• Clinical Research •

Effect of active vision therapy on contrast sensitivity in bilateral amblyopia

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Abstract
● **AIM:** To evaluate the effectiveness of combining patching with active vision therapy, compared to patching with placebo training on contrast sensitivity (CS) in pediatric participants with bilateral refractive amblyopia.

● **METHODS:** In this double-blind, clinical trial, 43 participants aged 5–8 with bilateral refractive amblyopia, unresponsive to spectacles, were randomly assigned to either the experimental group (active vision therapy plus patching) or the control group (placebo treatment with patching) for four months. Active therapy included anti-suppression, accommodative, vergence, and visual memory exercises. CS was measured at baseline and after four months, serving as key outcome measures.

● **RESULTS:** Forty participants (20 in each group) completed the study. The mean age for the experimental group (5 males) was 6.10±0.84y, and 6.50±1.15y for the control group (11 males). CS in the experimental group improved by 0.10 log (right eye), 0.14 log (left eye), and 0.07 log binocularly ($P \leq 0.03$). The control group showed no statistically significant enhancements in monocular or binocular CS ($P \geq 0.07$). Compared to the control group, the experimental group demonstrated a rate of change in monocular CS of 0.05 during follow-up time.

● **CONCLUSION:** Active vision therapy leads to significant and accelerates improvements in CS among children with bilateral refractive amblyopia.

● **KEYWORDS:** active vision therapy; bilateral refractive amblyopia; contrast sensitivity; children

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INTRODUCTION

Amblyopia is a common neuro-developmental disorder[1-2]. It is a prevalent cause of low visual acuity in both children and adults, often linked to strabismus, anisometropia, or both, during visual development[3]. The reported prevalence rates vary globally, with an estimated overall worldwide pooled prevalence of 1.36%[4]. Generally, the effectiveness of amblyopia treatment is determined by the improvement in visual acuity, although deficits in contrast sensitivity (CS) and stereopsis may still remain[5-6]. In addition to reduced high-contrast visual acuity, amblyopia can affect other monocular and binocular visual functions such as CS, visual processing, and stereo acuity[7]. Bilateral amblyopia, characterized by reduced best corrected visual acuity (BCVA) in both eyes, is often found in association with bilateral astigmatism or high hyperopia not corrected before the age of two years[8]. Etiologically, abnormal binocular interaction and suppression play key roles in the development of this type of amblyopia, and the majority of treatments primarily address optical correction, frequently not achieving full restoration of vision[9]. Studies have demonstrated that although traditional therapies such as patching improve visual acuity, they do not substantially affect other aspects of visual function such as CS or color vision. When evaluated for CS functions, the "good" eye of unilateral amblyopic patients performed abnormally compared with controls[10]. In contrast, modern therapies, such as perceptual learning, dichoptic training, and binocular therapy, have been reported to improve CS by up to 40%[11].

CS is a key parameter that activates cortical cells involved in vision processing[12-13]. Engaging in targeted contrast modulation exercises with customized stimuli leads to a marked improvement in CS[14]. For patients who do not respond to traditional methods such as patching and/or atropine, alternatives such as vision therapy, including anti-suppression techniques, virtual reality, and various exercises, may provide additional benefits and are worth considering as active treatment strategies. Tan and Fong[14] have demonstrated that neural vision enhancement therapy can even improve uncorrected visual acuity and CS in adult patients.

Vision therapy is an effective method for improving binocular vision that employs attention through feedback during therapy. This approach is utilized to expedite vision improvement and mitigate the risk of amblyopia regression[2]. Some studies have demonstrated that vision therapy can reduce treatment duration for bilateral amblyopia through various stimulations designed to enhance the visual system[2,15].

Since assessment of CS can provide important information on the visual function in amblyopia[10], the objective of this study was to investigate the effectiveness of patching combined with vision training versus patching with placebo therapy on CS in children with bilateral refractive amblyopia.

PARTICIPANTS AND METHODS

Ethical Approval This study received ethics approval from Ethics Committee of the Medical Sciences University (Approval code: IR.SBMU.RETECH.REC.1402.513). Written informed consent was obtained from the parents or legal guardians of all participants before enrollment, and the research complied with the Declaration of Helsinki principles.

Study Participants and Design Forty-three children aged 5 to 8y with bilateral amblyopia was enrolled at a private Vision Therapy Clinic in Shiraz, Iran, from February 2024 to July 2024. Prior to enrolment, all participants were examined at an Ophthalmology Clinic affiliated with Shiraz University of Medical Sciences, and underwent a comprehensive ophthalmologic examination. The participants included those with moderate bilateral amblyopia unresponsive to conventional treatment or those who had worn their optimal spectacle correction for at least two months without further improvement in visual acuity before enrolment. The BCVA of the participants ranged from 0.3 logMAR unit (6/12) to 0.6 logMAR unit (6/24) in each eye, with an interocular difference of less than 0.2 logMAR unit. Participants were included if they were hyperopic and/or astigmatic, with a cycloplegic refractive error in each eye greater than 3.00 diopters (D) of hyperopia and/or greater than 2.00 D of astigmatism[8]. Participants were excluded if they had any ocular pathology, strabismus, history of ocular surgery, or any phoria larger than 4 prism diopter (PD) at distance and/or near.

The sample size determination was conducted based on a recent study employing a similar methodology[16]. The effect size was determined using available visual acuity data in different groups. Analysis showed a total of 40 participants (20 participants per group), under the assumption of a type 1 error (α level) of 0.05 and 90% power, were required to discriminate the difference between the two groups. They were randomly assigned to either an experimental group or a control group. Randomization was conducted using four-piece block randomization, with participants evenly divided between the two groups. Eight blocks were selected randomly to ensure a diverse mix of participants. A random number between 1 and 6 was chosen eight times to select sampling members.

A double-blind method was used to minimize bias; neither the researcher nor the participants knew their group assignments. A staff member assigned participants into experimental and control groups based on the block randomization list. An experienced optometrist performed visual function assessments before and after therapy without knowledge of the participants' group assignments.

Clinical Examinations All participants underwent a comprehensive ophthalmic examination at enrolment, including BCVA using a digital chart (HDC-9000N/PF, Huvitz, Korea) at 4 m in logMAR unit form. Dry and cycloplegic refraction were performed with an autorefractor (HRK-8000A, Huvitz, Republic of Korea) before and after applying two drops of cyclopentolate 0.5% at 5-minute intervals. Retinoscopy (the Heine-Beta 200, Germany) was performed to validate the refractive measurements obtained through autorefraction. CS was assessed using the Freiburg contrast test (FrACT, version 3.7.1b) at a separate follow-up session, measured at five cycles per degree (cpd) with a 30-second exposure time. BCVA and CS were re-evaluated at the final visit after four months. The rate of change in monocular CS was calculated across the 4-month follow-up period.

Training Procedures The experimental group underwent 40 sessions of Vision Training System version 4 (VTS4) training in conjunction with eye patching, while the control group received a placebo therapy twice monthly, which involved watching a simple digital movie in-office using plano lens flippers. The patching regimen was 2h per day. Each training session lasted for 30min. The vision therapy sessions comprised complex monocular and binocular stimuli and aimed to train various visual skills as outlined below. All participants followed the same sequence of training exercises, with each exercise lasting approximately 4–5min.

Accommodation training started initially with monocular accommodative rock procedures using starting lenses of ±0.25 D, progressing to higher lenses in difficulty based on the participant's accommodation ability. This was followed by bi-ocular and binocular conditions to increase amplitude. Participants wore liquid crystal glasses while performing these exercises.

Pursuit exercises consisted of nine levels incorporating auditory feedback. The size of the visual stimuli was adjusted based on the participant's visual acuity; larger targets were used for individuals with worse visual acuity. These exercises aimed to reduce or eliminate suppression, with flippers integrated into the final phases.

Saccade exercises utilized two types of visual targets: directional targets and E-letter targets, with sizes customized to the participant's visual acuity. These exercises also functioned as anti-suppression therapy, incorporating flippers in the final stages of treatment.

Visual memory exercises utilized directional and E-letter targets displayed in flash mode, requiring the patient to recall and indicate the direction of the target after it disappeared. Flash durations varied from 10 to 0.1s depending on the child's performance. Targets were presented to each eye separately while the participant wore liquid crystal glasses, ensuring participation of both eyes in the memory task. These exercises were part of anti-suppression therapy, with flippers incorporated during the final phases.

Vergence exercises employed first-degree, second-degree, and stereoscopic vision targets to enhance fusion amplitudes at various distances and overcome suppression. The targets were positioned at both 6 and 1 m; when observing targets at 1 m, flipper lenses were used to integrate both accommodative and vergence systems. Anti-suppression exercises aimed at addressing peripheral and central suppression with shaking technology improve the visual system's functional skills.

The cheiroscope was employed for anti-suppression training. The targets were systematically arranged in a hierarchy from large to small and from a uniform background to a background featuring an image. This training was designed to reduce crowding effects in amblyopia.

Statistical Analysis The data were recorded and analyzed using SPSS software version 26 (IBM Corp., Armonk, NY). The Shapiro-Wilk test was used to assess the normality of the data distribution. A marginal model using generalized estimating equations (GEE) accounted for intra-individual correlation between the right and left eyes to examine the main effects of treatment type and time, as well as their interaction effects for the univariate variables. The correlation structure in the GEE analysis was considered unstructured. Given the non-normal distribution of the data, the Wilcoxon signed-rank test was used for within-group comparisons, and the Mann-Whitney *U* test was used for between-group comparisons. A significance level of 0.05 was set for all analyses in this study.

RESULTS

Forty-three participants (experimental group n=23, control group n=21) with bilateral refractive amblyopia were enrolled. Forty (20 participants in each group) completed the study and were included in the analysis. Three participants ceased their involvement in the study; two children withdrew from the vision therapy group (experimental), while one participant from the control group left due to relocation.

At baseline, there were no statistically significant differences in age or spherical equivalent refractive error between the two groups. The mean age was 6.10±0.84y in the experimental group and 6.50±1.15y in the control group (P=0.22). In respect to spherical equivalent (SE), the mean measurement for the right eye was 4.76±2.72 in the experimental group compared to 4.43±3.13 in the control group (P=0.73); for the left eye, the values were 5.09±2.89 and 4.47±2.78 in the experimental and control groups, respectively (P=0.49). The gender distribution included 5 males and 15 females in the experimental group, and 11 males and 9 females in the control group (P=0.05), which indicates a marginal difference in gender proportions. The hyperopic refractive error ranged from +2.00 to +13.00 D, and the astigmatic component varied from -0.5 to -5.00 D.

Given the clustered nature of the data, with measurements of BCVA taken from two eyes per individual. Right eye visual acuity values were 0.37±0.08 logMAR and 0.35±0.06 logMAR at baseline visit that changed to 0.14±0.08 logMAR and 0.26±0.09 logMAR in the experimental and control groups, respectively (P<0.001). For left eye, visual acuity values were 0.39±0.10 logMAR and 0.37±0.08 logMAR at baseline visit that changed to 0.14±0.08 logMAR and 0.27±0.10 logMAR in the experimental and control groups, respectively (P<0.001).

The margin model was utilized alongside the GEE method for analysis. All variables within both the experimental and control groups showed a non-normal distribution. Therefore, non-parametric tests were employed for comparisons between groups (Mann-Whitney test) and within groups (Wilcoxon test).

Table 1 presents the changes in CS for both groups from baseline to final visit after 4mo.

The baseline monocular CS was marginally higher in the control group compared to the experimental group (P=0.05). After treatment, the experimental group experienced an improvement in within-group monocular and binocular CS by 0.10 log in the right eye, 0.14 log in the left eye, and 0.07 log in both eyes (P<0.01 and P=0.03, respectively). In contrast,

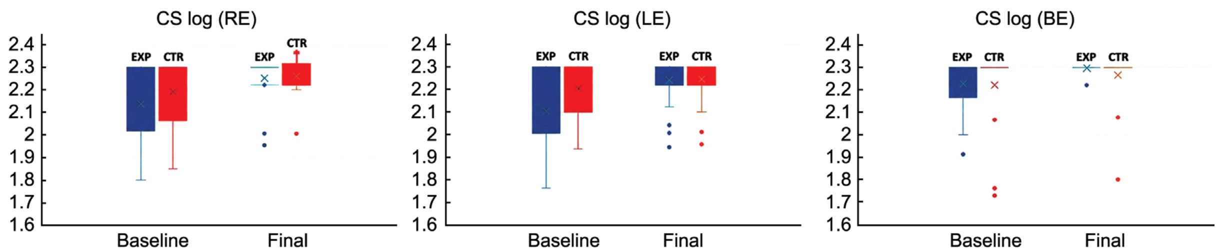

Figure 1 Contrast sensitivity (CS) changes from baseline to final visit EXP: Experimental group; CTR: Control group; RE: Right eye; LE: Left eye; BE: Both eyes.

Table 1 Intra- and inter-group comparisons of CS

Parameters	Experimental group	Control group	P^a
CS log (mean±SD)			
Baseline visit			0.05
RE	2.13±0.15	2.19±0.15	
LE	2.10±0.19	2.20±0.13	
Final visit			0.68
RE	2.23±0.13	2.26±0.09	
LE	2.24±0.12	2.25±0.10	
P^b	<0.01	0.49	
Baseline visit			0.68
BE	2.23±0.13	2.22±0.18	
Final visit			0.78
BE	2.30±0.02	2.26±0.12	
P^b	0.03	0.07	

[a]Inter-group comparison, [b]Intra-group comparison. RE: Right eye; LE: Left eye; BE: Both eyes; CS: Contrast sensitivity; SD: Standard deviation.

the control group did not exhibit a statistically significant improvement in either monocular (P=0.49) or binocular CS (P=0.07). Graphical displays of pairwise comparisons of CS from baseline to final visit are illustrated in Figure 1. The average rate of change in monocular CS was 0.05 over the 4-month follow-up.

DISCUSSION

Treating bilateral amblyopia presents significant challenges largely due to its complex etiological factors and the potential ineffectiveness of conventional therapies[17-18]. CS is an indicator of visual information processing in spatial perception[19-20]. In addition, compared to visual acuity, CS seems to have better correlation with subjective visual impairment and vision-related quality of life[21-22].

In this study, monocular CS, measured at five cpd, was slightly higher in the control group compared to the experimental group at baseline and showed no significant change following the four-month intervention period. In contrast, the experimental group exhibited a markedly greater improvement, with a statistically significant and accelerated rate of enhancement, approximately five times faster than that observed in the control group over the same duration. Furthermore, with regard to binocular CS, the experimental group achieved modest yet significant improvements, whereas the control group did not demonstrate any statistically meaningful change.

The improvement is not limited to statistically significance, but it is also clinically important because it can affect important aspects of visual performances. It also helps improve patients' ability to see better in glare and speed up visual processing. The improvement also has an important effect on a patient's quality of life[23]. In terms of clinical application, a patient without ocular disease may have good visual acuity but still complains of poor vision in some circumstances due to reduced contrast. According to previous studies, monocular CS visual perceptual learning can effectively enhance both monocular visual performance and binocular functions such as stereopsis[24]. In addition, CS, has been considered to be a predictive of visual performance in the real world. Enhanced CS will help the visual system to discriminate edges in various scenes, and effectively defines the boundaries of objects. The importance of CS testing lies in its ability to assess visual performance across the extent of spatial vision[8,25-26].

Perceptual learning develops with repeated exposure or practice with a stimulus, and training a visual task improves performance in an amblyopic eye including CS function[27-28]. Hebbian theory suggests that the strong concurrent activation of neuronal populations may enhance synaptic efficacy, thereby enabling neuroplastic changes within sensorimotor networks. These modifications are important in supporting the improvement of visual functions relevant to amblyopia treatment[29]. Recent research indicates that reduced CS is prevalent in amblyopic eyes, particularly at higher spatial frequencies. However, a subset of patients with more pronounced amblyopia exhibits reduced CS across the entire spectrum of spatial frequencies. This phenomenon is largely attributable to dysfunction within the parvocellular (P) and magnocellular (M) visual pathways[29-31].

Complete restoration of visual acuity after treating refractive amblyopia may not fully align other visual functions such as interocular CS. Jia *et al*[8] reported that following two years of treatment resulting in normalized visual acuity, children with refractive amblyopia exhibited persistent deficits in interocular CS, particularly at higher spatial frequencies. These findings support findings from our control group, which demonstrated that, despite enhanced visual acuity, patching therapy alone was less efficacious in improving CS. Incorporating active vision training enhances not only visual acuity and CS but also significantly improves foveal crowding in individuals with amblyopia[28]. While CS in bilateral amblyopia has not been examined in comparable studies, research involving children with unilateral amblyopia has demonstrated that the use of Eyetronix Flicker Glass, an anti-suppression method in which the lenses for both eyes alternately switch between opaque and transparent states, led to a significant improvement in CS at 6 cpd in the treatment group relative to the patching group after three months[32]. Employing a similar approach Yuan *et al*[33] reported that patients with unilateral amblyopia who received the intervention showed improvements across both low and high spatial frequency ranges, whereas those treated with occlusion therapy demonstrated gains limited to low spatial frequencies.

Visual deprivation induces atrophic changes in the layers of the lateral geniculate nucleus (LGN), leading to functional deficits characteristic of amblyopia, including reduced CS, diminished visual acuity, and impaired stereopsis. Conversely, targeted visual stimulation has the potential to promote neuroplasticity by enhancing existing neural pathways and facilitating the formation of new synaptic connections[34-35]. Repeated activation of the M and P pathways has been shown to increase grey matter volume and improve spatial-temporal processing impairments[36].

To our knowledge, the present study represents the first prospective, randomized clinical trial to assess the efficacy of active vision therapy in enhancing CS in patients with bilateral amblyopia. Neuroplasticity supports the effectiveness of active vision therapy, with evidence showing that such interventions facilitate the formation of new neural connections in both primary and extrastriate visual cortices, in particular by reducing suppression in amblyopic individuals[29,37]. Another strength of the study lies in its focus on a homogeneous amblyopia subtype, thus minimizing potential confounding variables.

One of the main challenges in conducting vision therapy research is the lack of standardized treatment protocols, due in part to the absence of clearly defined criteria for classifying treatment modalities—an issue insufficiently addressed in the existing literature[38-39]. The recruitment of participants with bilateral refractive amblyopia proved to be particularly time-consuming. Further prospective, controlled studies are warranted to systematically compare the therapeutic response across different amblyopia subtypes and to evaluate the efficacy of active vision therapy relative to conventional interventions. Better attention to these methodological differences may facilitate the development of more targeted and effective treatment protocols for amblyopia management.

There are some limitations of this study, including: since 4-month follow-up is relatively short for amblyopia studies and it is better to consider a longer follow-up period in the future studies. Due to the lack of cases with binocular amblyopia, the gender distribution of cases in the groups was unequal, although the difference was not significant, but this can be considered as a potential confounder. In addition, multicenter studies will help to better conduction of similar researches, to find more such cases.

In conclusion, active monocular vision training performed under binocular conditions resulted in significant and faster improvements in CS among children with bilateral refractive amblyopia. Furthermore, the findings suggest that CS should be regarded as a key outcome measure in the evaluation of treatment efficacy.

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