Received: 28 November 2023 | Accepted: 15 April 2024 | Published online: 17 May 2024

DOI: 10.1111/opo.13322

OPO THE COLLEGE OF OPTOMETRISTS

ORIGINAL ARTICLE

Effectiveness of optical treatment in amblyopia and validation of measuring spectacle compliance with the ODM

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Funding information
Stichting Lijf en Leven, Grant/Award Number: 36; Stichting Steunfonds Uitzicht, Grant/Award Number: UZ 2016-25; ODAS Stichting, Grant/Award Number: 2016-04

Abstract

Purpose: The improvement in visual acuity (VA) was determined during optical treatment in children with amblyopia before their participation in a randomised clinical trial comparing the effect of dichoptic video gaming using virtual reality goggles with occlusion therapy.

Methods: Children aged 4–12 years with an interocular VA difference ≥0.20 logMAR and an amblyogenic factor: strabismus <30Δ, ≥1.00 D anisometropia, astigmatism ≥1.50 D and/or hypermetropia ≥1.50 D were eligible for 16 weeks of optical treatment. Children with previous amblyopia treatment were excluded. Compliance with spectacle wear was measured electronically over 1 week using the occlusion dose monitor (ODM). The reliability of these measurements was verified. The main outcome was an increase in amblyopic eye VA from baseline to 16 weeks.

Results: Sixty-five children entered the optical treatment period. Mean age was 6.0 ± 2.2 years (range: 4–12 years; IQR 4.5–6.7 years). Amblyopia was caused by anisometropia in 53 (82%) children, strabismus in 6 (9%) and combined mechanism in 6 (9%). After optical treatment, mean VA improved by 0.20 logMAR (SD 0.28; $p < 0.001$) and 0.07 in the amblyopic and fellow eye, respectively (SD 0.20; $p = 0.03$). This resulted in 24 children (37%) with an interocular VA difference <0.20 logMAR and in 17% of children with VA at the start of 0.30 logMAR or worse. Poor VA in the amblyopic eye at baseline ($p = 0.001$) and high anisometropia ($p = 0.001$) were associated with VA improvement. On average, spectacles were worn 9.7 ± 2.4 h/day (range: 2.3–13.6 h); mean compliance was 73% ± 18% of estimated wake time. Only ambient temperature ≥ 31°C or when spectacles were worn on top of the head prevented a reliable ODM measurement.

Conclusions: VA improved by two lines resulting in more than a third of the children being treated sufficiently with spectacles alone and no longer being classified as amblyopic. The ODM proved to be a reliable method of measuring compliance with spectacle wear.

KEYWORDS
amblyopia, compliance with spectacle wear, optical treatment, refractive adaptation

Clinical trial registration: This study was part of a larger RCT study. This clinical trial is registered at Clincaltrials.gov with number NCT03767985.

INTRODUCTION

Amblyopia is a neurodevelopmental vision disorder in children due to a disturbance in early visual development, and requires timely detection and treatment during the sensitive period.[1] Causes of amblyopia include strabismus (38%), anisometropia (37%) and both strabismus and anisometropia (24%).[2] Another less frequent cause is visual deprivation, which may be due to ptosis (2%).[3] Previous investigations have demonstrated that optical treatment, also called refractive adaptation, is a necessary and distinct component of amblyopia therapy.[4-6] Despite various studies showing the importance of spectacle wear as a first step in amblyopia treatment,[5,7,8] this is still not common practice. On occasion, spectacles are provided simultaneously with occlusion therapy or not prescribed at all, being replaced with extra hours of occlusion therapy. The beneficial effect of spectacles has not only been demonstrated in children but also in adults.[9,10] Prescribing a proper optical treatment prior to occlusion therapy may pre-empt the need for further occlusion therapy. Moreover, children who still need occlusion therapy will commence this treatment with improved visual acuity (VA) in the amblyopic eye, possibly leading to better compliance and a shorter occlusion period.[3,7] Stewart et al.[5] stated that the average number of weeks required to achieve optimum VA during the optical treatment period was 14–15 weeks. We sought to highlight the need for optical treatment as a distinct component of amblyopia therapy.

In a randomised clinical trial (RCT; NCT03767985), we compared the effect of dichoptic video gaming using virtual reality goggles with occlusion therapy for newly diagnosed amblyopia in children *after* optical treatment. This 16-week optical treatment prior to enrolment was a prerequisite for participating in this study.[11] Compliance with spectacle wear was electronically monitored using the occlusion dose monitor (ODM). This device has been used in previous studies and proven to be a reliable device in measuring compliance with occlusion therapy.[12-15] The aim of this study was to investigate the VA increase during optical treatment, and to validate the use of the ODM for monitoring compliance with spectacle wear objectively under various conditions. In addition, we investigated the effect of VA at the start of treatment, as well as the effects of age, sex, refractive error, type of amblyopia and compliance with spectacle wear on the improvement in VA resulting from optical treatment.

Key points

- Spectacle correction during optical treatment is an important first step in amblyopia therapy, which resulted in sufficient treatment of amblyopia in approximately a third of the children.
- Even children with visual acuity ≥0.30 logMAR at baseline benefited from an optical treatment period, resulting in resolution of the amblyopia in 20% of cases.
- The occlusion dose monitor is a reliable method of measuring compliance with spectacle wear.

METHODS

Study population

Children aged 4–12 years with an interocular difference in VA (IOD) ≥0.20 logMAR caused by anisometropia, strabismus or both anisometropia and strabismus were recruited for a prospective randomised control trial (RCT) comparing the effect of dichoptic gaming with occlusion therapy (NCT03767985).[16] Eligible children were recruited from five clinics in the Netherlands (Haaglanden Medical Center [The Hague], Tergooi Hospital [Hilversum, Blaricum], IJsselland Hospital, HU Clinics University of Applied Science Utrecht and Erasmus MC University Medical Center, Rotterdam) between December 2017 and June 2020. The majority of the participants were from The Hague, which comprises a multi-ethnical and -cultural population. Exclusion criteria were previous treatment for amblyopia, a neurological disorder, other eye disorders of diminished VA due to medication, brain damage or trauma. Children with strabismus >30Δ were also excluded as this prevented them from playing the dichoptic action video game and therefore entering the RCT. The Ethics Committee of the Erasmus University Medical Center and the boards of the participating clinics approved the protocol and informed consent forms. Written informed consent from the parents or guardians was a prerequisite for participation. The research adhered to the tenets of the Declaration of Helsinki.

Study design

Eligible children received a routine ophthalmic examination by the treating orthoptist and ophthalmologist. This included the following: (1) baseline, post-cycloplegic-corrected VA using a tumbling E chart where possible. If they were too young, the Amsterdam Picture Chart, the Landolt C or Lea Hyvärinen charts were used; (2) ocular motility and (3) alignment using cover–uncover and alternating cover tests at 30 cm and 5 m. Cycloplegic refraction was performed using 1% cyclopentolate eye drops. Children received spectacles in cases of anisometropia with ≥1 D (spherical equivalent) difference between the two eyes, astigmatism with ≥1.5 D difference between the eyes in any meridian, hypermetropia (spherical equivalent) ≥1.5 D or ≥0.50 D myopia. Children were prescribed 0.50 D symmetrical undercorrection from the full cycloplegic refraction. Whenever possible, the cycloplegic refraction was confirmed subjectively. It was emphasised to the parents

that wearing the spectacles was a prerequisite for participation in the RCT. Parents were instructed to let their child wear their spectacles during all waking hours and it was made clear that this was an important component of amblyopia treatment and may lead to VA improvement. All children were referred to the research centre where the orthoptist (ET) carried out a standard orthoptic and ophthalmologic examination after 16 weeks of optical treatment. This included the following: (1) best-corrected VA with their own spectacles using the crowded tumbling E chart (precision-vision.com), (2) stereo acuity using the Randot Stereotest Wirt circles (stereooptical.com) at 40 cm, (3) contrast sensitivity using the Pelli-Robson chart (precision-vision.com) in older subjects and CSV-1000 (vectorvision.com) in the younger children, (4) ocular motility and (5) alignment with the cover–uncover and alternating cover test at 30 cm and 5 m. The research orthoptist assessed whether the child fulfilled the criteria of amblyopia (i.e., interocular VA difference of 0.20 logMAR or more) and could be included in the RCT.

Families who had informed the treating orthoptist they would not wear the prescribed spectacles were not recruited as this was a prerequisite for the RCT. We retrospectively assessed how many families refused the spectacles by going through the clinical files during the study period.

Occlusion dose monitor

Compliance with spectacle wear was objectively monitored using the electronic recordings of the ODM. The ODM is an investigational device used for study purposes only. Fielder developed the first prototype of this device in 1991, and this was modified by the Amsterdam University Medical Center.[17] In this study, the 2002 version of the ODM was used.[14,17] This technique has proven to be reliable for the assessment of compliance with occlusion therapy.[14] The ODM was attached to the temple of the spectacles using a standard occlusion patch from Orthopad (Trusetal Verbandstoffwerk GMBH, tshs.eu/en/index.html) or Opticlude™ (3 M™, 3mnederland.nl/—Figure 1), in order to monitor compliance with spectacle wear for 1 week. The ODM measured the temperature difference between the front and the back of the monitor every 3 min.[14] Sensitivity was set at 0.063°C. After a period of recording, the data were saved on a computer by means of a docking system.

The families were instructed to keep the ODM attached to the glasses for 1 week, after which they could remove it, keep it in the container provided and return it at the next appointment. It was made clear to the families that the device measured the amount of time the spectacles were being worn. The battery duration was sufficient for at least 1 week. Within the expert group of orthoptists, it was decided to measure the compliance with spectacle wear directly after the 16 weeks of optical treatment, as we expected children to be more used to their glasses and compliance would be more stable, compared to the first few weeks. It was important that the timing of the compliance measurement was the same for all children.

FIGURE 1 A 5-year-old girl wearing the occlusion dose monitor attached to the temple of the spectacles using an eye patch.

To investigate the reliability of these measurements, five members of the research group and their family members wore their spectacles with the ODM attached and kept diaries with time recordings of when the spectacles were worn. The ODM recordings and diaries were compared. In addition, measurements with the ODM attached to the spectacles were carried out under various conditions: (1) spectacles worn correctly; (2) spectacles on the table; (3) spectacles worn correctly but with the ODM placed upside down on the patch; (4) spectacles on top of the head; (5) spectacles in the case and (6) ODM on an occlusion patch being worn on the eye as a regular eye patch. Lastly, we investigated the influence of ambient temperature. We carried out measurements with the ODM on the spectacles, varying the room temperature from 18°C to 33°C to determine the temperature range preventing reliable measurements.

Outcome measure and statistical analysis

VA in both the amblyopic eye and the fellow eye were compared to the values after 16 weeks of optical treatment. The Wilcoxon signed-rank test was used to investigate whether the observed change was significant. The level of compliance was defined as the actual time spectacles were worn as measured by the ODM, divided by the number of waking hours. For the number of waking hours, the systematic review of Galland et al.[18] was used, which was dependent

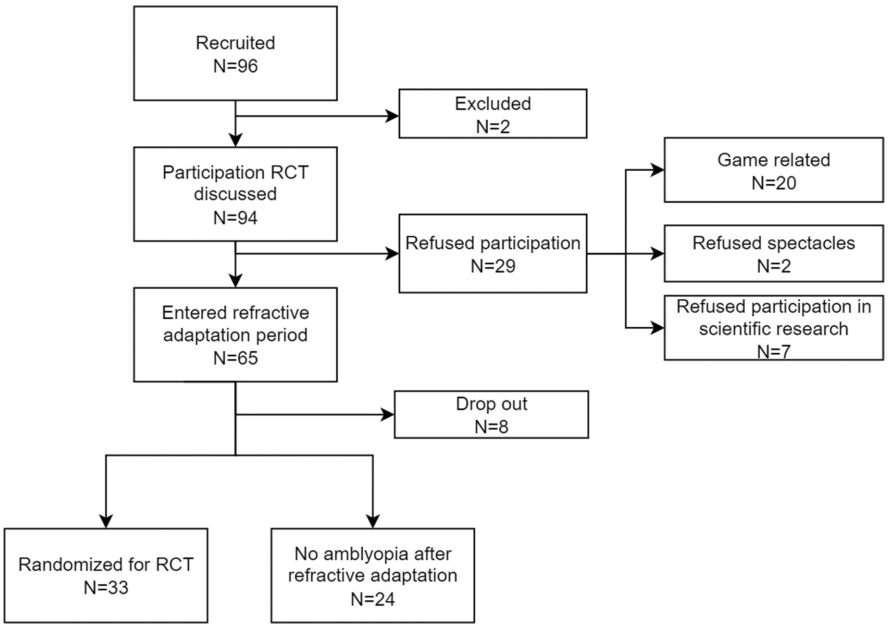

FIGURE 2 Flow chart of patient recruitment. RCT, randomised clinical trial.

on age, following the method of Maconachie et al.[19] This was expressed as a percentage. To determine the specificity of the ODM data when worn on the spectacles, the mean temperature difference and standard deviation were compared by means of Hotelling's-T2 test (comparing the averages of the variables, a method of multivariable analysis)[14] and the discriminant analysis. The relationship between the measured mean temperature difference and the ambient temperature was evaluated by means of the Pearson regression test.

Wilcoxon signed rank test was used to compare VA changes from baseline until 16 weeks. The effect of VA at the start, age, sex, refractive error, type of amblyopia and compliance with spectacle wear on VA changes during optical treatment was assessed using linear regression models. Statistical analysis was performed using SPSS statistics version 28 (ibm.com) and BiAS 11.10 (Epsilon 2019, bias-online.de).

TABLE 1 Baseline characteristics.

	All participants (*N* = 65)
Gender, female (*N*, %)	30 (46%)
Age (years, mean ± SD)	6.0 ± 2.2
Visual acuity amblyopic eye (logMAR, mean ± SD)	0.51 ± 0.39
Visual acuity fellow eye (logMAR, mean ± SD)	0.15 ± 0.19
Amblyopia cause (*N*, %)	
Anisometropia	53 (82%)
Strabismus	6 (9%)
Combined	6 (9%)
Spherical equivalent amblyopic eye (dioptres, mean ± SD)	+2.55 ± 3.14
Spherical equivalent fellow eye (dioptres, mean ± SD)	+2.08 ± 2.03
Anisometropia (dioptres, mean ± SD)	1.40 (1.70)

RESULTS

Study population

Ninety-six children were recruited for the RCT; two were excluded because of legal issues. Participation in the RCT was discussed with 94 families, of whom 29 refused to participate. Sixty-five entered and completed the 16-week optical treatment (see Figure 2). Mean age was 6.0 ± 2.2 years; 30 were female (46%). The mean spherical equivalent refractive error in the amblyopic eye (AE) and fellow eye (FE) was +2.55 ± 3.14 D and +2.08 ± 2.03 D, respectively (see Table 1). After the 16-week optical treatment period, eight participants dropped out, three refused further participation due to the time-consuming nature of the weekly visits to the clinic, three due to stopping of recruitment caused by the COVID-19 pandemic and two withdrew their participation.

Visual acuity

The mean VA, recorded under cycloplegia with optical correction at baseline was 0.51 ± 0.39 logMAR in the amblyopic eye, which improved on average by two lines after 16 weeks to 0.31 ± 0.31 logMAR ($p < 0.001$). Mean VA in the fellow eye at baseline was 0.15 ± 0.19 logMAR, which improved by almost one line to 0.08 ± 0.13 logMAR ($p = 0.03$).

The VA in children with anisometropic amblyopia ($N = 53$) improved by 0.23 ± 0.20 in the amblyopic eye and 0.07 ± 0.19 logMAR in the fellow eye ($p < 0.001$ and $p = 0.03$, respectively). For children with strabismus ($N = 6$), there was a mean change in VA for the amblyopic eye of −0.03 ± 0.43 logMAR (three improved and three deteriorated). The fellow eye improved by 0.17 ± 0.32 logMAR ($p = 0.92$) and $p = 0.16$, respectively. In children with both anisometropia and strabismus ($N = 6$), a change of 0.16 ± 0.32 logMAR and −0.07 ± 0.15 logMAR was observed in the amblyopic and fellow eye, respectively ($p = 0.28$ and $p = 0.29$, respectively). The interocular difference decreased on average by 0.14 ± 0.28 logMAR.

Overall, 24 (37%) children improved such that they no longer met the criteria for amblyopia (i.e., <0.20 logMAR interocular difference), thus making them ineligible for the RCT. Of these children, 21 had anisometropia, two strabismus and one had both anisometropia and strabismus.

Of the 35 children with VA at the start of therapy of 0.30 logMAR or worse (28 with anisometropia, two with strabismus, five with both anisometropia and strabismus), six (17%) were considered sufficiently treated after optical treatment (an interocular difference in VA ≤0.20 logMAR). Of these, five had anisometropia and one had both anisometropia and strabismus.

Of the 30 children with VA at the start of therapy of 0.30 logMAR or better (25 with anisometropia, four with strabismus and one with both anisometropia and strabismus), 18 (60%) were considered treated after optical treatment ($N = 16$ anisometropia, $N = 2$ strabismus).

Retrospectively we investigated how many new patients visited the recruiting orthoptists, required spectacles but refused to purchase them. There was only one child who refused the required spectacles and therefore was not referred to the research centre. VA in the amblyopic eye was 0.40 logMAR, which had not changed at the next visit, some 3–4 months later.

Compliance with spectacle wear with the ODM

Figure 3 shows an example of a 1-week ODM recording, while Figure S1 shows the study population categorised by compliance. The mean compliance with spectacle wear was 73% ± 18% (range: 16%–100%). Poor uncorrected VA in both the amblyopic and fellow eye at baseline was associated with a better spectacle compliance (Spearman correlation: 0.29 $p = 0.047$; 0.32 $p = 0.03$, respectively).

Only five children wore their spectacles less than 50% of all waking hours, with a mean compliance of 34% ± 13%. All five had anisometropic amblyopia. Their mean VA before spectacle wear in the amblyopic and fellow eye was 0.40 ± 0.51 and 0.01 ± 0.04 logMAR, respectively. This

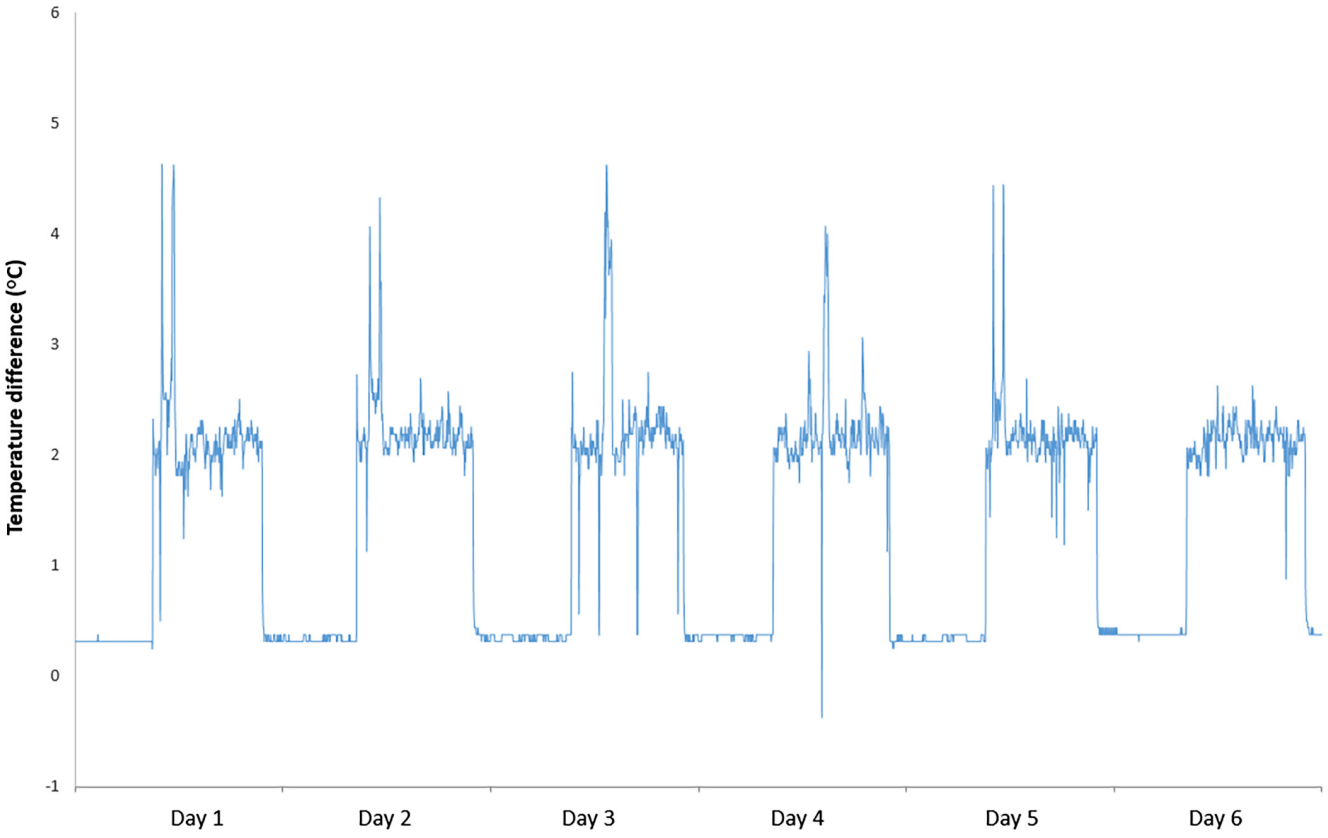

FIGURE 3 Example of a 1-week recording of spectacle wear with the occlusion dose monitor (ODM). The x- and y-axis show the day of the recording and the temperature difference between the front and back of the ODM in °C, respectively. The temperature difference when the spectacles were not worn was approximately 0°C.

improved to 0.24 ± 0.33 and 0.02 ± 0.08 logMAR, respectively, after optical treatment.

Factors influencing outcome

Univariable analysis showed that poor VA in the amblyopic eye at baseline ($p = 0.001$) and high anisometropia ($p = 0.001$) were associated with VA improvement. In contrast, age ($p = 0.14$), sex ($p = 0.41$), amblyopic aetiology ($p = 0.09$) and electronically monitored compliance with spectacle wear ($p = 0.84$) were not associated with the change in VA. Multivariable analysis showed that poor VA in the amblyopic eye at baseline was associated with VA improvement during the optical treatment ($p = 0.001$); children with strabismic amblyopia had less VA improvement compared with the anisometropic and combined children ($p = 0.003$). High anisometropia ($p = 0.54$), age ($p = 0.21$), compliance with spectacle wear ($p = 0.74$) and gender (0.86) were not significantly associated with VA improvement.

Compliance with spectacle wear and VA improvement

Figure 4 shows the relationship between VA improvement in the amblyopic eye and compliance with spectacle wear.

Strabismus

There were 14 children in this study with strabismus: two with fully accommodative esotropia, seven with partially accommodative esotropia, two with micro esotropia ($N = 2$), one intermittent exotropia and one with secondary exotropia. Of the two children with fully accommodative esotropia, one was considered treated after optical therapy and the other was not. All seven children with partially accommodative strabismus were *not* sufficiently treated with optical treatment (see Table 2).

Validation of measuring spectacle compliance with the ODM

Correspondence between the ODM measurements and diaries

Correspondence between the spectacle wearing times as measured by the ODM and the recorded diaries was 93%. The duration of measurements lasted >11 h. The mean time difference between the ODM measurements and the researchers' diary was 2 ± 1 min with a maximum of 5 min. This was due to a sampling rate for the ODM of 3 min.

Influence of ambient temperature

The ambient temperature influenced the temperature difference measured by the ODM following this formula: $y = -0.1496x + 4.678$ (where y is the temperature difference measured by the ODM and x equals the room temperature). As expected, high ambient temperatures (≥31°C) prevented reliable measurements with the ODM (Figure S2). The temperature difference was zero when the ambient temperature approached 31°C.

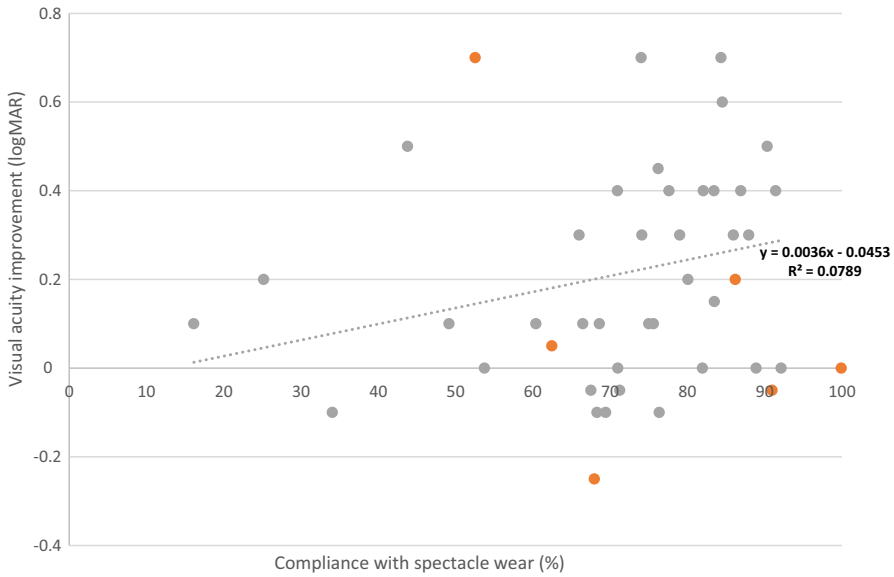

FIGURE 4 Scatterplot showing compliance with spectacle wear and visual acuity improvement with optical treatment. Each dot represents one subject. Note that some data points may (partially) overlap. Orange dots represent the children with strabismus.

Different locations

Several locations were tested to investigate whether the monitoring system could be deceived (Table 3; Figure S3). ODM measurements were carried out while the spectacles were worn correctly, with the spectacles in the spectacle case, while the spectacles were worn on top of the head and with the spectacles worn correctly but with the ODM placed upside down on the patch and while on the eye. These measurements are presented in Table 3.

Undesired situations as spectacles in the case or on the table could be distinguished from spectacles worn correctly with a low rate of false classification. The temperature difference measured from the patch worn on the eye was generally higher than on the spectacles. It was not possible to distinguish between spectacles worn correctly versus on top of the head.

DISCUSSION

This study highlights the necessity for optical treatment as an essential first step in the management of not only refractive amblyopia but also for amblyopia associated with strabismus and both anisometropia and strabismus. We found that VA improved on average by 0.20 logMAR in the amblyopic eye and 0.07 logMAR in the fellow eye, resulting in more than a third of the children being treated sufficiently with spectacles alone. The study population included a large number of children with mild amblyopia, a group often excluded from clinical trials. Some 37% of this group were treated sufficiently with optical treatment alone, emphasising the importance of spectacles, even in these mild cases. In addition, the results showed that the use of an objective monitor to measure compliance with spectacle wear is a reliable method.

These findings are comparable with the available literature. Stewart et al. ($n = 65$) found a significant improvement in VA of 0.24 logMAR in the amblyopic eye of children with anisometropia and/or strabismic amblyopia during optical treatment. In 13.8% ($n = 9$), no further amblyopia treatment was necessary.[5] Cotter et al.[7] ($n = 84$) showed that the mean VA improvement during optical treatment in children with anisometropic amblyopia was 0.29 logMAR, with 27% ($n = 23$) having resolution of their amblyopia. Additionally, the PEDIG group ($n = 146$) demonstrated that even in children with strabismus or a combined cause of amblyopia, optical treatment resulted in a clinically meaningful improvement in the amblyopic eye, with a mean improvement of 0.26 logMAR and 32% ($n = 41$) having resolution of their amblyopia.[8] However, in these studies, there was no electronic monitoring of compliance with spectacle wear.

The electronically monitored compliance with spectacle wear found in this study was relatively good, with an average of 73%. Compliance was monitored for 1 week. Spectacle compliance was measured directly after the 16 weeks of optical treatment, as we expected children to be more used to their glasses and compliance would be more stable, when compared with the first few weeks. We considered the most important aspect was that the timing of the compliance measurement was the same for all children.

Parents were told that spectacle wear was compulsory for participation in the trial. This statement alone could have resulted in better spectacle wear. The children who

TABLE 2 Subtype of strabismus with result of optical treatment.

Subtype strabismus	*N*	Sufficiently treated after optical treatment	Insufficiently treated after optical treatment
Fully accommodative esotropia	2	1	1
Partially accommodative esotropia	7	0	7
Microesotropia	2	2	0
Intermittent exotropia	1	0	1
Secondary exotropia	1	0	1

TABLE 3 Mean temperature differences (°C) with standard deviations (SD) measured by the occlusion dose monitor (ODM) in different locations.

	Spectacles worn correctly	In spectacle case	On top of the head	On the table	Worn correctly with ODM patched reversed	Eye patched
Number of tests	28	8	6	19	4	15
Mean temperature difference (°C, SD)	1.455 (SD 0.480)	0.067 (SD 0.064)	1.505 (SD 0.538)	0.039 (SD 0.056)	−1.327 (SD 0.548)	2.552 (SD 0.579)
Discriminant analysis: Rate of false classification	—	$p = 0.03$	$p = 0.37$	$p = 0.01$	$p = 0.0002$	$p = 0.11$
Hotelling's T2 test	—	$p < 0.00001$	$p = 0.34$	$p < 0.00001$	$p < 0.00001$	$p < 0.00001$

Note: Results of the discriminant analysis (rate of classification) and Hotelling's T2 test for comparison between measurements with the spectacles worn correctly are also displayed.

refused to wear the spectacles *a priori* were excluded from the trial. However, we determined the number of children who were missed following refusal to wear spectacles by retrospectively studying all newly diagnosed amblyopic children. We found that only one patient was not referred. VA did not improve in this child at their second visit to the orthoptist. Nevertheless, these findings were comparable with those of Maconachie et al.,[19] who reported an average compliance of 70%. They observed a moderate correlation between compliance with spectacle wear and the percentage improvement in VA during the optical treatment phase. We were not able to demonstrate this correlation, possibly because the present population represented a select group with a higher level and less variance in compliance.

Further, we found that children with poor VA in the amblyopic eye and high anisometropia at baseline showed more improvement in VA during optical treatment, according to the univariable analysis. Children with strabismic amblyopia improved less during optical treatment than the children with anisometropia or both anisometropia and strabismic amblyopia. Maconachie et al.[19] also found that individuals with anisometropic amblyopia improved more during optical treatment than those with strabismic amblyopia.

The results showed that the ODM positioned on the temple of the spectacles is a reliable method for measuring the duration of spectacle wear. The recorded diaries were in agreement with the objective recordings, which is in accordance with previous findings.[19] Indeed, the results were comparable with a validation study showing that use of the ODM for monitoring compliance with occlusion therapy is reliable.[14] The likelihood of misclassification was minimal for spectacles placed on a table or in their case. However, it was not possible to distinguish between spectacles worn correctly versus on top of the head. On the other hand, a child refusing to wear spectacles typically removes them entirely, rather than placing them on their head.

In conclusion, these results emphasise the necessity for optical treatment for all types of amblyopia, leading to sufficient therapy in more than a third of the children. When baseline VA in the amblyopic eye was 0.30 logMAR or worse, it represented adequate treatment in one out of six children. In addition, the ODM proved to be a reliable device for measuring spectacle wear compliance.

AUTHOR CONTRIBUTIONS

Aveen Kadhum: Conceptualization (equal); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); validation (equal); writing – original draft (lead); writing – review and editing (lead). **Emily T. C. Tan:** Conceptualization (equal); data curation (equal); investigation (equal); methodology (equal); writing – original draft (equal); writing – review and editing (equal). **Yaroslava Wenner:** Formal analysis (equal); investigation (supporting); validation (supporting); writing – review and editing (supporting). **Maurits V. Joosse:** Investigation (supporting); methodology (supporting); writing – review and editing (supporting). **Sjoukje E. Loudon:** Conceptualization (equal); data curation (equal); formal analysis (equal); funding acquisition (lead); investigation (equal); methodology (lead); project administration (equal); supervision (lead); validation (equal); writing – original draft (equal); writing – review and editing (equal).

FUNDING INFORMATION

The research leading to these results has received funding from the Uitzicht (Project no. UZ 2016-25), Stichting Lijf en Leven (Project no. 36) and ODAS Stichting (Project no. 2016-04).

CONFLICT OF INTEREST STATEMENT

All authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

PATIENT CONSENT STATEMENT

From all participants in this study, a written informed consent was obtained for participating in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Kadhum A, Tan ETC, Wenner Y, Joosse MV, Loudon SE. Effectiveness of optical treatment in amblyopia and validation of measuring spectacle compliance with the ODM. *Ophthalmic Physiol Opt*. 2024;44:945–953. https://doi.org/10.1111/opo.13322