Title: Predictive value of adherence to glasses wearing during amblyopia treatment.

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Abstract:

Importance:
Occlusion dose monitors (ODMs) have helped establish that better adherence to occlusion is associated with increased visual outcomes in amblyopia treatment. However, the role of glasses adherence is unknown.

Objectives:

1) Establish feasibility and reliability of objectively monitoring adherence to glasses wearing using age based norms; 2) establish the relationship between adherence to glasses wearing and visual acuity (VA) improvement after optical treatment and occlusion therapy; and 3) analyze the effect of age, gender, refractive errors and type of amblyopia and adherence to glasses wear on VA improvement.

Design: Observation, prospective, non-masked, cohort trial

Setting: Pediatric Ophthalmology clinic, Tertiary Care Hospital, UK

Participants: Newly diagnosed amblyopia subjects with anisometropic and/or strabismic amblyopia without previous treatment

Intervention: Objective monitoring of glasses and occlusion in 20 children with anisometropia and 20 with strabismic/mixed amblyopia. The trial consisted of two phases: 1) Glasses phase (18 weeks), and 2) Patching phase (glasses and occlusion for 10 hours a day for 12 weeks). Reliability of the glasses monitors was assessed comparing diary and monitor recordings in adults.

Main outcome and measures: Adherence to glasses wear (hours/day) and effect on visual acuity.

Results: Adherence to glasses was successfully monitored in all but one subject. Agreement between diaries and monitored times in adults was high (intraclass correlation coefficient=1.00 95% CI 0.999 – 1.00). Median adherence to glasses wearing was 70.0% (SD=±25.3%). A moderate correlation was observed between hours of glasses wearing and percentage VA improvement during the glasses phase ($r = 0.515$ $p = 0.001$). Multiple regression revealed age, type of amblyopia, and adherence to glasses wearing independently predicted VA after the glasses phase ($p<0.05$) and explained 42.0 % of the variability ($F(3,35)=8.457$ $p < 0.0005$). A strong correlation between glasses and occlusion adherence was observed ($r=0.719$, $p<0.0005$).

Conclusion and Relevance:

The results suggest that adherence to glasses wearing is less than optimal and highly variable but is important in achieving good VA. This study emphasizes the importance of encouraging children to not only have good adherence to occlusion therapy but also to glasses wearing.

Introduction

Adherence to amblyopia treatment has long been observed to be a limitation in achieving optimum visual outcome. In 2002, Searle et al,[1] reported, using questionnaires, that only 54% of patients achieve the full occlusion times prescribed by the orthoptist. Since the development of objective monitoring devices,[2] understanding the relationship between adherence and visual acuity (VA) improvement during occlusion therapy has provided insights into the importance of adherence and potential reasons for low adherence[3-6].
At present, objective monitoring of adherence has been limited to occlusion treatment and it is not clear to what extent adherence to glasses wear plays a role in visual outcome. With growing support, including guidelines from the American Academy of Ophthalmology[7] and the Royal College of Ophthalmologists[8], for a longer duration of glasses wearing alone prior to occlusion, the need for objective monitoring of adherence to glasses wearing is of increasing importance. Monitoring the amount of glasses wear could help to understand reasons and ways to improve non-adherence of uncorrected refractive errors worldwide[9].

The aims of this study were: 1) to establish feasibility and reliability of objectively monitoring adherence to glasses wearing; 2) to establish the relationship between adherence to glasses wearing and VA improvement after glasses wearing and occlusion therapy; and 3) to analyze the effect of age, gender, refractive errors, type of amblyopia and adherence to glasses wear on VA improvement.

Methods

Participants

Newly diagnosed children with amblyopia were recruited within a Pediatric Ophthalmology

clinic, Tertiary Care Hospital, Leicester, UK , between June 2008 and June 2013. Inclusion criteria included i) an inter-ocular difference in VA of ≥3 lines ii) anisometropic, strabismic or mixed amblyopia iii) aged between 3 and 12 years and iv) clinically significant refractive error of ≥1.5D in at least 1 eye or 1D difference between the two eyes. Subjects with stimulus deprivation amblyopia, bilateral amblyopia or amblyopia associated with neurological disorders and prematurity were excluded. Informed consent from parents/guardian was obtained for each participant. This study adhered to the tenets of Declaration of Helsinki and was approved by the Leicestershire local research ethics committee 1. The study was an extension of the registered trial: ISRCTN05346737.

Study design

A prospective cohort study design was carried out, the trial consisted of two phases: 1) a glasses wearing phase, where glasses were prescribed for all waking hours, for 18 weeks, and 2) a patching and glasses phase of 12 weeks, the patching phase. Occlusion was prescribed for 10 hours a day for 6/7 days a week following protocol set out by our previous occlusion study[12]. If the difference in VA was <3.00 lines after the first phase but remained >1.00 lines, the number of hours of prescribed patching was lowered (n=2). If the amblyopia resolved during the first phase, patching was not prescribed (n=4). Resolution of amblyopia was defined as improvement to an inter-ocular difference in VA of ≤1.00 line.

During the glasses phase, subjects attended at six week intervals and during the patching phase at three week intervals. For the duration of the study, recruited subjects wore glasses dose monitor (GDM) which were attached to the side of their glasses using cord and a patch (Figure 1). During the patching phase an occlusion dose monitor (ODM) was also given. At each visit the monitors were returned and a new monitor given.

At the initial visit all subjects underwent an orthoptic and ophthalmological examination, including cover test, VA (logMAR crowded test, Keeler Ltd, Windsor), stereoacuity (Frisby Stereotests), fundus check as well as a refraction using 1% cyclopentolate. The full cycloplegic prescription was given. Subjects were dispensed glasses but did not wear them until the first visit of the study. At each subsequent visit an orthoptic examination and VA assessment were performed. With the exception of the initial visit, all subjects were examined by the same research orthoptist. Strabismic/mixed amblyopia was defined as the presence of any manifest deviation at near or distance (with or without glasses) and with or without anisometropia. Anisometropic amblyopia was defined as a difference in the two eyes of spherical equivalent (SE) of ≥1.00D without the presence of a manifest deviation. All subjects with anisometropia without strabismus had motor fusion, assessed using 4 prism base out test. Microstrabismus was defined as a small angle strabismus that does not reveal itself on cover/uncover test.

Monitors

GDMs and ODMs adherence measurements were obtained using temperature differentials between two surfaces, as first developed by Simonsz *et al*[10, 11] and described in previous studies by our group.[6, 12] Monitors were developed in collaboration with the medical physics team at the University of Leicester Hospital Trust. Temperature readings were obtained every 10 minutes for the GDMs and every 5 minutes in the ODMs with a temperature resolution of 0.0625^{o}C. Readings were analyzed using Spike2v06 software (Cambridge Electronic Design, Cambridge, UK) using a threshold temperature difference of 0.3°C. To assess the reliability of the monitors, four adults were given GDMs for 1 week and asked to record wearing times in a diary.

Outcome measures

*Glasses adherence =(average no. of hours per day glasses worn/estimated number hours awake per day)*100*

Number of hours awake per day was estimated based on age using data from Galland et *al*[13].

*Occlusion adherence =(average no. hours per day patch worn/prescribed number of hours)*100*

Percentage VA improvement during each phase were calculated using the equation described by Stewart *et al*[14]:

% Change in amblyopia = (VAas–VAae)/(VAas-VAfe)*100

Where VAas represent logMAR VA in the amblyopic eye at initial visit, VAae the VA in amblyopic eye at the end of the phase or study and VAfe the VA in the fellow eye at the end of the phase or study.

Statistical analysis

Statistical analysis was undertaken using SPSS 22 (SPSS, Inc., Chicago, IL). Dose-response relationships were analyzed using the appropriate bivariate correlation test after normality was assessed using the Shapiro-Wilk test. Contribution of various factors including, age, gender, SE of amblyopic eye and fellow eye, type of amblyopia, stereoacuity and glasses adherence were entered into a step-wise multiple regression model to investigate their individual and combined effect on percentage VA improvement at the end of each phase. Stereoacuity measures were converted in to log values as described by Wallace and colleague[5]. For adherence data and VA measurements a modified intention-to-treat model was used throughout using last case carried forward to account for missing data and drop-

outs. If no adherence data or VA data was available for a phase the subject was not included in the model for that phase. Moreover, if subjects did not require occlusion therapy the adherence and VA measures for the subject were excluded for the patching phase analysis. As a secondary outcome we explored whether adherence during the early phases of treatment could predict visual outcome. This was achieved using data from the first monitor representing the first 6 weeks of treatment.

The sample size was determined by performing a preliminary analysis on 10 children with anisometropic and 10 strabismic/mixed amblyopia. The dose-response relationship between visual improvement in relation glasses adherence was significant for children with anisometropic amblyopia (r=0.779, p=0.008) but not for strabismic/mixed subjects (r=0.548, p=0.101). Consequently a sample size of 20 subjects in each group would be required to show a significant dose response (r=0.65 conservative estimate, α=0.05, power=85% assuming a 10% drop-out rate).

Results

Subjects

Forty amblyopic subjects, 20 anisometropic and 20 strabismic/mixed subjects were recruited. Subject demographics are shown in Table 1. No differences were identified in the severity of amblyopia between strabismic and anisometropic subjects (p = 0.673). There was however, a difference in age between the two groups with anisometropic subjects being significantly older (p=0.048). Four subjects (3 anisometropic subjects and one strabismic subject) did not complete the glasses phase of the study and one anisometropic subject dropped out during the patching phase. Six subjects completed the trial but 2 subjects were

prescribed less than 10 hours and 4 subjects no patching. A flow-chart of subjects through the study is shown in eFigure 1 in the supplement.

Reliability of glasses monitor

The recorded adherence to glasses wearing in adult subjects showed high levels of agreement between adherence measured electronically and subjective diaries (intraclass correlation coefficient=1.00 95% CI 0.999–1.00; F test with true value of 0 - p<0.0001; see eFigure 2 in the supplement). On average electronically monitored recordings were 6.6 minutes less than diary times (p<0.01) due to the first 'on' sample always falling after the glasses were worn and the last 'on' sample just before the glasses were removed. Temperature recordings from the monitors were found to be lower in the GDMs than in ODMs (median 31°C and 32°C respectively) but a difference threshold of 0.3°C between the two temperature sensors could reliably be recorded when glasses were being worn.

A total of 185 GDMs were given to the 40 subjects over the duration of the study, 88.1% of GDMs recorded data during the 6 weeks. This was comparative to 83.0% success rate achieved for the recording of occlusion by the ODMs. Only one subject (2.5%) had no successful recording of glasses adherence due to failing to attend any further appointments and 3 subjects (9.4%), who were prescribed occlusion, had no successful recordings of patching. The main cause of GDM failure (7.57%) was due to the monitor being lost by the subject. Other causes of failure included monitors stopping during the 6 week period (6 monitors) or monitors not starting due to technical failures (2 monitors).

Adherence to glasses wearing

Adherence to glasses wearing was highly variable (Figure 2A). The median adherence to

glasses wearing during the glasses period was 70.0% (SD=±25.3%) and the median adherence to glasses wearing during the patching phase in those in whom occlusion was prescribed was 76.3% (SD=±21.5%).There was no significant change in adherence to glasses over the course of the trial (Friedman: $X^2(4)=3.023$ p=0.554). There was no difference in adherence between two types of amblyopia for both phases (*p*=0.729).

Visual outcome

Changes in VA in both eyes are shown in Figure 3. An initial 2.00 line improvement was observed between week 0 and week 12, however, this improvement slowed to a 0.01 improvement between week 12 and week 18. Average percentage VA improvement during the glasses phase was 34.1% in anisometropic group and 27.3% in the strabismic group. There was no difference in visual improvement between the two groups in either phase (p>0.05*).* At the end of the glasses phase the amblyopia of 3 subjects (7.5%), 2 children with anisometropia and 1 child with strabismus, resolved. Two additional subjects were prescribed reduced patching and one subject no patching as the difference in VA was less than 3 lines after the glasses phase.

Visual improvement, characteristics and glasses adherence during glasses phase

A moderate dose response relationship was observed between adherence to glasses and percentage VA improvement during the glasses phase (n=39, r=0.462 p=0.003) (Figure 4A). Step-wise multiple regression analysis revealed age, younger having more than older children (Figure 4B), type of amblyopia, anisometropic more than strabismic, and glasses adherence predicted percentage VA improvement at the end of the glasses phase and explained 42.0% of the variability ($F(3,35)=8.457$, $p<0.0005$, $r^2=0.420$, adjusted $r^2=0.371$). All three factors individually contributed to the model ($p<0.05$). All other factors, including

gender, stereoacuity and SE in both eyes were found not to have an influence on percentage VA improvement (p>0.05).

Visual improvement, glasses adherence and characteristics during patching phase

During the patching phase there was no dose-response relationship observed between percentage VA improvement and adherence to glasses wearing (n=30 r=0.233 *p*=0.215). As shown in Figure 2B, adherence to occlusion was variable (median 61.9% SD=±27.6%). A moderate dose-response relationship was observed between percentage improvement in VA and adherence to occlusion (n=29, r=0.491, *p*=0.007) (Figure 4C). A strong positive correlation was seen between adherence to occlusion and adherence to glasses r=0.719, n=27, *p*<0.0005) (Figure 4D).

A step-wise multiple regression model to predict VA improvement during the patching phase, revealed that occlusion adherence could predict percentage VA improvement, (F (1, 25) = 10.887 *p* = 0.003, r^2 = 0.268). Adherence to glasses wearing, age, gender and type of amblyopia did not contribute to the model and were therefore excluded (p>0.05).

Predicting visual outcome from initial first 6 weeks of glasses wearing

Step-wise multiple regression revealed adherence to glasses wearing during the first 6 weeks, age, younger improving more than older, and type of amblyopia, anisometropic subjects more than strabismic predicted VA improvement during the glasses phase and individually contributed to the model (F(3,35)=8.504, p<0.0005, r^2=0.424 adjusted r^2=0.375). Adherence to glasses wearing and SE in the amblyopic eye also predicted final VA improvement and individually contributed to the model (F(2,36)=6.904, p=0.001 r^2=0.315

adjusted r^2=0.277). All other factors were found not to contribute and therefore were excluded from the model ($p>0.05$).

Discussion

Adherence to glasses wearing

This study highlights the importance of adherence to glasses wearing in the treatment of amblyopia, which has previously not been reported. We have shown for the first time that adherence to glasses wear can reliably be recorded during treatment, and correlates strongly to occlusion monitors. We have also shown that adherence to glasses during first 6 weeks of treatment can predict final VA.

Although this is the first study to report adherence to glasses wearing objectively, it is not the first study to observe poor adherence. One previous study, undertaken in the UK in 1998, [15] has described adherence to glasses through subjective monitoring of adherence by parents and orthoptists. Average adherence using this method was reported by the orthoptists as 79.5% and by parents as 78.5%. They also found that adherence to glasses wear was significantly correlated with the child's perception of the glasses and the number of favourable comments about the glasses to both the child and parents. Many other studies observing adherence to glasses wear have been undertaken in low socioeconomic countries where knowledge of glasses wearing is poor and often regarded as a negative intervention. [16] Adherence recorded using subjective methods in these areas is reported between 25.1–40.0%. [16-21] Low adherence was reported to be associated with negative social experiences and factors such as young in age, place of origin and subjective view of improvement with glasses.

Median adherence to glasses in our study was higher than in low socioeconomic countries (70% adherence). However, we found our subjects had lower adherence to glasses wearing than the previous UK study using subjective monitoring. Although glasses are increasingly accepted by Western cultures,[22] negative comments and standing out remain important issues. [15]

Visual improvement and adherence to glasses wearing

Our study has shown a moderate relationship between adherence to glasses wearing and VA improvement during optical treatment. The growing support for an extended glasses wearing prior to commencing occlusion makes this finding an important factor in achieving optimum outcomes and warrants further research to improve adherence. Similar to studies investigating occlusion adherence, intervention materials could be used to educate and improve adherence[12, 23]. In addition, we found that adherence to glasses in the first 6 weeks could predict overall outcome of treatment. This could therefore be used to highlight subjects during the early stages of treatment that may require intervention or education. Findings from the patching phase, consistent with previous research, showed a moderate dose response relationship between adherence to occlusion and percentage VA improvement. In contrast to previous studies, we found this relationship to extend up to 10 hours occlusion per day.[24] However due to the small number of subjects and a shorter patching phase than previous studies, our findings may be due to the quicker initial rate of improvement with longer hours of patching as described by Stewart *et al*. [25]

In addition to the dose response relationships with glasses during the glasses phase, we observed slowing of VA improvement during weeks 12 and 18 of glasses wearing where the vision appears to plateau. This suggests that 12 weeks, rather than 18, would be the

optimum length of time to allow children to adapt to their glasses in the majority of subjects. However, further improvement may be masked by the significant contribution of occlusion to VA improvement. Moreover we noted a number of other factors such as age and type amblyopia may predict visual outcomes during different phases of treatment. Further research, with a larger cohort of subject, may help to distinguish which types of patients benefit from treatment with extended periods of glasses wearing or earlier occlusion.

Limitations

Although all subjects who fulfilled the criteria of the study were asked to participate a number of families declined to do so. Therefore, it is possible, considering the increased commitment the study warranted, that subjects who entered the study were particularly motivated. It could also be possible that the monitors themselves could induce better adherence as the subjects and their guardians may perceive they are being "watched". In addition, we used an estimated hours per day rather than parental reporting due to several parents appearing to guess, perhaps due to high involvement in other areas of the study. However, regardless of these factors we still observed a range of adherences both to patching and glasses wear including adherences below 10% and observed a strong correlation with patching adherence.

Conclusion

In conclusion this study has described for the first time that reliable monitoring of glasses wear is possible and the use of objective monitors has potential to improve reliability of future research. We have also demonstrated that good adherence to glasses wearing leads to better VA improvement and is particularly important when glasses are prescribed alone.

Moreover, we have observed in our small cohort of patients, that 12 rather than 18 weeks maybe a more suitable length of time for glasses adaptation in the majority of patients. Monitoring adherence to glasses wear is important as problems of poor adherence to glasses wearing are not confined to amblyopia treatment and are increasingly recognised to also apply for refractive correction in general. Future research in this area, including understanding and improving adherence, is needed. The use of monitors could be facilitated by incorporating them in the frame of the glasses.

Author contributions: Dr Gail Maconachie had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design and obtained funding: Proudlock and Gottlob
Acquisition, analysis and interpretation of data: all authors
Monitor design: All authors
Drafting of manuscript: Maconachie
Revision and editing of manuscript: all authors

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Titles:

Figure 1: GDM on glasses

Figure 2: Adherence to treatment and effect on visual improvement

Figure 3: Average change in visual acuity over the course of the trial

Figure 4: Dose response relationships and correlation between glasses and occlusion adherence

Legends:

Figure 1: Position of glass dose monitor (GDM) on frame of glasses

Figure 2 A) Adherence to glasses wearing during optical treatment for all participants. **B)** Adherence to patching during patching phase for all participants. Dotted line represents the median adherence.

Figure 3: Average change in visual acuity with standard error bars, over the course the trial. Dark line represents the amblyopic eye, lighter grey the fellow eye. The dotted line represents glasses wearing only and the solid line occlusion and glasses.

Figure 4: A) Dose response relationship between adherence to glasses wearing and percentage improvement in visual acuity during glasses phase. **B)** Correlation between age and percentage improvement in VA during glasses phase **C)** Dose response relationship between adherence to patching and percentage improvement in VA during the patching phase. **D)** Correlation between adherence to patching and adherence to glasses wearing during the occlusion phase. Dotted lines represent 95% CI of the mean, circles – anisometropic group, squares – strabismic/mixed, crosses-subjects given reduced patching during the occlusion phase.

Table 1: Summary demographics for recruited subjects. Numbers in brackets represent standard deviation.

		Demographics		
		Anisometropic	Strabismic	All
Number		20	20	40
Age (years)		6.20 (±2.16)	4.90 (±1.36)	5.48 (±1.87)
Female %		44.44	50.00	47.50
Ethnicity	% Caucasian	83.33	72.73	77.50
	% Asian	16.67	27.27	22.50
Initial visual acuity difference		0.639 (±0.22)	0.668 (±0.21)	0.655(±0.21)
Amblyopic eye spherical equivalent		3.53 (±2.27)	4.80 (±1.41)	4.23 (±1.83)
Non-amblyopic eye spherical equivalent		0.81 (±1.37)	2.59 (±1.90)	1.78 (±1.89)
Stereopsis	Start of Trial	47.1%	11.1%	28.6%
	End of Trial	94.1%	38.9%	65.7%
Strabismic Group	% with anisometropia	-	63.64	-