participants' awareness maintained.

Exclusion criteria

Participants were barred in some conditions that can lead to interference of results or an increased risk. These were both parents being high myopes with SER ≤ -6.00D, which could signify a powerful genetic factor. Children suffering from strabismus, amblyopia, pathological myopia, or other eye diseases were not eligible. History of ocular surgery or trauma was the reason for exclusion to avoid confounding factors affecting results. Patients with skin allergies or needle phobia that would interfere with acupuncture treatment were excluded. Children receiving systemic or ocular medication known to affect myopia progression, or those with severe systemic illness such as uncontrolled diabetes or neurological illness, were excluded. These stringent inclusion criteria yielded an homogeneous study population that enabled proper evaluation of the additive effects of low-dose atropine and periocular acupuncture on mild childhood myopia.

Randomization and blinding

Randomization was by means of a computer-generated block randomization list of size 4 to permit even distribution into groups and equilibrium between the treatment and control groups. Preparation and safe storage of the randomization list were undertaken and maintained by an independent statistician who was not involved in patient recruitment or outcome assessment. Allocation concealment was made with the use of sequentially numbered, opaque sealed envelopes, which were only opened after participant recruitment to prevent selection bias.

Participants and parents were blinded to treatment allocation as sham acupuncture was designed to mimic the look and sensation of real acupuncture but without any true needling penetration. Outcome assessors and data analysts/statisticians were blinded throughout the trial duration to minimize performance and detection bias, as much as possible, to preserve the integrity of the study outcomes (Ebadi, 2025b).

Treatment protocols

Both groups received daily eye care in the form of wide-angle visual hygiene instruction such as limiting prolonged near work and ensuring at least two hours of outdoor time each day. Prescribing corrective lenses on demand was necessary to allow for clear distance vision in addition to

providing sufficient support to ensure optimal eyesight. Environmental and lifestyle changes were taught to caregivers to reduce visual stress and assist in myopia control. The treatment group participants received extra interventions, besides regular care. They were administered low-dose atropine (0.01%), implanted nightly in both eyes for 12 months, with compliance checked by returned bottle counts and by diaries kept by caregivers to reach an intended compliance rate of ≥80%. They also received periocular buried needle acupuncture performed by a single highly trained physician, only, to ensure consistency.

The following acupoints were required: Zanzhu, Yuyao, Sizhukong, Sibai, Taiyang and Jingming. 0.2 × 1.0 mm needles (Suzhou Medical Products Factory Co., Ltd.) were utilized, with each needle being inserted and left in situ for three days prior to renewal weekly. Nine weekly treatments (approximately two months) constituted one full treatment course, with six courses throughout the 12-month period. The control group was administered sham acupuncture using blunt-tipped needles on the same periocular acupoints without puncturing the skin, which can provide an effective placebo effect. No atropine drops were administered to this group to facilitate comparison among interventions while preserving study blinding.

Outcome measures

The secondary and primary outcomes: were assessed at four preagreed intervals: baseline, 2 months, 6 months and 12 months after treatment initiation. Primary outcomes were axial length change (AL), as determined by IOLMaster 500 and spherical equivalent refraction (SER) change, as determined by cyclolegic refraction. These were selected to quantify structural changes in ocular growth and refractive changes over the duration of time. Secondary outcomes evaluated the functional and safety endpoints of treatment. These were uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) measured by an international standard vision chart at a fixed distance of 5 meters under standardized illumination of 500 Lux. Accommodation function was also measured by a dynamic retinoscope and refractometer to evaluate amplitude and flexibility of accommodation. Safety evaluation involved monitoring rate of complications and all ocular or systemic adverse effects during the study period. Adherence to atropine and acupuncture session attendance were monitored as described; however, patient-reported acceptability (validated PROMs) was not prespecified or collected.

Cycloplegia protocol

For the purpose of giving uniform and reliable refraction measurement, two instillations of 1% cyclopentolate were given in each eye at 5-minute intervals. Measurement was taken 30 minutes after the last instillation so that there was sufficient time for maximum cycloplegia to establish. All parameters like spherical equivalent refraction (SER) and axial length were measured three times and their average was taken to minimize variability and enhance precision. All measurements were done under blinding of trained optometrists to group allocation to maintain objectivity and minimize the likelihood of assessment bias during the trial.

Adherence and compliance monitoring

Regular monitoring of adherence to both interventions was carried out to ensure reliability of study outcomes. Adherence to atropine was recorded by returned bottle counts and daily diaries submitted by caregivers and compliance was assessed as a proportion of expected doses received over the treatment period. Compliance with acupuncture was monitored by measuring attendance at sessions, with careful documentation of any sessions missed or attended partly to evaluate participant participation. Two approaches were used for statistical analysis: per-protocol analysis including only those participants who had ≥80% compliance and intention-to-treat (ITT) analysis including all randomized subjects regardless of degree of compliance. Both provided a balanced estimation of treatment effects and accounted for variance in compliance; however, adherence was not analyzed as a primary outcome and patient-reported acceptability (PROMs) was not obtained.

Safety observation

Side effects were carefully followed up and recorded on each follow-up visit to ensure participant safety throughout the study. Ocular side effects included symptoms like redness, pain, photophobia, blurred near vision and local infection directly associated with the treatment procedures or administration of low-dose atropine. Systemic side effects, like dizziness and allergic reaction, were also assessed to determine any more widespread treatment-related effects. All AE's were carefully graded "according to" severity levels: mild, moderate, or severe. Furthermore, any AE causing participant withdrawal from the trial was described in terms of its onset, duration and relationship with the intervention. This careful monitoring allowed for proper evaluation of the tolerability and safety of the combination therapy.

Statistical analysis

SPSS version 26.0 was utilized for data analysis. Continuous data were expressed as mean ± SD and contrasted between groups using independent t-tests for parametric data or Mann–Whitney U tests for non-parametric data. Categorical data were analyzed using the Chi-square test or Fisher's exact test where possible. Repeated-measures ANOVA was employed to compare changes over time between groups, accounting for baseline covariates to minimize confounding variables. For primary outcomes, between-groups mean differences were calculated and reported with 95% confidence intervals (CIs) and exact p-values for accuracy and transparency in reporting. A two-tailed p-value of less than 0.05 was employed in all analyses as the statistical significance cut-off point.

RESULTS

Uncorrected visual acuity (UCVA)
No statistically significant differences between groups were observed at baseline ($p > 0.05$). After treatment, the UCVA of the treated group (periocular buried needle acupuncture + low-dose atropine + basic care) was significantly superior at 2 months (1 course), 6 months (3 courses) and 12 months (6 courses) compared to the control group (sham acupuncture + basic care). Between-group mean difference at 12 months was 0.46 (95% CI: 0.41–0.52, $p < 0.001$) showing a significant improvement in distance vision (Table 2).

Best corrected visual acuity (BCVA)
BCVA was not different at baseline or at 2 months. At 6 and 12 months, however, the treatment group had significantly higher BCVA than the controls. The mean difference at 12 months was 0.21 (95% CI: 0.18-0.25, $p < 0.001$) (Table 3).

Cycloplegic equivalent refraction (SER)
At baseline, SER was similar between groups. At all follow-ups, the treatment group had significantly less myopic progression compared to the control group, confirming the structural protective effect of acupuncture and low-dose atropine (Table 4).

Amplitude of accommodation
Treatment group exhibited progressive increases in accommodative amplitude from baseline of 9 ± 1.3 D to 12 months of 13 ± 0.9 D. The control group declined slightly. Between-group difference at 12 months was 4.0 D (95% CI: 3.6-4.4, $p < 0.001$) (Table 5).

Accommodation flexibility
Flexibility improved steadily in the treatment group, while in the control group, it decreased steadily. The difference at the end was 6.0 D (95% CI: 5.3–6.8, $p < 0.001$) (Table 6).

Axial length
Axial elongation in both groups was observed over the long term, though more so in the control group, confirming the structural impact of combined treatment. Mean axial elongation at 12 months was 0.26 mm compared to 0.52 mm in controls, with a between-group difference of -0.26 mm (95% CI: -0.31 to -0.21, $p < 0.001$) (Table 7).

Adverse events
No serious ocular or systemic adverse events were noted. Mild transient discomfort or redness was reported by 2/40 (5.0%) of the treatment group, which spontaneously resolved without withdrawal. There was no withdrawal by any participant on account of side effects, once again confirming general safety.

DISCUSSION

Traditional Chinese Medicine (TCM) provides several options in treating myopia, the most widely studied non-medication intervention of which is periocular buried needle acupuncture (Zou *et al.,* 2024; Jiang *et al.,* 2022). The procedure provides sustained, stable stimulation of some periocular acupoints with minimal pain and is particularly well adapted to children. Based on TCM theory, stimulation of these points increases ocular blood flow, normalizes Qi flow and enhances ocular muscle coordination, which enhance vision and reduce visual fatigue (Tian *et al.,* 2022; Niu *et al.,* 2022).

Western medicine believes that acupuncture has the ability to modulate the autonomic nervous system by decreasing parasympathetic tone and increasing sympathetic tone (Li *et al.,* 2022). This physiological effect reduces ciliary muscle spasm, enhances lens elasticity and optimizes retinal image focus, hence the accommodation function (Yang *et al.,* 2025). However, as indicated in previous studies, acupuncture alone weakly influences axial elongation, the main culprit of myopia progression and lifelong visual morbidity (Kong *et al.,* 2024).

To offset this limitation, low-dose atropine (0.01%) was incorporated as an adjunct in this study (Horn *et al.,* 2025). Atropine is a non-selective muscarinic receptor antagonist that inhibits scleral remodeling and pathological axial elongation, thereby retarding the structural progression of myopia (Maulvi *et al.,* 2025). Unlike higher doses, low-dose atropine minimizes frequent side effects of near vision impairment and photophobia, which enables long-term, safe treatment in children (Chen *et al.,* 2025; Kong *et al.,* 2023).

Findings of this study indicate synergy between structural protection with the low-dose atropine and functional enhancement with acupuncture. Whereas atropine influenced anatomical change indirectly by suppressing ocular growth, periocular acupuncture directly enhanced visual function in terms of accommodative amplitude, flexibility and uncorrected visual acuity (Yu *et al.,* 2022). Together, these treatments provided both short-term functional gain and long-term anatomical preservation. Although adherence and attendance were monitored, quantitative adherence outcomes were not primary endpoints and are not reported; consequently, the holistic acceptability of the combined regimen cannot be established from these data. At 12-month follow-up, children in the combined treatment group demonstrated significantly less myopic progression, decreased axial elongation and better visual outcomes than controls. These results are in line with previous reports that atropine alone is able to reduce myopia progression by 50-60% in one year and combining it with non-pharmacological methods enhances overall efficacy (Yum *et al.,* 2022).

Table 1: Baseline characteristics of study participants

Characteristic	Treatment group (n=40)	Control group (n=40)	p-value
Age (years)	9.85 ± 1.78	9.65 ± 1.85	>0.05
Gender (M/F)	22/18	23/17	>0.05
SER (D)	-1.75 ± 0.68	-1.72 ± 0.70	>0.05
BCVA (distance)	≥1.0	≥1.0	—
Daily screen time (h)	≤2	≤2	—

Note: SER = Spherical equivalent refraction; BCVA = Best-corrected visual acuity; M/F = Male/Female.

Table 2: UCVA comparison between groups

Time point	Treatment group	Control group	Mean difference (95% CI)	p-value
Before treatment	0.40 ± 0.11	0.35 ± 0.12	0.05 (-0.02 to 0.11)	>0.05
1 course (2 m)	0.52 ± 0.12	0.31 ± 0.10	0.21 (0.16 to 0.26)	<0.001
3 courses (6 m)	0.60 ± 0.13	0.26 ± 0.08	0.34 (0.29 to 0.39)	<0.001
6 courses (12 m)	0.66 ± 0.14	0.20 ± 0.07	0.46 (0.41 to 0.52)	<0.001

Note: CI = Confidence interval

Table 3: Comparison of BCVA between groups

Time point	Treatment group	Control group	Mean difference (95% CI)	p-value
Before treatment	1.05 ± 0.09	1.05 ± 0.08	0.00 (-0.05 to 0.04)	>0.05
1 course (2 m)	1.05 ± 0.09	1.03 ± 0.07	0.02 (-0.01 to 0.05)	>0.05
3 courses (6 m)	1.17 ± 0.12	1.00 ± 0.04	0.17 (0.13 to 0.21)	<0.001
6 courses (12 m)	1.21 ± 0.16	1.00 ± 0.00	0.21 (0.18 to 0.25)	<0.001

Table 4: SER progression over time

Time point	Treatment group (D)	Control group (D)	Mean difference (95% CI)	p-value
Before treatment	-1.50 ± 0.66	-1.64 ± 0.61	0.14 (-0.09 to 0.38)	>0.05
1 course (2 m)	-1.53 ± 0.69	-2.02 ± 0.60	0.49 (0.36 to 0.63)	<0.001
3 courses (6 m)	-1.67 ± 0.66	-2.21 ± 0.61	0.54 (0.40 to 0.68)	<0.001
6 courses (12 m)	-1.81 ± 0.65	-2.55 ± 0.53	0.74 (0.60 to 0.89)	<0.001

Table 5: Accommodative amplitude changes

Time point	Treatment group (D)	Control group (D)	Mean difference (95% CI)	p-value
Before treatment	9 ± 1.3	10 ± 1.3	-1.0 (-1.7 to -0.3)	0.004
1 course	10 ± 1.1	10 ± 1.3	0.0 (-0.6 to 0.6)	>0.05
3 courses	12 ± 0.9	10 ± 1.2	2.0 (1.5 to 2.5)	<0.001
6 courses	13 ± 0.9	9 ± 1.1	4.0 (3.6 to 4.4)	<0.001

Table 6: Accommodation flexibility

Time point	Treatment group (D)	Control group (D)	Mean difference (95% CI)	p-value
Before treatment	6.5 ± 1.5	7.6 ± 1.7	-1.1 (-1.8 to -0.4)	0.002
1 course	8 ± 1.4	7 ± 2.0	1.0 (0.2 to 1.8)	0.015
3 courses	10 ± 1.3	6 ± 2.2	4.0 (3.1 to 4.9)	<0.001
6 courses	11 ± 1.2	5 ± 1.9	6.0 (5.3 to 6.8)	<0.001

Table 7: Axial length changes

Time point	Treatment group (mm)	Control group (mm)	Mean difference (95% CI)	p-value
Before treatment	24.24 ± 0.29	24.48 ± 0.28	-0.24 (-0.32 to -0.16)	>0.05
1 course	24.28 ± 0.29	24.63 ± 0.27	-0.35 (-0.42 to -0.28)	<0.001
3 courses	24.37 ± 0.29	24.78 ± 0.27	-0.41 (-0.48 to -0.34)	<0.001
6 courses	24.50 ± 0.29	25.00 ± 0.27	-0.50 (-0.58 to -0.42)	<0.001

Table 8: Summary of adverse events

Event type	Treatment group (n = 40)	Control group (n = 40)
Mild eye redness	2 (5.0%)	1 (2.5%)
Mild pain at acupuncture site	1 (2.5%)	0
Photophobia	0	0
Withdrawal due to adverse events	0	0

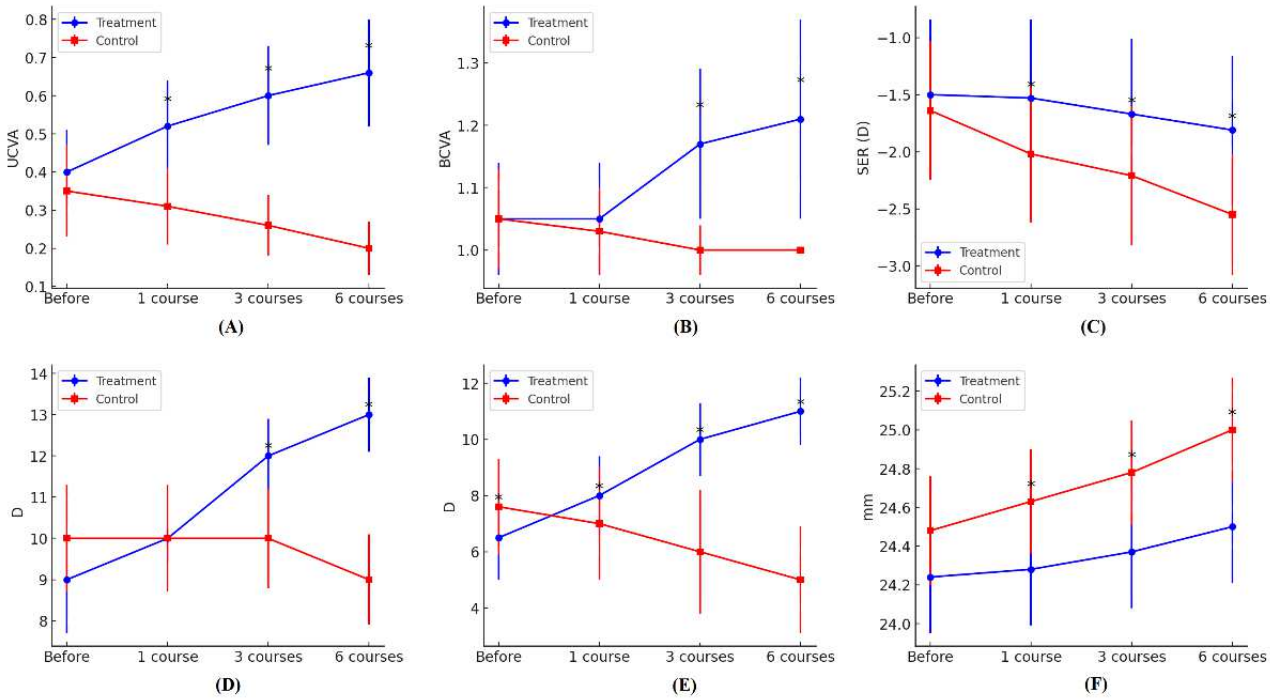

Fig. 1: Demonstrates time-course change for six main outcomes; (A) UCVA, (B) BCVA, (C) SER, (D) Amplitude of accommodation, (E) Accommodation flexibility, and (F) Axial length. Blue lines are treatment group, red lines are control group, with asterisks showing statistical significance ($p < 0.05$) and error bars showing ±SD.

From a tolerability standpoint, this two-modality regimen is minimally invasive and was associated with minimal treatment-related discomfort and no serious adverse events in this cohort, suggesting feasibility in pediatric practice (Morris *et al.,* 2024; Mulasso *et al.,* 2024). However, patient-reported acceptability was not measured with validated instruments and adherence was not a primary endpoint; therefore, acceptability claims and routine-practice recommendations should be made cautiously and confirmed in trials that include PROMs and standardized adherence metrics.

However, this study has certain limitations. The sample was quite small (n = 80), the trial was single-center and follow-up was limited to one year. These factors reduce the generalizability of the findings. Second, the trial did not include a low-dose atropine–only arm, which eliminates the ability to fully control for the independent effect of acupuncture. Pure placebo effects due to sham acupuncture and variation in patient compliance with nightly dosing of atropine or attendance at acupuncture sessions were not measured quantitatively. Subsequent research must include more extensive, multicenter groups of patients, longer follow-up periods and factorial designs to isolate the independent and additive effects of each treatment. Comparison with other treatments for myopia standards, such as orthokeratology and multifocal lenses, would more contextually position efficacy (Li *et al.,* 2024; Yang *et al.,* 2025).

CONCLUSION

Periocular buried needle acupuncture supplemented with low-dose atropine (0.01%) is a synergistic strategy with great potential in managing mild myopia in children. Low-dose atropine has largely halted structural progression by slowing axial elongation and acupuncture added benefits to visual and accommodative performance. This integrated approach reflects the anatomical and functional mechanisms of myopia control and it offers a non-surgical and safe treatment that offers a non-surgical, safe option; however, patient-reported acceptability and quality-of-life outcomes were not assessed and should be prespecified in future trials. While these findings are encouraging, larger

multicenter studies with longer follow-up are required to confirm these results, establish long-term safety and fine-tune clinical protocols for widespread use.

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Author's contributions
Jing Zhao, Hong-Liang Zhong, Zi-Ya Liu and Yi Xu contributed to the conception and design of the study. Jing Zhao and Zi-Ya Liu were responsible for data acquisition and analysis. Hong-Liang Zhong provided critical revisions for important intellectual content. Yi Xu supervised the study, provided overall guidance and is the corresponding author. All authors read and approved the final manuscript.

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Data availability statement
All data generated or analyzed during this study are included in this published article; no additional datasets were generated or made available.

Ethical approval
This study was a prospective, open-label clinical trial conducted at the Department of Ophthalmology, Wenzhou Hospital of Integrated Traditional Chinese and Western Medicine. The study protocol was approved by the hospital's ethics committee (Approval No. WH-2020-045). Written informed consent was obtained from the parents or legal guardians of all participants. The trial did not have a formal clinical trial registration number.

Conflict of interest
The authors declare that they have no competing interests related to this study.

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