

Visual Outcomes of Amblyopia Therapy

Melissa Anne M. Santos, MD, Marissa N. Valbuena, MD, MHPed, and Andrea Kristina F. Monzon-Pajarillo, MD

Department of Ophthalmology and Visual Sciences
Philippine General Hospital
University of the Philippines Manila
Ermita, Manila

Correspondence: Melissa Anne M. Santos, MD
Email: melissasantosmd@yahoo.com

Disclosure: No financial assistance was received for this study. The authors have no proprietary or financial interest in any products used or cited in this study.

ABSTRACT

Objective: To determine the visual outcome of amblyopia treatment and describe the relationship between age of onset and consult, compliance as measured by a patch diary, amblyopia subtype, and severity with the final visual outcome.

Methods: Thirty-two consecutive, newly-diagnosed cases of amblyopia, aged 3-8 years on initial consult, with no history of prior amblyopia treatment, were included. Patching was done based on current AAO recommendations and patients were followed up monthly for 6 months. Treatment success was defined as best corrected visual acuity (BCVA) better than 20/30 (0.17LogMAR), or a 3-line improvement from baseline, or stable isoacuity for at least 3 months. Treatment failure was defined as no improvement of BCVA after 3 months of occlusion therapy or a regression of 2 lines. Descriptive and correlation statistics were performed comparing age of onset and consult, amblyopia subtype, severity, and compliance with the main outcome measure of BCVA at 6 months.

Results: Sixteen (50%) attained treatment success. Patients seen earlier (age 2-5 years) had higher rates of success (75%) than those seen later (age 6-8 years) (35%). A moderately strong negative correlation ($r=-0.48$, $p=0.01$) existed between severity of amblyopia and final BCVA at 6 months. Overall compliance to patching was $88\pm 18\%$, with good compliance in the success group (92%) compared to fair compliance in the failure group (84%) and a moderate correlation between compliance and BCVA ($r=0.37$, $p=0.05$).

Conclusion: Treatment success was related to severity, compliance, and younger age of treatment. In the presence of good compliance, severity was a strong prognostic variable.

Keywords: Amblyopia, Patching, Compliance, Sensory Deprivation, Anisometropia, Occlusion therapy

Amblyopia is defined as a unilateral or bilateral reduction of best corrected visual acuity (BCVA) that cannot be attributed to the effect of any structural abnormality of the eye¹. It is objectively measured as a BCVA poorer than 20/40 (0.30 LogMAR) bilaterally or a difference in BCVA of 2 or more lines (0.2 LogMAR) using a Snellen chart or its equivalent. Common causes of amblyopia are strabismus, anisometropia, or high bilateral refractive error and visual deprivation.^{2,3}

The incidence of amblyopia is reportedly at 3.5% worldwide, 1.6% - 3.5% in the United Kingdom and 2.0% - 2.5% in the United States.^{1,4} Its prevalence varies in different ethnic groups. Amblyopia was detected in 2.6% of Hispanic/Latino children and 1.5% of African-American children.⁵ The overall prevalence in Singapore was 0.35% with no racial difference among Chinese (0.34%), Malays (0.37%), and Indians. The anisometropic form was most commonly seen in several studies.^{6,7,8} The outcomes of amblyopia showed varied results, with some indicating that visual acuity deteriorated more in patients with strabismic amblyopia, and others with anisometropic amblyopia compared to patients with the other types of amblyopia.^{5,6,7,9}

The Amblyopic Treatment Study (ATS) divided amblyopic patients into two groups based on severity. Mild to moderate amblyopia is characterized by a visual acuity of 20/40 - 20/80 (0.3 -0.6 LogMAR) while severely amblyopic patients have a visual acuity of 20/100 (0.7 LogMAR) to 20/400 (1.3 LogMAR).^{2,3} The aim of amblyopia treatment is to improve visual acuity and to prevent or reverse vision impairment.^{1,2} With timely intervention, the reduction in visual acuity caused by amblyopia can be completely or partially reversed.^{10,11} The ATS showed that more than 75% of amblyopic children less than 7 years of age had significant improvement in their BCVA to 20/30 [0.176 LogMAR] or better after treatment.¹² All patients with amblyopia should, therefore, be treated and the caregiver educated.

The principles of amblyopia treatment are as follows: eliminate any obstacle to vision, correct refractive error, force the patient to use the poorer eye by penalization with atropine or by patching of the better eye,¹² and lastly, surgery to treat the cause of the amblyopia, if applicable. These options may be used alone or in combination depending on the nature of amblyopia.¹³

The ATS 2A showed that patients with severe amblyopia had an improvement of 4.7 lines in those

patched full time and for at least 6 hours.¹⁴ ATS 2B showed a 2.4 line improvement in those with mild to moderate amblyopia when patched for 2-6 hours.¹⁵ A similar improvement was obtained with penalization with atropine. Both studies were conducted in the 3-7 year age group.^{1,2,11}

The American Academy of Ophthalmology (AAO) preferred practice pattern²-recommended schedule of treatment and follow-up was age-specific, with the longer follow-up periods for older patients. For the 2- to 8-year-old, follow-up ranged from 3-16 weeks when on high percentage occlusion (>6 hours a day) and 2 to 6 months when on low percentage occlusion (<6 hours). An average duration of treatment of 6 to 9 weeks was sufficient to result in improvement of vision.¹⁵

Reported rates of compliance for patching vary widely from 49 to 87%.¹² Low compliance to the patching regimen was identified as a major hindrance to the success of treatment.¹⁶ Compliance was found to be the most important factor affecting visual outcome⁷. The use of a patch diary was found to correspond well with an electronic Occlusion Dose Monitor (ODM).¹⁷ This allowed researchers to use the patching diary as an objective means to measure compliance. Though useful for recording purposes, diaries filled out by the patients were not enough to increase the overall concordance and compliance.¹⁸ Parental supervision and implementation increased the compliance to patching and recording on the diaries.^{19-21.}

Despite its worldwide prevalence, there is no published Filipino data on the visual outcomes following treatment. This data can guide practitioners in the treatment and follow-up of Filipino amblyopic patients.

Thus, this study determined the visual outcomes of amblyopia treatment with patching measured as best corrected visual acuity (BCVA). It also correlated the following factors with improvement in vision: age of onset, age of initial consult, amblyopia subtype or diagnosis, severity of amblyopia, and compliance using a patch diary.

METHODOLOGY

This was a descriptive study of newly diagnosed cases of amblyopia seen at the Pediatric Ophthalmology and Strabismus Clinic of the Philippine General

Hospital from May 2010 to December 2010. Included were all patients diagnosed with amblyopia between 3 to 8 years on initial consult, without previous amblyopia treatment, and whose parents gave consent to participate in the study. Patients diagnosed with delayed visual maturity (DVM) or global developmental delay (GDD) were excluded.¹⁶

This study was approved by the hospital ethics review board. Parental consent forms were written in both English and Filipino and were signed by parents of the participants. Study procedures conformed to the tenets of the Declaration of Helsinki. Patient data was kept confidential and identity was kept anonymous.

Baseline Examination

On initial consult, baseline data such as personal information, age of onset, gender, baseline BCVA (in LogMAR and Snellen), full cycloplegic refraction, ocular alignment, physical examination, diagnosis, underlying cause, amblyopia severity, and laterality were obtained. Visual acuity test was performed based on the level of literacy: LEA charts for those unable to read, and Snellen charts for the literate. Results of either tests were converted to LogMAR units.²⁰ All examinations were performed by a single clinician.

The patients were classified according to their amblyopia subtype:

1. Strabismic amblyopia – associated with strabismus where there was a strong fixation prevalence for the dominant eye and constant suppression of the non-dominant eye that was often deviated;
2. Refractive amblyopia – anisometropia or ametropia of 1D or greater in spherical equivalent or 1.5D or greater difference in astigmatism and absence of strabismus or ocular pathology;
3. Sensory deprivation amblyopia - a known or documented cause of sensory deprivation.¹⁸⁻²⁰

The severity of amblyopia was classified as mild/moderate with a BCVA between 20/40 and 20/80 (0.3-0.6 LogMAR) and severe with a BCVA of 20/100 – 20/400 (0.7-1.3 LogMAR).²

Intervention

The patients were prescribed eyeglasses, if needed. They were provided with monthly patching diaries where the eye to be patched and the prescribed number of hours were written. The better eye was

patched and the patching hours logged in the patching diary by the parents to be brought back at the next follow-up visit. Washable hand-sticked patches were given and new sets of patches were provided on follow-up. Treatment given was based on the AAO preferred practice pattern.²

Follow-up Visits

Monthly follow-up visits were conducted for 6 months. To enhance follow-up and prevent patient drop out, follow-up dates were agreed upon both by the examiner and the caregiver or on the same day as the patient's scheduled visit at the subspecialty clinic. At each visit, BCVA was measured first in the amblyopic eye, then in the fellow eye. Ocular alignment and short acting cycloplegic refraction were measured. Patching diaries were submitted and compliance to patching regimen was recorded with caregiver feedback. On follow-up dates when the patching diaries were not brought in by the caregiver, compliance was based on caregiver recall and recorded. Reasons for the absent diaries were noted.

In cases where there was no further improvement in BCVA of the amblyopic eye after 3 months of good compliance to occlusion with or without spectacle correction, or if there was regression in vision not corrected by a change in spectacles (BCVA), the patients were re-evaluated. If warranted, change in prescription lenses were given or surgical intervention suggested.

Outcome Measures

Treatment success was defined as a BCVA of the amblyopic eye of 20/30 (0.17 LogMAR) or better, or a 3-line improvement from baseline after 6 months, or stable isoacuity maintained for at least 3 months with ongoing treatment.⁴

Treatment failure was defined as the BCVA of 20/50 or worse, 0-2 lines of improvement of BCVA in patients after 3 months of occlusion of greater than 75% of all waking hours or a regression in BCVA of 2 lines.⁴

Percent compliance to treatment was defined as:

$$\frac{\# \text{ Hours of actual occlusion per month}}{\# \text{ Hours prescribed occlusion per month}} \times 100\%$$

Compliance was classified as "good" if >90%, "fair" if 70%-90%, and "poor" if < 70% or if with irregular entries in the diary.

Analysis of Data

Statistical analyses were performed using SPSS Windows 17.0 (SPSS Inc; Chicago, IL). Descriptive statistics were performed on the baseline data and Spearman's correlation was used to analyze relationships between compliance, age of onset, age of diagnosis, amblyopia subtype, and severity with the BCVA at the end of the 6 month treatment period. Individual progression of BCVA were plotted and observed for trends.

RESULTS

32 participants were included in the study, 19 females (59.4%) and 13 males (40.6%). Age of consult ranged from 3 to 8 years with a mean of 6 years and a mode of 8 years (29%). Recorded age of onset ranged from 2 to 6 years with a mean of 4.6 years.

All patients followed up for at least 6 months. No patient dropped out of the study. Patients who were seen and treated earlier (age 3-5 years) had higher rates of success (75%) compared to those treated later (25%) (Table 1). Average compliance between the 2 groups was similar and not statistically significant.

All strabismic patients, 67% of sensory, and 25% of refractive had severe amblyopia (Table 2). A moderate linear correlation ($r=0.39$, $p=0.05$) existed between the subtype and severity of amblyopia.

Table 1. Treatment Outcome Based on Age

Age of Consult	n (%)	Outcome		Compliance
		Success	Failure	
3-5	12 (37.5%)	75%	25%	87.9%
6-8	20 (62.5%)	35%	65%	88.5%

Table 2. Amblyopia Subtypes, Severity, Outcome, and Compliance in the Study Population.

Subtypes	Severity		Outcome		Compliance
	Mild-Moderate	Severe	Success	Failure	
Refractive n=20 (63%)	15 (75%)	5 (25%)	11 (55%)	9 (45%)	92.3% (good)
Sensory n=9 (28%)	3 (33%)	6 (67%)	2 (22%)	7 (78%)	81% (fair)
Strabismic n=3 (28%)	0 (0%)	3 (100%)	3 (100%)	0 (0%)	83.3% (fair)
Total	18 (56%)	14 (44%)	16 (50%)	16 (50%)	

Spearman's correlation between diagnosis and severity: $r=0.39$, $p=0.05$.

Table 3. Treatment Outcomes in the 3 Subtypes of Amblyopia

Outcome	Subtypes			Severity		Compliance
	Sensory	Strabismic	Refractive	Mild-Moderate	Severe	
Success (n=16)	2 (12%)	3 (19%)	11 (69%)	11 (69%)	5 (31%)	92.2% ("good")
Failure (n=16)	7 (44%)	0%	9 (56%)	7 (44%)	9 (56%)	84.4% ("fair")
Change 1-2 lines (n=7) (44%)	3 (43%)		4 (57%)	3 (43%)	4 (57%)	
No change (n=9) (56%)	4 (44%)		5 (56%)	4 (44%)	5 (56%)	

Half of the patients in this study achieved treatment success. Majority (69%) were diagnosed with refractive amblyopia and there was a good compliance to treatment in this group (Table 3). In the treatment failure group, 56% had refractive amblyopia while 44% had sensory amblyopia with fair compliance to patching. 44% had improvement of 1-2 lines in BCVA and 56% had no change. More than half (56%) of the patients in the treatment failure group were diagnosed with severe amblyopia (Table 3). There was a moderately strong negative correlation ($r=-0.48$, $p=0.01$) between severity of amblyopia and improvement of BCVA. No patient had a regression in BCVA. Figure 1 shows the change in average BCVA of an amblyopia eye at 6 months.

Overall compliance to patching in this study was $88 \pm 18\%$. Patients in the treatment success group had a 92% compliance compared with 84% in the treatment failure group. There was a moderate correlation between compliance and change in BCVA ($r=0.37$, $p = 0.05$). Reasons for poor compliance to patching were the child's refusal to patch (44%), inability to patch while the child was in school (31%), fear of patching the wrong eye (16%), and fear of the child being teased (9%).

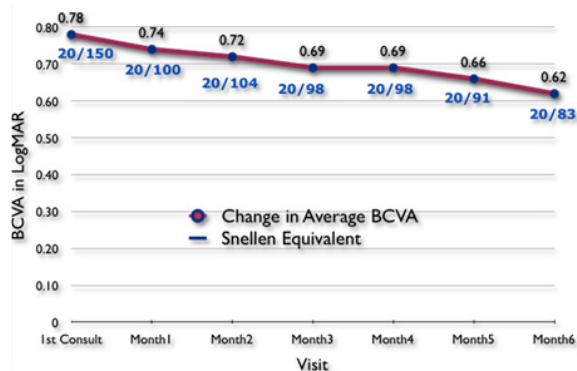


Figure 1. Change in average BCVA of an amblyopic eye at 6 months.

Ten patients had irregular reports on their patching diary or had follow-ups without their diaries. Of the 10, 4 participants did not have their diaries in 2 non-consecutive follow-up months. The other 6 had one follow-up visit without a diary. This resulted in a total of 18 follow-up visits out of the total 192 visits (32 participants x 6 follow-ups), or 9.3%, wherein the patching diaries were absent. The most common reason for not having the diaries on follow-up was forgetting to bring the diary (60%). Other reasons included losing or misplacing the diary and a damaged diary.

There were no reported allergies or skin intolerance to the patches.

DISCUSSION

For more than two hundred years, occlusion of the better eye has been used successfully in the treatment of amblyopia.^{1, 2} This study determined the factors that affected the visual outcomes and described how they affected BCVA after 6 months of treatment.

Subtype

Prospective studies in Ethiopia and New Delhi²³⁻²⁴ showed that strabismic amblyopia was more common than refractive or sensory amblyopia. Similar to our results, other studies²⁵⁻²⁶ demonstrated that refractive amblyopia was more common than either strabismic or sensory amblyopia. In a chart review by Tamayo (Tamayo C & Valbuena MV. Amblyopia profile at the Philippine General Hospital, 2010, unpublished data), sensory amblyopia was the most common in all pediatric age groups. They included consults seen over 3 years and even those with visual deprivation type of amblyopia who had already undergone intervention and given the best correction.

Age

The age of onset determined through caregiver recall, indicated that sensory and strabismic amblyopia were detected earlier due to noticeable eye findings, such as ocular misalignment or a dense opacity. Most patients with anisotropic amblyopia presented as orthophoria with eyes that appeared normal to the parent.¹⁸ This resulted in a later age of reported onset that usually occurred when the child started school and reported blurring of vision. Since the determination of the onset of amblyopia was based on parent recall,

the correlation between visual outcome with the age of onset was likely to be unreliable. A more reliable variable would be the age of the patient at initial consult which was also the age at initial treatment. Our study showed higher success rates in those treated at an earlier age, consistent with other studies.²³⁻²⁶

Compliance and Use of the Patching Diary

Good compliance to the prescribed patching regimen was seen in the treatment success group as compared to the fair compliance in the treatment failure group. A statistically significant linear relationship between compliance and change in BCVA was demonstrated by Loudon who showed that a low increase in visual acuity had statistically lower compliance rates.²³

In our study, the low incidence of absent patching diary (9.3%) on follow-up schedules made the recorded compliance rate a reliable variable. Nevertheless, reasons for poor compliance were addressed by longer chair time and more thorough explanation of the patching regimen. Other studies had suggested that poor compliance to the patching regimen was related to poor understanding of amblyopia and the treatment regimen²⁴⁻²⁵ and other psychosocial factors.²⁷ Our study had an over-all compliance of 88% compared to earlier studies with compliance ranging between 30 - 60%.^{18, 19} This increased compliance may have resulted from a combination of factors, such as more thorough written instructions on the patch diary utilizing diagrams and cartoons, monthly follow-ups where instructions were repeated and patient feedback was encouraged, and the checking and collection of patching diaries, all these may have incited a positive effect on compliance. During the monthly visits, the parents and caregivers were encouraged to ask questions so that misconceptions could be corrected.

The use of the diary allowed both the parent or caregiver and the patient to take an active role in the treatment by logging the hours on the diary. The diary was also a means where the caregivers were reminded of their tasks, and where they were able to write down their questions that were then answered at the next follow-up visit. Consistent with earlier studies, good rapport with the parents and regular advice to increase awareness on the need for patching enhanced compliance. The use of a patch diary coupled with long chair time on each monthly follow-up allowed the parents and caregivers to have a clearer idea of the disease and the treatment regimen.

Severity

Patients with mild to moderate amblyopia had a higher rate of treatment success (61%) as compared to severe amblyopia (36%). Compliance rates were not significantly different between the two groups. There was a strong negative correlation between severity and change in BCVA as demonstrated in this study. The severity of amblyopia is an important factor affecting the visual outcome in cases where compliance to patching is good. In spite of this, there can still be partial response to treatment as seen by a 2 line improvement in BCVA after 6 months of treatment in some severe amblyopia.

Outcome and Follow-up Period

Stable isoacuity after 9-10 weeks of treatment (2-3 months) was seen in earlier studies.²³⁻²⁶ Improvement of BCVA showed no change on months 3 & 4 (Figure 1) and may be misinterpreted as attaining stable BCVA. However, improvement of at least 1 line in the Snellen chart was seen from months 5-6, indicating that prolonged patching and follow-up of these patients are needed beyond 6 months.

Thus, future studies should include a larger sample size of each subtype of amblyopia with a longer follow-up period.

In summary, amblyopia treatment with occlusion was most effective in mild to moderate amblyopia. Early treatment of amblyopia resulted in higher rates of success. With good compliance, there was some improvement seen in those with severe amblyopia. A patching diary can be used to improve compliance and to increase the understanding of occlusion therapy.

REFERENCES

1. American Academy of Ophthalmology. Basic Course Series: Pediatric Ophthalmology and Strabismus. *American Academy of Ophthalmology*, 2008-2009.
2. American Academy of Ophthalmology: Pediatric Ophthalmology. Preferred Practice Pattern: Amblyopia. *American Academy of Ophthalmology*, 2007.
3. National Eye Institute. Amblyopia. February 8, 2010: <http://www.nei.nih.gov/health/amblyopia/index.asp> (accessed February 2010).
4. Stewart C, Fielder A, Moseley M. Objectively monitored patching regimens for treatment of amblyopia: a randomised trial. *Br J Ophthalmol* 2007; 335:707.
5. Multi-ethnic Pediatric Eye Disease Study Group. Prevalence of amblyopia and strabismus in African American and Hispanic children ages 6 to 72 Months. *Ophthalmology* 2008; 115:1229-1236.
6. Rosman M, Wong TY, Koh CL, et al. Prevalence and causes of amblyopia in a population-based study of young adult men in Singapore. *Am J Ophthalmol* 2005;143:551-552.
7. Menon V, Chadhuri Z, Saxena R. Profile of amblyopia in a hospital referral practice. *Ind J Ophthalmol* 2005;53:227-234.
8. Tong L, Chan YH, Gazzard G, et al. Longitudinal study of anisometropia in Singaporean school children. *Invest Ophthalmol Vis Sci* 2006; 47:3247-3252.
9. Levartovsky S, Oliver M, Gottesman N, et al. Factors affecting long term results of successfully treated amblyopia: initial visual acuity and type of amblyopia. *Br J Ophthalmol* 1995;79:225-8.
10. Williams C, Northstone K, Harrad RA, et al. Amblyopia treatment outcomes after screening before or at age 3 years: follow-up from randomised trial. *BMJ* 2002; 324:1549.
11. Foroozan RM. Visual stabilization following treatment for amblyopia. July 3, 2007: <http://www.medscape.com> (accessed January 19, 2010).
12. Pediatric Eye Disease Investigator Group. The clinical profile of moderate amblyopia in children younger than 7 years. *Arch Ophthalmol* 2002;120:281-287.
13. Foroozan RM. Patching vs atropine: Which is the better treatment for pediatric amblyopia. January 6, 2009: <http://www.medscape.com> (accessed January 19, 2010).
14. Pediatric Eye Disease Investigator Group. A randomized trial of prescribed patching regimens for treatment of severe amblyopia in children. *Ophthalmology* 2003;110:2075-2087.
15. Pediatric Eye Disease Investigator Group. A randomized trial of patching regimens for treatment of moderate amblyopia in children. *Arch Ophthalmol* 2003;121:603-611.
16. Ohlsson J, Baumann M, Sjostrand J, et al. Long term visual outcome in amblyopia treatment. *Br J Ophthalmol* 2002;86:1148-1151.
17. American Academy of Pediatrics, Committee on Children with Disabilities. Developmental surveillance and screening of infants and young children. *Pediatrics* 2001;108:192-195.
18. Chopovska Y, Loudon SE, Cirina L, et al. Electronic recording of occlusion treatment for amblyopia: potential of the new technology. *Arch Clin Exp Ophthalmol* 2005;243: 539-44.
19. Oto SP. Non concordance in amblyopia treatment: the effective use of "smileys". *Strabismus* 2002;10:23-30.
20. MyVision Test. Snellen - LogMAR visual acuity calculator by MyVision Test. 2011: <http://www.myvisiontest.com/LogMAR.php>
21. McManaway III JN, Bonsall D. Management of common pediatric neuroophthalmologic problems. In: Wright KW, Spiegel PH & Thompson LS, *Handbook of Pediatric Neuro-Ophthalmology*. Chicago: Springer Science+Business Media, Inc, 2006.
22. Wright MF. Pediatric Ophthalmology for Primary Care, 3rd ed. American Academy of Pediatrics, 2008.
23. Al-Zuhaibi S, Al-Harhi I, Cooymans P, et al. Compliance of amblyopic patients with occlusion therapy: A pilot study. *Oman J Ophthalmol* 2009;2:67-72.
24. Loudon SE, Polling JR, Simonsz HJ. Electronically measured compliance with occlusion therapy for amblyopia is related to visual acuity increase. *Graefes Arch Clin Exp Ophthalmol* 2003;241:176-180.
25. Menon VC. Factors influencing visual rehabilitation after occlusion therapy in unilateral amblyopia in children. *Ind J Med Res* 2005;122:497-505.
26. Park KS, Chang YH, Na KD, et al. Outcomes of 6 hour part time occlusion treatment combined with near activities for unilateral amblyopia. *Kor J Ophthalmol* 2008;22:26-31.
27. Searle AN. Psychosocial and clinical determinants of compliance with occlusion therapy for amblyopic children. *Eye* 2002;16:150-155.