

# Factors Affecting Compliance to Two-Hour Versus Six-Hour Occlusion Therapy Regimens for Treatment of Strabismic Amblyopia

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## Abstract

**Purpose:** To compare the effect of daily occlusion of the sound eye for two hours, without and with near vision exercises, versus six hours without near vision exercises, for the management of strabismic amblyopia and to determine the different factors affecting compliance to each treatment regimen.

**Methods:** Forty five children having unilateral strabismic amblyopia were divided equally into 3 groups. Group A received 2-hour daily occlusion. Group B received 2-hour occlusion combined with near vision exercises. Group C received 6-hour occlusion therapy. Patients were followed up for 6 months.

**Results:** The mean logMAR improvement was  $-1.03 \pm 0.57$ ,  $-0.63 \pm 0.66$  and  $-0.65 \pm 0.66$ , for groups A, B and C, respectively. The difference in mean logMAR improvement was significant ( $P < .001$ ) in groups A versus B and A versus C, but was insignificant ( $P = .748$ ) in group B versus C. Factors affecting compliance to each occlusion regimen were related to age, socioeconomic status, life pattern and season of the year.

**Conclusion:** The best outcome was achieved when 2-hour daily patching was combined with near vision activities. Higher compliance to two-hour occlusion with near vision exercises was attained in older, educated children. Six-hour occlusion was more suitable in younger and in uneducated children.

**Keywords:** Amblyopia; Occlusion; Eye patch; Near vision activities; Compliance

## Introduction

Amblyopia means reduced visual acuity, which is not improved by corrective glasses, in an eye that is otherwise normal. It is responsible for diminished vision in 1% to 2% of the childhood population and it is most often associated with strabismus or anisometropia [1].

Occlusion therapy remains the mainstay of amblyopia treatment. Opinions, however, vary on the number of hours of daily patching that should be prescribed, ranging from as little as 1 or 2 hours to as much as 24 hours per day [2-4]. No study had provided conclusive data on the optimal number of patching hours, until The Pediatric Eye Disease Investigator Group (PEDIG) conducted a randomized clinical trial, to compare 2 hours versus 6 hours of daily patching combined with 1 hour of near vision exercises, for the treatment of moderate amblyopia in children 3 to 7 years of age. PEDIG concluded that both methods produced an improvement of visual acuity of a similar magnitude [5].

Various near vision exercises may be combined with occlusion therapy. Colouring-in, completing a dotted picture, jig-saw puzzles, computer games and crossing out a particular letter wherever it occurs in a page of print, are different examples. Co-operation from patient, parent and schoolteacher is absolutely essential. Recently, fully automated computer programs are available for electronic recording. The program automatically modifies and advances the exercises as the patient's visual acuity improves. The ophthalmologist can follow the patient from the office via the internet [6].

The aim of this study is to compare the effect of daily occlusion of the sound eye for two hours, without and with near vision exercises, versus six hours without near vision exercises, for the management

of children with strabismic amblyopia and to determine the different factors affecting compliance to each regimen.

## Methods and Materials

Among children screened, 45 children having strabismic amblyopia met the inclusion criteria and were involved in a randomized, prospective study to compare two-hour occlusion therapy, with and without near visual activities and six-hour occlusion therapy. Informed consent was obtained from parents of children participating in the study. The study and data collection conformed to all local laws and were compliant with the principles of the Declaration of Helsinki.

Eligibility criteria for the study included a child aged 4 to 9 years having strabismic amblyopia. The latter was defined as corrected visual acuity in the amblyopic eye below 0.5 (after wearing of an optimal spectacle correction for a minimum of 4 weeks) in association with a heterotropia or a history of strabismus surgery.

Exclusion criteria were unwillingness to participate, inability to measure visual acuity using standard charts, a corrected visual acuity

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in the amblyopic eye worse than 0.1 or better than 0.5, eccentric fixation, anisometropia of 1 diopter or more spherical equivalent, associated ocular or neurological diseases, or prior intraocular surgery.

Clinical evaluation at entry into the study comprised: history taking, sensory testing, ocular motor examination, cycloplegic refraction, fundus examination and corrected visual acuity measurement using the Landolt C, tumbling E, or pictures. Spectacles, when indicated, were prescribed to within 1 diopter of the patient's cycloplegic refraction. Spectacles had to be worn for at least 4 weeks prior to randomization.

Patients were randomly assigned to one of 3 groups according to the patching regimen used. Each group comprised 15 patients. Daily patching of the sound eye to treat amblyopia of the other eye was carried out for: 2 hours without near vision activities in Group A, 2 hours with near vision activities in Group B and 6 hours without near vision activities in group C. Near vision activities performed comprised: coloring-in, completing a dotted picture, jig-saw puzzles and crossing out a particular letter wherever it occurs in a page of print.

Follow-up of patients was scheduled at intervals equivalent to 1 week per year of age for 6 months. As an example, a 4-year-old child was followed up every 4 weeks. At each follow-up visit, corrected visual acuity was measured in each eye using the Landolt C, tumbling E, or pictures. Prior to the six-month examination, no change in the treatment protocol was allowed.

Statistical analysis of the results was done. Prior to statistical manipulations, decimal corrected visual acuity was converted to logMAR acuity using the visual acuity conversion chart suggested by Holladay [7]. Comparison of the three groups was performed using the Kruskal-Wallis test, while comparison of each two groups was performed using the Mann-Whitney test. For all tests, a *p* value < .05 was considered significant.

A patient was considered compliant if the eye remained patched each day the prescribed duration of occlusion even if interrupted. Non-compliance was considered if the sum of patching hours was less than prescribed. In group B, failure to perform near vision exercises was considered as non-compliance.

## Results

Forty five children having strabismic amblyopia met the inclusion criteria and were involved in a randomized, prospective study to compare the effect of and compliance to, two-hour occlusion therapy, with and without near visual activities, versus six-hour occlusion therapy.

### Patients' Characteristics

Patients included 20 males (44.4%). Age ranged between 4 and 9 years. The age distribution of the patients included in the study is shown in Table 1. Decimal best-corrected visual acuity in the amblyopic eye at entry into the study was 0.1 to 0.33 among all patients and in each of the 3 groups. Mean logMAR values are highlighted in Table 2. The difference in mean logMAR values among the 3 groups was insignificant (chi-square = .107, *P* = .948) when analyzed using the Kruskal-Wallis test. Decimal best-corrected visual acuity in the sound eye at entry into the study was 0.8 to 1.0 among all patients and in each of the 3 groups. Mean logMAR values are depicted in Table 2. The difference in mean logMAR values among the 3 groups was insignificant (chi-square = 1.137, *P* = .566) when analyzed using the Kruskal-Wallis test.

### Outcome of Amblyopia Therapy

Decimal best-corrected visual acuity in the amblyopic eye after occlusion therapy was 0.25 to 0.67 among all patients and was 0.25 to 0.50 in group A and 0.25 to 0.67 in group B as well as in group C. Mean logMAR values are shown in Table 3. The difference in mean logMAR values among the 3 groups was significant (chi-square = 17.503, *P* < .001), when analyzed using the Kruskal-Wallis test. On comparing the mean logMAR values achieved in the amblyopic eye in groups A versus B and in groups A versus C, using the Mann-Whitney test, the differences were significant (*z* = -3.623, *P* < .001 and *z* = -3.549, *P* < .001, respectively). The difference in mean logMAR values between groups B and C was, however, insignificant (*z* = -.534, *P* = .594), when analyzed using the Mann-Whitney test. Decimal best-corrected visual acuity and mean logMAR values, recorded in the sound eye after occlusion therapy, were the same as those recorded at entry into the study.

Age range (years)	All patients N (%)	Group A n (%)	Group B n (%)	Group C n (%)
4 - <1=5	15(33)	2(13)	3(20)	10(67)
>5 - <1=6	15(33)	6(40)	5(33)	4(27)
>6 - <1=7	8(18)	3(20)	4(27)	1(7)
>7 - <1=8	3(6)	2(13)	1(7)	0
>8 - <1=9	4(9)	2(13)	2(13)	0

Table 1: Age distribution of patients included in the study.

Baseline characteristics (Mean+/-SD)	All Patients	Group A	Group B	Group C	P values**
BCVA in amblyopic eye (LogMAR)*	-0.74+/-0.19	-0.74+/-0.17	-0.74+/-0.2	-0.76+/-0.2	.948
BCVA in sound eye (LogMAR)*	-0.07+/-0.25	-0.14+/-0.35	-0.07+/-0.26	-0.01+/-0.04	.566

SD = Standard; BCVA = Best-Corrected Visual Acuity; \* = values obtained at entry into the study; \*\* = *p* values obtained when comparing the 3 groups together

Table 2: LogMAR BCVA at entry into the study.

Outcome (Mean+/-SD)	All Patients	Group A	Group B	Group C
BCVA in amblyopic eye (LogMAR)	-0.37+/-0.16	-0.50+/-0.10	-0.29+/-0.13	-0.30+/-0.13
BCVA in sound eye (LogMAR)	-0.07+/-0.25	-0.14+/-0.35	-0.07+/-0.26	-0.01+/-0.04
Improvement of BCVA in amblyopic eye (LogMAR)**	-0.77+/-0.65	-1.03+/-0.57	-0.63+/-0.66	-0.65+/-0.66

SD = Standard; BCVA = Best-corrected visual acuity; \* = values obtained after occlusion for 6 months; \*\* = indicates difference in BCVA before & after occlusion for 6 months

Table 3: Outcome of amblyopia therapy.



Comparing decimal best-corrected visual acuity in the amblyopic eye, before and after occlusion therapy, it was found that, at the termination of occlusion therapy, the visual improvement ranged from 0 to 0.57 among all patients and from 0 to 0.25, 0 to 0.51 and 0 to 0.57 in groups A, B and C respectively (Figure 1). Transforming these to logMAR values, the mean improvement is shown in Table 3. The difference in mean logMAR improvement among the 3 groups was significant (chi-square = 20.713,  $P < .001$ ) when analyzed using the Kruskal-Wallis test. On comparing the mean logMAR improvement achieved in groups A versus B and A versus C, using the Mann-Whitney test, the difference was significant ( $z = -3.972$ ,  $P < .001$  and  $z = -3.828$ ,  $P < .001$ , respectively). The difference in mean logMAR improvement between groups B and C was, however, insignificant ( $z = -.321$ ,  $P = .748$ ) when analyzed using the Mann-Whitney test.

The above results suggest that the best outcome was achieved when 2-hour daily patching was combined with near vision activities (group B). The outcome with 6-hour daily patching without near vision activities (group C) was insignificantly less superior. The outcome of 2-hour daily patching without near vision activities (group A) was significantly inferior. It is also noteworthy that compliance was better with 2-hour occlusion. Six-hour occlusion, however, attained a more rapid outcome in compliant children.

Lack of compliance was related to the child's age, socioeconomic standard, pattern of life and the season of the year. Among group A, reasons for non-compliance included: refusal of the child to patch the eye, the cost of adhesive eye patches being unaffordable by parents and development of mucopurulent conjunctivitis when the patch was used in summer time. Among group B, one reason for non-compliance was: the child and parents were living in the countryside and were illiterate. The child would spend the day in the farm and had no access to puzzles or other forms of near vision activities, which were beyond the scope of his knowledge and understanding. A second cause for non-compliance was the cost of adhesive eye patches, which was unaffordable by the parents. A third cause was an age that was too young to perform near vision activities (below 5 years old). A fourth cause was that the parents of the child spent most of the time at work, so did not have enough time to supervise the child while performing near vision activities. Non-compliance in group C was met with due to the following causes: inability to use the patch at school as it was cosmetically unacceptable, difficulty to perform homework assigned by the child's teacher while wearing the eye patch and inability to patch an eye while performing sports at the club after school time. The remaining waking hours were not enough to patch a total of six hours a day. Another cause was that the eye patch was prescribed at summer time. In this case, non-compliance was due to intolerance of the heat and sweat which made the patch a nuisance. In addition, development of more than 1 attack of mucopurulent conjunctivitis necessitated removal of the patch till cure. A last cause was that the cost of adhesive eye patches was unaffordable by the parents.

## Discussion

One method of treating amblyopia is patching of the sound eye to improve vision of the amblyopic eye. The amount of occlusion needed to maximize visual acuity in the amblyopic eye has been debated [8]. Though patching all, or almost all, waking hours is still recommended by some, part-time patching has been proven quite successful [9]. The Pediatric Eye Disease Investigator Group (PEDIG) [5] compared 2 hours versus 6 hours of daily patching, combined with at least 1 hour

per day of near visual activities in both groups, as two methods of treatment of moderate amblyopia in children younger than 7 years of age. PEDIG demonstrated that, when combined with 1 hour of near visual activities, 2 hours of patching provided a similar improvement in visual acuity to that attained with 6 hours of patching.

The present study differed from that of PEDIG in the fact that near visual activities were combined with 2-hour patching (Group B) but not with 6-hour patching (Group C). The present study, therefore, has a value in investigating whether 6 hours of patching without exercise could have comparable outcome with 2 hours patching with exercise for those who, for any reason, are unable to perform visual exercises. In agreement with the results of PEDIG, in the current study, 2-hour occlusion combined with near vision exercises provided a similar improvement in visual acuity to 6-hour occlusion. The results of the present study also agree with Holmes et al. [10] who supplemented occlusion by near activities and levodopa and with Mostafa and Sobhi,[11] who studied the effect of using CAM-vision stimulator for near visual activities. It is noteworthy that, in the present study, compliance was better with 2-hour occlusion. Six-hour occlusion, however, attained a more rapid outcome in compliant children.

A limitation to be mentioned in the current study, however, is the fact that the study was not blind, as the occlusion regimen was prescribed and follow-up was done by the same investigator.

Patching is cosmetically unacceptable to many. It causes emotional stress on both the child and the parents. This problem was encountered in the present work. The critical step in the management process, therefore, is to take time to convince the parents of the necessity, urgency and effectivity of occlusion therapy. Some manufacturers have attempted to make the patches more attractive and comfortable (Ortopad Orthoptic Eye Patches) [12]. These however, are affordable by parents of higher socioeconomic standard. Lower socioeconomic standard parents might not even afford to buy regular adhesive eye patches. This was met with in the current study. An economic patch was home-made by one parent in the form of a pirate made of leather and connected to an elastic band (Figure 2), thus obviating to need to buy adhesive eye patches.

Shorter duration of occlusion has various advantages. These include: better compliance, shorter periods of exposure to risk of trauma due to poor vision, higher productivity and longer duration of binocular vision (in case of intermittent strabismus).

The patching schedule has to be adapted to the family's lifestyle. Even if both 6-hour patch and 2-hour patch with near vision exercises provide a similar visual outcome, the clinician should meticulously tailor the type of occlusion regimen according to the individual patient's characteristics and conditions to achieve higher compliance. The clinician has to consider the child's age, socioeconomic standard,

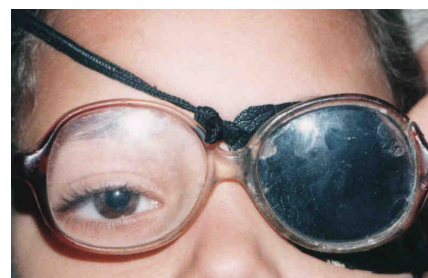
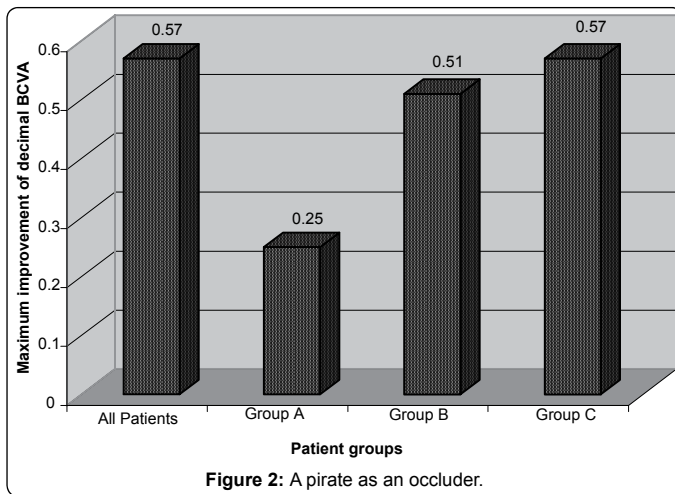


Figure 1: Maximal improvement in decimal best corrected visual acuity (BCVA) in the amblyopic eye 6 months after amblyopia therapy.





lifestyle and the season of the year when choosing either 6-hour versus 2-hour occlusion with near vision exercises. Near vision exercises are not feasible in very young children, illiterate children and those who do not receive enough parents' supervision. These, in addition, have plenty of time at home, where a 6-hour patching regimen would be easily acceptable. On the other hand, near vision exercises usually comprise part of the normal daily activities of educated children of higher socioeconomic standard, making amblyopia therapy enjoyable and improving the child's compliance. Moreover, these children spend a major part of their day at school, at sports, or performing homework. The remaining waking hours are not enough to allow the application of a 6-hour daily patch. Accordingly, 2-hour patching with near vision exercises are recommended in these children. At summer time, 6-hour patching is a nuisance due to heat and sweat, or risk of mucopurulent conjunctivitis, making 2-hour patching more practical.

In conclusion, two-hour occlusion therapy is adequate with better compliance, provided it is associated with near visual activities. This is especially suitable for educated children, of higher socioeconomic standard. Six-hour therapy, however, provides a faster response and may be recommended in younger or illiterate children, or those of illiterate or busy parents, where active home visual activities may not be feasible.

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