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Association Between Adherence to Glasses Wearing During Amblyopia Treatment and Improvement in Visual Acuity

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IMPORTANCE Occlusion dose monitors have helped establish that better adherence to occlusion is associated with improved visual outcomes in patients undergoing amblyopia treatment. However, the role of adherence to glasses wearing is unknown.

OBJECTIVES To establish the feasibility and reliability of objectively monitoring adherence to glasses wearing using age-based norms, establish the association between adherence to glasses wearing and improvement in visual acuity (VA) after optical treatment and occlusion therapy, and analyze the effect of age, sex, refractive errors, type of amblyopia, and adherence to glasses wearing on improvement in VA.

DESIGN, SETTING, AND PARTICIPANTS A prospective, observational, nonmasked, cohort study was conducted between June 8, 2008, and June 30, 2013, among patients at a pediatric ophthalmology clinic of a tertiary care hospital who were newly diagnosed with anisometropic and/or strabismic amblyopia and had not undergone previous treatment. The study consisted of a glasses phase (18 weeks) and a patching phase (glasses and occlusion for 10 hours per day for 12 weeks). Reliability of the glasses monitors was assessed by comparing diary entries and monitor recordings in adults.

INTERVENTIONS Objective monitoring of glasses wearing and occlusion.

MAIN OUTCOMES AND MEASURES Adherence to glasses wearing (hours per day) and effect on VA.

RESULTS Among 20 children with anisometropia (mean [SD] age, 6.20 [2.16] years; 11 boys and 9 girls) and 20 with strabismic or mixed amblyopia (mean [SD] age, 4.90 [1.36] years; 10 boys and 10 girls), adherence to glasses wearing was successfully monitored in all but 1 patient. Agreement between diaries and monitored times wearing glasses in adults was high (intraclass correlation coefficient, 1.00; 95% CI, 0.999-1.00). Median (SD) adherence to glasses wearing was 70% (25.3%). A moderate correlation was observed between adherence to glasses wearing and percentage improvement in VA during the glasses phase (r = 0.462; P = .003). Multiple regression revealed that age ($\beta = -0.535$; P = .001), type of amblyopia ($\beta = -0.347$; P = .02), and adherence to glasses wearing ($\beta = 0.287$; P = .04) were independently associated with improvement in VA after the glasses phase and explained 42% of the variability ($F_{3.35} = 8.457$; P < .001). A strong correlation between glasses wearing and occlusion adherence was observed (r = 0.719; P < .001).

CONCLUSIONS 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.

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Supplemental content

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Corresponding Author: Irene Gottlob, FRCOphth, MD, Ulverscroft Eye Unit, University of Leicester, Robert Kilpatrick Clinical Sciences Building, Leicester Royal Infirmary, Leicester, LE2 7LX, England (Ig15@le.ac.uk). A dherence to amblyopia treatment has long been observed to be a limitation in achieving optimum visual outcome. In a 2002 study using questionnaires, Searle et al¹ reported that only 54% of patients achieved the full occlusion times prescribed by the orthoptist. Since the development of objective monitoring devices,² understanding the association between adherence to treatment and improvement in visual acuity (VA) 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 to amblyopia treatment has been limited to treatment of occlusion and it is not clear to what extent adherence to glasses wearing plays a role in visual outcomes. With growing support for a longer duration of glasses wearing alone before occlusion, including guidelines from the American Academy of Ophthalmology⁷ and the Royal College of Ophthalmologists,⁸ the need for objective monitoring of adherence to glasses wearing is of increasing importance. Monitoring the length of time glasses are worn could help to understand reasons for uncorrected refractive errors worldwide and ways to improve nonadherence.⁹

The aims of this study were to establish the feasibility and reliability of objectively monitoring adherence to glasses wearing, establish an association between adherence to glasses wearing and improvement in VA after glasses wearing and occlusion therapy, and analyze the effect of age, sex, refractive errors, type of amblyopia, and adherence to glasses wearing on improvement in VA.

Methods

Participants

Children newly diagnosed with amblyopia were recruited within a pediatric ophthalmology clinic in a tertiary care hospital in Leicester, UK, between June 8, 2008, and June 30, 2013. Inclusion criteria included an interocular difference in VA of 3 lines or more; anisometropic, strabismic, or mixed amblyopia; age between 3 and 12 years; and clinically significant refractive error of 1.5 diopters or more in at least 1 eye or 1 diopter difference between the 2 eyes. Patients with stimulus deprivation amblyopia, bilateral amblyopia, or amblyopia associated with neurologic disorders and prematurity were excluded. Written informed consent from parents or guardians 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, consisting of a glasses wearing phase, where glasses were prescribed for all waking hours, for 18 weeks, and a patching phase of 12 weeks. In the patching phase, occlusion was prescribed for 10 hours per day for 6 or 7 days per week, following protocol established in a previous occlusion study.¹⁰ Patients also wore glasses in the patching phase. If the difference in VA was less than 3.00 lines after the first phase but remained more than

Key Points

Question Can monitoring adherence to glasses wearing objectively help understand patient outcomes during amblyopia treatment?

Findings In this observational cohort study, objective monitoring of adherence to glasses wearing was reliable and feasible. Adherence to glasses wearing in children was highly variable but, along with age and type of amblyopia, was associated with visual outcome at the end of the optical treatment.

Meaning This study supports the importance of encouraging good adherence to glasses wearing in addition to other forms of treatment for some cases of amblyopia.

Figure 1. Glasses Dose Monitor



Position of glasses dose monitor on frame of glasses.

1.00 line, the number of hours of prescribed patching was lowered (2 patients). If the amblyopia resolved during the first phase, patching was not prescribed (4 patients). Resolution of amblyopia was defined as improvement to an interocular difference in VA of 1.00 line or less.

During the glasses phase, patients visited the clinic at 6-week intervals and during the patching phase at 3-week intervals. For the duration of the study, patients wore a glasses dose monitor (GDM), which was 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 used. At each clinic visit, the monitors were returned and a new monitor given to the patient.

At the initial visit, all patients underwent an orthoptic and ophthalmologic examination, including cover and uncover test, VA test (logMAR crowded test, Keeler Ltd), stereoacuity test (Frisby Stereotests), and fundus check, as well as a refraction test using cyclopentolate, 1%. The full cycloplegic prescription was given. Patients 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 patients were examined by the same research orthoptist (G.D.E.M. or S.F.). Strabismic or 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 2 eyes of a spherical equivalent of 1.00 diopter or more without the presence of a manifest deviation. All patients with anisometropia without strabismus had motor fusion, assessed using the 4 prism diopter base-out test. Microstrabismus was defined as a small-angle strabismus that does not reveal itself on cover and uncover test.

Monitors

Measurements of adherence to GDMs and ODMs were obtained using temperature differentials between 2 surfaces, as first developed by Simonsz et al^{11,12} and described in previous studies.^{6,10} 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 for the ODMs, with a temperature resolution of 0.0625°C. Readings were analyzed using Spike2 software, version 06 (Cambridge Electronic Design), using a threshold temperature difference of 0.3°C. To assess the reliability of the monitors, 4 adults were given GDMs for 1 week and asked to record wearing times in a diary.

Outcome Measures

Adherence to glasses wearing was defined as the mean number of hours per day the glasses were worn, divided by the estimated number of hours awake per day, multiplied by 100. Number of hours awake per day was estimated based on age using data from Galland et al.¹³ Adherence to occlusion treatment was defined as the mean number of hours per day the patch was worn, divided by the prescribed number of hours, multiplied by 100.

Percentage VA improvement during each phase was calculated using the equation described by Stewart et al¹⁴:

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% Change in amblyopia = (VAas - VAae)/(VAas - VAfe)*100,
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where VAas represents VA in logMAR in the amblyopic eye at the initial visit, VAae represents VA in the amblyopic eye at the end of the phase or study, and VAfe represents the VA in the fellow eye at the end of the phase or study.

Statistical Analysis

Statistical analysis was performed using SPSS, version 22 (SPSS Inc). Dose-response associations were analyzed using the appropriate bivariate correlation test after normality was assessed using the Shapiro-Wilk test. Contribution of various factors, including, age, sex, spherical equivalent of the amblyopic eye and the fellow eye, type of amblyopia, stereoacuity, and adherence to glasses wearing, were entered into a stepwise multiple regression model to investigate their individual and combined effect on percentage improvement in VA at the end of each phase. Stereoacuity measures were converted to log values as described by Wallace and colleagues.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 dropouts. If no adherence

data or VA data were available for a phase, the patient was not included in the model for that phase. Moreover, if a patient did not require occlusion therapy, the adherence and VA measures for that individual were excluded for the analysis of the patching phase. As a secondary outcome, we explored whether adherence during the early phases of treatment was associated with visual outcome by using data from the first GDM, representing the first 6 weeks of treatment.

The sample size was determined by performing a preliminary analysis on 10 children with anisometropic amblyopia and 10 with strabismic or mixed amblyopia. The dose-response association between visual improvement owing to adherence to glasses wearing was significant for children with anisometropic amblyopia (r = 0.779; P = .008) but not for those with strabismic or mixed amblyopia (r = 0.548; P = .10). Consequently, a sample size of 20 patients in each group would be required to show a significant dose-response association (r = 0.65 conservative estimate, a = 0.05, and power = 85%, assuming a 10% dropout rate).

Results

Participants

Twenty patients with anisometropic amblyopia and 20 with strabismic or mixed amblyopia were recruited (Table). No differences were identified in the severity of amblyopia between patients with strabismic amblyopia (initial mean difference in VA, 0.668 [0.21]) and those with anisometropic amblyopia (0.639 [0.022]; *P* = .67). There was, however, a difference in mean (SD) age between the 2 groups, with patients with anisometropic amblyopia being significantly older than those with strabismic amblyopia (6.20 [2.16] vs 4.90 [1.36] years; *P* = .048). Four patients (3 with anisometropic amblyopia and 1 with strabismic amblyopia) did not complete the glasses phase of the study, and 1 patient with anisometropic amblyopia dropped out during the patching phase. Six patients completed the trial but 2 were prescribed fewer than 10 hours of patching and 4 were prescribed no patching. A flowchart of patients through the study is shown in eFigure 1 in the Supplement.

Reliability of GDM

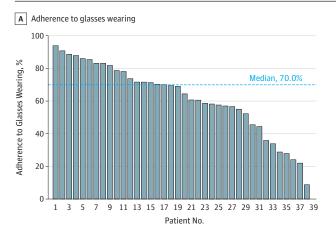
The recorded adherence to glasses wearing in the 4 adult participants showed high levels of agreement between adherence measured electronically and subjective diaries (intraclass correlation coefficient, 1.00; 95% CI, 0.999-1.00; P < .001[eFigure 2 in the Supplement]). Electronically monitored recordings were a mean of 6.6 minutes less than times recorded in the diary (GDM recorded mean [SD] time, 6.07 [4.01] hours; diary-recorded mean [SD] time, 6.18 [4.0] hours; P < .01) owing to the first temperature reading always taking place after the glasses were worn and the last temperature reading just before the glasses were removed. Temperature recordings from the monitors were lower in the GDMs than in the ODMs (median, 31°C and 32°C, respectively), but a difference threshold of 0.3°C between the 2 temperature sensors could reliably be recorded when glasses were being worn.

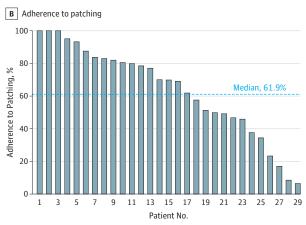
Table. Patient Demographics

Characteristic	Amblyopia Type		
	Anisometropic (n = 20)	Strabismic (n = 20) ^a	All (N = 40)
Age, mean (SD), y	6.20 (2.16)	4.90 (1.36)	5.48 (1.87)
Female, No. (%)	9 (45)	10 (50)	19 (48)
Race/ethnicity, No. (%)			
White	16 (80)	15 (75)	31 (78)
Asian	4 (20)	5 (25)	9 (23)
Initial visual acuity difference, logMAR, mean (SD)	0.639 (0.22)	0.668 (0.21)	0.655 (0.21)
Eye spherical equivalent, diopters, mean (SD)			
Amblyopic eye	3.53 (2.27)	4.80 (1.41)	4.23 (1.83)
Nonamblyopic eye	0.81 (1.37)	2.59 (1.90)	1.78 (1.89)
Stereopsis, No. (%)			
Start of trial	8/17 (47)	2/18 (11)	10/35 (29)
End of trial	16/17 (94)	7/18 (39)	23/35 (66)

^a A total of 13/20 patients (65%) had anisometropia.

Figure 2. Adherence to Treatment and Effect on Visual Improvement



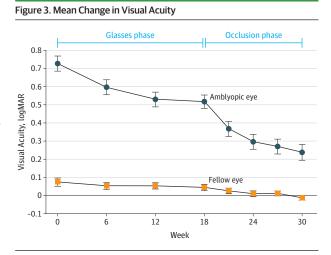


A, Adherence to glasses wearing during optical treatment for all participants. B, Adherence to patching during patching phase for all participants. Dotted line represents median adherence.

A total of 185 GDMs were given to the 40 patients during the study, and 163 GDMs (88.1%) recorded data during the 6 weeks. This rate was comparable with the 83% success rate achieved for the recording of occlusion by 93 of 112 ODMs. Only 1 patient (3%) had no successful recording of adherence to glasses wearing owing to failure to attend any further appointments; 3 of 32 patients (9%) who were prescribed occlusion had no successful recordings of patching. The main cause of GDM failure (14 [8%]) was loss of the monitor. Other causes of failure included monitors stopping during the 6-week period (6 monitors) or monitors not starting owing to technical failures (2 monitors).

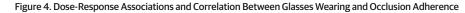
Adherence to Glasses Wearing

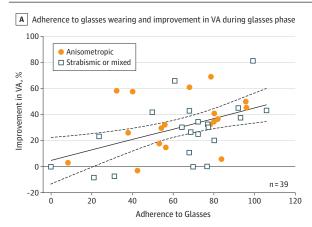
Adherence to glasses wearing was highly variable (**Figure 2**A). Median (SD) adherence to glasses wearing during the glasses period was 70% (25.3%), and median adherence to glasses wearing during the patching phase in those in whom occlusion was prescribed was 76.3% (21.5%). There was no significant mean (SD) change in rates of adherence to glasses wearing during the

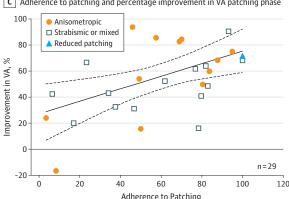


Mean change in visual acuity during the trial. Vertical bars indicate standard error. The dotted line represents glasses wearing only, and the solid line represents occlusion and glasses.

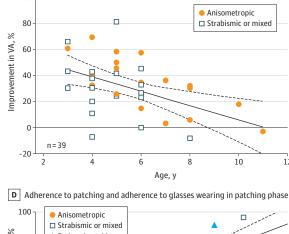
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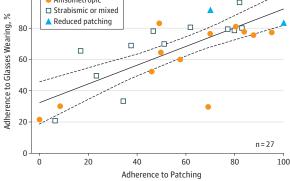
C Adherence to patching and percentage improvement in VA patching phase



B Correlation between age and improvement in VA during glasses phase

100

the mean.



and percentage improvement in VA during the patching phase (n = 29).

D. Correlation between adherence to patching and adherence to glasses

wearing during the patching phase (n = 27). Dotted lines represent 95% CI of

A, Dose-response association between adherence to glasses wearing and percentage improvement in visual acuity (VA) during glasses phase (n = 39) B, Correlation between age and percentage improvement in VA during glasses phase (n = 39). C, Dose-response association between adherence to patching

trial (-0.03% [16.2%]; Friedman: χ_4^2 = 3.023; P = .55). There was no difference in mean [SD] rates of adherence between patients with the 2 types of amblyopia in both phases (anisometropic amblyopia, 62% [22%]; strabismic or mixed amblyopia, 65.5% [26.9%]; *P* = .73).

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-line improvement between week 12 and week 18. Mean (SD) percentage improvement in VA during the glasses phase was 34.1% (20.8%) in the group with anisometropic amblyopia and 27.3% (23.1%) in the group with strabismic amblyopia (P > .05). At the end of the glasses phase, the amblyopia of 3 patients (8%), 2 with anisometropic amblyopia and 1 with strabismic amblyopia, resolved. Two additional patients were prescribed reduced patching and 1 was not prescribed patching as the difference in VA was fewer than 3 lines after the glasses phase.

Outcomes During Glasses Phase

A moderate dose-response association was observed between adherence to glasses wearing and percentage improvement in

VA during the glasses phase (n = 39; r = 0.462; P = .003) (Figure 4A). Stepwise multiple regression analysis revealed that younger age (Figure 4B), type of amblyopia (patients with anisometropic amblyopia improving more than patients with strabismic amblyopia), and adherence to glasses wearing were associated with percentage improvement in VA at the end of the glasses phase and explained 42% of the variability ($F_{3,35}$ = 8.457; $R^2 = 0.420$, adjusted $R^2 = 0.371$; P < .001). All 3 factors individually contributed to the model (age, $\beta = -0.535$; P = .001; type of amblyopia, $\beta = -0.347$; *P* = .02; adherence to glasses wearing, $\beta = 0.287$; *P* = .04). All other factors, including sex $(\beta = 0.006; P = .97)$, stereoacuity $(\beta = -0.340; P = .12)$, and spherical equivalent in both eyes (amblyopic eye, β = -0.128; P = .35; fellow eye, $\beta = -0.092$; P = .54), did not influence percentage improvement in VA.

Outcomes During Patching Phase

During the patching phase, no dose-response association was observed between percentage improvement in VA and adherence to glasses wearing (n = 30; r = 0.233; P = .22). As shown in Figure 2B, adherence to occlusion was variable (median [SD], 61.9% [27.6%]). A moderate dose-response association was observed between percentage improvement in VA and

adherence to occlusion (n = 29; r = 0.491; P = .007) (Figure 4C). A strong positive correlation was seen between adherence to occlusion and adherence to glasses wearing (n = 27; r = 0.719; P < .001) (Figure 4D).

A stepwise multiple regression model to predict improvement in VA during the patching phase revealed that adherence to occlusion was associated with percentage improvement in VA ($F_{1, 25} = 10.887$; $R^2 = 0.268$; P = .003). Adherence to glasses wearing ($\beta = -0.147$; P = .58), age ($\beta = -0.184$; P = .32), sex ($\beta = 0.163$; P = .34), and type of amblyopia ($\beta = 0.147$; P = .58) did not contribute to the model and were therefore excluded.

Association of Visual Outcome With Initial 6 Weeks of Glasses Wearing

Stepwise multiple regression revealed that adherence to glasses wearing during the first 6 weeks, younger age, and presence of anisometropic amblyopia was associated with improvement in VA during the glasses phase and individually contributed to the model ($F_{3,35} = 8.504$; $R^2 = 0.424$, adjusted $R^2 = 0.375$; P < .001). Adherence to glasses wearing and spherical equivalent in the amblyopic eye also was associated with final improvement in VA and individually contributed to the model ($F_{2,36} = 6.904$; $R^2 = 0.315$, adjusted $R^2 = 0.277$; P = .001). All other factors were found not to contribute and therefore were excluded from the model.

Discussion

Adherence to Glasses Wearing

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

Although this is the first study to objectively report adherence to glasses wearing in the treatment of amblyopia, 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 wearing through subjective monitoring by parents and orthoptists. Average adherence using this method was reported by the orthoptists as 79.5% and by parents as 78.5%. That study also found that adherence to glasses wearing was significantly correlated with the child's perception of the glasses and the number of favorable comments about the glasses to both the child and parents. Many other studies observing adherence to glasses wearing 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% and 40%.¹⁶⁻²¹ Low adherence was reported to be associated with negative social experiences and factors such as young age, place of origin, and subjective view of improvement with glasses wearing.

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

Improvement in VA and Adherence to Glasses Wearing

Our study has shown a moderate association between adherence to glasses wearing and improvement in VA during treatment for amblyopia. The growing support for an extended period of glasses wearing before starting 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 patients and improve adherence.^{10,23} In addition, we found that adherence to glasses wearing in the first 6 weeks was associated with overall outcome of treatment. This finding could therefore be used during the early stages of treatment to highlight patients who may require intervention or education. Findings from the patching phase, consistent with findings in previous research, showed a moderate dose-response association between adherence to occlusion and percentage improvement in VA. In contrast with findings from previous studies, this association extended up to 10 hours of occlusion per day.²⁴ However, owing to the small number of patients and a shorter patching phase than in previous studies, our findings may be owing 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 associations with glasses wearing during the glasses phase, we observed slowing of improvement in VA during weeks 12 and 18 of glasses wearing, in which the patients' vision appeared to plateau. This finding suggests that 12 weeks, rather than 18 weeks, would be the optimum length of time to allow children to adapt to their glasses for many patients. However, further improvement may be masked by the significant contribution of occlusion to improvement in VA. Moreover, we noted that several other factors, such as age and type of amblyopia, may be associated with visual outcomes during different phases of treatment. Further research, with a larger cohort of participants, may help to distinguish which types of patients will benefit from treatment with extended periods of glasses wearing or earlier occlusion.

Limitations

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

Conclusions

This study has described for the first time, to our knowledge, that reliable monitoring of glasses wearing is possible and the use of objective monitors has the potential to improve reliability of future research. We have also demonstrated that good

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Study concept and design: Farooq, Proudlock, Gottlob.

Acquisition, analysis, or interpretation of data: Maconachie, Bush, Kempton, Proudlock. Drafting of the manuscript: Maconachie. Critical revision of the manuscript for important intellectual content: Farooq, Bush, Kempton, Proudlock, Gottlob.

Statistical analysis: Maconachie, Proudlock. *Obtained funding:* Gottlob.

Administrative, technical, or material support: Maconachie, Bush, Kempton, Proudlock. Study supervision: Proudlock, Gottlob.

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adherence to glasses wearing leads to better improvement in VA and is particularly important when glasses are prescribed alone. Moreover, we observed in our small cohort of patients that 12 weeks rather than 18 weeks may be a more suitable length of time for adaptation to glasses wearing in most patients. Monitoring adherence to glasses wearing is important, as problems of poor adherence to glasses wearing are not confined to amblyopia treatment and are increasingly recognized 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 into the frame of the glasses.

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