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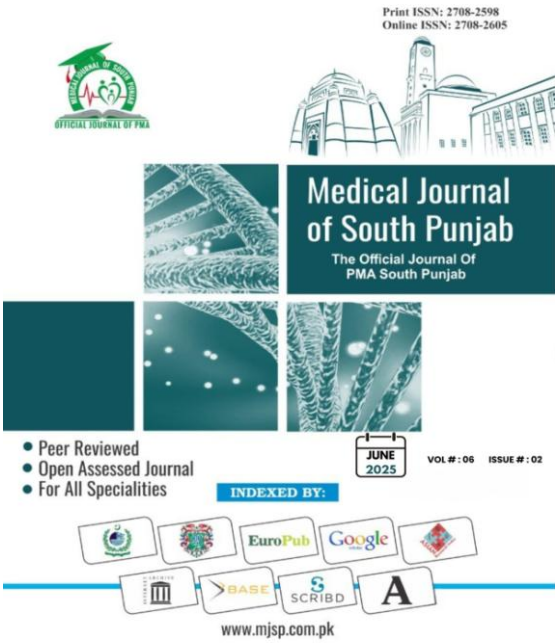

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Comparison of Mobile Software Therapy Versus Patching Therapy in Patients of Amblyopia

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ABSTRACT

Objective: To compare visual acuity and stereoacuity improvement in anisometropic amblyopic patients undergoing software versus patching therapy.

Methods: The study involved 44 children aged 6-12 years with unilateral mild to moderate anisometropic amblyopia (≥0.2 logMAR BCVA difference). Participants already undergoing two months of patching therapy were in the Patching Group; other preferring software therapy formed the Software Therapy Group. Visual and stereoacuity were assessed at baseline, 1st, 3rd, and 6th months.

Results: At the 6-month, both software therapy (0.27 ± 0.19, $p < 0.001$) and patching therapy (0.27 ± 0.11 $p = 0.003$) significantly improved visual acuity. The Software Therapy Group achieved higher mean VA (0.32 ± 0.16) than the Patching Therapy Group (0.29 ± 0.11), with a significant difference ($p = 0.022$). Stereoacuity also significantly improved in both groups: Software Therapy (0.50 ± 0.29, $p < 0.001$) and Patching Therapy (0.43 ± 0.17, $p = 0.002$). Compliance favored software therapy ($p < 0.001$), indicating potential benefits over patching therapy for anisometropic amblyopia.

Conclusion: Binocular software therapy excelled in improving visual and stereoacuity for mild to moderate anisometropic amblyopia, especially in younger children aged 6-9 years.

Keywords: Visual Acuity, Stereoacuity, Best-Corrected Visual Acuity, Software Therapy, Patching Therapy, Amblyopia

1. INTRODUCTION

Amblyopia, colloquially known as "lazy eye," derives its name from the Greek words for "dull sight" or "blunt sight."[1] This neurodevelopmental visual disorder primarily manifests as a decrease in best-corrected visual acuity (BCVA) and binocular diplopia, typically occurring in one eye but occasionally affecting both.[2] Despite extensive research, no organic cause has been identified, with its onset attributed to prolonged periods of insufficient visual experience during early childhood. [3]Common contributing factors include strabismus, refractive errors like anisometropia, and visual deprivation.[4, 5]

The pathophysiology of amblyopia involves cortical developmental disorders stemming from abnormal visual inputs to each eye during the critical period of cortical plasticity.[6]This leads to preferential processing of one eye over the other, resulting in functional deficiencies such as changes in binocular function, loss of stereopsis, and various perceptual distortions. The severity of vision loss ranges from mild to severe, with legal blindness being the extreme end of the spectrum.[7]

Individuals with amblyopia often experience compromised motor skills, including hand-eye coordination, focusing, grabbing, and stability, which are attributed to ocular motor dysfunction and fixation instability.Globally, amblyopia affects around 2-3% of the population, with children under 15 comprising a significant portion. In regions like Pakistan, where nearly half of the population falls within this age group, amblyopia ranks as a leading cause of unilateral visual impairment among adults under 60.[8]

Different kinds of amblyopia exist, including strabismic, deprivation, and refractive amblyopia, with the latter being the most prevalent. Anisometropic amblyopia, a subtype of refractive amblyopia, imposes high financial and psychological burdens on affected children and their families.[0] However, prompt detection and treatment are crucial for reversing visual loss, emphasizing the importance of early screening initiatives.[9]

Treatment options for amblyopia encompass a wide array of interventions, ranging from surgical corrections for underlying causes to non-invasive methods like refractive correction and patching therapy.[10] Patching therapy, considered the gold standard, involves covering the stronger eye to stimulate the weaker one. However, low compliance remains a significant challenge, necessitating alternative approaches like atropine penalization and dichoptic therapy with video games.[11]

Atropine penalization, involving the application of atropine drops to the healthy eye, has emerged as a viable alternative to patching, particularly in cases of compliance issues. [12] [13] Dichoptic therapy with video games represents a novel approach to amblyopia treatment, leveraging technology to provide binocular stimulation and encourage collaboration between the eyes.Recent advancements in mobile software have further expanded treatment options for amblyopia, offering accessible and engaging interventions for children. These software-based therapies, often incorporating elements of gamification, focused on enhancing visual abilities such as sharpness of vision, sensitivity to contrast, and depth perception.[14]

Dichoptic therapy with video games employs distinct visual stimuli presented to each eye, encouraging collaboration and equal contrast development. This binocular approach has shown promising results in improving various aspects of visual function in children with amblyopia.

In conclusion, amblyopia poses a significant public health challenge worldwide, necessitating comprehensive screening programs and innovative treatment modalities.

[15]With advancements in technology and ongoing research, there is hope for enhanced accessibility, efficacy, and patient adherence in amblyopia management, ultimately improving visual outcomes and quality of life for affected individuals.[16]

This clinical trial addresses the growing role of technology in medical interventions, and seeks to evaluate if mob ile software therapy can provide a viable alternative or complement to conventional patching method. The study will assess visual acuity outcomes, stereoacuity, and compliance of the patients, contributing valuable insights to optimize amblyopia management strategies.

2. METHODOLOGY

The Superior University Ethics Committee granted ethical approval, which followed the declaration of Helsinki's tenant. A quasi-experimental study was conducted from Decemeber 2023 – May 2024.

44 participants were enrolled in this quasi-experimental study from the eye departments of Sardar Bibi Hospital in Ferozwala and Al Habib Eye Trust Hospital in Shahdara. Children with unilateral mild to moderate anisometropic amblyopia, aged 6 to 12 years, who had been using optical correction for at least two months and whose visual acuity in the amblyopic eye was less than 0.1 logMAR , were included in the study. Children with neurological abnormalities, nystagmus, strabismus, history of ocular surgery, or refusal to participate were among the exclusion criteria. Twenty-two of the children in the study had patching therapy, in which the good eye was covered for two hours every day while they did tasks like writing and reading. The remaining twenty-two kids received amblyopia treatment with Amblyo-vision, a mobile software therapy program.

All children received a complete eye check-up, which involved examining the anterior segment of the eye using a slit lamp and the posterior segment of the eye using an indirect ophthalmoscope, conducted by an ophthalmologist, to detect any related eye conditions or issues.Visual acuity was tested by using logMAR chart at 4-meters. Then wet retinoscopy was done and at the day of PMT BCVA tested again. Binocular assessment was done by using worth-four d ot tes t, and stereopsis was tested by sing TNO test. Then VA and stereoacuity was measured in three follow ups after taking the baseline measurements. At First month, 3rd month and at 6th month.

The data exhibited a normal distribution as confirmed by the Shapiro-Wilk Test. As a result, parametric statistical tests were employed. The significance level was set at $p < 0.05$. An independent t-test was utilized to compare the mean values of visual acuity (VA) and stereoacuity between two therapy groups. A paired t-test was conducted to compare dependent paired variables within each group. To evaluate improvements over three follow-up sessions, a repeated measures ANOVA test was employed for dependent variables. Pearson correlation was used to assess relationships between independent and dependent variables within each group. Additionally, an independent samples t-test was employed to compare compliance scores between the two groups.

3. RESULTS

The study included 44 children diagnosed with mild to moderate anisometropic amblyopia. These children were equally divided into two groups: one treatment group which received software therapy and one control group received patching therapy. Each group was consisted of 22 children.

Table-2: Demographic and baseline characteristics of the participants

Characteristics	Total Participants (n=44)	Software Therapy group (n=22)	Patching Therapy (n=22)
Demographics			
Age Group (years)			
6-9 years	30 (68.2%)	15 (68.2%)	15(68.2%)
10-12 years	14 (31.8%)	7 (31.8%)	7(31.8%)
Gender			
Male	28 (63.6%)	13 (46.4%)	15 (54.5%)
Female	16 (36.4%)	9 (53.6%)	7 (45.5%)
School going children			
Yes	34 (75.0%)	14 (63.6%)	18 (81.8%)
No	10 (15.0%)	8 (36.4%)	4 (18.2%)
Amblyopia Characteristics			
Baseline VA (logMAR)			
0.1-0.3	14 (31.8%)	6 (27.3%)	8 (36.4%)
0.4-0.6	30 (68.2%)	16 (72.7%)	14 (63.6%)
Baseline Stereoacuity (Seconds of arc)			
480	12 (27.3%)	6 (27.3%)	6 (27.3%)
240	22 (45.5%)	10 (45.5%)	10 (45.5%)
120	10 (27.3%)	6 (27.2%)	4 (27.2%)
60	0 (0.00%)		
40	0 (0.00%)		
Severity of Amblyopia			
Mild	14 (31.8%)	5 (22.7%)	9 (40.9%)
Moderate	30 (68.2%)	17 (77.3%)	13 (59.1%)
Types of Anisometropia			
Myopic	21 (47.7%)	11 (50.0%)	10 (45.5%)
Hyperopic	14 (31.8%)	7 (31.8%)	7 (31.8%)
Astigmatism			
WTR (With-the-rule)	15 (34.1%)	8 (36.4%)	7 (31.8%)
ATR (Against-the-rule)	18 (40.9%)	9 (40.9%)	9 (40.9%)
Oblique	11 (25.0%)	5 (22.7%)	6 (27.3%)
Ocular History			
Family history of amblyopia			
Yes	14 (31.8%)	5 (22.7%)	9 (40.9%)
No	30 (68.2%)	17 (77.3%)	13 (59.1%)
Socioeconomic and Educational Factors			
Parental Education Level			
High school	12 (27.3%)	6 (27.3%)	6 (27.3%)
College	20 (45.5%)	10 (45.5%)	10 (45.5%)
Graduate	12 (27.3%)	6 (27.3%)	6 (27.3%)
Household Income Level			
Low	10 (22.7%)	5 (22.7%)	5 (22.7%)
Middle	22 (50.0%)	11 (50.0%)	11 (50.0%)
High	12 (27.3%)	6 (27.3%)	6 (27.3%)

Table-2:Comparison of BCVA and stereoacuity of amblyopic eye in software therapy and patching therapy groups.

Vision Measure	Software Therapy	Patching Therapy	p-value
At baseline	0.45 ± 0.20	0.51 ± 0.21	< 0.001
At 6th month	0.27± 0.19	0.22± 0.11	
Mean VA improvement	0.32 ± 0.16	0.29 ± 0.11	
At baseline	0.34 ± 0.10	0.39 ± 0.23	< 0.001
At 6th month	0.27 ± 0.07	0.23 ± 0.12	
Mean VA improvement	0.35 ± 0.12	0.26 ± 0.10	
At baseline	0.56 ± 0.16	0.57 ± 0.13	< 0.001
At 6th month	0.38 ± 0.09	0.33 ± 0.12	
Mean VA improvement	0.27 ± 0.07	0.23 ± 0.10	
At baseline	0.71 ± 0.32	0.68 ± 0.27	< 0.001
At 6th month	0.50 ± 0.29	0.43 ± 0.17	
Mean VA improvement	0.59 ± 0.21	0.37 ± 0.14	
At baseline	0.52 ± 0.17	0.57 ± 0.16	< 0.001
At 6th month	0.27 ± 0.08	0.35 ± 0.08	
Mean stereoacuity improvement	0.29 ± 0.09	0.23 ± 0.05	
At baseline	0.65 ± 0.12	0.59 ± 0.13	< 0.001
At 6th month	0.21 ± 0.08	0.32 ± 0.11	
Mean stereoacuity	0.31 ± 0.10	0.29 ± 0.13	

improvement			

Table 1. showed the descriptive analysis of baseline characteristics; the age distribution: 68.2% aged 6-9 years, 31.8% aged 10-12 years. Gender: 63.6% male. School attendance: 75.0% attending school. Baseline visual acuity: 31.8% had 0.1-0.3 logMAR, 68.2% had 0.4-0.6 logMAR. Baseline stereoacuity: varied. Amblyopia severity: 31.8% mild, 68.2% moderate. Anisometropia types: 38.1% hyperopic, 47.7% myopic. Family history: 31.8% had family history. Socioeconomic factors: varied educational levels and household income.

Table 2. shows the mean and SD values for VA and stereo acuity in software and in patching therapy group. Independent sample t test was utilized to compare the mean values of both groups and paired-t test was utilized to compare the baseline and 6^{th} month improvement in visual functions in each group. So at baseline, both software therapy and patching therapy show similar levels of visual acuity, with software therapy having a slightly higher mean logMAR value (0.32 vs. 0.29). There was significant difference ($p = 0.022$), demonstrating that patients undergoing software therapy had better initial visual acuity on average. After 6 months, there is a notable improvement in visual acuity for both therapies. However, software therapy shows a greater reduction in logMAR value compared to patching therapy (0.22 vs. 0.27). There was significant difference ($p < 0.003$), suggesting that software therapy leads to greater improvement in visual acuity over the 6-month period.

Similar to the overall visual acuity findings, at baseline, software therapy demonstrates a slightly lower mean logMAR value compared to patching therapy (0.34 vs. 0.39), with a statistically significant difference ($p < 0.001$).After 6 months, both therapies result in improvement in visual acuity. However, software again shows a greater improvement in logMAR value compared to patching therapy (0.27 vs. 0.23), with asignificant difference ($p < 0.002$).

At baseline, there is a smaller difference in mean logMAR values between software therapy and patching therapy compared to mild amblyopia cases, but it remains statistically significant ($p<0.001$).After 6 months, both therapies lead to improvements in visual acuity. Software therapy demonstrating a more substantial improvement in logMAR value compared to patching therapy (0.38 vs. 0.33). Significant difference was ($p < 0.001$).

At baseline, software therapy again showed a lower mean log seconds of arc value than patching therapy (0.51 vs. 0.75), with a significant difference ($p < 0.001$).After 6 months, both therapies result in improvements in stereoacuity. Interestingly, software therapy lead to a much greater improvement in log seconds of arc compared to patching therapy (0.32 vs. 0.81). The significant difference was ($p < 0.002$), showing that software therapy is more effective in improving stereoacuity over the 6-month period.

The study evaluated the efficacy of software and patching therapies in improving visual acuity and stereoacuity among children aged 6 to 12 years. Results revealed significant age-related differences in therapy effectiveness, with younger children consistently exhibiting stronger correlations between therapy and improvement. For the 6-9 years age group, software therapy demonstrated notably higher correlations with visual acuity improvement ($r = 0.85$ to 0.95) compared to patching therapy ($r = 0.70$ to 0.80) across all durations. Similarly, in stereoacuity improvement, the 6-9 years age group showed stronger correlations with software therapy ($r = 0.88$ to 0.93) compared to patching therapy ($r = 0.65$ to 0.75). Older children (10-12 years) displayed lower

correlations overall, though software therapy still outperformed patching therapy. These findings suggest that younger children respond more favorably and rapidly to both software and patching therapies, with software therapy yielding greater and more consistent improvements in visual acuity and stereoacuit y.

Table:3 Compliance score differences between the two therapies.

Compliance	Group	Mean	SD	t-value	Sig. (two side)
Children's compliance behavior	Patching Software	2.53 4.44	0.59 0.42	-20.93 4	0.000
Children's compliance attitude	Therapy Software	2.23 4.08	0.43 0.61	-19.79 7	0.000
Parent's compliance behavior	Therapy Software	2.62 4.33	0.53 0.45	-18.66 4	0.000
Parent's compliance attitude	Therapy Software	2.83 4.65	0.65 0.43	-16.99 0	0.000

Table 3. showing the children in the Patching Group demonstrated significantly lower compliance behavior (M = 2.53, SD = 0.59) than the Software group (M = 4.44, SD = 0.42), $p < 0.001$.Children in the Therapy group exhibited significantly less favorable compliance attitudes (M = 2.23, SD = 0.43) than those in the Control group (M = 4.08, SD = 0.61), $p < 0.001$.Parents in the Therapy group displayed significantly lower compliance behavior (M = 2.62, SD = 0.53) than those in the Patching Group (M = 4.33, SD = 0.45), $p < 0.001$.Parents in the therapy group held significantly less positive compliance attitudes (M = 2.83, SD = 0.65) than those in the Patching Group, $p < 0.001$.

4. DISCUSSION

A retrospective nonrandomized clinical trial study was conducted on unilateral amblyopic children aged between 3 – 12 years. Patients were allocated into two groups. The first group received simultaneous treatment, involving both glasses and patching therapy at the initial visit. The second group underwent sequential treatment, starting with glasses alone at the first visit and then adding patching therapy at the second visit. This study found that the median improvement in visual acuity of the amblyopic eye was comparable between the simultaneous treatment group (median improvement of 0.40 logMAR with an interquartile range [IQR] of 0.56 to 0.30) and the sequential treatment group (median improvement of 0.40 logMAR with an IQR of 0.52 to 0.27).

The sequential treatment group demonstrated superior improvement in stereoacuity (median 5.12, IQR 4.00–7.51) compared to the simultaneous treatment group. This study involved 38 children aged 3–10 with unilateral amblyopia, with assessments conducted at baseline and after one month. Both groups showed significant improvement in best-corrected visual acuity (BCVA) after 30 days of therapy (case: $P = 0.003$, control: $P < 0.001$), but no significant difference was found between the groups ($P = 0.54$). Similarly, stereoacuity improved significantly in both groups ($P < 0.001$), with no significant difference between them before and after therapy. Children in both groups played games for approximately six hours over one month, with compliance rates of 86.5% (therapy group) and 72% (control group). No significant difference was found between the two therapies.

Another randomized study on 40 anisometropic amblyopic children (ages 2–12) compared Occlu-tab therapy to conventional patching. Both groups showed significant improvement in visual acuity (VA) at weeks 6, 7, and 8 ($P < 0.001$). However, the Occlu-tab group exhibited superior BCVA improvement (0.33 ± 0.25) compared to the patching group (0.14 ± 0.18) after eight weeks. Similarly, a study involving children aged 5–16 compared

software-based therapy to patching, finding significant VA improvements in both groups (software: 0.32 ± 0.11 logMAR, $P < 0.001$; patching: 0.27 ± 0.19 logMAR, $P < 0.001$), with no significant difference between them. Another study of 52 amblyopic children divided into patching and software therapy groups found significant BCVA improvement in both at one month ($P < 0.001$), with a higher effect size in the software group at six months (0.54 vs. 0.48).

In our study, two groups—software therapy (1 hour/day) and patching therapy (2 hours/day)—were compared, with VA and stereoacuity measured at follow-ups. Software therapy showed greater VA improvement (0.32 ± 0.19 vs. 0.29 ± 0.11, $P < 0.022$) and better stereoacuity (0.59 ± 0.21 vs. 0.37 ± 0.14) compared to patching. Children aged 6–9 exhibited stronger correlations with VA (*r* = 0.85–0.95) and stereoacuity (*r* = 0.88–0.93) improvements in the software group than in the patching group (*r* = 0.70–0.80 and *r* = 0.65–0.75, respectively). Older children (10–12) had lower correlations, though software therapy still performed better. Compliance was significantly higher in the software group ($P < 0.001$), aligning with previous findings that younger children show greater improvement with active therapies.

5. CONCLUSION

The study concluded that binocular software therapy showed superior results than patching therapy for enhancing visual acuity and stereoacuity in children with mild to moderate anisometropic amblyopia. Specifically, binocular software therapy appears to be a promising treatment option for addressing mild to moderate cases of anisometropic amblyopia, particularly among children aged 6 to 9 years old.

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