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Measuring Treatment Adherence in Myopia Control

Current Practices and Future Directions

Rebecca M. Dang, PhD,[1] *Isabelle Jalbert, PhD,*[1] *Alex Hui, PhD,*[1,2] *Pauline Kang, PhD*[1]

Topic: Treatment adherence is an essential consideration for both health providers and researchers evaluating the effectiveness of treatments of progressive childhood myopia. This narrative review provides an overview of methods used to measure treatment adherence and examines how adherence has been assessed in myopia control studies.

Clinical Relevance: Despite its importance, adherence has not been consistently measured or reported in myopia control trials, limiting the reliability of conclusions regarding treatment efficacy, dose relationships, and safety. Examining current approaches and highlighting methodological trends and gaps will inform future research.

Methods: Exploratory searches of literature were undertaken to identify relevant studies conducted between 2014 and 2024. Studies were included if they met the following criteria: (1) reported on treatment adherence outcomes, (2) involved pediatric populations, and (3) evaluated a myopia control intervention. Reference lists of included articles were scanned to identify additional relevant studies.

Results: In the context of research in myopia control interventions, direct measures of adherence are often impractical and largely dependent on the intervention being examined. This has led to inconsistent reporting of adherence outcomes across studies. Consequently, most studies to date have relied on indirect methods, particularly self-reported data, because of the limited availability of reliable electronic monitoring tools and the inaccuracy or inappropriateness of dosage counts.

Conclusions: It is recommended that researchers prioritize treatment adherence as a key outcome and select context-appropriate methods that minimize bias and error. Optimal measurement of adherence outcomes will support more robust analyses of treatment dose-response relationships and ultimately inform the clinical care of myopic patients.

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Treatment adherence is an essential consideration for both health providers and researchers.[1] It is defined as "the extent to which the persons' behavior (including medication taking) corresponds with agreed recommendations from a health care provider."[2] The term represents a shift away from historical use of the term "compliance" which inappropriately emphasized patient obedience to the health care provider, and also acknowledges the shared responsibility and collaboration between the treating practitioner and the health care user.[3]

Even when effective treatments are available, poor adherence to the intervention can lead to research or clinical outcomes that underestimate its true efficacy. Higher levels of medication adherence have been associated with reduced hospitalizations and disease-related medical costs.[4–6] In contrast, nonadherence to treatment has been associated with poorer outcomes, disease progression, and increased burden on the health care system.[5,7–9] As such, improving adherence may have a greater impact on clinical outcomes than advances in treatments.[2] Unfortunately, poor treatment adherence is widespread, with average adherence rates, defined as the proportion of prescribed doses actually taken by the patient, of approximately 50% across multiple chronic conditions,[10,11] including childhood ocular conditions such as amblyopia[12,13] and congenital glaucoma.[14] Nonadherence also places a significant financial burden on health care systems, with annual costs estimated to exceed 100 billion euros or dollars in both the European Union and the United States.[15]

Treatment adherence to myopia control interventions within both clinical research and patient care (once interventions are available on the marketplace) have been understudied. Although interventions to treat progressive myopia are increasingly used in clinical practice,[16] a patient's adherence to prescribed interventions has not been well investigated,[17] but is an essential outcome to

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make valid conclusions about the safety and efficacy of treatments.[18] Inaccurate estimates of treatment adherence or overlooking treatment adherence outcomes can result in effective treatments being determined ineffective and can also cause dangerous escalation of treatments or miscalculation of dose-response relationships.[19]

This narrative review proposes to summarize currently available treatment adherence outcomes and methods used within myopia control clinical trials, informed by exploratory searches of literature to identify relevant studies. Searches were conducted using electronic databases including PubMed and Google Scholar between 2014 and 2024. Search terms included combinations of keywords such as "myopia control," "adherence," "compliance," "orthokeratology," "atropine," and "multifocal contact lenses." Studies were included if they the met the following: (1) reported on treatment adherence outcomes, (2) involved pediatric populations, and (3) evaluated a myopia control intervention. Reference lists of included articles were scanned to identify additional relevant studies. Because of the narrative nature of the review, no formal risk of bias assessment or protocol registration was undertaken. The goal was to provide a descriptive summary of current approaches and to highlight methodological trends and gaps to inform future research. This study is a narrative review of previously published literature and does not involve the collection or analysis of new human data; therefore, ethics committee or institutional review board approval was not required.

This will be preceded by a brief overview of available adherence measurement methods, their characteristics, and the advantages and disadvantages of each. Finally, recommendations for the most appropriate monitoring approach for treatment adherence in future myopia control studies will be discussed.

Reporting Treatment Adherence

The European Society for Patient Adherence (ESPACOMP) Medication Adherence Reporting Guideline (EMERGE) developed reporting guidelines for clinical trials to report treatment adherence outcomes.[20] These guidelines were designed to standardize reporting of treatment adherence to optimize the efficiency and effectiveness of research in adherence and related fields. The guidelines divide adherence in the following 3 distinct temporal phases[20]:

1. Initiation: the first dose of a treatment or intervention
2. Implementation: the extent to which a patient's actual dosing corresponds to prescribed regimen
3. Discontinuation: when a patient stops treatment of their own initiative.

Studies that aim to measure adherence to interventions prescribed as a single dose may be most interested in the initiation phase, but studies that investigate treatments that involve multiple, daily, or indefinite dosing may instead be more interested in the implementation phase. Considering the phase of adherence, the EMERGE guidelines recommend that clinical trials include, at a minimum, the following 4 reporting criteria:

(a) Phase/s of medication adherence being investigated

(b) Operational definition of each phase studied

(c) Method by which adherence was measured for each phase studied

(d) Results of analysis for each phase studied.

Methods of Measuring Treatment Adherence

Adherence to a prescribed intervention can be measured using direct or indirect, and objective or subjective methods.[19] The most appropriate method should be selected with consideration of the study's objectives, the type of treatment being assessed, the adherence phase measured, the adherence outcome measures selected, and to minimize errors or biases.[21,22] As such, there is no single gold-standard method to measure treatment adherence but selection should be tailored depending on the study design and objectives. Table 1 summarizes direct and indirect methods of assessing treatment adherence with examples from the myopia control intervention studies for context. Not all methods of measuring treatment adherence are an appropriate fit for all types of myopia control interventions, with suitability depending on the treatment characteristics, the frequency of "dosing," and the outcome of interest. For example, because of the recommended once daily dosing associated with prescribing of atropine eyedrops and red-light based therapy, studies investigating these therapies are typically interested in adherence rates. Although red-light based therapy can vary in light intensity and duration of treatment, these instrument settings are preset by researchers and so previous studies have only collected yes/no responses expressed as adherence rates, but have not considered whether participants are looking into the instrument for the duration of the treatment. This should be considered for inclusion in future studies.

In comparison, optical interventions for myopia control such as spectacles and contact lenses (CLs) are interested in the duration and pattern in which an eye is exposed to the optical intervention each day and over time. This is due to the known temporal effects of optical defocus on refractive development as demonstrated in animal studies.[23] As such, typical adherence outcomes for myopia control spectacles and CL studies include weekly wear duration (days per week),[24,25] daily wear duration (hours per day),[25–27] or insertion and removal times, from which daily wear time is calculated (Table 2).[24–40] In orthokeratology for myopia control, optical changes occur both with and without the lens on eye, and therefore lens wear duration does not have the same implications as with myopia control soft CL and

Table 1. Summary of Direct and Indirect Methods of Assessing Treatment Adherence with Examples in the Context of Myopia Control Intervention Studies (Adapted from Lehmann et al[22])

Method Category	Method to Measure Treatment Adherence	Example in Myopia Control Intervention Trial(s)
Direct methods	Medication or metabolite concentration in blood serum or urine	Although there are currently no proven and effective biomarkers, the choroid has been investigated as a potential predictor of myopic development and progression and may have future application.
	Biological markers in blood tests	
	Ingestible or wearable microsensors	
Indirect methods	Tablet counts	Counting daily atropine vials or contact lens packaging
	Pharmacy refill/insurance claims data	Reviewing daily contact lens purchases or atropine prescription refills
	Self-report through various modalities (questionnaires, logs, diaries, and validated instruments)/interviews with carers or proxies	Daily diaries for spectacle wear, or interviews at study visits
	Electronic devices fit to medication packages that record instances of use	Although there are currently no devices developed specifically for myopia control interventions, examples could include spectacle sensor patches or wearable devices attached to spectacle frames designed to monitor children's visual behavior, which can track when spectacles are worn.
	Clinical outcomes/health care provider's report	NA

NA = not applicable, or that no myopia control examples are available.

spectacle wear. As such, studies that investigate adherence to orthokeratology typically focus on how closely participants adhere to CL care regimens (i.e., cleaning solutions) and scheduled follow-up visits,[41,42] rather than the duration of lens wear that is pertinent for other optical type interventions.

Direct Methods

Direct methods involve tangible data collection techniques such as the direct observation of treatment, or the measurement of drug/metabolite levels in blood or tissue. Direct methods are objective and do not rely on participant responses, and are typically viewed as more accurate than indirect methods.[19] However, direct methods sometimes have the disadvantage of producing only a dichotomous yes/no type adherence result without revealing patterns or causes of nonadherence, and can be resource intensive and costly especially if trained personnel are required.[19] In addition, direct methods can still be deceived or overcome, for example with patients hiding oral medications under their tongue while being observed taking their medication. Sophisticated wearable microsensors that can measure adherence remotely without requiring involvement of participants are increasingly becoming available,[43] for example, CLs that monitor intraocular pressure or glucose levels in tears.[44,45] Currently, direct methods are of limited use within myopia control intervention studies because of the lack of known and measurable metabolite(s).

Indirect Methods

In the absence of suitable biomarkers and given the impracticality of using direct methods to measure adherence, many clinical trials use indirect methods. Indirect methods rely on the measurement of secondary outcomes or other indicators of treatment adherence, such as counting used packaging or measuring increases in spectacle frame temperature associated with being on a patient's face.[19] Indirect methods are also classified as objective or subjective depending on whether or not they rely on patient responses (self-report).

Objective Methods

Objective methods of treatment adherence can include electronic monitoring systems or dosage count. Electronic monitoring systems involve modifying an intervention's packaging to electronically and automatically record the date and time of the activation of a device as a proxy for intervention delivery.[46] Electronic monitoring systems are noninvasive and remote, and are able to collect extensive data including the pattern of use of an intervention or medicine, time stamps, and number of instilments.[18] Electronic monitoring systems are generally easier to implement than direct methods and are therefore typically used as the reference standard for evaluating other methods of measuring treatment adherence.[19] However, their use is dependent on the existence or development of valid and effective electronic monitors.

Within myopia control clinical trials, the use of electronic monitors has been limited to red-light therapy instruments, some of which have sensors that automatically log when treatments are triggered.[47–50] Data are sent to researchers in real-time, allowing reminders to be sent to participants if adherence targets are not met. However, a significant limitation of this approach is that the device is unable to detect whether a subject is truly looking into the red-light therapy device, only that it has been switched on. Although none have yet been used to monitor atropine therapy, electronic monitors in the form of Medication Event Monitoring System caps have been proposed for use by the Childhood Atropine for Myopia Progression study.[51] Medication Event Monitoring System caps have the added benefit of recording the time at which doses are taken, allowing investigations of patterns of adherence. Such systems have not yet been used in myopia control CLs or spectacle studies.

Table 2. Summary of Clinical Studies that Measured Treatment Adherence in Myopia Control Soft Contact Lenses and the Methods Used to Collect Treatment Adherence Outcomes

	Study Design			Method in Which Adherence Was Measured for Each Phase Studied				Results of Analysis for Each Phase Studied	
Study	*Myopia Control Intervention*	*Study Design/n*	*Study Duration (mos)*	*Treatment Adherence Measurement Method*	*Data Collected*	*Person Who Reported*	*Frequency of Data Collection*	*Recommendations for Wear*	*Average Achieved Wear Times (Mean ± SD)*
Cheng et al[28]	Novel CL designs, daily replacement	RCT, n = 44, 49, 45 (3 Tx groups), n = 47 (control)	6	Self-report (method not specified)	Typical insertion and removal times during weekday and weekend	Child/parent	Study visits (1, 4, 13, and 26 wks)	10 hrs or more, 7 days a week	12.6 ± 1.6 (Tx CL #1), 12.2 ± 1.8 (Tx CL #2), 12.7 ± 1.6 (Tx CL #3), and 13.1 ± 1.4 (control CL) (all measured at the 26-wk visit, hours per day)
Sankaridurg et al[25] Weng et al[30] (secondary study outcomes)	Novel CL, daily replacement	RCT, n = 103, 101, 98, 104 (4 Tx groups), n = 102 (control)	24	Self-report (survey)	Average days worn per week	Child	Study visits (1-mo, then every 3-mos)	Wear CLs upon waking and for all waking hours 7 days a week	Adherence was reported as proportion of patients who were adherent vs. nonadherent.
Walline et al[29] Walline et al[31] (protocol)	Biofinity MFCL, monthly replacement	RCT, n = 98, 98 (2 Tx groups), n = 98 (control)	36	Self-report (survey)	Typical insertion and removal times during weekday and weekend (reported), and average weekdays and weekends worn (not reported)	Parent	Study visits (annual visits only)	"As often as they could comfortably do so"	11.0 ± 4.4 (averaged across study duration hours per day)
Ruiz-Pomeda et al[32] Prieto-Garrido et al[33] (secondary study outcomes)	MiSight 1-Day CL, daily replacement	RCT, n = 46 (Tx), n = 33 (control)	24	Method not reported (method not specified, possibly parental questionnaire of child's daily activities)	Average daily wear times	Not specified	NA	6 days a week, not to exceed 15 hrs per day	11.78 ± 2.08 (weekdays) 7.25 ± 4.67 (weekend) for the Tx group at the 12-mo visit (hours per day).

Table 2. (Continued.)

Study	Study Design			Method in Which Adherence Was Measured for Each Phase Studied				Results of Analysis for Each Phase Studied	
	Myopia Control Intervention	*Study Design/n*	*Study Duration (mos)*	*Treatment Adherence Measurement Method*	*Data Collected*	*Person Who Reported*	*Frequency of Data Collection*	*Recommendations for Wear*	*Average Achieved Wear Times (Mean ± SD)*
Chamberlain et al[24]	MiSight 1-Day CL, daily replacement	RCT, n = 53 (Tx), n = 56 (control)	36	Self-report by "asking" (method not specified)	Typical insertion removal times during weekday and weekend, and average days per week lenses worn	Child	Study visits (1-wk, then 1, 6, 18, 24, and 30, 36 mos)	10 hrs a day, 6 days a week	13.7 ± 1.5 for the Tx group and 13.3 ± 1.5 for the control group (weekdays), 12.4 ± 0.9 for the Tx group and 12.1 ± 1.2 for the control group (weekend) at the 36-mo visit (hours per day). Mean weekly wear was 6.5 days per week for both groups.
Lam et al[26]	Experimental MFCL, 6-mo replacement	RCT, n = 65 (Tx), n = 63 (control)	24	Self-report (daily diary/log)	Daily wear in hours	Not specified	Daily	5–10 hrs per day	6.46 ± 2.16 (Tx) and 6.30 ± 1.65 (control) (study average, hours per day)

This study reported adherence as the proportion of participants who were adherent versus nonadherent. Additional studies that were identified but did not report adherence outcomes include Ip et al,[34] McGrady and Ramsey,[35] Vrijens et al,[36] Zhang et al,[37] Stirratt et al,[38] Garber et al,[39] and Williams et al.[40]
CL = contact lens; MFCL = multifocal contact lens; NA = not applicable; RCT = randomized controlled trial; SD = standard deviation; Tx = treatment.

Table 3. Summary of Clinical Studies that Measured Treatment Adherence in Myopia Control Spectacles and the Methods Used to Collect Treatment Adherence Outcomes

Study	Study Design			Method in Which Adherence Was Measured for Each Phase Studied			Results of Analysis for Each Phase Studied	
	Myopia Control Intervention	*Study Design/n*	*Study Duration (mos)*	*Treatment Adherence Measurement Method*	*Person Who Reported*	*Frequency of Data Collection*	*Recommendations for Wear*	*Average Achieved Wear Times (Mean ± SD)*
Bao et al[27]	Peripheral defocus spectacles (SAL and HAL)	RCT, n = 54, 53 (2 treatment groups), n = 50 (control)	24	Self-report (questionnaire)	Unsure, but likely child	Study visits and additional phone interviews	>6 hrs per day, every day of the week	13.4 ± 0.29 (SAL), 13.4 ± 0.24 (HAL), and 13.9 ± 0.24 (SVL) (averaged across study duration, hours per day)
Lam et al[65]	Defocus incorporated multiple segment spectacles	RCT, n = 79 (treatment), n = 81 (control)	24	Self-report (phone calls, questionnaires)	Not specified	Not specified	Full time except sleeping and showering	15.5 ± 2.6 (DIMS) and 15.3 ± 2.1 (SVL) (hours per day)
Rappon et al[66]	Diffusion optic technology spectacles	RCT, n = 88 (test lens 1), n = 75 (test lens 2), n = 93 (control)	12	Self-report (questionnaire)	Parent-reported	Study visits	Constant wear except for sleeping, swimming or contact sports	≥12 for all group (hours per day)

DIMS = defocus incorporated multiple segments; HAL = highly aspheric lenses; RCT = randomized controlled trial; SAL = slightly aspheric lenses; SD = standard deviation; SVL = single vision lens.

Dosage count involves comparing the number of dosage units that have been used to the number of dosages intended to be taken within a given time interval; this assumes the number of "missing doses" corresponds with the number of used doses.[19] These results are sometimes expressed as the "medication possession ratio," which represents the ratio of used doses to prescribed doses. Dosage count has typically been used in atropine studies, either counting used/unused vials[52–54] or by estimating the number of used dosages from the weight difference in the atropine bottle before and after dispensing.[55] Dosage count also has potential for use in CL studies. It is, however, prone to error resulting from participants unintentionally discarding unused or used dosages. Because of this, dosage count tends to have poor concordance with electronic monitoring systems.[56–58] Indeed, dosage count is thought to overestimate adherence in comparison to self-report methods,[53] highlighting the need to include both subjective and objective approaches when investigating treatment adherence. Dosage count is sometimes combined with self-report (refer to *Subjective Methods* section)[53–55] in line with current recommendations to use both objective and subjective methods.[19]

Retrospective use of existing records such as prescription refill data can be considered a proxy or extension to dosage counts based on the assumption that prescription refill behavior mimics medication taking behavior.[19,59] Use of prescription refill data measures adherence in a postmarket clinical environment in contrast to the more controlled and potentially unnatural context faced by patients enrolled in clinical trials, which may influence treatment adherence behaviors. Prescription refill data are also prone to administrative and data accuracy related issues such as missing values and replicate prescriptions and these can have significant effects on adherence measurement.[60]

Subjective Methods

Subjective self-report is the most frequently used method to measure treatment adherence owing to its ease of implementation and the ease by which it allows collection of secondary outcomes such as adherence patterns and barriers to adherence.[22] The exact method used to collect self-reported adherence data can vary widely. Data collection can be conducted remotely or in-person; it can be captured using verbal, nonverbal, written, or electronic methods.[61] Self-report relies on the accuracy of participant reports and is thus subject to recall bias[61] and social desirability bias, that is, the tendency for people to present themselves in a more favorable fashion.[62] As a result, self-report is considered less reliable and is thought to overestimate adherence compared with objective measures such as electronic monitoring systems.[63] Other limitations of subjective reporting include incomplete returned surveys and susceptibility to fabrication such as "hoarding," where participants fill in self-report diaries "in bulk" retrospectively.[64]

Self-report is the most common method used across atropine, myopia control CL, and spectacle studies

Table 4. Summary of Clinical Studies that Measured Treatment Adherence in Atropine and the Methods Used to Collect Treatment Adherence Outcomes

	Study Design			Method in Which Adherence Was Measured for Each Phase Studied	Results of Analysis for Each Phase Studied	
Study	*Atropine Concentration, %*	*Study Design/n*	*Study Duration (mos)*	*Treatment Adherence Measurement Method*	*Adherence Definition*	*Adherence Outcomes**
Loughman et al[52]	0.01	RCT, n = 204 (treatment), n = 68 (control)	24	Dosage count	≥75% of recommended doses	NA
Repka et al[53]	0.01	RCT, n = 62 (treatment), n = 125 (control)	24	Family-reported daily diary and dosage count	≥75% of recommended doses, used as an enrollment exclusion criteria.	93% of treatment group, 96% of placebo group were adherent from daily logs. Dosage count was presented in a cumulative figure.
Moriche-Carretero et al[78]	0.01	RCT, n = 177 (treatment), n = 184 (control)	60	"Asked for, in all visits"	Not reported, poor adherence was used as an exclusion criteria for analysis.	NA
Zadnik et al[54]	0.01 and 0.02	RCT, n = 164 (0.01%), n = 247 (0.02%), n = 165 (control)	36	Self-report e-diary via mobile phone application, and dosage count	Not reported.	E-diary data not presented. Mean doses used 88% (placebo), 86% (0.01%), and 88% (0.02%)
Hieda et al[68]	0.01	RCT, n = 86 (treatment), n = 85 (control)	24	Self-report e-diary via mobile phone application	≥75% of recommended doses.	86% (placebo), 83% (0.01%), unsure which method.
Wei et al[69]	0.01	RCT, n = 110 (treatment), n = 110 (control)	24	Daily diary	≥80% of recommended doses, used as an exclusion criterion for analysis.	NA
Yam et al[70]	0.01, 0.025, and 0.05	RCT, n = 110 (0.01%), n = 108 (0.025%), n = 109 (0.05%), n = 111 (control)	12	Daily diary	≥75% of recommended doses	90% (placebo), 91% (0.01%), 95% (0.025%), 94% (0.05%)
Chia et al[71]	0.01, 0.1, and 0.5	Randomized, no control. n = 75 (0.01%), n = 141 (0.1%), n = 161 (0.5%)	24	Daily diary	≥75% of recommended doses	99% (0.01%), 97% (0.1%), 99% (0.5%)
Chua et al[55]	1	RCT, only 1 eye included in study. n = 200 (treatment), n = 200 (control)	24	Daily diary and dosage count (via weighing of bottles)	NA	NA

All studies recommended daily use of atropine eye drops. Dosage count was calculated as the number of used ampoules returned divided by the number of days elapsed.
NA = not available; RCT = randomized controlled trial.
*Percentages may refer to proportion of doses used, or proportion of participants who were adherent as defined by the adherence definition. Additional studies that were identified but did not report adherence outcomes include Porter et al.[72]

Table 5. Summary of Clinical Studies that Measured Treatment Adherence in Red-Light Therapy and the Methods Used to Collect Treatment Adherence Outcomes

	Study Design			Method in Which Adherence Was Measured for Each Phase Studied	Results of Analysis for Each Phase Studied	
Study	*Recommended Dosing*	*Study Design/n*	*Study Duration (mo)*	*Treatment Adherence Measurement Method*	*Adherence Definition*	*Adherence Outcomes*[a]
Liu et al[48]	650 ± 10 nm at 1600 lux twice a day, 3-min each, with an interval of ≥4 hrs between treatments (7 days per week)	RCT, n = 40 (treatment myopes), n = 45 (treatment premyopes), n = 40 (control myopes), n = 45 (control premyopes)	12	Electronic monitoring, automated and built into the device. Reminders if there were no log ins for 2 consecutive dates.	≥75% of prescribed treatments, poor adherence used as an exclusion criteria.	86% adherence in myopic cohort, 84% in premyopic cohort.
Xu et al[49]	650 ± 10 nm at 1600 lux twice a day, 3-min each, with an interval of ≥4 hrs between treatments (7 days per week)	RCT, n = 55 (treatment), n = 56 (control)	12	Electronic monitoring, automated and built into the device. Reminders if there were 2 treatments missed.	NA	Median of 84% of doses used.
Dong et al[74]	Desktop red-light therapy at 0.29 milliWatts (Eyerising; Suzhou Xuanjia Optoelectronics Technology). Three min per session, twice daily, with an interval of ≥4 hrs.	RCT, n = 55 (treatment), n = 56 (control)	6	Child or parent-reported daily diaries. Reminders if adherence <12 sessions per week.	≥12 sessions per week, poor adherence used as an exclusion criteria.	88% adherent in treatment group, 95% adherent in control group.
Chen et al[73]	630 nm at 0.35 ± 0.02 milliWatts, twice a day, 3-min each, with an interval of ≥4 hrs between treatments	RCT, n = 51 (treatment), n = 51 (control)	12	WeChat group including all children, for which subjects were required to upload photos of the treatment.	≥85% of prescribed treatments.	NA
He et al[47]	650 ± 10 nm, twice a day, 3-min each, with an interval of ≥4 hrs between treatments (5 days per week)	RCT, n = 139 (treatment), n = 139 (control)	12	Self-report by teachers or parents. Reminders about intervention each week.	NA	Median 60% of doses used.
Wang et al[75]	650 ± 10 nm, twice a day, 3-min each, with an interval of ≥4 hrs between treatments (5 days per week)	Retrospective multicenter analysis, n = 434	12	Electronic monitoring, automated and built into the device. Reminders if adherence <80%.	NA	Average 81.7% of prescribed doses.
Jiang et al[50]	650 ± 10 nm at 1600 lux twice a day, 3-min each, with an interval of ≥4 hrs between treatments (5 days per week)	RCT, n = 117 (treatment), n = 129 (control)	12	Electronic monitoring, automated and built into the device. Reminders if adherence <80%.	≥80% of prescribed treatments.	75% adherent in treatment group.

Additional studies that were identified but did not report adherence outcomes include Rickles et al[76] and Svarstad and Chewning.[77]
NA = not available; RCT = randomized controlled trial.
[a]Percentages may refer to proportion of doses used, or proportion of participants who were adherent as defined by the adherence definition.

(Tables 2–4),[24–40,48–55,65–77] likely reflecting the practical constraints of other methods. Myopia control CL and spectacle studies typically use surveys or daily diaries that are answered or completed either during study visits or taken home,[25–27,31,65,66] or captured remotely through phone calls.[65] Daily diaries completed by parents/guardians have also been used to monitor atropine eye drop[55,70,71] and light-based treatment adherence.[47,74] A phone messaging group where parents/guardians were required to upload the photo of the child using the red-light therapy machine daily to the group was another method employed by study investigators; however, there were concerns with maintenance of study participant confidentiality.[73]

Adherence Measurements in Myopia Control Studies

Treatment adherence is an outcome of increasing recognition in myopia control research, with its significance continuing to grow. The method employed to assess adherence varies across studies and is likely influenced by the type of intervention and the corresponding feasibility of accurately measuring adherence. The frequency at which adherence outcomes are measured within studies involving various myopia control interventions and the levels of adherence reported using each method are described here. Myopia control studies that have measured treatment adherence are summarized in Tables 2 to 5 according to the minimum criteria described in the EMERGE guidelines. No studies reported the phase or the operational definition by which adherence was measured, but all seem to measure the implementation phase from study descriptions.

Myopia Control Contact Lenses

Less than half of identified myopia control CL studies (6 of 13 studies) included treatment adherence as a measurement outcome, and its inclusion was more frequent in more recent studies (Table 2). Most studies reported daily wear time (hours of CL worn per day)[25,26] or typical insertion and removal times (from which daily wear time is calculated).[24,28,29] Daily wear times generally aligned with the durations recommended by researchers, although the actual recommended wear time varied between studies. Older studies typically had lower wear time recommendations ranging between 5 and 10 hours per day,[26] or as long as children "can comfortably do so,"[29,31] and so measured wear times range from 6.5 to 11 hours per day. In contrast, more recent studies had longer or more specific wear time recommendations, likely based on the potential association between wear time and improved myopia control outcomes.[26] As such, wear time recommendations in more recent studies have ranged from ≥10 hours per day[24,28] to all waking hours,[25] leading to higher average reported wear times of 11.8 to 13.7 hours per day.[24,28,29,79]

Studies that reported weekly CL wear also found wear days close to the studies recommendations of ≥6 days a week, with one study identifying an average weekly wear time between 6 and 7 days per week,[80] and another study reporting 64% to 75% of children meeting the 6 days per week recommendation.[25]

Myopia Control Spectacles

All identified studies investigating myopia control spectacles measured treatment adherence via self-report methods (3 studies, Table 3). Wear time durations were high, at 12 to 13 hours per day, 5 days a week, and notably, were not significantly different compared with children using single vision spectacles.[27,66] Interestingly, wear durations were similar regardless of whether they were reported by the participant[27] or the parent.[66]

Atropine

Most studies investigating the effectiveness of atropine for myopia control monitored treatment adherence (9 of 10 studies, Table 4). Studies tended to define participants as adherent if >75% of prescribed atropine doses were used, which is equal to using atropine 5.25 days per week.[53,68,70,71,81] Adherence was generally rated high through self-report via daily logs, with 83% to 98% of children using their low dose atropine eyedrops ≥75% of the time.[53,70,71] Similar high adherence was found with dosage count, with 81% to 90% of children using ≥75% of prescribed atropine doses.[81]

Red-Light Therapy

Most identified studies investigating red-light therapy also monitored treatment adherence, likely because of the incorporation of the electronic monitor within many red-light instruments (7 of 9 studies, Table 5). Treatment adherence rates ranged from 60% to 84% for red-light therapy instruments.[47,49,50] Studies that report the proportion of participants that were adherent according to a set adherence criteria found 84% to 86% of participants used ≥75% of prescribed doses[48] and 88% to 95% used 12 of 14 prescribed doses.[74] Two studies collected adherence data, but did not report adherence outcomes.[48,73]

Additional Analyses Related to Treatment Adherence Outcomes

Adherence outcomes have been used to investigate the dose-related response to efficacy in several myopia control interventions including myopia control CLs and spectacles, red-light therapy instruments, but not atropine eyedrops. Whereas some myopia control CL studies have found a positive association between wear time and myopia control efficacy,[25,26,28] others did not (Table 3).[29,32] A key difference between the studies that found a relationship between wear time and myopia control efficacy was the frequency of data collection time points. In the 3 studies where a relationship was found, data were captured frequently: 2 studies used self-report daily diaries given to participants to take home,[25,26] and the third study collected

data at study visits occurring at weeks 1, 4, 13, and 26.[28] In comparison, the 2 studies that were unable to demonstrate a similar relationship either collected data much less frequently, with data collected at annual study visits,[29] or did not specify the adherence method used.[32] This is consistent with the conclusions of another study investigating MiSight 1-Day CLs for myopia progression, which monitored participants at 1 week, followed by months 1, 6, 18, 24, 30, and 36, with researchers determining the "high level of wear time compliance did not provide sufficient variation to evaluate the effect of wearing time on myopia progression."[24]

The relationship between adherence and the efficacy of myopia control spectacles has been investigated in one study (Table 4).[27] Children who wore their myopia control spectacle lenses ≥12 hours per day had greater myopia control compared with those that did not (0.28 ± 0.04 vs. 0.43 ± 0.06 mm axial length change, $P = 0.03$), which was not found in the single vision spectacle control group. Although 2 other spectacle lens studies collected adherence data, they did not investigate the relationship between wear time and myopia control efficacy (Table 4).[65,66]

A relationship between adherence to red-light therapy and myopia control efficacy has been identified in one study[50] but conversely this was not found by other studies.[48,49] In the first study, linear mixed models identified there was a significant positive relationship between treatment compliance and myopia control for both axial elongation and refractive progression ($P < 0.001$).[50] Comparison of children with adherence <50% compared with >75% found treatment efficacy increased from 44.6% to 76.8% axial length control compared with no treatment. The latter study found that the adherence rate was not significantly correlated with 12-month axial length change in red-light treatment groups.[48] However, using the instrument <75% of prescribed doses was a reason for study discontinuation, and this could have masked a possible relationship.

Treatment adherence has also been used as an eligibility criterion in many atropine studies. Two studies dispensed atropine eyedrops during an initial run-in period of 2- to 4-weeks before study commencement, with sufficient adherence during this period used as an eligibility criterion for enrollment.[53,67] Alternately, other studies have used implementation adherence measured throughout the trial duration as criteria for inclusion in the data analysis set.[69,78]

Recommendations and Future Studies

There are no established methods of measuring treatment adherence with myopia control interventions, and although this remains an area of future research, it is likely different methods will be most appropriate depending on the myopia control intervention under investigation.[21,22] Clinical studies investigating myopia control interventions are currently limited to indirect methods of measuring treatment adherence in the absence of appropriate direct methods and lack of reliable metabolites to quantify adherence. Indirect methods can be objective or subjective, and whereas objective methods are said to be less prone to bias, evidence suggests that a combination of multiple subjective methods could provide better sensitivity than use of a single objective measure.[34] As such, current recommendations are for the incorporation of both objective (electronic monitoring systems or dosage count) and subjective methods (self-report) for the measurement of treatment adherence outcomes.[19] Dosage count has particularly poor reliability as it is known to overestimate adherence compared with self-report[53] and has been shown to have poor concordance to electronic monitoring systems.[56–58] As such, electronic monitoring systems are the preferred objective method but are only common practice in red-light therapy devices,[47–49] and to date, have only been included in 1 atropine study protocol.[51] Electronic monitors used in the investigation of other ocular conditions have the potential to be used within myopia control studies. For example, in amblyopia treatment studies, electronic monitors attached to spectacle frames use changes in temperature as a proxy to detect when and how long spectacles were worn by participants,[35,36] and can be used in myopia control spectacle studies. Wearable sensors used to measure children's visual behavior have been used to measure spectacle lens wearing time in low hyperopic children, an application that could be easily used in myopia control spectacle studies.[37] There are also wearable microsensors that measure glucose levels in tears or intraocular pressure,[44,45] and a future extended application enabling the measurement of CL wear time may also be feasible.

The absence of trustworthy objective indirect methods for measuring treatment adherence has led researchers to rely on subjective indirect methods, including self-report, which are prone to various forms of bias as previously described. Efforts should be made to reduce social desirability concerns[62] as it can add significant systematic error to measured treatment adherence outcomes.[38] Methods of reducing social desirability include the use of asynchronous approaches such as written surveys,[62] to address the increased bias observed with face-to-face methods such as verbal surveys.[39] Prefatory statements that acknowledge the common challenges of complete adherence can also be added to the start of surveys, which reduce perceived judgment or the desire to report perfect adherence.[40] For example, "Taking drops is difficult for a lot of people, and it is not uncommon for people to miss doses from time to time. Please try to remember as best you can what actually happened and not what you intended to have happen or what you think other people want you to report." Alternatively, surveys could also include a validated item or question that would allow researchers to statistically adjust for social desirability during data analysis.[38]

Recall periods should also be optimized to balance the effects of recall bias and repetition fatigue.[38] Recall bias occurs when participants do not accurately remember past events or experiences, and can be addressed with shorter recall periods, for example, daily measurements. This strategy is particularly advantageous when assessing

specialized populations, such as those who are cognitively impaired or children,[38,40,82] or when more granular data are required.[61] However, frequent data collection risks introducing repetition fatigue where respondents may tire of the surveying process and provide suboptimal or incomplete responses.[72,83] As such, recall periods should be carefully balanced between recall bias and repetition fatigue to ensure both accuracy and participant engagement.

The reliability of subjective methods can also be enhanced through the use of standardized surveys and computer administration of these surveys.[38] Many validated and standardized surveys have been designed for use of chronic health conditions such as hypertension,[76,77,84,85] and generally provide better correlation with electronic monitors than nonstandardized self-report surveys.[86] The development and validation of adherence survey items specific to myopia control studies is a key area of future research. Electronic methods of self-report or e-diaries allow participants to directly input information into a computer database, significantly minimizing biases related to social desirability, interviewer characteristics, and questionnaire structure.[87] Additionally, they reduce the burden of paper handling and data entry, minimize missing values, and studies have reported good user acceptance compared with paper-based surveys.

All future myopia control intervention studies should include adherence as a study outcome to make valid conclusions about the safety and efficacy of treatments and report based on ESPACOMP EMERGE.[20] Based on current understanding, it is recommended that future studies of adherence to myopia control interventions incorporate both objective and subjective methods to measure treatment adherence outcomes, which are appropriate to the treatment of interest and phase of adherence. Although electronic monitoring systems are the preferred objective method, capabilities are currently limited for myopia control intervention studies and therefore, subjective methods are often used. When using subjective methods, they should be asynchronous, with prefatory statements normalizing nonadherence. Subjective methods can also be enhanced by using standardized surveys and computer administration. Optimal recall periods should be selected to balance recall bias and repetition fatigue to ensure both accuracy and participant engagement.

While ascertaining the levels and patterns of adherence, future studies of myopia control treatment adherence need to also investigate potential barriers and reasons for nonadherence to treatment. A previous study investigating parental attitude to myopia control in preschool children identified side effects, lack of understanding of long-term drug use, lack of conducive environment, and lack of friendly medical services as barriers.[88] Future studies should consider measuring compliance at different time points to assess for changes throughout the treatment period. Short study durations may overestimate compliance, and it remains unclear whether adherence declines over time.[17] Finally, adherence to myopia control interventions has only been investigated within clinical trials, which may not be reflective of patient behavior in clinical settings. Investigations into the level of adherence in clinical practice is required.

Conclusion

Treatment adherence is an outcome of increasing interest in myopia control research, with the frequency of its inclusion within myopia control studies depending on the type of intervention and ease of measurement. It is recommended that all future myopia control interventions include adherence as a study outcome measure, to ensure valid conclusions can be made about the efficacy of treatments, and report these based on the ESPACOMP EMERGE.[20] Methods should be chosen with consideration of the type of treatment being assessed, study's objectives, and to minimize error and biases.[21,22] If subjective methods must be used in the absence of appropriate electronic monitoring systems, efforts should be made to minimize error introduced by social desirability and recall bias, and repetition fatigue.[19] Future studies can additionally investigate the barriers and reasons for nonadherence to treatment, as well as the changes in adherence at different time points throughout myopia control treatment.

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[1] School of Optometry and Vision Science, Faculty of Medicine and Health, University of New South Wales, Sydney, Australia.

[2] School of Optometry and Vision Science, University of Waterloo, Waterloo, Canada.

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CL = contact lens; **EMERGE** = European Society for Patient Adherence (ESPACOMP) Medication Adherence Reporting Guideline; **ESPACOMP** = European Society for Patient Adherence.

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Correspondence:
Pauline Kang, PhD, Level 2, Rupert Myers Building, North Wing, Gate 14, Barker St, UNSW, Sydney 2052, Australia. E-mail: p.kang@unsw.edu.au.

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